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## CSER

**Centre for Studies in Ethics and Rights**  
An Institute of Anusandhan Trust

# Ethics in Health Research A Social Science Perspective

Editors

**AMAR JESANI  
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**CSER**

**Centre for Studies in Ethics and Rights**  
(An Institute of Anusandhan Trust)

# Ethics in Health Research

## A Social Science Perspective



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Ethics in Health Research  
A Social Science Perspective

*Edited by*

Amar Jesani, Tejal Barai-Jaitly

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**I**

# **Introduction**





# 1

## **Social sciences and bioethics**

### **Creative tensions in health studies**

**Amar Jesani**

**Tejal Barai – Jaitly**

Ethics and its practice and development have very different historical trajectories in medicine and social sciences. In medicine, the codification of right and wrong practices was an imperative — since practitioners dealt with life and death every day—even at a time when medicine and medical practice was very young. In social sciences, there was no such imperative and the development and application of ethics has come about in a different way. These historical differences in the manner of development of ethics make the formulation of a code of ethics in social science research in health a challenge.

The social sciences comprise relatively young disciplines that are intellectually rich. Under the rubric of social sciences are the disciplines of anthropology, sociology, economics, psychology and many others. Within each, specialised sub/multidisciplinary areas have also emerged, including those specific to work in the field of health and medicine. Systematic empirical work in social sciences began in the later part of 17<sup>th</sup> century receiving a major impetus in the 19<sup>th</sup> century when several countries began to institute the practice of systematic data collection through censuses. In the last three centuries, a multiplicity of sources of empirical social science data have emerged with the data collected and generated by governments being supplemented with those from universities, institutions, inquiry reports, NGOs, and so on. The corpus of empirical and theoretical material produced by various disciplines of social sciences is vast and complex. Besides, the social sciences provide lively theoretical debates with continuous refinements in old theories and the formulation of new theories to explain social reality.

The practice of medicine, on the other hand is very old, dating back to ancient times. Medical practice, even in early times, required systematic empirical work to enable it to address human diseases and ill health. Practitioners had to devise and innovate appropriate means for collecting, storing, retrieving and correlating data so that new methods of treatment and care could be promoted. Because medical practice dealt with illnesses and life and death situations, inevitably coming into contact with individuals and communities when they were most vulnerable, all systematised medical practices developed certain codes of conduct, formal or informal, voluntarily accepted by groups of healers or mandated by the state. One finds references to such codes in the Indian systems of medicine, in the Hippocratic tradition, the Jewish and Islamic traditions, and many others. Such codes of conduct influenced the nature of relationship between healers and patients and also among healers belonging to the same group or practising the same kind of healing methods. In the last three centuries modern scientific medicine developed at a rapid pace with path-breaking discoveries and the increasing use and domination of technologies for investigating and treating illnesses and epidemics. It began also to borrow and amend the older codes of conduct regulating medical practices. In fact, the existence of such codes of conduct played a role in the professionalisation of healing practices and was instrumental in persuading society to allow the medical community to organise, regulate and monitor its practice without an overseeing external authority.

### **Bioethics, a formal discipline**

Unfortunately at crucial times in history these codes of conduct/professional ethics have not been able to prevent the massive misuse of medical skills and the participation of professionals in such misuse resulting in gross violation of human rights of those affected. Indeed, the widespread misuse of medicine under the Nazis in Germany and large parts of Europe, so well documented during the Nuremberg trial and by extensive research studies, was a turning point in the development of bioethics. Around that time too, the massive expansion of medicine as a techno-managerial complex brought to the fore new problems in the way medicine was practised

and medical research undertaken. In the context of finite resources and existing power structures and hierarchies in society, medicine confronted new dilemmas and controversies about who gets what and how (and so also who researches what and how). Consequently, the health professions came under considerable social pressure to collaborate with professionals from other disciplines – particularly philosophers and legal professionals – in the process of development of ethics and its practice. So emerged the formal discipline of bioethics in the 1960s.

In sum, even though bioethics has antecedents in the ancient tradition of empirical research and professional ethics, the modern discipline of bioethics is much younger than the disciplines of social sciences. This, one might add despite the fact that ethics is a sub-discipline of philosophy and ethics is often called ‘practical philosophy’. Although bioethics uses, increasingly, empirical social science data as the evidence base for its arguments, social scientists (other than philosophers and legal professionals) have not played a dominant role in the emergence of bioethics as a systematic discipline. Interestingly, bioethics came of age around the same time, in the 1960s and 1970s that medical sociology was emerging as a formal discipline. Indeed, these two developments did not take place in isolation and were in fact, influenced by one another, sometimes in agreement and at other times in confrontation leading to mutual respect and exchange.

### **Creative tensions**

Social sciences examine and explain social reality. Studying the behaviour and conduct of human beings and the social institutions and structures created by them; understanding their complex interaction with each other and with the environment, and identifying the factors that contribute to the social environment are the essential ingredients of social science research. Since ethics is also the science of describing social conduct and judging its appropriateness (deciding whether it is right or wrong, good or bad), there is a significant overlap between the disciplines of social sciences and of bioethics.

There is also considerable tension between the two disciplines. In the last half a century bioethics has engaged itself strongly with

normative ethics, finding ways to evolve universal principles and methods to judge right and wrong. Indeed, the emergence of 'principalism' (relying on the application of the four principles of autonomy, beneficence, non-maleficence and justice) to analyse various moral situations and find universal and consistent ways of resolving ethical problems in place of traditional theories (deontological, teleological, etc) has also emphasised the pre-occupation with normative ethics and its commitment to universalism. Besides, this period also witnessed the rise of autonomy as a primary principle within the principalism approach, thus reducing the relative importance of principles of justice and non-maleficence. This in part has made bioethics appear to be a western, specifically, American enterprise, carrying within it a politics not wholly suitable to the developing world.

Not surprisingly, social scientists have been quick to point out the follies of the new claims of universal wisdom coming from bioethics. More so because as a discipline, one of the strong points of social sciences is to understand the morality and value systems that different cultures cherish and practice. In consequence social scientists define their project as being to sensitively understand, explain and analyse social reality, rather than passing judgment on how people live their moral lives. Such a perspective looks at ethics with unease, as its 'relativism' does not go down well with the 'universalism' of bioethics.

In the last decade, there have been lively interactions and debates among social scientists, particularly ethnographers who have an inclination towards the relativist position, and bioethicists. Lester Coutinho (pp 107-130) in this volume illustrates this point well. He explores how entwined and interconnected are the principles of social justice, non-maleficence and beneficence through the philosophical as well as practical framework in ethnographic research.

This engagement is gradually producing a greater understanding among the disciplines. The contribution being made by each to the other is significant. Bioethics is opening up to social sciences in a big way so that its empiricism and evidence base is strengthened and its theoretical foundations refined. Social sciences have been increasingly recognising and confronting ethical problems in their

research practices, and acknowledging the need to have normative ethics-based guidelines and codes to prevent the misuse of research and its science. Tejal Barai-Jaitly (pp 90-104) explores the basic concepts of ethical research. Ethics is the vital and effective link as well as the balance between the needs and the rights of the participants, researchers, and the social science discipline. She points out that while individual perspectives towards ethics and the dynamics during research may vary, the potential of harm because of unethical research remains.

### **Contribution of social sciences to bioethics**

The field of bioethics has accorded a greater respect for social science than has traditional philosophy which regarded the former as merely a source of empirical material for philosophical arguments. Indeed, ethics is no longer considered to be a simple derivative of philosophical theories, but also a response to the changing social reality, particularly the increasing awareness of rights and their assertion by people. The primary issue of human rights violations, a famous concern of many social sciences, particularly political science has been an important focus of every controversy and scandal in ethics. In each human rights violation as the basis of ethical controversy or scandal, the heightened concern has had a lot to do with the social position of the people whose human rights were violated. Invariably these people happened to be the dispossessed, oppressed and exploited, stigmatised and marginalised strata. Thus, social stratification, hierarchies, social vulnerabilities and so on have found significant theoretical and empirical space in the bioethics discourse thus ensuring a respectable position to sociology and anthropology as disciplines.

The empirical work of social science contributes not only to the understanding of social behaviour, social relations, structures and changes in bioethics, but it is useful in understanding how bioethics operates at the ground level in health practices and research. An increasing number of social scientists are looking at the functioning of institutional research and clinical ethics committees and the relationship between researchers and their subjects or participants; documenting processes like informed

consent process; understanding the influence of social background and relationship of researchers on their choice and outcome of research, and so on. Ritu Priya (pp131-137) elaborates, for instance, on how qualitative public health research that studies public health programmes and policies can show up serious ethical complications are a consequence of the value loaded nature of these policies and programmes.

Social sciences are also contributing to the understanding of how and why bioethics rose as a discipline, its relationship with the increasing regulation and oversight of research and professional work and above all, in understanding the impact that such an aggressive rise of bioethics in the developing world is having on the nature and trajectory of research. Priya (pp 131-137) argues that research that studies people's health related behaviour, health related perceptions and health services research influences social values and health perspectives and raises ethical dilemmas because of the divergent views and interests of the numerous participants. **The context of research includes local social disparities on one hand and global politics and neo-imperialism on the other. The negative social consequences of these processes are felt most by the previously marginalised at both the international and local community levels. Thus, Priya asserts, there is no one perspective or value framework that we can consider 'the best' and use as a reference point for evaluating the impact of qualitative research on processes of social change.**

In the discussion on ethics, the primary issue is often the difficulty of separating ethical issues from others. Indeed, what is considered an ethical issue is of great importance, but has the least clarity. Are only those issues framed within the boundaries of four principles to be recognised as ethical issues or can issues framed using the social theoretical frameworks also be looked at as ethical issues? In fact, as the field of bioethics increasingly breaks the narrow boundaries of the doctor-patient and researcher-subject relationships and applies itself to national and international policies, the relationship of social forces in health and research at the larger levels, or even at the micro level it starts to pay attention to the power relationship among various parties involved in research. Bioethics too has started recognising 'other issues' as a part of

ethical issues. Power relations are sometimes to do with outcomes and a researcher's perceptions of benefit to her, to participants and to society at large.

Coutinho elaborates these issues at some length. 'What good will come about from your research or, how will your research benefit us?' are questions that are often raised. As researchers, Coutinho writes, our answer has often been little more than an expression of our own hope (or perhaps hopelessness) that the research would, through an advancement of our knowledge about a particular social (health) issue, positively influence both policies and practices. Research, he points out, is a time consuming activity. Given this why should people want to participate in research?

Lastly, social sciences are rich not only in empirical material but also in theories. These are very important because by no stretch of imagination are the four dominant principles of bioethics foolproof and immutable; and hence, there will always be a need to constantly check and re-check the relevance of the existing principles to find answers to ethical problems, and of course in determining whether new principles were emerging or whether it is necessary to formulate.

### **Contribution of bioethics to social sciences**

Although the social sciences took time to formally incorporate normative ethics in their practices, these disciplines were sensitive to ethical problems in their work from the very beginning. Unlike the natural sciences social sciences constantly deal with human beings in their research. And human subjects at some stage, do talk back, ask questions, protest intrusions and indeed, can refuse to cooperate in the research enterprises. This inevitable resistance from below to any perspective in social sciences research that does not grant an agency to the subjects or participants has made social scientists sensitive to the field reality. Indeed, the protest from below, the recognition of the human rights of the participants and politics surrounding the kind of research pursued contributed heavily to the rise of ethical concerns in social science research. In no way can the science that studies the behaviour of people and their social organisations remain immune to the study of its own behaviour and that of its practitioners.



Ghanshyam Shah (pp 23-34) in his lead paper elaborates on why and how the social sciences, not being value free, affect behaviour and influence policy. A code of ethics is essential to maintain minimum uniformity in understanding researchers' role in society, their accountability, transparency in objectives and method, and fraternity among the researchers. But it is not sufficient for ethically good research. Do standardized codes of ethics in research facilitate or hamper good research? Undoubtedly, research integrity of the person is at the core of all research. However, ethical guidelines, and mechanism for implementation alone are not enough for developing socially oriented research.

While the movement of social sciences away from its initial theoretical moorings in the natural sciences (use of natural science paradigm) has helped in making them more sensitive to ethical issues, the real impetus came in the same way as it did in the biomedical sciences – the protests from below, controversies, scandals, etc. raising issues of human rights' violations and the improper behaviour of the social scientists. Often new areas of research have thrown up entirely new ethical dilemmas. As social sciences moved towards the applied research ethical challenges began to have an increasing impact forcing the applied branches of the social sciences to evolve and formulate normative ethical guidelines and codes.

Two papers look at the issues and challenges in the relatively new area of researching with women. Neha Madhiwala asserts that while every researcher and participant is entangled in a network of power relations researching women inevitably absorbs into the interaction several other players without whose assent, women may not act. It is this lack of autonomy of women that raises slippery slopes during social science research with them. It complicates the principle of consent and of privacy. Researching women and simultaneously researching a community viewed as 'oppressors' or service providers for abortion care presents special challenges, for it is as necessary to ensure the rights of oppressors as of the oppressed participants of research. Sunita Bandewar explores this difficult terrain through a detailed and rich documentation of the ethical challenges that she and her team had to confront and the

dilemmas –in solving them in the course of two research studies with women in the context of abortion.

### **Indian context**

The volume of research, the funding available and the number and nature of organisations and institutions undertaking social science research in health have multiplied manifold over the past decade. There is a burgeoning of multidisciplinary and collaborative research with large sponsorships and incentives. Against this background Sandhya Srinivasan (pp 75-89), focuses on the status of medical research in India (in the context of ethics), providing a brief analysis of national and international ethical guidelines and some ethical principles in research.

There is also the growing acknowledgement of the interdependence of disease and ill health to social circumstances and behaviour. For instance, combating AIDS is not seen in isolation of its social causes and impact. Evidently, topics of social inquiry have become more personal and sensitive. What migrant workers do in their hours after work or how often a sex worker has unprotected sex seems to have become more our 'business' than theirs! What makes the application of ethics in social science research even more critical is the fact that in India there is a clear multi-paced evolution and development of culture and changing social norms.

Radhika Chandiramani and Lesley Jane Berry's paper (pp 159-180) addresses some of the ethical issues encountered in the field of research on sexuality. It illustrates ethical challenges that arise in research and intervention in a country where the socio-cultural context is often inimical to the sexual and reproductive rights of individuals, especially of women. The paper also discusses issues related to the need for services versus competence of providers, and the concepts of confidentiality, privacy, and anonymity are discussed in the context of intervention.

Some of these problems are also evident when social scientists are involved in research involving persons with mental disorder. These complications are brought out clearly by Soumitra Pathare and Bhargavi Davar (pp 141-155) through a detailed discussion on seeking informed consent from those who are mentally ill. They

have tread on the very specific terrain of studying and working with mentally ill and have raised dilemmas with respect to informed consent as a result of issues of competency and the voluntary nature of consent and autonomy.

Social science research in health today is an area that is growing by leaps and bounds and is a serious professional pursuit for many in our own country. And as any profession it needs to have its ground rules – or ethics. Having a professional code of ethics can only enhance the respectability of a profession. If we question the acts of doctors indulging in malpractices, it is because there is a code of conduct one can indicate non adherence to.

Ethics in medical (biomedical and clinical) research then has been an area of debate, even in India, for a very long time. In social science research in health, on the other hand, little attention has been paid to the rights of participants and researchers and their violations. As a result of this neglect, ethics is a murky area of work. Faced with these concerns, we were motivated to publish this collection of experiences of fellow social scientists and draw coherent lessons from them.

The passage of the present book is through the endeavour of evolving ethical guidelines for social science research in health (pp 35-52) through a consultative process. While the research for the guidelines was underway, we found that there is almost no documentation of ethical dilemmas faced by social scientists in our country. While we were aware that our fellow social scientists have been responsive to the ethics of research, the lack of documentation was a critical gap. As Padma Prakash (pp 225-237) points out journals and publications can play an important role here and in ensuring adherence to codes of ethics. Ethical codes of conduct cannot be effectively implemented in isolation and may be enforced in several different ways. One, is to conscientise the members of the profession to observe the rules, second, is to effectively police the system, and a third is to create links with associated disciplines or community of practitioners who together can form a network of conscience keepers.

Thus consultations on ethical guidelines and the documentation of experiences in research were processes that were undertaken simultaneously. While the guidelines were published in November

2000, the present volume has been delayed due to unavoidable reasons. We have attempted to put together papers, most commissioned for this volume, that describe, enunciate or elaborate relevant principles in ethics in this area. Some papers elaborate on practitioners' experiences that illustrate these principles and enrich their discussion. In the course of this organising and editing this volume, we have gained a tremendous respect for fellow researchers from multiple disciplines, who, even though there is little documentation on ethical dilemmas have painstakingly debated and resolved challenging ethical issues.



**II**

**Ethics: Role and Relevance**



## 2

# Code of ethics

## Issues and dilemmas in social science research

### Ghanshyam Shah

Following the guidelines of the United Nations Universal Declaration of Human Rights and the World Medical Association Declaration of Helsinki, Finland, the Indian Council of Medical Research (ICMR) has prepared a code of ethics for biomedical research. The objective of the code is to protect human rights of the individuals who are being studied. Accordingly, free consent of the people who are the subject of experimentation is the essential pre-condition of the research. We all know that the present code suffers from several lacunas. More than that, it is not properly observed in all studies. The poor are still vulnerable when it comes to being enrolled for participation for experiments. They are used as guinea pigs.

Discussion on the ICMR's document is beyond the scope of the present deliberation. What is to be noted however, is that a code of ethics exists for biomedical research. It may also be noted that a similar code also exists for life sciences where animals are used for experiments. Needless to emphasise that the ethical code of conduct is a prerequisite to protect human rights. But at the same time, a mere document delineating the codes is not sufficient guarantee for the protection of the rights of the people. Those who are insensitive to the rights of the others are capable of finding ways and means to subvert the code of conduct. At the same time conscientious and moralist scholars often face several dilemmas that may involve placing priority on certain principles over others. No code of ethics or guidelines can be full proof, nor can any code encompass all eventualities.

Nevertheless, a code of ethics is essential for maintaining a minimum uniformity in understanding researchers role in society,



their accountability, transparency in objectives and method and fraternity among the researchers. But it is not sufficient for ethically good research. One may also wonder whether the standardised code of ethics in research (CER) facilitates or hampers good research. We have to address these issues.

In India, research in the field of social sciences have grown significantly during the last five decades. But so far there is no code of conduct or ethical guidelines in the country for social science research. Neither the Indian Council of Social Science Research (ICSSR) nor the University Grant Commission the nodal organisations for sponsoring research in universities and research institutes have formulated any guidelines in CER. None of the professional associations such as Anthropological Society, Indian Sociological Society, Political Science Association, Psychology Association, the Indian Science Congress or the Indian Academy of Social Sciences has so far prepared CER for the guidance of their members. The subject has not received serious attention from social scientists. We do have a few studies on fieldwork experiences that touch upon ethical issues related to the researchers relationship with the respondents, confidentiality of information, autonomy of informants, etc. But these experiences have not been seriously debated. In India, we only have JA Barnes (1977) three lectures on The Ethics of Inquiry in Social Sciences delivered at the Institute for Social and Economic Change. I wonder why social scientists who study human beings and social institutions and social scientists who sit in policy-making bodies at various levels, frequently write commentaries on socio-economic processes and events have refrained from addressing ethical issues affecting them and society. A positivist approach may be one important explanation for such indifference to the subject. But I submit that this is not a full explanation. We have to stir our sensitivity and raise larger philosophical and moral issues regarding our responsibilities towards society.

Let me hasten to clarify that when I say that there is no CER, I do not mean that social science researchers are not guided by ethical values in conducting the studies. To be sure, the researcher at an individual level is guided by certain values in selecting a particular problem for the study or formulating a hypothesis. Also, the method

for data collection, analysis of the data, interpersonal relationship among the researchers, dissemination of the findings, etc are also not free from influences of personal ethical values. Like others, a social scientist imbibes values as a member of a class or religious denomination, caste, region, etc. Their understanding of social sciences and their ideology for social transformation set moral values for their studies. Sometimes for exigency, or under certain compulsion, they give up certain values and follow others. These are, by and large, personalised ethical values. These vary from individual to individual and situation to situation. They are individual codes of ethics and not the code of ethics and guidelines of social scientists as a community. One is accountable to oneself or in some cases to the employer or sponsoring agencies but not the peer group of social scientists. In other words, such ethical values tend to be subjective.

### **Why do we need ethical guidelines or codes of ethics?**

A social or collective code has some objective criteria shared by the community as a whole that provides collective identity as 'professionals' such as social scientists, sociologists, economists, anthropologists, etc. The collective identity helps in the growth and the pursuit of the profession. It creates checks and balances against individual idiosyncrasies. It can provide space to an individual scholar to maintain one's autonomy. CER can guard an individual researcher's freedom vis-à-vis the conditions of the sponsoring agencies related to method of data collection, confidentiality of the study, accountability, etc. CER can mobilise collective support to the individual scholar to protect one's academic freedom. At the same time I do not rule out the possibility that CER may be used by vested interests (who may not be interested in research) as an instrument to prevent a creative scholar from undertaking genuine research and raising unconventional questions. One should guard against the collective coercion of a small clique. Such coercion is detrimental to change, and growth of knowledge.

A code of ethics is necessary for all social groups to harmonise social relationships and develop consciousness among the members for common objectives. Professionals have added responsibilities as they occupy important positions in society. They are expected

to contribute to the well being of society. Social scientists are professionals in this sense. They study society. More often than not their studies receive financial support from public bodies. Even the funds from the private agencies ultimately come from the public. Further, irrespective of the sources of the funds, they obtain information from members of society. Those who provide information expect that the research would ultimately be beneficial to society at large. Hence, social scientists are responsible and accountable to society.

No science is value free. Social sciences are certainly no value force. Studies provide inputs in policymaking, rule formation, and implementation of policies and adjudication of laws. They affect people; therefore social science researches have to be guided by code of ethics to protect the interests of those whom social scientists are studying. A code of ethics is necessary even for those who follow a positivist approach and claim to be value free and objective. They cannot escape from responsibility towards the people who provide information, share emotions and energy. Moreover, they work in organisations and get assistance from several persons in their research. In the absence of consciously evolved CER rules, procedures and norms for interpersonal relationship and organisational role are arbitrarily decided in favour of those who are in authority. Superiors who wield power often ignore the contribution of the fellow researchers who are in junior positions. Such a situation is not conducive to the growth of research. It is bound to create tensions among the researchers and also between researchers and other sections of society. If the violation of rights of the people in the name of scientific studies continues unabated and if credibility of research is repeatedly questioned by various sections of society it is possible that elite of civil society, funding agencies and the state may try to impose rules on research. If that happens it would endanger autonomy of social science research. Therefore, it is the best course for the professionals themselves to consciously debate various aspects of their code of conduct and evolve CER spelling out their responsibilities, accountability and transparency of their conduct.

Integrity is the core of code of ethics. Though integrity is multidimensional, we refer here the norm in relation to data

collection. We sometimes hear allegations that in some studies the researchers or their representatives had not visited the area and not met the so-called respondents.<sup>1</sup> Investigators write answers in the questionnaires on behalf of the respondents. In short, the data is 'cooked'. This is nothing but dishonesty. Such information is worth garbage. It is useless. If this is not checked and we social scientists do not express our concern or remain indifferent, in the long run it will discredit the research and adversely affect the profession. Genuine and honest researchers would also suffer.

### **Changing nature of research**

The scope for exploration in theoretical issues at the initiative of social scientists has recently declined in all developing countries. Theoretical research is facing a heavy financial crunch. Scholars are compelled to take sponsored, so called applied research. Not only the number but has also coverage of sponsored research in terms of variation in issues and topics of study has increased. In several cases the researchers have no say in methods of data collection. Some of the changes in focus and method in research are directly related to quality and objectivity of research, autonomy of researchers, and researcher and participant's relationship. They also affect the course of utilization of research findings. All these involve a number of moral issues, which have bearing on CER.

Let me first of all clarify that that I do not subscribe a view that there is a dichotomy between theoretical and applied research. All research has both theoretical and applied aspects. Research is a pursuit to find out a pattern in phenomena. It is an endeavour to gauge and/or speculate relationship among various variables and to draw generalizations that may be tested, verified or rejected by others. For that, facts are collected, interpreted and re-interpreted. Such theoretical explanations are valuable inputs not only for the state in its policy formation and implementation, but also for social institutions of civil society. They are also relevant in the emerging social processes. Theoretical postulates are examined and assessed in several ways, not only in the form of empirical evidences. All this is possible of course, if the researcher has time, aptitude and competence for reflection.

Since the late 1970s, the ICSSR has given priority to and emphasis on policy research. It is expected from the scholar of the ICSSR-supported project that the research should have policy recommendations at the end of the study. Fortunately, the term policy is still maintained as broad concept and not confined only to the policy of the government of the day. For the conscientious scholar, relevant research cannot be devoid of social policy. But the problem arises when the notion of policy is narrowed down to the prescribed policy of the sponsoring agencies. Such discourse impinges on the freedom of the researchers.

In several cases, the sponsoring agencies restrict dissemination of the findings. It rules out the possibilities for verification and alternative interpretation of data, the cardinal principles of scientific research. The funding bodies use the research findings for expanding their interests – social, political and financial. For them knowledge is power. They buy information. For that they retain or hire professional researchers. For them, those who give information or share their experiences are treated as subjects or objects of the research. The latter have no say in the whole exercise. Neither do they know the consequences of such studies on their life. Some communities have rightly begun to question this unequal relationship.

Often the sponsoring agencies and the researchers consider applied research as micro studies applicable to specific situation. Such studies are treated as fact finding inquiries. They are sponsored with a view to find out corrective measures for a particular programme. For example, the health ministry is interested in studying the family planning programme to find out why young couples do not use contraceptives. Or, sponsoring agencies are interested in exploring the possibilities of selling a particular idea or product. The study on people's perception on lottery is an example. Or, some micro studies are related to evaluation of programmes. Such studies have instant concern for intervention. In such a concern, the scope for understanding the complexities of society is narrow. It is often a historical. It is repetitive, hardly adds to the growth of knowledge. They have potential to corrupt research priorities of the scientists and hamper their creative talents. Studies sponsored by the health ministry on population policy are case in point. These studies are dictated by a foreign power, geared

into neo-Malthusian framework. They have been focussed on family planning and control of population. They have not only used a vast public resources and talents but also misdirected policy priorities. At present, the studies on AIDS and HIV have the same story to tell. Social scientists often get into such research because huge funds are available. T. N. Madan had rightly observed nearly 20 years ago. Unfortunately research seems to have become the enemy of scholarship in this country and most social scientists seek instant *nirvana* through what passes for social research on urgent issues [Madan 1982].

### **Confidentiality and accountability**

Several areas of research increasingly impinge upon very personal and sensitive aspects of life. Anthropologists now study interpersonal family relationships and customs, psychologists study marital relationship, sociologists study domestic violence and sexuality, ethnic identity, political scientists study voting preferences, opinion and perception on public events, political participation and so on. Economists study consumption, choices, etc. These issues of study seek personal information not only about income and expenditure but also about personal relationships, likes and dislikes, preferences, emotions, desires and also fantasies from the participants of the study. Not only do these participants expect confidentiality but also they have right to know how and why the information that they parted with is used. It is unethical if this information is used against their interests.

All researchers who have done fieldwork in India generally face the following questions from the respondents: “why are you doing this study?”, “who has sent you?”, or, “who provided finances for your work?”, “what will we get by answering your questions?” and so on. These are genuine and legitimate questions. Conscientious and efficient researchers try to answer these questions to convince the respondents about their bona fides. One reason for such response is that the researchers realize that true or real information cannot be obtained from the respondents without winning their confidence. This is done not for ethical reasons but for doing good research. It is a strategy to collect the required information. It is okay so far as it goes. But it also involves ethical

issues such as right to information and accountability of the researchers. Often scientists have an arrogance that pursuit of science is for public good. And they are doing scientific research which, by definition, aims at serving the larger interests of the society. This contention is on flimsy grounds and should be challenged. I submit that so-called science and technology have helped those who are in power to perpetuate their dominance. Even assuming that scientific studies are for the larger good, questions remain: who decides the public good? Do the respondents have the right to judge whether the particular research is for public good or not? And, how far is the 'public good', good for her (including him)? A respondent is as much a citizen of this country as the researcher is. Therefore, she has a right to know the purpose of the research and the benefits – real or imaginary – that she is likely to get. She also has the autonomy to participate in the research and to choose whether to answer the questions or not. It is an obligation of the researcher to respect these rights of those who directly or indirectly participate in research by providing data.

### **Codification**

Some of the above notions of ethical conduct need to be codified for sharing common understanding. Without codification, ethical values cannot be implemented. They remain like sounding brass and tinkling cymbal. Codification, however, is based on pre-conceived concepts and categories. It is for brevity. Even a most rigorous codification cannot always cope with social dynamics related to space and time. It cannot capture all social complexities and subtle destinations.

Moreover, whenever a code, particularly when a code of conduct takes institutional form, there is a fear while evolving procedures and mechanism for implementation, that it may hamper the creativity of exceptional scholars. Moreover, if adequate care is not taken, and they get implemented mechanically, they may lose underlying spirit and perspective of CER. In the process dissenting views may get ignored and suppressed. We have to be aware of this danger. Does that mean that we should give up the exercise of preparing CER? Should we helplessly watch the present state of affairs, which tend to violate the freedom of a vast majority?

Present day social science research increasingly takes people for granted and caters to the interests of the state, the ruling and dominant classes. Should social scientists who talk about transparency and accountability remain above these norms? Moreover, autonomy of the researchers is in danger in a situation where the funding agencies decide agenda for research. Social scientists are used as an instrument to collect information. If this situation were allowed to continue for long, I am afraid that the credibility of social science research would be at stake. It is time to begin our exercise to protect the autonomy of citizens and scholars. Formation of CER is a small beginning. At the same time we should also be aware of the pitfalls of codification and we should think about checks and balances which can take care of dissent, complexities and subtle differences.

Codes of ethics are not neat and foolproof, nor applicable to all situations. They cannot be treated as administrative rules. Sometimes there are conflicting moral dilemmas such as protecting individual autonomy or cultural ethos of the community. Sometimes, the situation is so conflicting that a sensitive person is left perplexed as to what stand should one take? For instance, how do we reconcile anonymity and confidentiality with verification of the data? Protection of privacy and personal interests of the respondents is *sine qua non* for CER. How to assure this is a challenge. Some suggest that the researcher should not take down the name and other identification marks of the participants so that the anonymity of the latter can be maintained. Or, whatever information that the participants had given should not be shown to anyone. The information should remain confidential between the researcher, particularly the one who is collecting data, and the participants. Confidentiality is an important ethical value to guard the autonomy and interests of the participants. But at the same time verification of the data is an important component of research. If another researcher is not allowed to see the information and has no right to verify in the field with the respondent who had given information, then we have to believe the field investigator who claims to have collected the data. What are the implications of such a position? In a large-scale survey a field investigator collects information from a large number of respondents. Suppose that she



is instructed not to take names of the respondents, how would her supervisor check the data to see whether the information is correct, relevant or appropriate to the study? If the checking of the data were not possible, the possibility of the cooking up of such data would increase. Further, we also know that there are a few studies in which the data had been either cooked or misreported for ideological or strategic reasons. If the possibility of verification of the data by other social scientists is ruled out on the pretext of confidentiality the very basis of research gets shaken. Moreover, the possibilities of restudy of the same community over a period of time by other scholar would not arise. Hence comparative perspective to understand changing social processes would be lost. Data would become private property.

It is the moral duty of the researcher to report her findings to the participants. The latter have a right to know what the researcher has written and what are her interpretations of the information that they gave. This, however, involves a number of intricate issues. For example (a) Should the researcher report back to an individual respondent or should she report to the community? (b) Should she report to the community as a whole or to all segments of the community? (c) If the latter, which are and how are the segments be identified? (d) How does one prevent the dominant elite or groups from using the information for their own advantage and against the marginalised groups? Take an example of a study on domestic violence against women. Consider that for such a study the data is collected from female and male respondents. Is it not possible that males would use the information to further strengthen their own position? Or, the study on leadership in a community that reveals corrupt and manipulative practices of a few leaders who grab the resources of the poor. If the researcher reports the findings of the study soon after data collection it is likely that the corrupt leaders might prevent the researcher from disseminating the findings to all the segments of the society. How does one deal with such situation?

An important ethical guideline is that the researcher should tell the objective of the study in a simple language to the respondents and take their consent for the study. But it is not always easy in all social science studies. It is difficult the explain relationship of abstract variables in simple language. Some social anthropologists

begin the study by exploring broad processes, and in due course of time they study many aspects about which the scholars were not aware for at the time of data collection. They reflect on data and may look at it from a different perspective than with what they began before the inquiry. In such a situation what should one tell the respondents? Sometimes some respondents do not want to talk about their behaviour and relationship because they fear that such information might adversely affect their activities. Take an illustration of the dilemma of a young scholar who was interested in studying a traditional healer and his relationship as well as modus operandi with the patients. He met a healer and explained his purpose. The latter gave some excuses for not giving information. The researcher assured him that he had only 'academic' interests. But that did not work. The healer instructed his touts that the researcher should not remain in the vicinity of the area. The researcher tried another healer and met with the same consequences. He then selected another district and visited a healer as a patient and not as a researcher. How do we judge his behaviour?

### **Ongoing exercise**

It is not easy to evolve a code of conduct that can apply in all situations. It is possible that at present our notions of privacy, confidentiality, autonomy, etc. are not understood; in the same way by all communities. Moreover these notions of the community might also undergo changes. It is possible that our notion of privacy is more individualistic and from a western tradition, than what is prevailing among the villagers on certain aspects of life. Therefore, we have to continuously define and debate several ethical issues.

It is of greatest importance to keep ethical problems under continuing scrutiny and debate in journals, in training programmes, in public forums with social scientists taking an initiative in the process, in order to provide increasingly instructive principles for clarifying ethical issues in social science research [Hobbes 1968].

At the end let me repeat that a code of ethics or ethical guidelines, and mechanism for implementation alone are not enough for developing socially oriented research. It also requires the overall development of healthy institutions, rigorous training in social science research, overall transparency and spread of democratic

values. Laying down guidelines is one of the ways that can contribute to the growth of meaningful and socially committed research for a better social order. The present effort of formulating ethical guidelines in the form of 'Ethical Guidelines for Social Science Research in Health' is the beginning of a collective endeavour to do so with a view to:

- Create sensitivity among social scientists for larger social good.
- Develop social commitment and responsibility of the researchers.
- Evolve common terminology and concepts across disciplines that facilitate the evolution a new paradigm of research that is socially productive and responsible.

**Notes:**

1. I am using the term 'respondent' for the person who is responding to the questions of the researchers. He may be called informant. Ideally I would like to call her (including him) as participant in research because she is participating in research by giving information or allowing the researcher to observe her behaviour. Of course, she is generally not involved, by the researcher; in formulating the study.

# 3

## **Ethical guidelines for social science research in health**

### National Committee for Ethics in Social Science Research in Health (NCESSRH)

#### **Members**

Ghanshyam Shah, Manisha Gupte, Sarojini Thakur,  
Ashok Dayalchand, Lakshmi Lingam, Padma Prakash  
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Radhika Chandiramani, Thelma Narayan

#### **Coordination & Research**

Amar Jesani, Tejal Barai

### SECTION I

#### **Preamble**

- I.1. There has been a steady growth of research in the social sciences and in social science research in health in India. A wide range of research topics and issues including those that have the potential to seriously invade the privacy and security of individuals are being studied. Methodologies employed for such research have also expanded in range and depth. There is a considerable increase in the types and numbers of individuals and institutions<sup>1</sup> undertaking such research and those sponsoring and funding it.
- I.2. While it is encouraging that social science research and social science research in health are getting the attention they deserve, the growth of research without social and ethical commitment could adversely affect the credibility of research, the autonomy of researchers<sup>2</sup>, the quality of research and the rights of participants<sup>3</sup>. In fact, there is a growing concern about

indifference to ethics in some the social science research in the field of health in India.

- I.3. Social and ethical commitment and self-regulation are, therefore, imperative for all parties in research, namely, institutions undertaking research, researchers, funders/sponsors<sup>4</sup> and those who publish material generated from research. Their individual and joint efforts are needed in order to achieve consensus on a common framework for research, and to improve and strengthen the system and environment in which research is conducted. Enunciation of ethical principles and formulation of necessary guidelines for research are, therefore, a part of such a process, and also a necessary and desirable step.
- I.4. This document contains ethical principles and guidelines formulated by a national committee with the additional inputs of individuals from different institutions and disciplines. While it has immediate specific applicability for social science research in health, it is relevant for social science research in other fields as well. For medical and clinical research some of the ethical guidelines may be different.
- I.5. The ethical principles and guidelines for social science research in health, given in this document, are developed for the following purpose:
  - (i) To sensitise and protect researchers who are often under pressures from various quarters/forces while undertaking research.
  - (ii) To preserve and promote the autonomy of research through the observance of ethics, ethical values and ethical self-regulation.
  - (iii) To protect and promote the human rights of participants and to sensitise and encourage researchers and organisations to respect participants' rights and needs.
  - (iv) To improve quality, legitimacy and credibility of social science research in health.
  - (v) To make ethics an integral part of the planning and methodology of research, and to enable organisations and individuals to develop appropriate mechanisms for ethical self-regulation.

- I.6. The ethical principles and the guidelines given in this document do not, by themselves, resolve all ethical problems and dilemmas, which may confront researchers. For each dilemma and conflict they face, researchers may be required to balance the demands made by moral principles of research. The resolution of the dilemma may best be arrived at in concrete relation to the context and circumstance(s); it may involve a decision privileging one principle over another.
- I.7. The experiences in using this document may be shared. Keeping in mind the immediate and long-term interests of the larger sections of people and the autonomy of researchers, the ethical guidelines given in this document may be refined through periodic reviews.

## SECTION II

### **Ethical Principles for Research**

- II. 1. Four well-known moral principles constitute the basis for ethics in research. They are:
- (i) *The Principle of Non-maleficence*: Research must not cause harm to the participants in particular and to people in general.
  - (ii) *The Principle of Beneficence*: Research should also make a positive contribution towards the welfare of people.
  - (iii) *The Principle of Autonomy*: Research must respect and protect the rights and dignity of participants.
  - (iv) *The Principle of Justice*: The benefits and risks of research should be fairly distributed among people.
- II. 2. Ten general ethical principles, presently relevant for social science research in health in India, are as follows:
- (i) *Essentiality*: For undertaking research it is necessary to make all possible efforts to get and give adequate consideration to existing literature/knowledge and its relevance, and the alternatives available on the subject/issue under the study.
  - (ii) *Maximisation of public interest and of social justice*: Research is a social activity, carried out for the benefit of

society. It should be undertaken with the motive of maximisation of public interest and social justice.

- (iii) *Knowledge, ability and commitment to do research*: Sincere commitment to research in general and to the relevant subject in particular, and readiness to acquire adequate knowledge, ability and skill for undertaking particular research are essential prerequisites for good and ethical research.
- (iv) *Respect and protection of autonomy, rights and dignity of participants*: Research involving participation of individual(s) must not only respect, but also protect the autonomy, the rights and the dignity of participants. The participation of individual(s) must be voluntary and based on informed consent.
- (v) *Privacy, anonymity and confidentiality*: All information and records provided by participants or obtained directly or indirectly on/about the participants are confidential. For revealing or sharing any information that may identify participants, permission of the participants is essential.
- (vi) *Precaution and risk minimisation*: All research carries some risk to the participants and to society. Taking adequate precautions and minimising and mitigating risks is, therefore, essential.
- (vii) *Non-exploitation*: Research must not unnecessarily consume the time of participants or make them incur undue loss of resources and income. It should not expose them to risks due to participation in the research. The relationship within the research team, including student and junior members, should be based on the principle of non-exploitation. Contribution of each member of the research team should be properly acknowledged and recognised.
- (viii) *Public domain*: All persons and organisations connected to research should make adequate efforts to make public in appropriate manner and form, and at appropriate time, information on the research undertaken, and the relevant results and implications of completed research.
- (ix) *Accountability and transparency*: The conduct of research must be fair, honest and transparent. It is desirable that

institutions and researchers are amenable to social and financial review of their research by an appropriate and responsible social body. They should also make appropriate arrangements for the preservation of research records for a reasonable period of time.

- (x) *Totality of responsibility*: The responsibility for due observance of all principles of ethics and guidelines devolves on all those directly or indirectly connected with the research. They include institution(s) where the research is conducted, researcher(s), sponsors/funders and those who publish material generated from research.

## SECTION III

### **Rights and Responsibilities of Researchers and Institutions**

#### **III. 1. Relationship between researchers and institution**

- III. 1.1. Institutions have a responsibility to respect the autonomy of researchers and the ethical guidelines for research.
- III. 1.2. Institutions should create and maintain an environment with adequate support systems to enable researchers to follow ethical guidelines.
- III. 1.3. Institutions have a responsibility to take appropriate and adequate steps for protection against pressures inimical to the observance of ethical guidelines for research.

#### **III. 2. Protection and promotion of integrity in research**

- III. 2.1. Researchers have a right, as well as a responsibility, to refrain from undertaking or continue undertaking any research that contravenes ethical guidelines, violates the integrity of research and/or compromises their autonomy in research, including design methodology, analysis and interpretation of findings and publication. If they feel that their rights are being violated, or that the study is unethical, they should make all possible efforts at making corrections. In the event of failure of remedial measures they should exercise their right to terminate the study or to opt out of it.



- III. 2.2. Researchers should undertake only such research that according to their understanding will be useful to society or for the furtherance of knowledge on the subject.
- III. 2.3. Researchers should not undertake secret or classified research, any secret assignment under the garb of research nor research whose findings are to be kept confidential. Researchers have a right as well as responsibility to make all necessary efforts to bring the research and its findings to the public domain in an appropriate manner.
- III. 2.4. Researchers have a responsibility towards the interests of those involved in or affected by their own work. They should make reasonable efforts to anticipate and to guard against possible misuse and undesirable or harmful consequences of research. Researchers should take reasonable corrective steps when they come across misuse or misrepresentation of their work.
- III. 2.5. Researchers should ensure that there is honesty and transparency at every stage of research as these are indispensable for good and ethical research.
- III. 2.6. Researchers should ensure that there is no fabrication, falsification, plagiarism or other unethical practices at any stage of the research; and that the findings of research are reported accurately and truthfully. They should also ensure protection of historical records and preservation of study material.
- III. 2.7. All parties involved in research and dissemination of its findings should inculcate and practice sensitivity and respect for culture and other aspects of the group or community studied.
- III. 2.8. Researchers must ensure respect, protection and promotion of rights of participants. Criteria for the selection of participants of research should be fair, besides being scientific.
- III. 2.9. Peer review should be an essential part of every research endeavour or initiative, and should be sought at various stages of research.

### **III. 3. Relationship among researchers**

- III. 3.1. Principal researchers are responsible for the ethical conduct of research by all juniors, assistants, students and trainees. At the same time juniors, assistants, students and trainees have an

equal responsibility for ethical conduct and observance of ethical guidelines.

- III. 3.2. The juniors, assistants, students and trainees have a right to receive, and principal researchers have a responsibility to provide/impart, proper training and guidance regarding all aspects of research, including ethical conduct. The principal researchers should delegate to the juniors, assistants, students and trainees only those responsibilities that they are reasonably capable of performing on the basis of their education, training or experience, either independently or under supervision.
- III. 3.3. No researcher should engage, personally or professionally, in discriminatory, harmful or exploitative practices, or any perceived form of harassment. Nor should the researcher impose views/beliefs on or try to seek personal, sexual or economic gain from anybody, including other researchers, juniors, assistants, trainees and students.
- III. 3.4. Researchers should not deceive or coerce other researchers, including juniors, assistants, trainees and students into serving as research subjects/participants, nor use them as cheap labour.
- III. 3.5. Researchers should be co-operative, responsive, honest and respectful about the interest, opinion/view, capability and work of other researchers, including juniors, assistants, trainees and students.
- III. 3.6. While working in the team on a research project, at the outset, all members of the team have a right to know and document all aspects of research including ownership of the data. This procedure also applies to the participation of students doing their own research in a project team. Students should have the right to opt out of a research project without having to face adverse consequences.
- III. 3.7. In addition to researchers, other individuals such as administrative staff of the organisation conducting research or that of the research setting, etc may be associated, in some way, with the research. All of them should be briefed on ethical issues and the guidelines, including the need to protect the rights of participants and the confidentiality of identifiable data.

### **III. 4. Data sharing**

- III. 4.1. Sharing of data should be done in a form, which is in consonance with the interests and rights of the participants. Researchers who have conducted the study and the institution where the study is conducted are fully responsible for ensuring the protection and promotion of the interests and rights of participants while sharing or making public available data in any form.
- III.4.2. The researchers involved in a particular research and the institution where the research is conducted, have a joint right over and ownership of all raw data, including those identifying the participants. Along with this right, they are fully responsible for ensuring that when such data, including those that identify participants, are shared with other researchers, all necessary measures are taken and followed to maintain confidentiality, by those researchers with whom data are shared.
- III.4.3. Data that do not identify participants and their whereabouts, in the form of anonymous or abstracted facts, may be commonly shared, if necessary even before the publication of the study, among researchers, peer reviewers, or may even be made available to the public.
- III.4.4. As far as possible, researchers and institutions should ensure that relevant summary findings of the research are taken back to the research participants in a form and manner that they can understand. In this process they should take into consideration the possible social harm that such information might cause to the research participants.

### **III. 5. Reporting and publication of research**

- III. 5.1. Reporting of research and its results is the right as well as duty of every researcher and institution that conducted the study. When they agree to delegate this responsibility to funder(s)/ sponsor(s) or any other individual(s)/organisation(s), they should do it only if they have received mutually agreed and expressed commitment to publish/disseminate the results/report within a stipulated period.

- III. 5.2. The results should be reported irrespective of whether they support or contradict the expected outcome(s). Researchers should also disclose in their publications, the source(s) of funding and sponsors, if any, unless there is a compelling reason not to do so. The findings should also explain the methodology used, as well as how, in actual practice the ethical guidelines were followed, ethical dilemmas encountered and resolved, etc.
- III. 5.3. *Authorship credit*: The following guidelines should be followed for giving authorship credit while reporting the research in any form:
- (i) Authorship, and its sequence in case of more than one author, should be based on the quantum of contribution made in terms of ideas, conceptualisation, actual performance of the research, analysis and writing of the report or any publication based on the research. Authorship and its sequence should not be based on the status of the individual in the institution or elsewhere.
  - (ii) All other individuals not satisfying the criteria for authorship but whose contribution made the conduct and completion of research or publication possible should be properly acknowledged.
  - (iii) A student should be listed as principal or first author on any multiple authored publication that substantially derives from the student's dissertation or thesis.
  - (iv) Appropriate credits should be given where data or information from other studies or publications is quoted or otherwise included.
- III. 5.4. Researchers should avoid dissemination of the results of research before they are peer-reviewed or published in appropriate journals. When such results are disseminated through the popular media, extra care should be taken to ensure that even those media persons not specifically trained in social science and health issues and research, are able to comprehend the limitations and implications of research results. Journalists and the media that publish these research results have a responsibility to do so truthfully and honestly.

- III. 5.5. When institutions and/or researchers publish a report or any other documents based on research, they should make adequate efforts to ensure their easy availability and accessibility.

## SECTION IV

### **Rights of Participants**

#### **IV. 1. Relationship with the participants**

- IV. 1.1. Participants should be seen as indispensable and worthy partners in research. Researchers should recognise and ensure that respect, protection and promotion of the rights of participants are made intrinsic to every stage and level of research undertaken by them.
- IV. 1.2. Research undertaken should not adversely affect the physical, social and/or psychological well being of the participants. The risks and benefits of the research to the prospective participants must be fully considered; research that could lead to unnecessary physical harm or mental distress should not be undertaken. Researchers should make adequate provision for the comfort of the participants as well as for protection against all possible and potential risks.
- IV. 1.3. The criteria for selecting research participants should be fair. The easy accessibility of the participants alone does not constitute a fair criterion for their inclusion in research as that will make them bear an unfair share of the direct burden of participation. At the same time, it should be borne in mind that no particular group or groups should be unfairly excluded from research, as that could well exclude them from the social understanding of their situation, and can also unfairly exclude them from direct, indirect or potential benefits of research.
- IV. 1.4. Unless consent on mutually beneficial arrangement is obtained, institution and student should not use community or research setting as a constant and long-term resource for data collection for curricular research or training in an institution.
- IV. 1.5. The relevant social, cultural and historical background of the participants should be taken into consideration and given appropriate importance in the planning and conduct of research.

- IV. 1.6. Researchers should not impede the autonomy of participants by resorting to coercion, promise of unrealistic benefits or inducement. Participants and communities should not be exploited and the time taken for data collection from these sources should not be inordinately long.
- IV. 1.7. Participants are autonomous agents and must have the right to choose whether or not to be part of the research. They also have the right to change their decision or withdraw the informed consent given earlier, at any stage of the research without assigning any reason.

## **IV. 2. Informed consent**

- IV. 2.1. Voluntary and informed participation of individuals or communities is necessary for research. Their participation should be based on informed consent; the greater the risk to participants, the greater is the need for it. Informed consent is essential to protect the participants, not the researchers and institutions.
- IV. 2.2. Consent for participation in research is voluntary and informed only if it is given without any direct/indirect coercion and inducement, and is based on adequate briefing given to the participants about the details of the project. The briefing should be given both verbally and in writing in a manner and language that the participants know and understand. In the prevailing circumstances in India, often, it may not be possible to obtain signed informed consent of the participants in social science research in health. It is however essential that the participants are furnished with written information giving adequate details of the research. Researchers have a duty to ensure that the participants comprehend the information given.
- IV. 2.3. The verbal and written briefing of the participants, in the manner and language they understand, should include the following details:
- (i) *Purpose of research*: The goal and objective of research should be presented in simple local language.
  - (ii) *Identity of the researchers*: Name and address of researcher(s), the institution(s) and the main person of the

ethics committee/ethical review board or any such ethics group of the institution.

- (iii) *Identity of others associated with the research*: Name(s) and address of chief consultant(s), funder(s) or sponsor(s), etc., if any.
- (iv) *Why selected*: Reasons or method for selecting the particular locality, community and/or any other setting; and individual(s) or group(s) within that, for participation in the study.
- (v) *Harms and benefits*: The possible, anticipated and potential benefits and/or harms (direct/indirect, immediate/long term) of research and their participation.
- (vi) *Privacy, anonymity and confidentiality*: Information on the extent of privacy, anonymity and confidentiality that will be provided to participant(s). This must include, at least, the firm commitment that privacy, anonymity and confidentiality of data identifying participants will be strictly maintained. In case the data identifying participants is to be shared with or made available to individuals/organisations not in the research team, information about them (their names, addresses etc.) should be provided.
- (vii) *Future use of information*: The future possible use of the information and data obtained, including use as a database, archival research or recordings for educational purposes, as well as possible use in unanticipated circumstances, like its use as secondary data should be made known to participants. Such use should be only of anonymous or abstracted information and data, and should in no way conflict with or violate the maintenance of privacy, anonymity and confidentiality of information identifying participants.
- (viii) *Right not to participate and withdraw*: Participants should also be informed about their right to decline participation outright, or to withdraw consent given at any stage of the research, without undesirable consequences, penalty and so on. The participants should be informed that they are free to object to and refuse to allow the use of data gathering devices, such as camera, tape recorder, etc.

(ix) *Right to get help*: The researcher should try and get all the possible help that the participants might require. The researcher also has a responsibility to help the participant(s) in cases of adverse consequence or retaliation against the participant(s) by any agency due to their participation in the research. Information, which may contribute to the improvement of quality of life of the participants, should be passed on to concerned person(s), official(s) or the agencies.

IV. 2.4. If the data collection from the participant(s) is done in more than one sitting or contact and there is a long time period between the sittings/contacts, informed consent should be sought each time.

IV. 2.5. In some cases, revealing the identity of the group of participants, groups, village(s), neighbourhood(s), etc, in the report could have an adverse effect on members/residents there. Sometimes the researchers are not able to anticipate the possibility of adverse effect at the time of conducting research and publishing reports. Researchers should take care that the study communities and/or localities are not identified or made identifiable in the report unless there are strong reasons for doing so. If the researcher(s) and institution intend to identify them in the report, participants' informed consent allowing such disclosure should be obtained.

IV. 2.6. *Non-disclosure of all information*: In some specific situations and research issues, it is not practically possible to carry out research if all the details of the study are revealed to participants. This may be due to genuine difficulties in accessing participants, possibility of affecting change in behaviour or responses, etc., when the details are revealed. Thus, it is not possible to obtain the informed consent in the same way as described above. In such cases, the following should be done:

(i) A detailed justification for not revealing all necessary information must be provided in the research proposal and methodology and should be subject to peer and ethical reviews. Only on approval in peer review, should such research be undertaken.



- (ii) The participants' right to privacy, anonymity and confidentiality gains additional importance in such cases as they do not know fully the real purpose or objective for which they provide information.
- (iii) Even if through a peer review process it is accepted that some of the information about the study need not be revealed, participants must be provided the rest of the information. Under no circumstance should the researchers withhold the information regarding physical risks, discomfort, unpleasant emotional experiences, or any such aspect that would be a major factor in taking the decision to participate.
- (iv) As far as possible, debriefing should be done with the participants after completion of the research, giving reasons for not providing full information. As a part of the debriefing process, it might often be necessary to provide services such as counselling and referral.

IV. 2.7. *Consent where gatekeepers<sup>5</sup> are involved:* In some situations there may be a need to obtain permission of the 'gatekeeper' to access the participants for research. The following care must be taken in such situation:

- (i) Permission obtained from the gatekeeper must not be substituted for the need to take separate and full informed consent of the participants. The rights of participants in such situation are the same as in all other cases and need determined protection.
- (ii) For obtaining permission of the gatekeeper, no pre-condition demanding sharing of information or data obtained should be accepted.
- (iii) In the process of research or data collection, adequate care should be taken to ensure that the relationship between the gatekeeper and the participants is not jeopardised.
- (iv) Greater care should also be exercised in protecting participants and their interest while publishing and disseminating results of research.

IV. 2.8. Informed consent in the case of research with children (below the age of fourteen years) should be sought from the parents/guardians as well as the children themselves. Where

the parents/guardians consent to participate, and the children have declined, the rights of the children should be respected. The consent from parents/guardians should be waived only in special cases such as child abuse. Peer review is indispensable and the protection of children especially from the immediate consequences of research gains prime importance.

#### **IV. 3. Privacy, anonymity and confidentiality**

- IV. 3.1. Anonymity and confidentiality are the inherent rights of all participants. The right whether to remain anonymous or to be identified lies with the participant. It becomes all the more important in research projects dealing with stigmatised, sensitive or personal issues and information.
- IV. 3.2. Possibility of the breach of confidentiality and anonymity should be anticipated, addressed and explained to the participants.
- IV. 3.3. Appropriate methods should be devised to ensure privacy at the time of data collection. These methods are also essential to ensure the validity of data.
- IV. 3.4. The obligation to maintain privacy, anonymity and confidentiality extends to the entire research team, other researchers in the institution, the administrative staff, and all those (from or outside the institution) not directly associated with the research who may possibly have access to the information.
- IV. 3.5. While deciding on what information should be regarded as private or confidential, the perspective of the participant(s) on the matter should also be given adequate importance.
- IV. 3.6. Researchers should maintain appropriate anonymity and confidentiality of information in creating, storing, accessing, transferring and disposing of records under their control, whether these are written, automated or in any other medium.

## SECTION V

### **Rights and Responsibilities of Peer Reviewers/Referees**

- V. 1. The purpose of peer review and refereeing is to improve and advance research, and facilitate observance of ethics. Researchers should be encouraged to make themselves available for such work and subject their own work to such a process.
- V. 2. Researchers should accept the role and duties of peer reviewer and referee only for the research in the fields they have adequate knowledge and expertise. They must also be fully aware of the ethical aspects of research and publication.
- V. 3. When called upon to act as peer reviewer and referee, researchers have an ethical duty to undertake it objectively, impartially and constructively.
- V. 4. If the peer reviewers/referees have any actual or potential conflicts of personal or professional interest with the work under review, they should either disclose the same or decline to review the work concerned. In such situations, their role should be decided on the basis of the type and severity of the conflict of interest.
- V. 5. When malpractice in research or violation of ethics are discovered, the researcher/peer reviewer has the ethical responsibility to take appropriate steps to report it.

## SECTION VI

### **Rights and Responsibilities of Editors and Publishers**

- VI. 1. Before accepting the research based articles for publication, editors and publishers have the right and duty to ensure that such material is, duly reviewed by referees deemed by the publication to have the relevant expertise and knowledge in the particular field.
- VI. 2. As social scientists and as journalists, editors are responsible for ensuring that the editorial policy and instructions to authors reflect the ethical concerns and the guidelines for research. Referees and editorial staff should be made aware of the editorial policy including the need for articles/papers to adhere

to prescribed ethical norms. Contributors should be informed that the material submitted for publication should carry appropriate credits. Fabricated, falsified or plagiarised information should not be entertained.

- VI. 3. If, after the publication of material, any doubt is raised about its ethical status or ethical conduct of the study on which the said material is based, editors should take appropriate corrective steps.

## SECTION VII

### **Rights and Responsibilities of Funders and Sponsors**

- VII.1. Funders and sponsors have the right to expect that researchers and institutions report the progress of their work and submit a copy of the final report on results of research as per the schedule agreed in advance.
- VII.2. Funders and sponsors have a right to get a copy, if any, of the ethical guidelines for research followed by the researchers and institutions. They also have a right to expect that the research proposal submitted for funding or sponsorship by researchers and institution contains necessary information on ethical issues in and ethical conduct of the particular research proposed.
- VII.3. The funders and sponsors of research should respect the ethical guidelines for research and should not expect researchers and institutions to undertake research or conduct it in any way contrary to the ethical guidelines.
- VII.4. Where sponsors and funders also act, directly or indirectly, as gatekeepers and control access to the participants, researchers should not devolve onto the gatekeeper their responsibility to obtain separate and full informed consent from participants and protect all rights of the participants.

## SECTION VIII

### **Organisational Mechanism for Ethics**

While ethical guidelines are not administrative rules and the conscience of researchers may be the best guide for ensuring that ethics are followed in research and for resolving ethical dilemmas, conduct of research cannot be completely left to the discretion of individual researchers. Institutions and researchers involved in social science research in health should create appropriate institutional or research project based mechanisms to ensure ethical conduct of research and implementation of guidelines.

#### **Notes:**

1. Institution is any organisation (public, private or voluntary) undertaking research.
2. Researcher is any individual directly involved in research or a research project.
3. Participants are individuals or groups from and/or on whom the researchers collect information for research.
4. Funders/Sponsors are individuals and organisations (public, private or voluntary) providing full or part funding and/or sponsorship for the research.
5. Gatekeepers are those who control researchers' access to participants. They could be persons in-charge of research setting, a community leader whose advise or instruction the participants follow, or any other without whose consent the researchers are unable to obtain access to participants.

**III**

**Epidemiological, Biomedical  
and Social Science Research**



# 4

## Ethics and epidemiological research

### Dilemmas and concerns in Indian milieu

#### Madhukar Pai

With the intense heat generated over allegations of unethical HIV research, the ethics of health research are being debated world over [Angell 2000a; Lurie and Wolfe 1997]. The Indian government [Mudur 1997; Sharma 2001] and the media [*New Indian Express* 2000; *The Economist* 2000] have voiced concern that the third world might be 'reduced to one big lab' for human experimentation by western researchers. In this context, the 'Ethical Guidelines for Social Science Research in Health' [NCESSRH 2000] is a welcome development and could inform the debate within India.

Historically, the Nuremberg Code [Nuremberg Military Tribunal 1949] was one of the earliest ethical guidelines on research [Katz 1996]. The World Medical Association [WMA] Declaration of Helsinki [WMA 1964; 2000] the Belmont Report [National Commission for the Protection of Human Subjects 1978] and the Council for International Organisations of Medical Sciences International Guidelines [CIOMS 1991; 1993, 2002] are other examples. Some of these guidelines have been recently revised [WMA 2000] or are currently under revision [CIOMS 2002]. Guidelines intended specifically for epidemiologists have been developed by agencies like the CIOMS (1991) American College of Epidemiology [ACE 2000] and the International Epidemiological Association [IEA 1990]. In India, the Indian Council for Medical Research [ICMR] recently finalised its guidelines on biomedical research [ICMR 2000]. Despite the panoply of guidelines, problems remain. In this review, I will not discuss these well-known guidelines. They have been reviewed elsewhere [Levine 1986, Coughlin and Beauchamp 1996, Weed and Coughlin 1999]. I will



focus on some ethical issues that I perceive to be relatively more relevant or are topical.

### **Ethics of bad science**

According to the CIOMS guidelines,

A study that is scientifically unsound is unethical in exposing subjects to risk or inconvenience and achieving no benefit in knowledge' [CIOMS 1991]. According to the Committee on Publication Ethics [White and Williamson 2001]

'Good research should be well justified, well planned, appropriately designed, and ethically approved. To conduct research to a lower standard may constitute misconduct.' Bad science is considered unethical. Altman 1982 summarised the ethical implications of poorly conducted research,

- The misuse of patients by exposing them to unjustified risk and inconvenience :
- The misuse of resources, including the researchers' time, which could be better employed on more valuable activities, and
- The consequences of publishing misleading results, which may include carrying out of unnecessary further work.

Altman also discussed what he called the scandal of poor medical research,

What should we think about a doctor who uses the wrong treatment, either willfully or through ignorance, or who uses the right treatment wrongly? Most people would agree that such behaviour was unprofessional, arguably unethical, and certainly unacceptable. What then, should we think about researchers who use the wrong techniques (either willfully or in ignorance), use the right techniques wrongly, misinterpret their results, report their results selectively, cite the literature selectively, and draw unjustified conclusions? We should be appalled. Yet numerous studies of the medical literature...have shown that all of the above phenomena are common. This is surely a scandal.' [Altman 1994].

In India, researchers without adequate training or understanding of research methodology sometimes conduct medical

research. This, I suspect, is particularly true of medical professionals. Many doctors graduate with very little training in epidemiology and biostatistics. These are grossly neglected areas of medical education [Rajagopalan 1997]. Given this scenario, it does not come as a surprise that there is a paucity of good quality medical research, and only a few Indian journals are indexed and of good quality [Reddy et al. 1991, Nundy 1998]. Many Indian papers go unnoticed and have a very small impact [Arunachalam 1997]. Much of the Indian medical research may be largely irrelevant to the health problems of the country [Arunachalam 1997]. Another survey demonstrated that there are many medical colleges in India, which do not contribute even one peer reviewed publication in a year [Arora et al. 1996].

Bad science is particularly dangerous in experimental studies. On the one hand, it may be unethical to introduce into general use a therapy or drug, which is totally untested or poorly tested. As Sir Bradford Hill put it,

The ethical problem is, indeed, not solely one of human experimentation; it can also be one of *refraining from human experimentation.*’ [Hill and Hill 1991 emphasis added].

On the other hand, a clinical trial should not be undertaken when, because of the absence of randomisation, blinding, or sufficient number of subjects, it is unlikely to provide a conclusive answer [Hulley and Cummings 1988]. Indeed, it is important that a researcher embarking on a clinical trial make every effort to design the trial well and pay attention to all the core methodological issues in the trial. It is quite common to see reports concluding that no inference could be made about the efficacy of the new treatment because of inadequate sample size. Why put human lives at risk and waste a lot of resources when the research question is unlikely to be satisfactorily answered?

The NCESSRH [2000] guideline states, ‘Sincere commitment to research in general and to the relevant subject in particular and readiness to acquire adequate knowledge, ability and skill for undertaking particular research are essential prerequisites for good and ethical research.’ What are the ethical implications of research done by those who are disinterested in doing research? The Medical Council of India and the National Board of Examinations require

dissertations for completion of postgraduate degree programmes. It is a well-known that not all postgraduates are interested in research and dissertations sometimes get hastily put together days before the examinations. Plagiarism, fabrication, and 'recycling' of old dissertations are not unknown [Gitanjali et al.1998]. Needless to say, because dissertations are mediocre they hardly get published. Some authors have asked whether this practice of submitting dissertations serves any meaningful purpose [Gitanjali et al.1998]. One solution may lie in improving the quality of medical education in India, better teaching of research methodology at the undergraduate and postgraduate level, training of guides and teachers, increasing resources for research and recognition and rewarding of researchers for their contribution. Ultimately, students have to perceive research as an activity that is inherently interesting and rewarding. They should see research as the basis for generating evidence for clinical practice. When that happens, the learning objective behind dissertations may be fulfilled.

Some institutions in India now offer degree programmes in epidemiology and public health. These programmes should include mandatory, post-graduate level coursework in ethics. Such courses are offered in several schools of public health in the US and UK, and detailed curricula [Goodman and Prineas] and textbooks exist to enable such training [Coughlin and Beauchamp 1996]. For those working in the clinical field, ethics workshops and lectures should be organised. Groups like the Medico Friend Circle and Forum for Medical Ethics in India have attempted such activities.

### **Research involving pharmaceutical industry**

Leading western biomedical journals have facilitated a debate about pharmaceutical industry sponsored clinical research [Angell 2000b, Weatherall 2000, Bodenheimer 2000]. There is now a growing sense of unease in the research community about the risks of such sponsorship. The International Committee of Medical Journal Editors [ICMJE] recently released a document entitled *Sponsorship, authorship and accountability*. This document discusses the problems involved with industry-sponsored trials, and outlines the new policies that are being adopted by journals [Davidoff et al. 2001].

Clinical trials have become very controversial in India. Suddenly, India appears to be the top destination for multi-national companies planning to conduct trials [*The Economist* 2000]. According to reports, there has been a 400 percent increase in the filing frequency of investigational new drugs with the Drug Controller General of India [DCGI] during 1999-2000, as compared to the figures for the previous year [Narendranath 2000]. Lower costs of conducting trials, faster patient recruitment, availability of well-trained medical professionals and high-tech hospitals, fluency of English among health professionals, and a high disease burden in the country are some of the reasons given for this trend. The current DCGI has been quoted as saying 'India has a vast pool of patients, qualified doctors, and good hospitals that make it an attractive site' [Mudur 2001]. In parallel, there are now Contract Research Organisations that conduct trials for pharmaceutical companies [*The Economist* 2000]. Pharmaceutical companies are also collaborating with western universities for conducting trials. Given the recent allegations [Mudur 2001, Bagla 2001] of unethical human experimentation, there is a need to examine issues related to industry sponsorship. While a more extensive review can be found elsewhere [Pai and Colford 2002], the core issues are summarised here.

There is a concern that India has become an attractive testing ground for experimental products. As a result, the Indian government is examining the role and conduct of clinical trials closely. On May 16, 2001 the Ministry of Health proposed new rules to rationalise the system of approval of new drugs and conduct of clinical trials and post-marketing surveillance [Sharma 2001]. Drug companies are now required to provide the DCGI trial protocols and names of investigators who will be involved in the trials. A system for random auditing of clinical trial centres has been proposed and this will also cover private hospitals. Also, there are indications that the Indian government will not approve trials of new treatments when they are done exclusively in India.

A major difference with industry-sponsored research is the fact that trials are often done to promote the approval of a new drug or device rather than test a scientific hypothesis [Davidoff et al. 2001]. Sponsors attempt to influence the design, conduct,

analyses and interpretation of the trials supported by them [Angell 2000b, Bodenheimer 2000]. Researchers may not have complete control over issues such as ethical concerns, design issues, analysis, and publication. Even when physicians can participate in the design and analyses, they often tend to be left out of the process during the publication phase [Bodenheimer 2000]. Given that patients may participate in trials for altruistic reasons, the ICMJE state, ‘...the use of clinical trials primarily for marketing, in our view, makes a mockery of clinical investigation and is a misuse of a powerful tool’ [Davidoff et al. 2001].

In India, pharmaceutical companies are legally required to perform clinical trials to obtain approval from the DCGI for marketing new drugs. Any new drug manufactured or marketed in India has to be approved by the DCGI [Sharma 2001]. The permission to conduct clinical trials for new drugs is also granted by the DCGI. To meet such regulatory requirements, companies may approach academic institutions, private hospitals and private physicians to conduct their trials. The companies may sometimes view and treat these institutions as contract research organisations, rather than academic collaborators. They may offer financial inducements and gifts (such as equipment) to the hospitals for participating in these trials. For individual physicians, the inducements may include honoraria, speaker’s fees, gifts, supplies of drug samples, and national/international trips for attending conferences and meetings. Such inducements are widely used by drug companies in India and in other countries for drug promotion and marketing [Lal 2001].

Drug companies usually approach reputed physicians with large, successful practices. The companies then encourage these physicians to enrol participants for the trials according to protocols set out by them. The physicians may be expected to passively adhere to these protocols without allowing for their input into the design. While these physicians may be excellent clinicians, they may lack the research expertise necessary for properly conducting clinical trials. Furthermore, they may not always fully comprehend the ethical issues involved in any trial. As a result, they may find themselves involved in research that may be poorly designed, and therefore, unethical. Since trials may be done for regulatory

purposes, the sample sizes may be small. Anecdotally, I have seen trial protocols with very small sample sizes. Such trials simply could not have adequate statistical power (sample size) to pick up the treatment effects they were designed to identify. This, by itself, could be considered unethical because an underpowered study would not be able to answer the research hypothesis conclusively.

Institutions that conduct these trials may have little control over the data. The data are usually ‘owned’ by the drug companies and, once the drug is approved, companies may choose not to publish the data. Drug companies have been reported to suppress findings that are not favourable to their products [Rennie 1997, Blumenthal et al. 1997]. There are instances of companies analysing and publishing the data secretly, without involving the original investigators. The scandal involving the drug Synthroid is an apt example [Rennie 1997]. Synthroid, a synthetic brand name thyroxine, is manufactured by Boots Laboratories (now called Knoll Pharmaceuticals). In 1987 Boots had contracted with researchers at the University of California at San Francisco to study whether Synthroid was more effective than other generic thyroxine preparations. The study concluded that Synthroid was no better than other generic thyroxine preparations in the market. Boots waged a major campaign to discredit the study and do everything it could to prevent the trial results from being published. A *JAMA* editorial [Rennie 1997] on this issue in the Journal of the American Medical Association (*JAMA*) warned ‘scientists should never sign any agreement that give their sponsors veto power over publication’.

Conflict of interest is always a concern with clinical trials. There are reports of doctors getting paid huge sums of money for recruiting patients for trials [Eichenwald et al. 1999a]. Clinicians have also been found guilty of coercing patients [Eichenwald et al. 1999b]. The involvement of physicians in drug trials has raised concern whether the dual role of physician-researcher is a conflict of interest because the objectives of research and patient-care differ a great deal [Levine 1992]. Levine [1992] calls physician-researchers ‘double agents’ and suggests that whenever one individual attempts to play both roles simultaneously, the Institution Review Board [IRB] has to protect the interests of the patients. This issue was brought out sensitively in ‘Miss Evers Boys’, an

Emmy award-winning film on the infamous Tuskegee study. In this study, African American males with syphilis in Macon County, Alabama, were denied treatment for many years in order to document the natural history of the disease [Jones 1981]. In the movie, Miss Evers (playing the role of Eunice Rivers, a public health nurse in the real Tuskegee study) is an African American nurse who takes care of these patients with syphilis. On the one hand, she believes in the importance of the scientific study (which, she is told, is ‘for the greater good of the community’) while on the other hand, she is desperate to provide her ailing patients with penicillin (which she knows is very effective). It is worth noting that in 1997, 65 years after the Tuskegee study first began, President Bill Clinton formally apologized on behalf of his country to the survivors of the study and their families.

How do Indian journals address sponsorship and conflict of interest? We did a survey of 15 leading biomedical journals, and abstracted data from the ‘Guidelines to Contributors’ sections of these journals [Pai and Colford 2002]. Eight of 15 journals (53 percent) required disclosure about funding support but only three (20 percent) required disclosure about personal or financial conflict of interest. None of the journals required information about the role of the sponsor, the degree and type of involvement of the sponsor, information regarding the authors’ access to data, and control over the decision to publish the results. Are western journals any better? In a survey of 48 journals in the US, 20 (42 percent) reported that they had policies requiring disclosure of conflicts of interest [McCrary 2000].

What can be done about these issues? To begin with, we need to be aware of the problems involved with industry-sponsored research. We need to learn from the experiences of researchers and institutions that have encountered these problems. The ICMJE document needs to be read and debated widely. When approached by an industrial sponsor, researchers and IRBs should debate the advantages and disadvantages of accepting such an offer or contract. If the hospital does not have an IRB, one should first be constituted before accepting any offer. While working for a private hospital, we have had offers to become involved with sponsored research. In these situations, the IRB of the institution debated the issue,

and, as an institution decided against accepting such offers. During the review process for a proposed study, if the proposal is accepted, the IRB of the hospital should refuse to sign any contract or agreement, which denies the institution the right to design, analyse and publish data independently of the sponsor.

Patients need to be in a state of personal equipoise to justify participation in any clinical trial [Lilford et al. 2001]. Equipoise refers to a state of genuine uncertainty about the relative advantage of one therapy over another in a trial. In the informed consent process, patients should be told upfront that the trial is being done to meet regulatory and marketing needs rather than to answer a scientific question. This information is vital to allow a patient to make a truly informed decision about participation.

We need data regarding the number of trials conducted in India, sources of their funding, and information about the role of sponsors in these trials. Such data, as shown in a recent survey, can be revealing [BMJ 2001]. A survey of 268 trials published by six leading journals, showed that,

Just over a third were supported wholly or in part by industry, and only 9 percent failed to give the source of funding. In the trials supported by industry, a third did not provide any information on the authors relations with industry. The type and degree of the involvement of the funding source was disclosed in only eight percent of cases.

In the absence of a registry or database of trials, such data is hard to come by in India. Research agencies like the ICMR could initiate an effort to register all clinical trials in India.

There may be substantial underreporting of clinical trials in the medical literature [Chalmers 1990]. As articulated by Chalmers, 'failure to publish an adequate account of a well-designed clinical trial is a form of scientific misconduct that can lead those caring for patients to make inappropriate treatment decisions. The NCESSRH guidelines (2000) emphasise, 'reporting of research and its results is the right as well as duty of every researcher and institution that conducted the study'. We need information about how many trials are conducted and published in India. This is particularly relevant if public funds are used to conduct trials. Concerns have been raised about the accountability of individuals



and institutions regarding funds spent for research [Arunachalam 1997]. Again, this process will be facilitated if there was a registry of trials. Editors of medical journals need to revise their guidelines to cover current developments in publication ethics, and explicitly demand information on sponsorship and conflict of interest.

### **Authorship and publication ethics**

Authorship of papers is a difficult issue. Often, it is not clear how authorship should be granted and how the sequence of authors should be decided, though there are examples of how health researchers have attempted to evolve policies for their own institutions [Jesani 1996]. Generally, in our milieu, authorship is hardly discussed and debated among all those involved in research. Sometimes, the senior person or the principal investigator usually decides on authorship unilaterally. Junior researchers may not have the authority or willpower to question such decisions. The practice of including the name of the senior faculty member/head of the department is all too common. ‘Gift coauthorships’ are not uncommon either [Engler et al. 1987]. This is particularly the case in research labs where the head of the lab or the person who provides some research facility gets authorship even if s/he was never involved in the research. Sometimes this phenomenon works in the reverse. There are instances where excellent studies have never been published or publication delayed for years because of disputes among researchers over authorship. In Europe, the Committee on Publication Ethics [COPE] [White and Williamson 2001] investigates cases of scientific misconduct and publication disputes. The COPE guidelines should be of help to all those struggling with publication related misconduct issues and disputes.

We do not know what proportion of the research work in India gets published. There have been discussions on the low output of publications from India [Nundy 1998; Pandya 1990; Reddy et al. 1991]. In our environment, it is not uncommon for researchers not to publish their work. This is partly because promotions and career advancements are rarely made on the basis of number of publications. While it is probably good not to publish poor quality studies, it is sad that quite a good number of well-done research studies are often unpublished because of laziness and a laid back

attitude towards publishing. It could also be that papers don't get published because our researchers lack knowledge and guidance in how to write scientific papers. It is also a widespread practice not to publish or present negative studies. Also, busy clinicians may not have the time to write up their research. Thus, not publishing enough has to be understood in the context of our wider problem of lack of resources for research, poor leadership, lack of encouragement and good guidance. Organising workshops on how to write journal articles might help. Journals like the *National Medical Journal of India* have attempted to do this.

### **International research ethics**

International health research is increasingly becoming common and many institutions in India now collaborate with foreign institutions. This is partly because foreign researchers find it much easier to get population based data in India than in their own countries. Indian researchers get technical inputs and funding from their western counterparts. While international collaboration is important, it creates unique problems [Benatar and Singer 2000]. Firstly, a fundamental, age-old dilemma is whether ethical standards should be the same everywhere (ethical universalism) or is it inevitable that they differ from place to place depending on local culture, and circumstances (ethical pluralism). 'Standard of care' has not been well defined and this continues to be a source of much confusion. Secondly, there is a concern that standards set by developed countries can be considered the norm. Thirdly, as pointed out by Benatar and Singer [2000], 'few commentators on research ethics have taken into consideration the injustice of 90 percent of all medical research being undertaken on those diseases that cause 10 percent of the global burden of disease'.

The HIV clinical trials showcase these dilemmas. Mother to child transmission is a major concern with HIV. In 1994, a trial of Zidovudine (AZT) clearly showed that when AZT was given to the mother during pregnancy and to the newborn, HIV transmission was greatly reduced [Connor et al. 1994]. The findings were so impressive that the US Public Health Service made this regimen the standard of care in the US. Unfortunately, this drug regimen (called ACTG 076) is prolonged and expensive. Several trials were

then launched, all in developing countries, to test efficacy of shorter regimens. However, shorter regimens were not compared against the 076 regimens, instead they were compared against placebo groups. Can a placebo arm be justified in a trial when there is an effective therapy already available? It is generally accepted that it is unethical to do a placebo-controlled study when some therapy is already existent. No patient should be denied some therapy even if it is not very effective. Controversy erupted when a paper [Lurie and Wolfe 1997] titled 'Unethical trials of interventions to reduce perinatal transmission of the human immunodeficiency virus in developing countries' was published. These critics charged that since AZT was shown to be effective in reducing the mother to child transmission, no pregnant woman with HIV should be denied AZT in any trial. Giving placebos to one half of the study participants was unethical, they claimed. They also claimed that these trials were all being done in developing countries and none of them would have passed ethical scrutiny in the developed countries. Since ethical standards should be universal, these trials should have never been allowed in the developing countries, they argued. They also made a plea that 'residents of impoverished, postcolonial countries, the majority of whom are people of colour, must be protected from potential exploitation in research' [Lurie and Wolfe 1997]. The editor of the *New England Journal of Medicine*, echoed these sentiments by writing that,

The Declaration of Helsinki requires control groups to receive the 'best' current treatment, not the local one. The shift in wording between 'best' and 'local' may be slight, but the implications are profound. Acceptance of this ethical relativism could result in widespread exploitation of vulnerable Third World populations for research programs that could not be carried out in the sponsoring country [Angell 1997]

In their defence, those involved the placebo-controlled trials made a plea for understanding the local realities of doing research in developing countries [Varmus and Satcher 1997]. In these countries, standard of care is vastly different from what exists in developed countries. In most developing countries, women do not get AZT during pregnancy. Also, these studies address an urgent

need in the countries where they are being conducted. Shorter and less expensive regimens of AZT could bring it within the reach of many poor countries. They argued that placebo-controlled trials offer more definitive answers about the safety and value of interventions in the setting in which the trials are performed. Other researchers have also opined that,

At the very least, the highest standard of care practically attainable in the host country should be provided to all the study participants. There is no obligation to provide study participants with the highest standard of care attainable elsewhere in the world.' [Perinatal HIV Intervention Research in Developing Countries Workshop Participants 1999].

The latest twist in this tale is the controversial revision of the Helsinki Declaration [Enserink 2000] in October 2000. After years of debate, the WMA approved the revision, which clearly argues against the use of placebos in trials when treatment already exists. The paragraph 29 of the declaration states,

The benefits, risks, burdens and effectiveness of a new method should be tested against those of the best current prophylactic, diagnostic, and therapeutic methods. This does not exclude the use of placebo, or no treatment, in studies where no proven prophylactic, diagnostic or therapeutic method exists'. [WMA 2000].

This revision was met with jubilation from patient and consumer groups, and disbelief from some researchers, academic institutions, and research agencies. The revision has put several agencies in a bind, including the US Food and Drug Administration [FDA] in order to test a drug for approval on the US market, the FDA would have to use protocols that the revised declaration specifically rejects [Enserink 2000].

Under fire from FDA and others, the WMA released this 'clarification' in October of 2001,

The WMA is concerned that paragraph 29 of the revised Declaration of Helsinki (October 2000) has led to diverse interpretations and possible confusion. It hereby reaffirms its position that extreme care must be taken in making use of a placebo-controlled trial and that in general this methodology should only be used in the absence of existing proven therapy.

However, a placebo-controlled trial may be ethically acceptable, even if proven therapy is available, under the following circumstances: where for compelling and scientifically sound methodological reasons its use is necessary to determine the efficacy or safety of a prophylactic, diagnostic or therapeutic method; or where a prophylactic, diagnostic or therapeutic method is being investigated for a minor condition and the patients who receive placebo will not be subject to any additional risk of serious or irreversible harm (WMA 2000).

The issue continues to unfold, with the CIOMS releasing in January 2002 its revised draft guidelines [CIOMS 2002]. This draft is broadly in tune with the revised Helsinki document, but takes a tougher stance against placebo controls. It cites the clarification of the revised Declaration of Helsinki and states,

The present guideline endorses the intent of the clarification. It is, however, more restrictive and requires more stringent justification of exceptions to the general rule regarding control groups in controlled clinical trials.

Needless to say, the dust has not settled on the debate on universalism versus pluralism. Some authors have argued that there should be a compromise between the two extremes [Levine 1996]. According to Levine, the CIOMS guidelines reflect a satisfactory compromise, holding that some ethical standards are universal while acknowledging the legitimacy of some degree of pluralism. Some commentators from developing countries, however, have argued that western ethical standards are being imposed on them by people who lack the insight into problems and constraints that exist in developing countries. Guidelines like the Nuremberg Code and Helsinki Declaration are now considered western constructs. The CIOMS guidelines come closer to global validity than its predecessors [Levine 1986]. Like India, countries like South Africa and Uganda have drafted ethical guidelines for their own use [Loue et al 1996]. Should each country draft its own ethical guidelines? If so, would that be the ultimate triumph for the ethical pluralists?

Many ethical guidelines are vague on the universalism versus pluralism problem and the NCESSRH, guideline reads,

The relevant social, cultural and historical background of the participants should be taken into consideration and given appropriate importance in the planning and conduct of research.

This is not very helpful when faced with a real situation. In fact, none of the accepted guidelines really address this issue satisfactorily. As Levine (1986) states,

An inevitable feature of any document that aspires to global validity is that the fundamental principles must be stated at such a level of abstraction that they do not seem to prescribe or proscribe very many behaviours.

Authorship of papers, which arise out of international collaborations, is another problem. It is common to see a foreign researcher as the first author though the study idea might have emerged from India and all the fieldwork and data analysis might have been done in India. Ownership of data is another issue. In biomedical research, sometimes, human samples are sent to western countries for analysis. Once the samples are sent to foreign investigators, who owns the data? I have heard of instances where complex molecular level work is done on such samples and the data published without any of the Indian researchers as co-authors.

### **Ethical or institutional review boards (ERB/IRB)**

According to Levine, IRBs,

Are the most important social control mechanism to assure the ethical conduct of research involving human subjects, by contributing to the education of researchers in matters related to research ethics in general, as well as by guiding researchers to comply with ethical and legal expectations as they carry out specific research projects [Levine 1996].

The Nuremberg Code [1949] and the first Declaration of Helsinki [1964] made no mention of committee review or approval of research. Committee review was first mentioned in the 1975 revision of the Declaration of Helsinki. In the 1990s, CIOMS and other international guidelines outlined the need for review and approval of all research involving human subjects.

Levine (1996) has reviewed the evolution of IRBs in the United States. The federal law in the US legally mandated IRBs in

the 1970s. IRBs were vested the responsibility and authority for approving or rejecting proposals to conduct research involving human subjects. Originally, the purpose of the IRB was to safeguard the rights of individual research participants by reviewing risks and benefits and by ensuring adequate informed consent. Subsequently, IRBs also took on the responsibility for ensuring equitable selection of participants and equitable access to research. The IRB was never meant to review activities related to medical *practice*. In more recent times, given the legal climate of the US, IRBs are thought to afford the institutions and the researchers some protection against litigation.

The US regulations require every IRB to have at least one non-scientist, and at least one member not affiliated with the institution (a community member). Gender diversity is also required. When IRBs were first introduced, there were several criticisms and dissenting opinions among medical researchers about unnecessary obstruction of progress and stifling of creative work. The criticisms became more strident when the scope of IRBs was expanded to cover social and behavioural research. As a result of these criticisms, some types of research were exempt from IRB oversight. For example, surveys involving only interviews are exempt unless information is recorded in such manner that participants can be identified directly or through identifiers linked to them [Levine 1996].

The IRB system in the US has its limitations [Levine 1996]. Firstly, IRBs may not be competent to provide definitive judgements about scientific merit. This notion is controversial. Some believe that IRBs have an obligation to scrutinise and demand changes in the design of the study while others believe that most IRBs are incapable of providing more than a superficial assessment of study methods and validity. Secondly, IRBs tend to be dominated by professionals and scientists whose perceptions about research may not be the same as those of participants and community members. Thirdly, IRBs are bureaucratic and inflexible. Researchers are often frustrated about the long time delays and the voluminous paperwork demanded by IRBs. The system has been a particular source of problem for those doing multi-centric research involving several institutions and countries. These investigators need to obtain IRB

clearance from each one of the participating centres. In the 1980s, the regulations were revised to prevent duplication of effort. Currently, many IRBs accept the review of other IRBs with which they have some 'reciprocal understanding'. Despite these criticisms, IRBs are now an accepted part of the research process in the US. The criticisms are now focused more on logistics rather than on the need for IRB review.

Though Indian literature on IRBs is limited, it is generally recognised that not all hospitals in India that do research have ERBs or IRBs [Pandya 1996, 1998]. To generate some data on this issue, I undertook a survey of major medical and research institutions in Chennai. Responsible persons (usually ERB members or research staff) in 15 major institutions were contacted. These institutions were not randomly selected and therefore the inferences are tentative. The institutions included government hospitals, medical colleges, private and corporate hospitals, and research centres. All the institutions were involved in teaching and claimed to be involved in health research (nine institutions had conducted clinical trials). On an average, these institutions had published about eleven papers each during the year 1999. 12 of 15 (80 per cent) institutions reported that they had research committees to oversee research activities. When asked about how active these research committees were, 50 per cent reported that the committees were either totally inactive or not very active.

9 of 15 (60 per cent) institutions reported that they had ethics committees or ERBs. However, the composition of one ERB out of nine varied from project to project, thus only eight of them had fixed ERBs. The membership size varied from 4 to 12. Data on the composition of the ERBs revealed that they predominantly comprised of males (on an average 84 per cent of the members were males), in-house staff, and medical professionals (there were three ERBs where non-medical members made up only 25 per cent of the total number or less). Interestingly, six of eight ERBs had lawyers, and four of eight had social workers. In five of eight ERBs, the chairpersons were doctors. Some ERBs were very active (meeting up to six times a year) while others never met or met only once a year. Six of nine ERBs reported that not all research projects were submitted for ERB review. Generally only those projects,



which involved new drugs, interventions or invasive procedures were submitted. Eight of nine institutions reported that the ERBs provided inputs on study validity in addition to ethical review. Four of nine ERBs had rejected projects on ethical grounds at some time or the other. Seven of nine institutions reported that every effort was made to publish results of studies even if the results were unfavourable to sponsoring agencies. Only four of nine ERBs had provided some ethical guidelines to the research staff.

From the limited data, it appears that not all institutions have ERBs and not all have active or functioning ERBs. Existing ERBs are heterogeneous in composition and level of activity. The compositions of ERBs is biased in favour of males, hospital staff and doctors. Also, existing ERBs often encounter some difficult problems [Pandya 1996, Alberti 1995]. Those who form a part of the ERB often have limited training in bioethics and the process of ethical and scientific review of proposals. They may also lack the background necessary to identify flaws in study design. I have been a part of an ERB in a hospital that conducts clinical trials. When I joined this ERB, I had no experience or training in ethics and ERB issues. I suspect I am not the only person to join an ERB without a clue as to how the process worked. Another observation relates to how protocols get presented in ERBs. In the US, IRBs require researchers to present their protocols in language fully understandable by a non-scientist. I have often noticed the non-scientist members in our ERB struggling to understand the technical issues, which are inherent in clinical trials (complex study designs, pharmacological information, sample size estimation, etc). Non-scientists might have genuine difficulties in understanding all the technical details. In such situations, I have noticed a reluctance on their part to question and seek clarification. Neither do researchers put in enough effort to simplify the technical information for the lay people and clinical trials get approved without much debate. Such problems have been recognised and have led to educational programmes for IRB members in the US [Kefalides 2000].

In India, we need more ERBs, better awareness about the role of ERBs, and training for ERB members. Currently we do not have any laws or regulations that mandate or govern ERBs in India. Even if governmental institutions like the ICMR and its affiliated

centres followed the ICMR ethical guidelines and enforced ERB review in their setting, such regulations may not apply to several private institutions, non-governmental organisations and research centres. Increasing the number of ERBs and improving the performance of the existing ones is an important priority for India. In the long term, legal regulations may be needed to ensure ERB review across all research settings.

Having said that, ERB review may not always guarantee ethical research. In the US, strict procedures and regulations govern IRB review. Despite the safeguards, there have been allegations of unethical research. Research at the Johns Hopkins University was recently shut down by the federal government, for lack of oversight [Marshall 2001]. The university was rapped for alleged infractions that include failure to approve every study in a ‘convened meeting’ of the IRB [apparently, approvals were after email discussions], lack of proper informed consent, exposure of human subjects to a drug not approved by the FDA, and failure to report an adverse event [death of a healthy volunteer in an asthma study]. This University was also embroiled in the recent allegations of unethical human experimentation at Regional Cancer Centre, Thiruvananthapuram [Bagla 2001].

## **Conclusions**

To improve ethics in our research, we need to address issues like ethical review, informed consent, ERB, sponsorship and conflict of interest. These issues need to be openly discussed and debated by all those who are involved in research. Better awareness, by itself, will help. Ethics must become a part of all research-oriented training and medical education in India. Education of our researchers in bioethics and ensuring that ERBs review research projects is also important. While these changes might ensure better ethical standards in our research, we will still have to contend with bad science. We thus need to also focus on improving the quality of our scientific work. Improving the science in our research requires better medical education, better training in research methodology [for both students and faculty], more resources for research, and encouragement and recognition of good research work.

*Note* : [The section on research involving the pharmaceutical industry is based on an earlier publication [Pai and Colford, 2002] and is reproduced in part with permission from the *National Medical Journal of India*. I am thankful to Dr. Amar Jesani and Dr. Sunil Pandya for their inputs in the ERB survey. The contribution of all those who responded to the anonymous, confidential, ERB survey is also gratefully acknowledged. Finally, I would like to acknowledge training support from the Fogarty AIDS International Training Program [D43-TW00003-14] this funding source had no involvement whatsoever with the content of this paper.]

## 5

# Overview of ethics in medical research in India

**Sandhya Srinivasan**

Trials of drugs to prevent vertical transmission of HIV, involving over 16,000 pregnant HIV-positive women in Asia and Africa, were criticised for using placebo controls despite the availability of an effective treatment [Lurie et al 1994 and Lurie and Wolfe 1997]. More recently, a study of risk factors for HIV transmission in Uganda intentionally did not provide STD treatment to the control group, or ensure partner notification of HIV-positive participants, in order to obtain its results [Angell 2000, Quinn, et al., 2000, Wawer 1999]. These ethical controversies in developing countries have highlighted the urgent need for discussion of the subject. Moreover, such research could not have been conducted in developed countries.

The issue is of particular relevance to India as it promises to become a major site for research on human beings. There is already a long and controversial history of contraceptive testing in this country [Bauxamana 1985, Kusha 1985, Prakash 1985, Sathyamala 1995, Report of the Women and Health Cell meeting 1995, Discussion on Depo-Provera, 1995, Forum for Women's Health. The Case against Anti-fertility Vaccine 1995, Phadke 1995, Mehra 1992, Ravindra 1999, Saheli 1998, Women and Health Cell of MFC 1996]. Research commenced recently on HIV vaccines and AIDS drugs [Raghunathan 1999, *Issues in Medical Ethics* 2000, *Indian Express* 1998, *The Times of India* 1998, Chinai 1998]. In addition, India's large population with diseases of the poor as well as of the better-off has attracted a number of contract research companies undertaking clinical trials for pharmaceutical companies in the West, to make it a centre for drug testing internationally. The potential returns are believed to be considerable. A clinical trial here would reportedly cost a third of what it would in the US, and the US Food and Drugs Administration may soon accept data from

trials anywhere in the world, as long as they meet its standards of data collection. It is worth noting that poor standards of health care have been cited as one of the reasons trials in India will be cheaper and give results faster than in the US [Bagla 1999, Chowdhury 1995, Ahmed 1998].

These developments occurred even as changes were proposed in international ethical guidelines for research on humans - The Declaration of Helsinki and the Council for International Organizations of Medical Sciences [CIOMS] in the International Ethical Norms for Biomedical Research Involving Human Subjects [Schuklenk 1999]. Among the proposed changes that prompted some concern [Schuklenk 1999] was one that the level of health care required for participants would be determined *not* by the standards of the sponsoring researchers country, but by the '*local standard of care*'. (The implications of the revisions in the Helsinki Declaration actually approved in the World Medical Association's October 2000 meeting deserve detailed comment elsewhere. Also see PAN 2000 in this volume).

In India, guidelines for biomedical research involving humans were finalised in July 2000. In May 2000 the Centre for Enquiry into Health and Allied Themes (CEHAT) held a meeting by the Indian Council for Medical Research (ICMR) to present a draft code of ethical guidelines for social science research in health. These guidelines, Ethical Guidelines for Social Science Research in Health have since been finalised (NCESSRH 2000). The ethics of medical research in India should be discussed in this context.

### **Medical ethics in India**

The ICMR guidelines joined a relatively sparse body of literature on medical ethics, in practice and in research, in India today. Current medical practice does not seem to have produced a well-developed discussion on the subject. Traditional systems of medicine were clearly associated with one or the other religious world-view [Francis 1996, 1997, Christakis 1992, D'Souza, 1999] and social system, which in turn may have facilitated the development of coherent sets of guidelines for medical practice. Today, discussion of medical ethics may be more complex in an environment of multiple systems of medicine (dominated by

allopathy), and the unregulated growth of privately financed health services and medical colleges focusing on commercial gain. There have been frequent reports of negligent medical practice, and aggrieved patients have been supported by the growth of consumer rights organisations and other voluntary organisations to promote ethical practice. Institutional avenues for the redress of such complaints have been relatively ineffective. Discussion of medical ethics in India has resulted in limited analysis of the ethical conflicts in medical practice, and the link between the principles involved and the conditions in which they are discussed.

### **Ethics of biomedical research in India**

Researchers embarking on a study involving human beings must ask themselves a number of questions before starting work. Is the research necessary and relevant to the community being studied? How does one ensure, that researchers' intentions are not unduly influenced by funding agencies that may have their own agendas? Is the researcher competent and does s/he have the resources necessary to carry out the work properly? Are there any risks to potential participants, and if so; should the research be considered at all? Have participants given their informed and voluntary consent? What measures are taken to protect participants' privacy, and to prevent their exploitation? What measures are taken to ensure that the community benefits from the research findings? Such issues must be considered and reckoned with before the study starts, during the research process, and once work is completed [Pilgaokar 1995, ICMR 1997].

Do researchers in India routinely ask such questions of themselves? In the absence of a central registry of biomedical research in the country, it may be impossible to arrive at a reliable picture of the quality of research in this country: how much money is spent, by whom, what researchers set out to study, study designs, who the participants are, whether the study have received clearance from an ethics committee, the research findings, their application, and so on. Further, reflection on the ethical issues involved in medical research on human beings does not seem to be a serious concern of researchers in India.

One measure of ethics in research is the relevance of research. Reviews of articles from India in indexed publications between 1981 and 1985 found a poor correlation between the subject matter of research in India and research needs as identified by morbidity and mortality data. The majority of research focused on problems more commonly found in wealthy societies, such as heart disease, cancer and neurological disorders, which concern a relatively small proportion of the Indian population. Little research concerned problems common in India, such as malaria, tuberculosis, or blindness [Arunachalam 1997, 1998, Nundy 1998]. Research in public hospitals has been questioned for its concentration on technology-intensive research in super-specialities rather than in fields relevant to Indian conditions such as infectious diseases, occupational health, trauma and burns management [Nagral 1994].

A recent report concludes that less than less than 10 percent of the world's health research budget is spent on conditions that account for 90 percent of global disease. Though pneumonia and diarrhoeal disease are believed to represent about 11 per cent of the total global burden of disease, only about 0.2 per cent of health research funding is spent in this area [BMJ 2000]. Thus research in India seems to be following trends in international research.

It is felt that the distance between research and the community's needs is reflected in the practice of medicine. Current medical practice is driven by the demands of commerce and prestige rather than by a research-based understanding of disease, its causes and treatment [Sethi 1999].

### **Awareness towards ethics**

Questionnaire-based studies of medical personnel [Murthy et al 1986, Sriram, TG, et al 1991] provide some insight into the perceptions and background of people doing research. The vast majority of respondents do not report any training in medical ethics. More than a fourth of respondents in one study [Murthy et al 1986] reported that there were no ethical problems to be encountered in medical research. A tiny fraction of them were aware of all the components of informed consent. Varying proportions of respondents recognised the existence of ethical issues in different

medical situations. Only 44 per cent believed that there were any ethical issues to consider in community research.

Most of the 629 physician respondents in another study reported no formal training in medical ethics. Almost half of those conducting research did so with participants' oral, not written, consent. The reported constraints to consent were patient illiteracy and inability to come for regular follow-up. There was a gap between respondents' perceptions and standard guidelines on information for informed consent. Physicians who had done an orientation course in medical ethics, and those with prior research experience, were more aware of ethical issues [Sriram, TG 1991].

### **Ethics committees**

The conduct of ethical research requires the presence of an active ethics committee. However, it has been suggested that ethics committees function poorly in the absence of institutional support. They are often set up in order to enable clearance of research proposals; committee members do not have the training, time or interest to fulfil their responsibilities; and institutional politics corrupt the review process. Finally, proceedings of committee meetings are kept confidential, preventing transparency in functioning [Pandya 1996].

Institutions with relatively active ethical review processes do exist, but these are perceived to be the exception rather than the rule. In fact, an ICMR survey of its affiliated institutions revealed that many of them did not have active ethics committees, and the ICMR itself does not have the infrastructure necessary to monitor their functioning.<sup>1</sup>

### **Publication of research**

Few institutions have guidelines establishing authorship of research publications [Ganatra 1996]. Similarly, publications and research organisations do not always have clear-cut guidelines for submission, including a statement of the ethical review process.<sup>2</sup> Medical journals report receiving many submissions describing ethically reprehensible research.<sup>3</sup>

Ethical research also requires the dissemination of research findings, particularly to the community of participants for their



benefit. However, such transparency may rarely exist. For example, official research programmes do not necessarily describe the strategy by which research findings are transmitted to the medical community and the affected public [MFC 1985]. Research sponsored by pharmaceutical companies, is often controlled by them, and negative findings are not submitted for publication [Nagral 1994].

In sum, ethics does not seem to be a priority in medical research in India today. This situation is a product of many factors. Research seems to be driven by the economic opportunities it presents, and the needs articulated by the group funding the research. Trends in medical practice focus on profits and favour technology-intensive treatments, and this produces research questions irrelevant to the problems of the majority. Ethics is not part of the curriculum in any but a few medical colleges. Inequalities already inherent in the doctor-patient relationship are heightened by widespread poverty, lack of access to health care and the belief that health care is not a right but a privilege. Existing guidelines and monitoring infrastructure are inadequate.

### **Some ethical issues in health research**

Without a comprehensive survey of research, it is difficult to assert what the most commonly encountered ethical issues in India are. However, it would not be inaccurate to suggest that the fundamental ethical questions faced by researchers in India today relate to the forces involved in formulating research questions, the vulnerability of poor populations and the use of research findings.

### **Informed consent**

The difficulties of getting informed consent are exacerbated by the low priority accorded to it by researchers, and by the conditions in which potential participants live. It may be difficult to obtain informed consent from the poor - not because of literacy levels but because their need for health care may make them more vulnerable. Truly informed consent is crucial to ethical research.

Medical personnel often report that patient or participant illiteracy is the commonest constraint to obtaining informed consent. In fact, a study showed that patients are able to understand

details of their treatment, though they had more difficulties if they were older, poorer or less educated [Sanwal et al 1996]. Participants in medical research may not be aware of exactly how they would and would not benefit. The information gained through their participation would benefit others. Potential participants may see the trial as an opportunity for some free health care.

Though researchers conducting a leprosy vaccine trial reported conscious efforts to obtain written informed consent from the individual participants, only 38 per cent of those surveyed were aware that the vaccine was meant to protect against leprosy. As many as 21 per cent said they did not know the purpose of the vaccine. It is also worth noting that the research team felt it best not to mention, in the consent form, the double-blind nature of the study, the multiple arms of the trial, or the presence of a placebo arm, though the study design was discussed with the ethics committee supervising the trial [Gupte and Sampath 2000].

### **Study design**

Ethical issues related to study design will probably become a significant subject of debate in the future. With the launch of a number of HIV-related trials in India, controversies already hotly debated elsewhere are getting articulated here. At least one study was reportedly forced to change its design following protests from local organisations.<sup>4</sup> Ethical issues relating to the proposed HIV vaccine trials in India have been discussed in detail recently [Mehendale 2000]. It is pointed out that trials among groups with a high incidence of HIV infection are easier and more cost-effective, especially if done on people who have not had access to anti-retroviral therapy. Opposition has already been expressed to the proposal that participants with break-through infection need not receive three-drug therapy because it is not financially sustainable [Schuklenk 2000].

### **Confidentiality**

Researchers sometimes do not respect participants' right to complete privacy and confidentiality. For example, presentations at medical conferences have on occasion displayed unmasked photographs of participants, a blatant violation of their rights.

## **Follow-up**

Follow-up of participants is both an ethical requirement and a scientific necessity for good research. Yet there are many indications that researchers do not bother to maintain long-term contact with participants, even as they report the findings of such research. This has been often reported in contraceptive trials.

## **Use of research**

Finally, the proposed and actual use of data presents a major ethical issue. How many poor Indians can afford any of the drugs being tested on them? Is it ethical to test drugs or procedures, which will not be available to the community after the research is over? Pharmaceutical companies have on occasion admitted that they cannot provide drugs found effective through trials in poor countries, to the participating community.

## **International guidelines**

International statements on modern medical research ethics date back to the Nuremberg Code of 1949, a response to atrocities committed by Nazi doctors on prisoners in the name of medical research. The Nuremberg Code was supplemented by the World Medical Association's Declaration of Helsinki [2000] first presented in 1964, and revised a number of times since then. Both documents lay down general principles for ethical medical research on human beings. The Declaration states that research must be properly designed and carried out by competent people, risks assessed, participants' integrity preserved, informed consent obtained, results accurately published. The Helsinki Declaration's guidelines on clinical research emphasise that physicians' responsibilities to their patients override their role as researchers. Even when doing non-clinical biomedical research, "the interest of science and society should never take precedence over considerations related to the well-being of the subject". Such documents lay the foundation for protection of research participants. Controversies regarding certain advances in research have led to the development of national guidelines on, for example, genetic research, or cloning.

International guidelines have served to set standards for research. They have also been the foundation of national guidelines in various countries. Guidelines can guide the practice of research, in the presence of other enabling factors. Some of these enabling factors may be: the infrastructure for monitoring research ethics, the possibility, in a given country, of legal action against unethical research, a doctor-patient relationship which is less conducive to abuse by doctors, and functioning health services. International guidelines also serve as a basis for discussion in the international community.

Further, organisations such as the National Institutes of Health and the Centres for Disease Control in the US require that research funded by them in other countries meet their ethical guidelines.

However, most of the frequently cited examples of unethical research in India are cross-cultural, whether funded by national health organisations, by pharmaceutical companies in the West, or by international organisations.<sup>5</sup> It is also worth noting that a report on quinacrine sterilisation of thousands of poor women in Asia without their informed consent — accepted to be blatantly unethical research — was published in at least one reputed journal in the West [Hieu 1993].

### **National guidelines**

There is no government body responsible for maintaining ethical standards in all research conducted in this country. However, the Indian Council for Medical Research is responsible for the ethical standards of research in its institutions.

It was only in 1980 that the ICMR issued its first policy statement on the subject [ICMR 1980]. The document provided a brief description of basic ethical principles, the need for informed consent particularly concerning research on vulnerable groups the question of inducements, the role of an ethics committee, publication policies, and so on. It also referred to requirements for the clinical evaluation of new drugs, and of traditional medicinal plants.

All research institutions were urged to set up ethics committees to review research proposals and monitor on-going research. Proposals would have to be approved by the research

institution's ethics committee in order for the ICMR to consider their funding. The ICMR would expect the local ethics committee to monitor research, but reserved the right to review it as well. If the research institution did not have such a committee at the time, the ICMR would provide the necessary review on a short-term basis. Research papers would not be considered for publication in the ICMR's journal, the *Indian Journal of Medical Research*, without evidence of approval from an ethical committee.

The 1980 policy statement is supplemented by documents referring to research in specific areas. Some of these are listed below:

In 1988, the Drug Controller of India [DCI] issued a gazette notification on requirements and guidelines on clinical trials for import and manufacture of new drugs, for the first time bringing in rules on drug testing in India.

In 1994, the ICMR published guidelines for the conduct of clinical trials for contraceptives. This document describes the various steps mandatory to the contraceptive approval process and identifies the institution responsible for conducting the research at different stages, as well as the responsibility of investigators and monitoring authorities. The ICMR's ethics committee would review all pre-clinical documentation, data, and proposed trial protocol, while separate approval from the DCI regarding the trial protocol would be mandatory for each phase of the trial. However, though two members of the ICMR's ethics committee have signed the document, there is no mention of the manner in which participants would be recruited, the importance of informed consent, the need to provide treatment of side effects or complications, or long-term follow-up of trial participants. Nor do the guidelines say anything about the history of ethical controversies in contraceptive research.

In 1997, the government published revised guidelines [now finalised] to monitor and regulate the exchange of human biological material as part of collaborative biomedical research. It exempted recognised labs such as WHO collaborative centres or WHO reference centres, but required that all other research projects involving the export of biological tissues get permission from an ICMR committee [Mudur 1997].

These documents do not identify or comment on the relevant ethical issues in depth, and do not provide a comprehensive framework for research ethics. In any case, they have had limited influence on research, partly because the ICMR has been unable to provide institutional support towards implementation. Nor has it been possible to rely on medical councils to ensure that doctors follow the Code of Medical Ethics. Besides, questionable research sometimes does not depend exclusively on Indian doctors. For example, the quinacrine sterilisation method was also taught to a network of unlicensed practitioners, and the entire project was coordinated by two American doctors.<sup>6</sup> In sum, though some institutions are able to develop and implement internal guidelines, and seem motivated on their own to produce ethical research, current ethical guidelines and regulations have had limited influence on the conduct of medical research.

For example, though the ICMR refused to fund an Indo-US research project involving implantation of foetal tissue in the eyes of Indian patients with retinitis pigmentosa, pointing out that "...undertaking clinical trials on Indian subjects for an experiment which was not being conducted on US subjects was not ethical," it stated that it could not stop the research [Mudur 1997]. Similarly, US-based doctors contacted people with HIV infection through a Bombay-based organisation, and injected them with a vaccine based on a strain of bovine immunodeficiency virus. Action was taken against the local organisation involved only because one of the patients' relatives filed a criminal complaint [Mudur 1999].

More than 30,000 poor Indian women were sterilised with the anti-malarial drug quinacrine, with no evidence of informed consent, monitoring or follow-up, before the DCI gave an undertaking to the Supreme Court to ban the procedure which is unapproved by the WHO. Quinacrine sterilisation was promoted openly at professional meetings of gynaecologists, and through networks of practitioners. The drug controller was forced to act only after a writ petition was filed in the Supreme Court challenging the practice as unethical. Incidentally, the court has not asked for a follow-up of the women who have been experimented on [Pollack and Carignan 1993, RHM 1997, Rao 1998].

## **ICMR guidelines**

'Ethical guidelines on Biomedical Research Involving Human Subjects' were finalised by the ICMR in 2000. The draft guidelines were circulated and public discussions organised.<sup>7</sup>

The general principles set out in the document are admirable: The research must be essential; informed, voluntary consent must be obtained; participants should not be exploited; their privacy must be respected; risks must be minimised; researchers should be competent; procedural requirements must be complied with; the findings should be applied for the benefit of all; all those connected with the research should be held responsible for its ethical functioning; and the guidelines should be complied with both in letter and in spirit.

However, the guidelines have been criticised for not responding to gender and class inequalities inherent in Indian society,

Ethical guidelines should go beyond technicalities and build effective safeguards so that the unequal power relationship between researchers and subjects is neutralised and no new avenues of exploitation of research subjects are opened up. The current document falls short of these objectives [Saheli 2000].

The proposed guidelines identify five areas for discussion: human genetics research; transplantation research including foetal tissue transplantation; clinical evaluation of drugs/devices/vaccines/herbal remedies; epidemiological research, and assisted reproductive technologies.

The guidelines give equal importance to areas commonly researched and those of limited relevance in India. A large part of the document is devoted to the ethics of research in genetic testing, organ transplantation and assisted reproductive technology, though there is little original research in these areas in India. What is needed in these areas is a clear definition of what research constitutes in these areas, and a statement on the relationship between clinical practice and research.

On the other hand, frequently researched areas are not discussed in detail. For example, the proposed guidelines have little to say about the ethical issues involved in research on drugs and vaccines.<sup>8</sup> They also do not make a strong statement on the ethical

issues related to collaborative research, an area that is receiving much attention for its potential to exploit poor communities [Schuklenk 1999].

They do not even mention contraceptive testing, though this may deserve a separate discussion in the guidelines. A detailed set of suggestions has been made for this area [Saheli 2000].

The guidelines presume that education is linked to informed consent, and the use of community leaders to obtain consent is supported

With large segments of our population, given their level of education, the full understanding in the sense of industrialised countries may not be achievable.”[ICMR 2000 : 36].

This presumption has been challenged by many researchers.<sup>9</sup> It has been suggested that the draft undermines basic principles by indicating that the importance of research could override the need for written informed consent by the individual participant for each study [Saheli 2000].

The guidelines on epidemiological research do not discuss the importance of the subject of research. It can be argued that truly ethical research must look for solutions to the health problems specific to this country’s people. It has already been suggested that much research in India does not address the needs of the community [Arunachalam 1998].

There is nothing said about the ethical implications of various trial designs, ignoring the current debate on the use of placebo controls when a proven treatment exists. They only note that information on the drug research protocol should include a description of plans to withdraw or withhold standard therapies during research.

The guidelines do not directly address laboratory-based research that may use established drugs or procedures, including invasive and possibly risky procedures.<sup>10</sup> They do not address medical therapy, surgical operations, radiotherapy, chemotherapy and other interventions being carried out in day-to-day practice. Nor do they address the need to follow up trial drop-outs, the need for drugs found effective in trials to remain available to the participants, and the need for a regularly updated database on the medical research being conducted in the country (Pandya 1998).



## **Guidelines for social science in health**

The '*Ethical Guidelines for Social science research in Health*' on ethics in social science research in health [NCESSRH 2000] is a document complementary to the ICMR guidelines, which are concerned with biomedical research.

The guidelines note that the growth in research, funding for research and inadequate self-regulation all enhance the potential for unethical research. It articulates the broad principles governing social science and health research, covering issues in research ethics ranging from the pressures of funding agencies and the need to protect participants, to publication ethics and the implementation process. It also articulates, in detail, issues concerning the relationship between researchers, informed consent, participants' rights, data use and reporting of findings.

A practical framework to work through common ethical issues in the planning and undertaking of research could also be useful. Some suggested questions for inclusion in this framework are:

- Does the study design raise any ethical issues? How are they resolved?
- Is there a conflict between the service provider's and researcher's roles, and if so, how is this conflict resolved?
- What are the obligations of the researcher to the community being researched?
- Do the expected benefits justify the research, and what assurance is there that the benefits reach the participants' community?
- In research on interventions otherwise unavailable to the participants, is there scope for inducement or coercion in the process of obtaining consent? What measures are taken to prevent such influences?
- Is there long-term follow-up for research on health interventions?

The guidelines are meant for voluntary implementation by institutions and individuals doing research. This would be an important step towards encouraging ethical research. It is possible that the publicity given to such a code [document] will put pressure on institutions and individuals to adopt the code and discourage violations of the guidelines.

In the long run, however, for any code to be effective, it must apply to all research in this country. Links also need to be established with existing national and international organisations responsible for ethical research, and with medical journals in which the research is published. At the same time, implementation would have to be supported by a multi-pronged effort to promote ethical principles in research, through medical education and through discussion in the larger community.<sup>11</sup>

### **Notes**

1. V Muthuswamy, personal communication
2. Amar Jesani, S. K Pandya, Anil Pilgaokar, Yash Lokhandwala, personal communication
3. P Sahni, personal communication
4. Meena Seshu, personal communication
5. The US Centres for Disease Control and National Institutes of Health funded nine of 15 controversial trials on vertical transmission of HIV. Private organisations in the West funded quinacrine sterilisation in Asia and testing of Bovine immunodeficiency Virus vaccine on HIV patients in Mumbai.
6. R Dasgupta, personal communication
7. V. Muthuswamy, R. Narayan, personal communication
8. This section is based on comments from interviews with a number of medical professionals and activists, including SK Pandya, A Pilgaokar and Y Lokhandwala.
9. R Narayan, personal communication
10. Mario Vaz, personal communication
11. R. Narayan, C. M. Francis, personal communication

# 6

## Ethics in social science research

### Some basic components

#### Tejal Barai – Jaitly

Social science is a reflexive science. It essentially means that it is a study of human beings by human beings, including those beyond the researcher and the participant, resulting in certain outcomes. These outcomes could be anything from simple data generation to policy recommendations or formulation. The significance of these outcomes may be different for different people, including both the researcher and the participant, even the sponsors or funders. It is as result of this very intrinsic nature of Social science that ethical dilemmas arise [Barnes 1977]. Ethical dilemmas arise at all stages of research. These dilemmas may arise as a result of external factors or can arise as a result of certain aspects or facets of the study. However, what is important is the fact that they inevitably do, can have the potential to cause harm, damage or injury. The harms not just to the participants of research and to a larger population but also to the research discipline, thus, affecting its credibility. The injury might not have been anticipated, or it might have been anticipated but not addressed. The sensitivity and the awareness to the possibility of injury or harm, and the conscious and honest effort to prevent and resolve these issues are what I refer to here as ethics in research. Ethics is also the vital and effective link and the balance between the need and the rights of the participants, researchers, and the social science discipline.

From the selection of the research problem to the publication of the research findings, research is ripe with situations and circumstances that raise ethical issues : A researcher being pressured to alter the findings of his study, the completion of questionnaires without venturing into the field; a study conducted on a handful of critically ill patients to test their levels of anxiety etc. Or consider the case where women might be interviewed on issues of marital relationships or sexual behaviour in the presence of some member of her family. All these instances raise serious ethical issues.

Anticipating, addressing and minimising these harms and risks are essential. Harms need not be physical harms. Studies can be harmful, in the sense that they have the potential to affect a person's dignity, or cause anxiety, shame, embarrassment, and even a loss of autonomy. Harms can also be in the form of material harms, such as loss of land, or imposition of taxes or levy.

This paper is a modest attempt to bring out some basic ethical issues associated with various areas and stages of research.

### **Relevance of research and data**

Let us then begin with the essentiality or the relevance of research. When we decide to do research on a particular aspect of an issue, what are the reasons behind it? An important motivating factor could be a personal interest in the issue. There are other factors too that affect our choice of research and these are directly related to the issue itself. The reason could be dearth of knowledge on that issue and a need to understand and /or increase awareness towards it, among others. A research problem could be of macro relevance such as its contribution to the overall development of our country, or it could be of micro-relevance, that is, it could be an effort towards understanding the situation or say the specific needs of a community. But the bottom line is that it should be relevant and the need justified.

Social science research can help develop knowledge about humans, their interactions, behaviour, etc., in different contexts, and exploring the scope of this knowledge for practical use. These we see as some of the benefits of research. The Indian Centre for Social Science Research [ICSSR] in its various reports and seminars have time and again acknowledged that research studies should have some amount of social relevance (for instance, in their Survey of Research in Sociology and Social Anthropology 1969-1979). Indian sociologists, anthropologists, economists, and researchers from all the branches of social sciences have been stressing the need for undertaking relevant research for a long time [Bhatnagar 1981].

The issue of relevance or rather non-relevance stands strong even today. Consider then, an issue where a lot of research has already been done, that too on the same aspect and with the same methodology and tools are used. For instance, if I were interested in doing a research study that aims to find out the state of mind or the anxiety of grossly

sick patients what are the ethical questions that can be raised? It can raise the question of justification of such a research, where there is already a vast amount of reliable information. The question would be, are we looking for anything new? Moreover, the research deals with participants in a very critical state in both physical as well as psychological terms. The research would lead to subjecting these critically ill patients, who are already stressed and suffer from anxiety, to more stress and more anxiety. What if there is no provision for post-research counselling? Moreover, is it not a known fact that critically ill patients would suffer from high levels of anxiety? Would it not have been better to do such a research as a retrospective study? How do the participants feel about being studied in that state, since is it not precisely this, i.e. the state of mind of these patients that was to be studied? Sutton and Schurman (1999) report precisely this, during an investigation of a sensitive issue of organisational death, where the informants thought that it was rude to study them at a time when they were in deep distress.

Concern is also raised in the research community about research agendas being laid down by the knowledge industry of the West [Khanna 1996]. Are such agendas and research priorities relevant and in tune with the priorities and realities of our country? The nature and directions of research are influenced by the funding or sponsoring agency. Researchers and issues that are considered safe may get the funding [Useem et al 1983]. Directing the kind of research has its consequences on the social science discipline, since the researchers might simply go in for research that has a better chance of receiving funding, and these need not necessarily be the most pertinent or relevant. The issues of relevance then need to be seen against the backdrop of 'neo-colonialism' as some call it. It has been seen as a threat to the social science discipline in our country. Neo-colonialism seeks to "penetrate, to mystify and influence social science concerns in respect of theories and problems" [Singh 1991].

Research in social science is fast becoming an unregulated commercial sector. Researchers are also known to be doing a vast amount of research beyond their field of expertise, and studies are often conducted in a hurried and superficial manner, with crude methodologies and crude techniques [Krishna 1991]. Irrelevant, poorly

justified and badly done research can have serious ethical implications and harms.

Can specific kind of data generation raise any ethical questions? Jawaharlal Nehru, for the 1951 Census, instructed the Census Commissioner not to collect data on castes (except scheduled castes and scheduled tribes as a result of the special attention guaranteed to them in the constitution). In Assam, the 1981 Census enumeration could not be done as a result of the controversy about data on mother tongue. It can, however, be argued that such data is essential, and the solution is not simply cutting out sensitive questions. Ignorance to these issues can prove even worse. Where such data are indispensable and relevant, effectively addressing the potential of harm and conflict that can be caused by such issues and scientific maturity to handle such data and its outcomes are essential. Effective addressing of these issues means that the potential to cause harm is minimised or preferably totally eliminated. For instance, ensuring the anonymity of the identity of participants is one such way [Bose 1991; NCESSRH 2000].

Sometimes, tools of research comprise of lengthy questionnaires that carry irrelevant questions, irrelevant to the objectives of the study. This too can raise ethical dilemmas. What can one do with so much additional information? Is it fair to subject the participants of the study to questions that probably might not be used at all? Lengthy questionnaires mean longer interview sessions. Is this ethical in a study especially if it is associated with something that might be traumatic for the participant to deal with?

### **Choice of methodologies and participants**

Let us consider next, the choice of methodologies and of study population. How can these be prompt ethical issues? Apart from the fact that the sponsors and funders can direct these [Useem et al 1983], the choice of inappropriate methodologies and study population itself can raise ethical issues. How and what effect would a particular choice made by the researcher have on individual participants and on society? One may not be in a position to anticipate all the issues or harms involved, but the possibilities and the potential should be considered. Consider then an instance where focus group discussions is the choice of methodology for getting information on, say sexual behaviour in rural areas. What are the possible harms that can be caused? First,

considering the research setting, the choice of methodology is highly inappropriate in terms of responses sought. In a closed rural community, is it possible that a woman may openly admit to having a premarital affair? Where such facts are revealed by unfriendly neighbours, it leads to humiliation and ridiculing of the participants, and thus unethical. Thus choice of methodology and framing of research questions should be in consonant with the culture and background of the respondents. When not, the potential to cause harm increases.

Easy accessibility of participants is not a fair criterion for selection of participants in a study, since they might then have to bear an unfair share of burden. The Punjab Government, way back in the early 20<sup>th</sup> century did not grant permission for a research trial to be conducted where the participants were prisoners [Das et al 1997]. However, on the other hand, there may be certain problems that are closely associated with a specific description of the population. Excluding them from research would result in poor understanding of their situation.

Moreover, assuming that the research is socially relevant, faulty methodologies or choice of participants could then lead to faulty policies, causing extensive harm. Researchers should bear in mind that information and decisions drawn from their research findings and report have the potential of affecting not only individuals, but also an entire community or even a larger population. Moreover methodologies and studies that give a very superficial view of a situation or a practice could spell disaster for that population.

### **Integrity and autonomy of researchers and institutions**

What do we mean when we say integrity and autonomy of researchers? The challenges and dilemmas that any research can pose are tremendous. However, what happens during fieldwork can be as a consequence of the researcher not having autonomy or the research could have been 'directed' by another party.

Integrity of a researcher implies that the researcher should not engage in unethical practices. It may be in the form of fabrication of data or manipulation to suit desired outcomes or in the form of false promises of confidentiality to secure co-operation. For instance a researcher assured confidentiality to prospective participants to learn about their religious practices. They were told that their secrets would not be revealed, when the entire purpose of such a study was to learn

the customs, traditions as well as religious practices of this community. Moreover, these have been documented on the basis of information secured from other more co-operating participants [Jindel 1975].

Challenges to integrity and autonomy can come from various sources such as the funding agencies, the participants themselves or even at times the politicians. Researchers have also been known to be asked to change research findings to suit a particular policy, which the agency or department under which the research is conducted, is interested in pushing forward or supporting. T. N. Madan (1967) cites an instance where a government anthropologist was asked to change the findings of the study in a way so that the particular community could be declared a scheduled tribe. The anthropologist in question was a man of immense integrity but there might be others who succumb to such pressures. Researchers working in the government also face situations that raise dilemmas. For instance, while evaluating developmental work, the researcher may be forced to be tactful in order to preserve 'good relations' with colleagues. They could also be forced to change findings to fulfil the governments need to present a hopeful future to the citizens, and the fact that the government has monopoly over such data, can encourage such alteration of data [Srinivas 1972]. Such challenges can originate under various settings, not just under research conducted by the government. The integrity of the researcher then plays a pivotal role, where researchers need to challenge such a recommendation, request or order. Integrity also means that the researcher should continuously enhance competence to do research, and herein lies the commitment to do research.

Participants can themselves request the researcher to enter wrong data or alter some information. For instance, during the socio-economic survey of Hyderabad and Secunderabad city area by the Indian Institute of Economics (1957), one participant shared very honestly all facts about his ups and downs in the share market. However, when the researcher needed to record his assets, he requested that smaller figures be entered than the actual. Instances such as these are common. They emphasise the need for competency, integrity and ethical sensitivity on the part of researchers, research institutions and organisations. Researchers, institutions and organisations should strive to protect their autonomy and freedom to research, and should not allow themselves to be put in a position that leads them to compromising



their integrity. They should challenge questionable methodologies or other threats to the sanctity of research. In other words, researchers should strive to protect their autonomy, integrity and the ethics of research, as far as it is in consonance with ethics in research, and contrary challenges exist.

The prospective participant after being furnished with the adequate information has the right to choose whether he wants to be a part of the research, or otherwise. The exercise of this right freely is the principle of autonomy. The researcher should not obstruct this right, by resorting to coercion, deception, or deprivation of essential information, or promise of unrealistic benefits or excessive reimbursement. Though the principle of autonomy presents an important yet difficult problem in our country, it is however indispensable. The respondents autonomy and dignity should be respected, and they should not only be told about the purpose of the research, but also their right to decline participation.

Autonomy of participants can be easily compromised in the case of women and children, or where the participants are say, the inmates of a prison and access needs to be sought through gatekeepers. Further, where a distinct hierarchical structure exists, researchers can find it difficult to approach the participants in an independent way since they are all working in an interdependent framework of rights and responsibilities. It is often acknowledged here that participants are subtly coerced into 'volunteering'. Such participation can even increase a person's emotional discomfort. The responsibilities of the researcher towards the participants thus increase.

Where the principle of autonomy relies on information, we need to address the issue of informed consent. What would be your first reaction when someone was to come to our door and request us to answer a few questions? Would you not want to know where the person is coming from, what is the purpose of the interview, or what kind of questions are going to be asked? In case you do agree to part with some time to answer the questions, would you not want to know if the information that you have given remain confidential or would your name be identified in the reports? Why should participants of our studies not be given this same right to informed consent?

Informed consent taken orally is not acceptable. However, obtaining signatures from participants is not only difficult in our

research settings, but often, participants are also afraid of signing written material. What is suggested in the NCESSRH Guidelines [2000], is that information about the details of the project should be given in a manner and language the participants understand. This should be done in a verbal manner as well as in a written manner. The participants thus have a copy of all the information about the project with the names of the research team organisation, etc., in the form of a pamphlet in the vernacular language.

The right to informed consent has various aspects to it and can give rise to some sticky contexts (as can be the case about all aspects of research!). What if the participants were children? Consent then would need to be taken not just from the parents but also from the children. Where the participants of research are children in an institutional setting say, a remand home, then the consent to talk to the children and make them a part of their study needs to be taken from the 'gatekeepers'. Children, especially delinquents, are known to be submissive and yielding in nature [Kothari et al 1992]. They may also carry with a fear of 'authority' in this case, the remand home authorities, and may not be in a position to say 'no' to something that was 'sanctioned' by them. This makes it essential for researchers to make participants aware of their right to decline participation without undesirable consequences.

It is often suggested that researchers should also provide help in a form that is required and that can be given by the researchers. For instance in a study looking into the prevalence of gynaecological morbidity the researchers felt that to arrange for any required care was an important ethical aspect and also essential in order to seek participation [Koenig et al. 1996]. Can this however then raise the issue of inducement, thus affecting the autonomy of participants?

It is found that on sensitive issues, researchers need to have additional abilities. The relationship between the researcher and the participants is especially different in studying sensitive topics, and raises even more complicated dilemmas. The researcher then has to be well-equipped to provide support for two purposes. One to seek a more effective co-operation from the participants, and second, to enable the researchers themselves to handle the stress from researching sensitive issues.

Participants may find a particular research to be intrusive where the research deals with the private sphere of the participants [Lee 1993]. However, what is considered private and personal and what is not varies from person to person and community to community. This makes it essential for researchers to view it from a participant's perspective.

The presence of a researcher can also be seen with fear, from fear of sanction or from fear of disclosure of certain activities that the participants would not want to disclose. The researcher could thus be seen as a threat. However, this may not always be so. For instance in one particular survey the researcher was perceived to be the deputy minister trying to ascertain the details of the misery of the poor first hand and it was hoped that some relief would soon be provided! [Indian Institute of Economics 1957]. Where the researchers makes effort to gain cooperation by trying to effectively ward off negative perceptions, they should also make efforts to ward off *false perceptions*. Consider another study where the research team was escorted by a health worker in a jeep – seen as a symbol of governmental authority. The health worker informed the team that, ‘the team would be received with the reverence villagers habitually extend to government functionaries’ [Balakrishnan 1993]. It is then the research teams responsibility to clarify their identities. It then amounts to the need for effective informed consent, addressing this issue.

### **Privacy anonymity and confidentiality**

Privacy, anonymity and confidentiality are the indispensable rights of the participants. These are essential for the protection of the participants from the harmful and the undesirable consequences of research. Information collected from the participants should be disseminated in a form that does not lead to revealing of the identities of the participants. Protection of identities does not simply mean using pseudo names. A study can violate these rights even without revealing names. What if the study identifies to some extent, the research setting, and through community maps, marks the houses of participants and associates them with forms of sexual behaviour such as ‘extra marital affair’? One can only imagine the potential of harm that can be thus caused to the participants. One can even anticipate its potential affect on the credibility of social science research.

Privacy is essential at the time of data collection. It has often been argued that this is a difficult prospect in India and that it is a 'western' concept.<sup>1</sup> However, the concept of privacy is not new in our country. In 1958, a study conducted by the Bharat Seva Samaj [1958] in the slums of Old Delhi gave specific instructions to make sure that no crowd gathered around the participants at the time of the interview. Where the concept is not new, why then the practice? Sure, ensuring privacy might be difficult, but where we have adopted so many other western concepts for our research, why not the concept of privacy? Moreover, there have been recent instances of studies that have felt the strong need for ensuring privacy at the time of data collection.

Consider a study that looked into induced abortions in a rural community, an investigator conducted the actual interview, while other family members were engaged in dummy interviews [Ganatra et al. 1994-96]. One might feel that it would be unethical to engage in 'dummy interviews', since there is 'deception' involved. Further, it would also be unethical since it means collecting data through these dummy interviews that will not be used. However, should there be no dummy interviews? Considering that abortion being a highly stigmatised issue and researchers' ethical priority is to protect the participants, then the balance, as I see it, is more in favour of devising innovating ways (unless of course they are highly ethically debatable) to ensure privacy.

The importance of these rights and the recognition of the potential of harm that information collected through studies and surveys can be judged by the fact that the Census Act, 1948, clearly lays down that data collected in the household schedule and individual slips are confidential and aggregate.

A number of researchers see the practice of privacy, anonymity and confidentiality essential even for trust building. For instance in a study on sex workers in Kolkatta, the participants were asked to fill up self-monitoring cards giving relevant details, but no personal identification. They were then asked to put all the cards together. The cards were mixed and the participants were asked to identify and pick up their individual cards. All of them failed to do so [Bhattacharya et al 1994]. This ensured privacy, anonymity and confidentiality made the participants confident to participate in the study, and went on to reveal intimate and personal information. In another instance, in a

study of gynaecological morbidity, the researchers reveal that the women were more willing to reveal gynaecological problems once they were confident that the confidentiality of information would be ensured [Koenig et al. 1996].

However, it is not always necessary that the participants would not want to be identified. Such was the case in T. N. Madan's study on Kashmiri pandits [Barnes 1977]. T. N. Madan, himself a pandit, was very well accepted by the community. This gave him access to information on disputes and other very confidential information, which he earlier did not have access to. He was also at times asked to intervene in family disputes. He then found it ethically unacceptable to identify the name of the village, even as a pseudonym (doubting the effectiveness of using one), since the information he thus collected was on the basis of the trust the participants placed in him as a result of him being identified as being one of them. Things were made simple for Madan when the participants of the study themselves insisted that the identity of the village need not be disguised at all.

It can be argued that total and absolute privacy, anonymity and confidentiality cannot be given to the participants for the simple reason that information is commonly shared with other researchers. This then brings us to the issue of ethics in data sharing and dissemination.

### **Data sharing and reporting and publication of research**

Data and information is often shared amongst researchers. While this itself is a good practice, the information thus shared should be non-identifiable, and in consonance to the rights of the participants. It is necessary that the participants be informed about this aspect of research, since rights of privacy, anonymity and confidentiality and sharing of data are obviously linked.

Data sharing can also be desired by the participants themselves may be curious to know the responses of others and may expect the researcher to share such data. The researcher should decline such a request, but also expressly reveal that the information be shared with a selected few. As the word spreads, participants would stop asking questions as a result in establishing trust and confidence in the researcher [Bhatnagar 1981].

Sharing of data should not be a condition for gaining access since even though the gatekeepers often assert that they have the interests

of prospective participants at heart, it need not necessarily always be so. A similar approach should be taken wherever the participants or the study population is accessed via a gatekeeper. Where the research is sponsored by the gatekeepers themselves, the anonymity of the participants is very essential, including the names of those who have declined participation. Revealing of identifiable data to the gatekeepers can lead to extensive harm to the participants. Even where data is required to improve the conditions within, say a prison it can be argued that this too requires only non-identifiable facts.

Fabrication, falsification of data, plagiarism are other widespread ethical violations, and should not be indulged in at any stage of research. The potential for the fabrication of data is high at the time of data collection, when some researchers may themselves be tempted to fabricate and falsify data. However, at times even the participants may insist on entering data, other than the one they might have revealed to the researcher earlier. Plagiarism also extends to the data and writings of juniors and students, not just amongst peers. Where due credit is not given to the substantial inputs of the juniors and students, this would then amount to plagiarism and exploitation.

One of the important causes of plagiarism in our country is that the researchers are not good at reporting and publishing of their researches. Researchers sometime make presentations of their findings in meetings but do not publish them. There is so much good research and significant data that remain unpublished and consequently a lot of research is conducted on the same issue repeatedly. Further, poor dissemination or not disseminating the research at all leads to the defeat of one of the most important purposes of undertaking research, that of increasing knowledge for the benefit and betterment of society and for the increasing information on issues that are crucial for the betterment of the people. What use is collected and stored knowledge, if it is not published and disseminated?

However, publication of researches carries with it inherent ethical complications. From publication of poor quality research, which has its own harms, to not effectively camouflaging the study. Identification of participants through such reports can lead to extensive harm not just to the participants of research but also to the researchers themselves as well as the entire research endeavour. Implications or the impact of

a study may not necessarily be immediate. They may be observed long after the study is completed.

One way of handling this is to take the results of the study and the reports back to the participants - a form of an extended debriefing. This could however to some extent be seen as a threat to the academic freedom of the researcher [Useem and Marx 1983]. But, where a participant has very strong objections to certain information, the researcher would anyway be ethically obliged to either remove it or camouflage it more effectively, without distorting the data.

### **Politics of social science research**

The ethics of social science research cannot be taken into consideration without some reference to the politics of social science research. The politics of research inevitably impinge upon the ethics of research. The interests of the powerful or the vested interests can direct research right from the selection of the research topic or agenda to the publication of research results or rather their non-publication. Political and administrative groups are known to act as pressure groups to that affect and even change the outcome of the research.

As mentioned earlier control over research funds may determine the direction of research and thus what is researched and what is not, may not necessarily be directed by a strongly felt need to research these areas. On the contrary it might eventually lead to the neglect of research into areas and issues that desperately need looking into. The harm however is not just caused to society, but also to the researchers themselves.

Going beyond setting of agendas of research, vested interests can obviously influence almost all other aspects of research. Let us consider research findings. Researchers may be forced to present a different reality than the actual. One can only imagine the 'efforts' that can go into presenting such a picture, which can be anything fabrication of data or 'laundering' and can be indulged in by anyone in the hierarchy, from the junior most research investigators to their more powerful bosses. For instance, a study that may be a part of a larger group of studies reveals results that may not be in tune to the results of the rest of the studies. Tuning or adjustment is what can be then done [Srinivas 1987]. Or, consider the study cited earlier by T. N. Madan, where a government anthropologist was asked to change the findings of a study

to have a particular community declared a scheduled tribe. The implications can be tremendous.

There is, however, the other side. The more powerful, the controllers of money should not always be seen as tyrants. They are not ignorant of the interests of the society and the participants. It is when interests diverge or differ, do conflicts arise. And when these differences impinge on matters related to ethics in social science research, it then becomes difficult for researchers to uphold their own rights and rights of the participants.<sup>2</sup>

## **Conclusion**

Unethical research cannot only have an obvious impact on the participants of the study, however, going further, it can also affect the credibility of the social science discipline. This in the long run can lead to crippling or stagnation of institutions, researchers or the discipline itself. It can also lead to the creation of a false public knowledge or set of facts, leading to misguided policies.

Confirming to ethics in research may not be easy. Dynamics and perspectives differ. Each situation has its own complexities and ways to handle. Influencing forces too exert their pulls and pressures. It may be argued it may not thus be the responsibility of a singular researcher. It is that of all those associated with the entire research endeavour.

However, it is we researchers who form the most crucial link between the participants the society, those funding research and those who use research results to formulate policies. It is not just our duty to protect our integrity and autonomy and to protect the participants of research, where the threat exists, but it is also our right, our right to academic freedom. If we give up our rights and duties, to confirm to ethics in research, the credibility of social science research and the belief in the entire system, of inputs i.e. in terms of the research endeavour itself, and the outputs in terms of data or policies, and thus benefits, is threatened. It is our duty to go into a critical self-reflection of our work our practices and our goals.

There are no magical formulas to solving ethical dilemmas in social science research. However, what can be done is to become aware and identify and effectively raise, debate and attempt to solve these issues. It should never be forgotten that while individual



perspectives towards ethics and dynamics during research may vary, the potential of harm of unethical research remains.

### **Notes**

1. The author had given a number of presentations to initiate a debate on the draft NCESSRH guidelines. This argument has come up at least on two different occasions at the time of these presentations.
2. This should however not become an excuse to diverge from ethics by researchers.

**IV**

**Anthropological and  
Qualitative Research**



# 7

## ‘What good will come from your research?’

### Looking beyond ethical guidelines

#### Lester Coutinho

Some years ago at an international workshop on reproductive health I asked one of the speakers presenting findings from a study conducted in rural India to explain the process by which subjects/informants had been enlisted for the study in question. The study was based on both social and medical (clinical) data about male reproductive health. My concern stemmed from the showing of slides of naked male bodies from the community with the variously affected genitals, with no attempt made to disguise the identity (faces) of these persons. Of graver concern was the fact that body fluid samples had been gathered from these respondents for the purpose of various laboratory tests, but they were not informed about the nature or purpose of these tests. The concerned researcher (a medical doctor) reported that upon finding that one person was found to be HIV positive, a health worker was dispatched to the village to inform the person. The infected person ‘confessed’ to having visited a sex worker who had recently moved in from a metropolitan city. The researcher was unable to provide details about what follow-up was made available to these two individuals since they had both left the community soon after these events. The researcher was a bit taken aback with the questions on the methodological and ethical implications of the research, especially the questioning of whether or not the participants had been informed about the nature of medical tests to be carried out and the implications of the results of such tests. A member from the audience speaking in defence of the researcher said, ‘we are concerned about the welfare of poor people... that is the only ethics that matters, we desire to do good...so there is no other ethical question’. Later, some Indian delegates at that workshop told me that I had ‘failed to be loyal to the Indian research community, by raising such questions of a fellow-

Indian before an international audience'. My concern was that we had failed two individuals in that community who perhaps most needed to be cared for. The motivation to write this paper stems partly from this and other similar experiences. But more importantly, the motivation stems from my own experience of doing research on health issues and the emerging proliferation of health research in the Indian context.

Researchers in the social sciences, especially those whose research brings them into direct interaction with people, are often faced with this question posed by their respondents in the field, viz., what good will come about from your research or, how will your research benefit us. The question has often been asked of me during my research on health and development issues in rural and urban communities. Several colleagues engaged in similar research have shared such experiences. This question becomes particularly demanding when it is asked by persons from underprivileged sections of society who do not have access to adequate health care, but can be equally challenging when asked by those (irrespective of their social class) who are acutely cynical about any social research. On the one hand there is hope of the research becoming a resource to those participating, and on the other hand, for some there is the hopelessness of any kind of research. As researchers, our answer has often been little more than an expression of our own hope (or perhaps hopelessness) that the research would, through an advancement of our knowledge about a particular social (health) issue, positively influence both policies and practices. We do know from numerous examples that health research has been able to advance or better inform our understanding of particular predicaments and to some extent also bring about changes in the policies and practices of more responsive institutions or the researched community itself.<sup>1</sup>

It is not uncommon to hear researchers say that they do not think it necessary to engage with the question: 'what good will come out of your research', either in terms of the specific interests of the community/people researched, or in terms of the policy implications of their research. It is not my claim that all research on issues of health or development must be informed by utilitarian motives only, so that we only produce 'useful knowledge', which is what a well-meaning but overly regulatory code of ethics might actually end up prescribing and regulating. My concern is that more than ever before the researchers are being asked the question about the usefulness of research not by

state agencies, or some regulatory body, but by the very communities/people we work with. The question has different implications in varied contexts. Some researchers might argue that their ultimate accountability is not to the communities they work with, but to their particular discipline and the community of researchers, or that usefulness of a particular research should be viewed in broader terms rather than just ‘benefits to the researched community/individuals’.<sup>2</sup> While not disputing these views, we as researchers can no longer hide away from the fact that the question stares us in the face, and that we need to engage with it creatively and honestly. We need to recognise the challenge of taking up a more politically and morally engaged research not because of “a tortured process of critical self-reflexivity as of the insistence of some my (our) anthropological subjects” [Scheper-Hughes 1995 pp 410].

In response to the question, ‘what good will come from your research’, we may argue that one way of treating the question is to offer answers, through research, that enhances our understanding of social problems and sooner or later may inform policy and practices. In training field researchers I have often suggested this response, with a caveat that we do not know to what extent or over what time span the findings of a particular research may actually prove beneficial. This extended temporal dimension over which a particular research finding may prove useful is to be understood in conjunction with the possibility that the findings of a particular research may benefit not those who participated in the research, but other individuals/communities. However, we need to be critical and perhaps also suspicious of such an argument given the experience of medical research where one set of bodies becomes the site for research and experimentation, whereas the benefits not only accrue to another set of bodies, but in doing so excludes the first set, thus raising the issue of social justice. The controversy of AIDS vaccine trials in countries like Thailand, is a case in point. Further, given the manner in which biomedical research is presently tied up with market forces [see Rabinow 1995], and with the increasing nexus between biomedical and social science health research, social scientists need to be increasingly critical of being party to research protocols that might lead to an unfair or discriminatory distribution of the benefits.

There is, however, an alternative way of the approaching and engaging with the question. This can be done by a simple query - whether or not our research (in terms of it being a process of learning), includes those elements that would allow for the possibility of doing good (which includes, but is not restricted to impossibility of doing harm). The oft-used phrase – ‘doing good research’ - is to my mind inclusive of two dimensions; one points to the process and the other to the outcomes; and these two cannot be mutually exclusive.

I would like to make a distinction between the potential of doing harm, as opposed to the potential of doing wrong. Much of our ethical concern with reference to concepts of informed consent or confidentiality is often primarily aimed at the possibility of the research process doing harm as opposed to benefiting the participants. This is largely due to an emphasis on utilitarian ethics wherein subjects are viewed as holders of certain rights that must not be violated through a predetermined set of obligations enunciated as the principles of non-maleficence (not cause harm) and beneficence (contribute to welfare). However, if we were to conceptualise ethical issues not in only in relation to these principles, but instead focus on the question of ‘doing good’, then the moral implication is opened up to the possibility of ‘doing wrong’ rather than just harm. An act may harm without wronging, it may wrong without harming, or it may do both – wrong and harm [Wax and Cassel 1980]. Alasdair MacIntyre (1984) suggests that the possibility of doing wrong increases and doing harm decreases as we move away from medical research to field-based research.

Ensuring that persons participating in a research are not wronged entails not just assurances of informed consent and confidentiality, but more importantly, an understanding of the particularities of the male reproductive health study, which I discussed at the outset of the paper. In the context, the researchers might not have caused any harm to the community. Even the shortfalls in the process of obtaining consent to conduct laboratory tests of the various body fluids may not have produced any harm to the community or individuals (except for the one person who tested positive). But perhaps the community as a social body was wronged. The question is not whether the end results of a research process are harmful or beneficial, but rather whether the process of research is one that addresses the concerns of ‘doing good’ as opposed to ‘doing wrong’. And the possibility of doing wrong is

not restricted to questions of consent and confidentiality, but extends to the entire process of doing research, which necessarily includes the dissemination and further use of the information/knowledge produced. I am not suggesting that wrong can be measured against some objective scale, a code or statutes, but rather I am proposing that the possibility of doing good or wrong must be weighed in the particular social and moral contexts within which research is carried out. This entails recognising the subjects of our research as partners in the research process. (I shall return to larger implications of this proposition in a later section on social justice.)

As it is not possible to exhaustively deal with the numerous concerns of ethics and health research, this paper is limited to critically examining three central concerns - informed consent, confidentiality and social justice. For the purposes of this paper these are not just constituted as ethical principles or constructs, but as practices of doing ethnographic research. I shall not treat the subject as a classical philosophical debate on ends and means, but drawing on my own research experience of ethnographic health, research focus on some key issues upon which much of the recent debates on ethics of social science research in health are hinged. The thread through which I attempt to weave these three issues is the overarching question of this paper, *viz.*, under what conditions does ethnographic research (on health issues) have the possibility of doing good? I shall try to demonstrate how and why the concerns of informed consent, confidentiality and social justice are intrinsic to the practice of doing social science health research. However, in doing so I shall plead a case for moving away from a strictly normative, codified, contractual and prescriptive understanding of these ethical principles. The paper argues that the considerations of informed consent, confidentiality and social justice which are tied to each other and, hence, inform both the 'constitution of the research object' (what is to be researched, including research questions and research design), and the 'research process' (methodology, data gathering and analysis). Moreover, ethical considerations are at times, unfortunately appendages in research proposals and at best are vaguely articulated responses to 'ethical code/guidelines'<sup>3</sup> or some form of ethical principles of research. In such cases, the prosthetic discussions do not inform the research process nor are they informed by the practice of doing research.<sup>4</sup>



Given the dynamic nature of any social research, especially ethnographic research, it may not be possible to anticipate all or any of the outcomes of our research prior to the actual carrying out of research. Ethnographic researchers unlike medical or clinical researchers have little control over the process or the subjects/informants of the research. More importantly ethnographic field researchers have no ‘conceptual control’ [Wax and Cassel 1981]. The contextual unpredictability of the ethnographic encounter does not permit for an a priori knowing of the specific ethical issues that are likely to emerge. So at best when required to anticipate the ethical issues and to evolve strategies for dealing with these prior to the research, the ethnographer is compelled to provide broad generalisations – an exercise which Wax and Cassel (1981) describe as one of ‘futility and mendacity’. The exercise of anticipating ethical issues that may arise during the process of the research is itself not futile. However, the exercise is rendered futile when it is assumed the research no longer needs to continually engage critically with the anticipated and the unanticipated ethical issues that emerge as the research is carried out. The dynamic nature of ethnographic research necessarily demands a continued questioning of the assumptions of the research, and hence also of the ethical issues anticipated.

### **Ethnographic health research**

The need to recognise the particularities of specific contexts of research for a meaningful engagement of the ethical issues is one of central propositions of this paper. Health research as whole is a contentious field, not only because it involves various social sciences, but more importantly, because it is carried out in the shadow of medicine, science and bio-technology, which are seemingly based in far more universalistic discourses. While there is no denying the struggle for disciplinary hegemony between various social science disciplines, we have to also acknowledge similar tensions between the social and medical sciences. Like the medical sciences, social research on health is often expected to produce ‘useful knowledge’ largely because it deals with a category of human experience that is marked by suffering. However, this has at times entailed assuming that the social and cultural context of health issues are merely of significance for negotiating the delivery of medical science and its

practices (mostly western biomedicine). This has largely resulted in a kind of social science health research that has sought to further enable the medical sciences. In the specific context of medical anthropology, Scheper-Hughes (1990) has argued for a need to shift away from *clinical* medical anthropology' to critical medical anthropology because the former does not call into question the materialist premises of biomedicine, nor does it make any epistemic breaks from scientific medicine (as did social anthropology from the colonial world and its hegemony).

Ethnographic research (sociological or anthropological) in health is meant to focus on the ethno-medical, the social, cultural, and political dimensions of health issues rather than positivist biomedical scientific paradigms. In recent years there has been an increasing tendency to 'reduce the complexity and richness of anthropological knowledge to a few reified concepts' [Scheper-Hughes 1990]. In the Indian context ethnographic research on health has often been reduced to examining health seeking behaviour, illness (patient) narratives, health beliefs, doctor-patient relationship, explanatory models, and more recently 'knowledge-attitude-practice-behaviour' studies (KAPB) – all of which reflect a clinical bias. While recognising the importance of these categories that enable us to "make present the connections between individual bodies and social bodies, we must also understand that such categories have evolved through the norms and institutions of biomedicine' [Das 1999: 126]. Studies based on such categories, though at times critical of biomedical practices, have failed to examine the larger political-economic context of health issues. A more critical engagement with health issues necessitates synthesising the macro-level understandings of political economy with the micro-level sensitivity and awareness of conventional anthropological research [Singer 1990]. This does not mean abandoning the micro-level contexts, individual and collective experiences or cultural specificities of health issues. Scheper-Hughes and Lock (1986) caution against such a depersonalising of the subject and the content of medical anthropology by only focusing on the analysis of social systems and thereby neglecting the particular, the existential, the subject content of illness, suffering and healing as lived events and experiences. Medical anthropology can approach social life as a totality of

interconnected processes where macro-level structures and forces are not extrinsic to beliefs, behaviours and relationships [Singer 1990].

I have briefly discussed what is expected of ethnographic health research, and its increasing uncritical shift towards biomedical scientific paradigms as laying the ground to discuss how issues of confidentiality and informed consent cannot be framed within the concerns of biomedical scientific practice. With health research being increasingly carried out by organisations that are also involved in doing health interventions, which are largely biomedical in nature, or by social scientists who uncritically accept the biomedical model of health (hence have a stable and universal theory of disease, patient-user and doctor-provider as opposed to a theory that is local, specific and dynamic), there is also the tendency to frame confidentiality and consent primarily in terms of the doctor-patient relationship. However, we need to conceptualise ethical issues outside of a biomedical scientific discourse, because only then will social science health research itself be able to make an epistemic break from biomedical and positivist science.

Finally, I would like to emphasise that ethnographic research is premised upon the need for ‘thick descriptions’ that can only be obtained through a reasonably intense and sustained engagement with the object of research. It is this process, which produces relationships of trust, and affords in-depth insights. The increasing use of ‘qualitative techniques’ for rapid research in health is welcome, but is fraught with the risk of undermining both theoretical as well as ethical concerns of research. Besides the emphasis on the speedy completion of research, the relationship between the researcher and the respondents here is far more transient than in research involving the use of more intensive methods of research. The considerations of confidentiality and informed consent discussed below are specific to health as an object of research as constituted within the practice of doing ethnographic research based in anthropological /sociological methods and theory. Here the researcher is ‘called into the stories and lives of others by the moral process of engaged listening and by the commitment to witnessing’ [Kleinman 1999:89]. This listening and witnessing is not produced by the objective fact of a consent form or the assurance of anonymity – it is produced continuously and negotiated at every stage of the ethnographic encounter.

Practitioners of more rapid research methods perhaps also have to ask themselves similar questions, and though they may gain insights from the discussions that follow, they need to locate these questions within their specific methodological frameworks. This task is urgent given the proliferation of corporate groups that undertake such research on health issues on behalf of government and international agencies. The demand for speedy completion of research coupled with the profit-making interest of these corporate agencies has resulted in data that is quickly gathered, analysed and made available as the basis for policy making. Policy makers increasingly rely on such knowledge produced through the use of rapid research methods that reflect little or no ethical and epistemological questioning of the production of knowledge. Thus information generated through a focus group discussion and that which emerges from a structured questionnaire or an in-depth interview are at once comparable and compressible into the category of 'qualitative data' with little reflection on the varied nature of the data. Furthermore, the fashionable mix of qualitative and quantitative methodologies in such research has rendered the qualitative data to mean a few fancy quotations that reflect peoples' perceptions and attitudes, without any in-depth analysis based on theoretical foundations. It is not totally unknown that such large corporate research agencies have 'mechanised' research so that there is now a neat division of labour between the formulation of a research problem, the development of appropriate data gathering instruments, the gathering of data, the analysis of data, and the preparation and presentation of findings. These competing corporate agencies bid for research, and once awarded a research bid, seek to maximise profits through a cutting down of 'production' costs (including time). This results in a compromise with the research process. Such research is devoid of personal interest and investment in the research process.

The purpose of briefly discussing this emerging scenario of research on health and other development issues is to firstly suggest that a laying out of any code or guidelines of ethics for research must take into consideration the contemporary organisational and institutional contexts of research. The emergence of research as part of the agenda of NGOs that were primarily launched as intervention and programs based organisations also needs to be critically examined to understand the organisational and institutional context of health

research today. This change is often informed by the donor and funding agencies that have begun to appreciate the logic of intervention/programs being informed by research. It is important to point out that 'qualitative research' in the context of the such corporate research agencies and the intervention driven NGO sector is often uncritical of the epistemological foundations or the conditions under which knowledge is produced and the relationship between the worlds of people, ideas and objects. Such an approach to research, especially health research, itself produces the possibility of doing harm and/or wrong to the people or issues it seeks to understand and represent.

With qualitative health research being conducted in the context of diverse organisational and institutional arrangements that directly impinge upon issues of methodology and the larger research process, it is not surprising that ethical issues are reduced to a matter of few principles, consent forms and assurances of confidentiality. My concern here is not to critique or dismiss the significance of such research but instead to emphasise that because health research is a category that includes a diverse range of methods, theories, and practices, there are bound to be plural articulations and interpretations of the ethical concerns. The preamble to The Guidelines recognises this plural, diverse and rapidly expanding context (see Introduction and Paragraph 1 of Preamble). We also need to recognise that within what is loosely and broadly called qualitative health research there also exists diversity of method, theory and practice. This is bound to be reflected; in the articulation and resolution of ethical issues. In what follows, I attempt to reflect on the question of confidentiality and informed consent from within a particular practice of ethnographic research.

### **Confidentiality as social relationship**

During the fieldwork for gathering information on the 'childhood immunisation practices' in Surat district, a colleague learned from some auxiliary nurse midwives (ANMs) that instead of administering 0.5 ml of the DPT vaccine, some ANMs administered only 0.25 ml. Their reason for doing so was the fear that often children developed fever after being administered this vaccine. This led mothers (and other caretakers) to conclude that the vaccine caused the fever and hence they refused to bring the child for subsequent doses of the vaccine. Also, the ANMs pointed out that they did not have adequate

stocks of paracetamol tablets to treat the fever. From their local experience they had concluded that giving a 'lesser' dosage reduced the 'risk' of the child getting fever, and this ensured that the mother returned for other vaccines. Of course, their concern for ensuring that the child returned was informed by the target-driven approach of vertical programs [Coutinho, Bisht and Raje 2000].

The field investigator had over a period of almost six months developed a relationship of trust with the ANMs. She had been living and travelling with them as they visited various villages. They no longer felt that they were being watched or monitored and hence had begun feeling more secure in sharing information with the researcher. The matter was brought to the attention of senior researchers and the principal investigators. There were two conflicting issues at stake; firstly of confidentiality (towards the ANMs who had informed us of the practice); and secondly of beneficence (towards the children who faced the risk of not developing immunity due to this practice). Of concern was also the fact that if the matter was brought to the attention of the concerned health authorities, the ANMs might be selectively targeted for 'punishment' and would also lose esteem among colleagues who might also be engaging in similar practices. We ultimately, chose to instruct those ANMs who had informed us about such vaccination practices that this was a wrong practice, which they should discontinue. We also explained to them the greater risk the children faced if they continued such practices. In the final report and various other papers and dissemination workshops this practice was discussed but neither names of neither the ANMs, nor the primary health centres (PHCs) were disclosed though the district was identified.

This case is not unique, and similar and more challenging issues have emerged in doing research on issues such as illicit drug use [see Fitzgerald and Hamilton 1996], sexual health and behaviour [see Ringheim 1995], doctor-patient relationship and use of pharmaceutical products. In each of these cases it is not enough to record 'wrong practices'. The challenge in ethnographic research is to understand and explain why and how these practices are produced. The very object of research demands an approach/methodology that subsumes confidentiality, and this informs what we may seek to know and how we may come to know it. The increasing use of covert techniques, like the simulated client method (as in some recent studies on quality

of care provided by doctors and Registered Medical Practitioners (RMPs) treating persons with sexually transmitted diseases) not only raises the ethical question of consent of the provider, but also of confidentiality which is to be understood as that which emerges from a relationship of trust (see Madden et al 1997 for a detailed discussion). Confidentiality understood as a relationship entails that it is shared by two or more individuals. And because it is a relationship, it has specific contexts within which it is meaningful. Even though similar knowledge may exist outside such a relationship (of confidentiality), the relationship within which it is produced, and the wider social relationships it produces are different.

To further this idea of confidentiality as embedded in social relationships, I shall draw upon the concept of 'poisonous knowledge' [Das 2000]. A family and or some members of the family/community may share the knowledge of an individual illness. This knowledge within the context of specific relationships enjoys a relationship of confidentiality and hence a particular meaningfulness. Outside that relationship, the information maybe constituted as 'poisonous knowledge' as it allows for not only altering the relationship to that particular information but also alter the relationships between individuals (who share that knowledge). As social scientists doing (ethnographic) research on health, we need at the outset to attempt to imagine, and understand, within what contexts and relationships is a particular information confidential, and how availability of that information in other contexts may alter the meaning of that information and the relationship between those who share this information. Confidentiality is hence to be constantly produced between individuals and collectivities that share particular universes of meanings. The fact of a particular individual suffering a stigmatising health condition is meaningful in one particular way within the universe of meanings shared by the researcher and the informant. Therein lies the relationship of confidentiality. The same information outside that particular relationship and universe of meanings must 'transform' itself to be meaningful within another kind of relationship embedded in a different universe of meanings and context, so that the meaning it shares within one context does not become poisonous (danger/harm producing) to its earlier context. Hence information about an individual's illness or a particular health/medical practice must be divested of those aspects

which may constitute it as poisonous knowledge when it is to be shared among those who share a relationship as health researchers, policy makers, or law enforcing agencies. The information can only be shared in other contexts, as in a research paper, so as to make it meaningful to the intended audience. This knowledge may be represented in a manner that does not harm the relationship (context and universe of shared meanings) within which it was first gathered. I shall not labour the point further, and proceed to examining how confidentiality in social science research is to be understood as distinct from confidentiality in the doctor-patient relationship, and biomedical research. I am not suggesting that the two are antithetical to each other, but the nuances are significantly different.

It is unfortunate that often parallels are drawn between the relationship of doctors and their patients, and between social scientists and their informants. Even though confidentiality is instrumental to both, Robinson (1991) has argued that the role of confidentiality in social science research is more significant than in medical context because of the expectations of the participants in the particular relationships. In this sense confidentiality of clinical situations should be distinguished from confidentiality in research situations. Unlike in clinical situations, the initiator of the relationship (encounter) in the social sciences is the researcher and not the informant, as opposed to the client being the initiator in the clinical encounter. In both cases the purpose of confidentiality is to protect the patient/informant and through that protection offer the possibility of effective practice of medicine and social science respectively. In the clinical encounter confidentiality is primarily (though not exclusively) aimed at protecting the 'physical person', as opposed to social research where the primary aim is to protect the 'social person' [Cassell 1982]. This distinction between the social body and the clinical (biological body) and the distinct nature of harm that can be produced is crucial if we are to understand the varied contexts of confidentiality. The social body is faced with graver danger because it's subject matter is related to a wider audience [Robinson 1991].

Further, unlike clinicians and medical researchers, social scientists are not formally or legally bound by a unified code of ethics that informs their practice. Confidentiality in social science research remains a loosely defined term. Even in the British Sociological



Association Code of Practice, the researcher is only required to 'make clear the nature of confidentiality offered' and not give guarantee of confidentiality that may not be fulfilled. On these grounds social science research may be criticised for not having a universal or a priori sense of confidentiality. Since knowledge produced through social science research recognises its situated-ness, the character of the ethical norms for confidentiality is equally situated. This pluralist position should not be mistaken for a relativist ethical stance. Since, the researcher is the initiator of the relationship, he/she has the obligation of understanding the particular demands of the informant's particular expectations. Also, 'the situated-ness of confidentiality may arise out of the particular kinds of social research' [Robinson 1991]. The kind of confidentiality negotiated through ethnographic research may be very different from that negotiated through survey or rapid research. The nature of knowledge produced by, and the scale and focus of these different research methods allows for different kinds of negotiations and relationships of confidentiality.

Finally, unlike the clinical encounter, the context in which social science research takes place is crucial to interpreting the nature of confidentiality. At one level this requires a distinction between what is (perceived to be) private and what is public information [Robinson 1991]. At another level, we need to distinguish between collective good (harm) and individual good (harm), while recognising that there may be disagreement as to what constitutes collective good, or who represents collective good. Also, often confidentiality has been weighed in terms of individual interest versus public health interest. There is as much a public health interest as an individual interest in fostering a 'regime' of confidentiality. However, this does not mean that there are no limits to confidentiality. In weighing the pro and cons of confidentiality the single most important principle to be born in mind is not the diffused sense of individual interest versus public interest, but the assessment of the real (situated) danger/risk posed to various individuals in diverse contexts. Even though not all harm can be anticipated, unintended outcomes effected by the knowledge produced may inform the formation of new kinds of social alliances. Confidentiality is not an end in itself. It is negotiable variously in diverse contexts but aims for the possibility of doing good and the impossibility of doing harm/wrong. This situated approach also

recognises that not all individuals (informants) are equal and hence the possibility of doing good (no harm/wrong) would be relative to the degree of vulnerability and risk faced by various groups.

### **Producing informed consent**

Within the wider debate on informed consent the central issue has been whether or not patients should influence medical decisions. Here we must at the outset make a distinction between informed consent for normal therapeutic procedures, informed consent in the context of new medical technologies (for e.g. new drugs, vaccines or surgical procedures), informed consent for diagnostic procedures such as HIV testing, and informed consent for social science health research.<sup>5</sup> There have been two broad orientations that have governed discussions on the issue of consent: on the one hand there is the framework where the autonomy of the patient is subordinated to his well-being (and at times also the well-being of the public), and on the other there has been the framework wherein respect for the patient and the exercise of his autonomy has been primary. The ethic of the former is geared towards outcomes, while the ethic of the latter is geared towards the procedure of informed consent.

In medical ethics there has been much uncertainty and confusion not in terms of what constitutes informed consent, but more importantly how are we are to obtain informed consent, especially in the context of non-literate societies, and in cultures where the doctor-patient relationship is primarily one of total trust, or like the relationship between researcher and informant is inflected by power and hierarchy. A pertinent question to pose in order that we may arrive at a more practical and useful understanding of the concept is what purpose(s) does informed consent serve. It certainly cannot be argued that informed consent is in an end in itself, but is a means towards other ends. One of the most important arguments in favour of informed consent is that it is meant to protect subjects from possible harm (thus creating or enhancing the scope of the possibility to do good). Informed consent in the context of social research cannot be understood in the same way as in a case of diagnostic testing for infectious and communicable diseases (e.g. HIV), or invasive surgery, the trial of an experimental vaccine or new medical technology. The nature and degree of harm in these diverse cases varies. A patient has the right to

understand what are the benefits and risks of a particular medical procedure. Similarly, an informant has the right to know to what ends the information given will be used, the nature or risk and vulnerability s/he may encounter having given the required information. Informed consent primarily is about creating the possibility of a relationship not only between the social researcher who initiates the encounter with the informant, but also between the informant and the research objectives and final outcomes. While it is true that data, especially ethnographic data may be examined and analysed in a manner not anticipated at the outset of the research, the informant needs to be made aware of this possibility. Thus informed consent does not only entail explaining potential dangers and risks, but also recognising uncertainties. If in the context of ethnographic research we claim that given its unpredictable nature it cannot be bound to an a priori set of ethical principles, then we must also recognise the possibility of uncertainties of the outcomes not just for researcher, but also for those who participate in such research. In as much as confidentiality is a relationship that the ethnographer builds with an individual or a community, so also is obtaining consent.

The procedure for obtaining informed consent has been an equally contentious issue in bioethics and social science research ethics. The printed form is common in most countries, but it has become increasingly evident that such procedures are not effective in communicating the risks and benefits of a particular medical procedure or social research process. This aspect becomes even more crucial when the research concerns issues that are likely to have implications not just to individual's social body but also the body politic (or specific groups like women, children, migrants, sex workers, etc).

The criticism against written information to obtain consent becomes particularly relevant in non-literate societies, as is the case in large parts of India and other developing countries. Studies have shown that patients read and sign these printed forms but are later unable to recall what they read and whether they have read it at all [see Riecken and Ravich 1982]. As a procedure for obtaining consent, the printed form has also been criticised for being a token action to fulfil the legal requirements, rather than to communicate information to the concerned individual [Gostin 1995]. A more significant criticism against the printed form as a procedure for obtaining informed consent

is that the language (technical terms) used cannot be comprehended even by educated persons. Alternatives like the use of videotapes, brochures, group discussion, professional counselling have been suggested, but unfortunately we do not have much information based on research on the effectiveness of such procedures. There needs to be a more serious application of mind to determine what procedures for obtaining consent would be effective and relevant in diverse situations. Even if consent is assumed through a particular relationship that the researcher (especially ethnographers) may share with individuals or a community, these processes need to be adequately fore grounded in the dissemination of research findings.

I would like to briefly allude to the debate on the impossibility of producing/obtaining informed consent on the grounds that it may not be possible to ever comprehensively explain in the context of ethnographic research all the aspects of risk/danger/harm that the research may entail for the informants. Such an argument falls apart when consent is understood as choice based in the recognition of partial or incomplete knowledge (of risks/harm), rather than choice based on complete/full knowledge. Consent may be considered informed so long as the information shared includes the doubts and uncertainties that the researchers face about the research process; but this cannot become the basis for doing away with the need for obtaining consent.

In an increasingly used methodology of undercover researchers either in clinical, hospital, pharmacy or community settings, the question of consent is more complex. The Council for International Organisations of Medical Sciences (CIMOS) in collaboration with the World Health Organisation (1991) published guidelines for the ethical review of epidemiological studies where it was stated that researchers maybe justified in not seeking consent if to do so would be impractical or frustrate the purpose of the study. The same argument may be extended to other kinds of research on health issues, including social science research. The interesting issue here is the assumption that the desire to know or to understand a particular phenomenon is of higher moral value than all else, including consent. Unconnected anonymous testing of blood for HIV or other infections for epidemiological studies may be justifiable on such a basis. However, this allowance has the potential of misuse both in medical and social science research. As social scientists we need to set the limits of what

is it that frustrates the purpose of a particular research. If the objectives of the study are so fragile that the availability of that knowledge to the community may frustrate the research, then we also need to have the certainties that the compromise with the process of obtaining consent does not produce any possibility of harm or risk for those whom we study. If for whatever reasons this certainty is not available to the researchers, then such a compromise is untenable.

In ethnographic research the ethical concerns of confidentiality cannot be disassociated from those of informed consent. Both are embedded within social relationships, and are practices that are coterminous with each other. Informed consent like confidentiality is to be situated in relation to the object of research, the objectives of research, the research methods used, and the situated-ness of the ethnographer-informant relationship.

### **Towards an ethics of social justice in health research**

Meaning is a form of politics, and the processes of knowing (the production of knowledge) are also informed by politics. As stated at the outset of the paper, social science research on issues of health are inherently intended towards producing useful knowledge, but we also need to be critically aware of the corollary question: to whom would such knowledge be useful? Most codes and guidelines of ethics pay much attention to respect for autonomy, but pay much less emphasis on social justice issues. In the Indian context and that of other developing countries, we have to also take into cognisance as an ethical issue the serious inequalities in access to adequate health care services. What aspects of health care are researched are not always informed by social justice issues, but more often by agendas set by funding agencies, state policies (which may themselves be skewed towards the elite) and international organisations whose agenda may be informed by interests of developed countries, multi-national pharmaceutical companies, and other stake holders in the international health sector.

Social justice may be described as a contested domain, and yet we have adequate evidence from previous social science research to explain how social inequalities produce health and illness. The less privileged sections of society have a greater burden of morbidity and also spend more on seeking 'good health'. In this context, the question

begging attention is what health issues should be researched by social scientists, and additionally on what basis are we to set our priorities? The issue is contentious. Das points out that ‘the processes of globalisation raise problems of equity in health care not only in ensuring equal access but also in making it necessary to prioritise which diseases will receive resources from international organisations and national programs’ (1999:103). And we may ask the same of social science research on health - what kinds of health problems should be researched in countries like India? Das (1999) takes the argument further by suggesting that it is time for bioethics (and also for social science research) to address the larger questions relating to health as a public good as opposed to a private resource.

The moot question is how are researchers to address the problem of social suffering stemmed in health issues? Faced with the question, ‘what good will come from your research’, posed by those who suffer from ill health, what might our answer be? It is perhaps time for a questioning of what is social in social science research on health: is it the method that makes it social science, or are the questions and the problems framed as social concerns. Taking cue from Scheper-Hughes (1990) suggestion that illnesses that enter the universe of the clinic are equally a reflection of the ‘tragic experiences of the world’, I would argue that any meaningful engagement with health draws us into a world of social suffering. Social science health research therefore is inextricably an engagement with suffering. Hence, the ethnographic encounter with others’ experiences of suffering demands an explicit ethical orientation to the other not as ‘spectator’, but as ‘witness’ [Scheper-Hughes 1995]. As witness then the ethnographer has the responsibility of becoming involved and engaged in the suffering s/he witnesses. The old axiom of anthropology of dispassionate observation, and non-engagement so as to remain objective, is to be critiqued for being as much an ethical and moral position as perhaps ‘taking-sides’. Thus ethnography (in the context of human suffering) entails an ethical imperative, which is not a priori, but one that emerges from the particular context of the research. The ethical imperative is often hastily and easily translated as activism. The more challenging task is to be able to create the possibility for advocacy through a witnessing that affords a more insightful and critical understanding for advocacy, policy or activism.

Within ethnographic research, and particularly anthropology, the relevance of research for advocacy aimed at bringing about change has been much debated. Anthropologists like Hastrup and Ellass have argued that advocacy is incompatible with anthropology as ‘no cause can be legitimated in anthropological terms’ (1990:301). Their argument rests on a very neat and clear-cut divide between ‘basic anthropology’ and ‘applied anthropology’, so that advocacy is located within the realm of ‘applied’. Such a divide has been turned on its head by Frederick Barth, who is reported to have said, ‘the difference between basic and applied anthropology is that basic research is more applicable’ [cited in Mathiesen 1990]. The contrived split between basic and applied is also based on a very narrow view of anthropology / ethnography leading to ‘amoral relativism’ [Grillo 1990]. Such a split has allowed for a possibility of dubbing applied as ‘atheoretical’. The case may well be that often applied research because of the institutional context within which it is conducted, lacks the rigor of theoretical analysis. The lack of the latter does not in anyway make research more amiable to or efficient for advocacy, but I dare suggest may actually not only make it less efficient, but also dangerous. It is the rigor of theoretically well-grounded ethnographic research that can provide insights that enhance the possibility for effective advocacy. Mathiesen (1990) makes the point more poignantly; ‘commitment to improve the world is not a substitute for understanding it, if for nor no other reason than that the latter can very well be accomplished without the former. That improvement can be achieved without understanding is less likely’ (1990: 308-09). The desire to understand the world is not readily available for translation into action rooted in the desire to improve the world. But then, can we at all have a desire to understand without concern? Robert Paine (1985) suggests that an anthropologist without concern is not anthropologist at all.

So if we can acknowledge that ethnographic/anthropological research on issues of human suffering like illness, stems from a ‘concern’ that in turn produces the desire to understand (or minimally a dialectic between the two), then we need to propose an ethic of concern that not only informs the research process, but that is also informed by the research process. In some contexts the very process of doing research may lend itself to the possibility of ‘raising the context awareness of the people themselves, so that they may eventually

become better equipped to plead their own cause' [Hastrup and Elsass 1990: 306]. However, in other cases it may be the continued task of the researcher through her/his work to conscientise others to recognise and respond to a particular human predicament. More fundamentally the ethnographer is called to an ethic of care and responsibility that forms the basis of an ethic of social justice.

### **Beyond the Guidelines**

In the process of answering the question that I set out to address in this paper, several other questions have emerged, one of which I would like to briefly address in this concluding section, *viz.*, whether or not the Guidelines or a code of ethics for health research is needed not just for the practice of ethnographic research but also for social science research in general? One may playfully now ask the question, what good will come out of a code of ethics? Who are we accountable to? We do not have a code of ethics for social science research in general, for sociology or anthropology, so why do we need one now? The answer to this question is partly addressed the preamble of the Guidelines (see particularly sections 1.5 and 1.6 of the Preamble). It is unlikely that the Guidelines, in spite of the participatory processes through which it has been produced, will gain favour with many (health) social researchers. I have already heard some dismissive remarks from sociologists and anthropologists who feel that the Guidelines is completely unnecessary; that ethics is too complex an issue to be reduced to a few a principles; or there is nothing very innovative about a code of ethics. My own discussions on just two aspects, confidentiality and consent, have drawn attention to some of this complexity, the gray zones, the points at which the distinction between ethical and unethical is blurred. Some colleagues have cautioned that a well meaning code or guidelines of ethics can instead of becoming the basis for self regulation and reflection, become an instrument that could only frustrate research if it were to be rigidly implemented by some regulatory body. At present social scientists are not accountable to a code of professional ethics, as are doctors or medical researchers. The anxiety is valid. The concern has emerged in earlier debates on normative ethics that would determine how research is conducted as opposed to meta-ethics, which would explore the rational basis for moral principles and value judgements [see



Jorgensen 1971]. In renewed debates within anthropology on the need and implementation of codes of ethics, it has been suggested that an ethical code for anthropologists is almost useless [Pels 1999]. The most significant debates and advances in ethical thinking have taken place at the scandalous moments of a particular discipline. In medical science perhaps the events associated with Tuskegee and Nuremberg would be the better known as one of the outstanding moments of scandal. These scandalous moments allowed for the emergence of ethical thinking that permanently altered the way in which medical research was to be carried out. And yet the scandals continue.

As social scientists we must recognise (without being apologetic) that the Guidelines is certainly not a perfect document, neither is it the final word on the issue. But it is a significant contribution at a time when social science research in general, and health research in particular; have expanded phenomenally in India. The Guidelines is primarily meant to be a catalyst to a process of reflection and dialogue among health researchers and social scientists in general. This entails looking beyond the Guidelines. Perhaps other social contexts or newer moments of scandal will demand revisions, as has been the case with the code of ethics of the American Anthropological Association. In fact, the only way of engaging with the Guidelines is through a stance of looking beyond it, so that it becomes enabling rather than crippling. Hence, instead of funding agencies demanding a note on ethical concerns and how these are to be addressed prior to the research process, what is needed is a process that enables a researcher to critically examine ethical issues and make moral choices during the process of research. We need further documentation of these processes, not evidence of signed statements of assuring confidentiality and obtaining consent. We would have failed the process initiated by the National Committee for Ethics in Social Science Research in Health (NCESSRH), if the Guidelines were to become an instrument of regulation, rather than an instrument that enables us to develop a capacity for an 'emergent ethics, a set of moral agreements composed contingently, perhaps inconsistently, but at least appropriate for the situation at hand' [Pels 1999].

At the risk of sounding parochial, the final question I seek to address is how does ethnography as a mode of doing research enable us to address the ethical issues discussed herein. A part of the answer

to this lies in recognising the situated-ness of the object of research, the research questions, and the researcher. Such a recognition would entail that ethnography should move towards self-reflexivity, wherein the researcher recognises her/his moral subject-positioning, and equally that of the object of research. This also entails that besides producing an ethnography of the health issues itself, there is need to construct an ethnography of what is the particular (local) ethical framework which informs peoples' health concerns, how are larger ethical concerns informing their local concerns, and nature of the researcher's own ethical concerns. Any analysis of the research questions must be interwoven with these ethical concerns. The ethical imperative can emerge in the confluence of recognising conflicting and intertwining ethical perspectives and moral positions. Kleinman's (1999) recommendations for an 'ethnographic moment for bioethics' may be extended to an ethics for social science health research as well. A code of ethics cannot hope to answer or give solutions to the ethical issues that emerge in the process of doing research, because 'ethics is characterised by a spirit of radical inquiry; it does not supply solutions for moral dilemmas, but it does undertake to provide a rational framework for understanding the complexities of moral judgement' [Smith 1980:453]. Hence, it may not be task of the researcher to ensure that the knowledge produced through research may actually 'do good', but in clarifying these issues through ethnographic practice, allows for 'evolving the conditions for such an outcome' [Kleinman 1999].

Ethnographic research seeks to understand what people are (and not) saying, doing, thinking, feeling, experiencing, in relation to whom, how, where, when and why, i.e., it attempts to understand a particular set of issues contextually. The challenge for those engaged in ethnographic research is not make to claims of whether or not a code of ethics laying out prescriptions of what ought to be done was followed to the letter or not, but to explore the contextual nature of moral/ethical dilemmas faced in the process of doing research. In addressing the question 'can ethnography save medical ethics', Hoffmaster (1992) draws our attention to how actual moral decision making is situational – 'it is tailored to the particular demands of particular circumstances, as well as the capacities and limitations of the persons enmeshed in those circumstances' (1992:1425). Such an approach will allow for a critical engagement with MacIntyre's theory (1993) that ethnography

which is based on a description of others is only possible through a definition of the other in opposition to the self, and hence is always duplex and therefore unethical. Looking beyond a code of ethics then includes examining the ethics of the production of knowledge. Ethnographic research based in anthropological theory necessitates an ethics of doubt that makes possible a dialogue [Copans 1999]. In looking beyond a code, the ethnographer/researcher needs to create (and recreate) her/himself not as a bearer of a given code of ethics, but as an ethico-moral agent engaging with other ethico-moral individuals and communities. Looking beyond entails engaging in a negotiation and dialogue with others and ourselves in diverse contexts. This necessarily means recognising as Christakis (1992) suggests that ethics is a 'form of local knowledge(s)' that need to be critically engaged with each other rather than in conflict. However, the looking beyond also entails 'navigating between the simplicity of universality and the evasion of the complexity of ethical relativism, between intellectual hubris and moral paralysis' [Christakis 1992: 1089]. A creative and honest engagement with the question 'what good will come from your research' inflected by its vernacular accents, and particular contexts creates the possibility of looking beyond *a* code of ethics.

### Notes:

1. Recently this has been particularly demonstrated in the context of research on women's sexual and reproductive health, which led to rethinking of population policies and the integration of reproductive health into primary health care in India.
2. These responses emerged during discussions with colleagues and a wide range of researchers working on health issues in developing countries.
3. The Guidelines refers to the 'Ethical Guidelines for Social Science Research in Health' of the National Committee for Ethics in Social Science Research in Health (NCESSRH). The terms guidelines and code are generic and do not refer to any specific document unless specified.
4. Most funding agencies require research proposals to include a section on 'ethical considerations' and also to address the question of how they plan to deal with the anticipated ethical issues. Ethical issues here get constituted as external (to the objectives of the research and the research methodology) blocks that have to be strategically overcome.
5. See Barrie 1980, for a detailed discussion on ethnographic fieldwork and the difficulties of informed consent.

# 8

## Qualitative research in public health

### Perspectives and ethics

#### Ritu Priya

There has been an explosion of qualitative research in public health over the 1980s and 1990s. It has delved into a wide range of issues, from the most public to the most private, often relating to some of the most socially and culturally sensitive of subjects. It has wide and deep ramifications for approaches to health service development and for changing social perspectives. Yet there has been little discussion of its ethical dimensions. Many of the issues dealt with are socially contentious and therefore there is a need to develop mechanisms for resolving them in accordance with ethical principles (non-maleficence, beneficence, autonomy, confidentiality and justice as enunciated, for example, in the 'Ethical Guidelines for Social Science Research in health' [NCESSRH 2000]). Avoiding addressing them at this stage may harm the cause of qualitative research in public health as well as the cause of public health itself. This note attempts to raise some of the general issues that have emerged from specific instances of conflict related to qualitative public health research. It should be read as a sort of loud thinking and an invitation for some brainstorming.

While some basic rules of ethical conduct of medical research can be extended on the issue to social science research in public health, some specificities of the latter raise additional ethical issues. Biological safety is the first prerequisite of medical research. For example, the clinical trial of a drug must ensure that there is only a low acceptable level of risk of side effects to the persons to whom it is administered. Should not the same principle of non-maleficence be applied to the likely negative social impact?

Secondly, the well accepted ethical guidelines for medical research are based on a notion of rights of the individual, for instance 'ensuring confidentiality' of persons undergoing a

screening test such as that for HIV infection, or 'taking informed consent' for any experimental medical procedure from the individual undergoing it. This is logical because the individual patient is the unit for intervention in clinical medicine. But for public health where the 'total population' and its subgroups are the units for action and analysis, should the ethical principles not be applied at that level?

If we accept both these propositions it would mean that rules for ethical conduct of qualitative research should include:

Mechanisms should be evolved for obtaining informed consent from the group being studied [and not only from individuals within it) after providing it with information about the objectives of the research and its possible negative consequences. Its impact, including that of its findings, on social processes affecting the study population and its sub-groups should be considered. Data with socially negative connotations should be presented in a way that they do not stigmatise a specific community or group.

### **Assessing impact of qualitative research**

The obvious question that needs to be addressed here is, how do we assess the impact of the research on social processes?

An understanding of the context in which research is being undertaken is crucial to assess its probable impact. There are primarily two kinds of social science studies in health. There are those that are purely addressed to social science agendas and attempt to analyse social processes through health issues. The second kind, relating to public health programmes and policies [FRCH 1994 and Viswa 1998], are the ones addressed in this article. The objectives for such research are commonly linked to public health programmes in order to know how the particular population or community will respond to the pre-decided programme strategy, and how best to operationalise it.

This qualitative health research thus primarily focuses on : (i) People's health-related behaviours (childcare and dietary practices, sanitation and hygiene, sexual behaviours, treatment seeking for illness, etc.), (ii) health-related perceptions (about the body and its functioning, illness and disease, preventive and curative measures, and the available treatment-providers and health care

services), and (iii) health services research (structure and processes of institutional functioning, interaction between different categories of personnel, interaction of care-providers with lay people, etc). Thus, public health programmes and policy agendas greatly influence qualitative research. In turn, such research can feed and influence them.

Qualitative research findings can be used for action within formal organised structures (as advocacy tools for policy and programme formulation, and for improving management of programmes and services). Health sector reforms of the 1990s illustrate this use of qualitative health research. They can also be used for socio-cultural intervention involving action in the 'community' for bringing about changes in knowledge, attitude and behaviour, through health education, community mobilisation for health issues or/and empowerment of socially weaker sections. This often implies questioning and changing existing social perspectives and values within the community and the health system. The action against gender disparities in recent years is an excellent illustration of this. The issue of 'sexuality' is another such example, but which has less clarity and greater contention about the desirable directions of change. Another contentious issue is the worth and role of folk and involves value positions on relationships between human beings and between them and nature.

The influence of qualitative research on social values and health perspectives raises a set of ethical dilemmas because of the divergent views and interests that they represent at several levels. On the one hand is the notion of health of lay people in all societies. This has been found to relate health status to basic need fulfilment, quality of life, social environment, and emotional well being [Herzlich 1973; Castro 1995; Priya 1995]. On the other is the formal public health structure primarily shaped in the present by the bio-medical paradigm of health and the technocratic approach to public health problems. The latter position promotes the application of 'universal' strategies through centrally controlled, technology-based programmes which play down the significance of the social context of ill-health and health interventions [Petersen et al 1996]. This involves non-responsiveness to local context and priorities and an inordinate power of the 'expert' and the international bureaucrat

over 'lay people'. The failure of public health in the past has highlighted the negative consequences of the approach [Banerji 1985].

Further, the context of research includes local social disparities on the one hand and global politics and neo-imperialism on the other. Within the study population or group that is often defined by geographic and administrative boundaries, there is diversity, for example, of caste, class and gender. Dominant sections within the community (upper caste and class, male) will favour perspectives that help maintain their superior status, and oppose social interventions that threaten their position. The 'universal' international strategies, with their liberal democratic perspective giving equal rights to each individual irrespective of gender, caste, class or race, are then more attractive than the communitarian approach [Kiss 1999]. The current dominant international development discourse promotes the liberal perspective, gaining support of one section of progressive forces at the local level.

However, in the context of international politics and the hegemony of the 'northern' perspectives on the policies of the 'southern', which creates the dilemma in accepting the international discourse as the desirable social perspective and value framework to which all communities and peoples must be channelised. In the current situation, significant determinants are the economic structural adjustment policies (SAP), which bring with them ramifications in other spheres. According to one view, SAP creates an environment that allows the dominating biomedical and technocratic paradigm of public health to make even greater inroads into southern countries [Rao 1999]. Others add to this analysis the understanding that SAP and technocratic programmes bring with them an aggressive cultural promotion of consumerism and individualism that are essential for establishing market mechanisms and breaking down local collectivities and social support structures. This results in economic, social and cultural degeneration of societies of 'the south', which breaks their self-confidence and weakens their ability to regenerate themselves, thereby further legitimising the dominance of 'the north'.

The negative social consequences of these processes are felt most by the previously marginalised at both the international and local community levels. The international intervention and the neo-

liberal perspective from which it draws its legitimacy is thereby a negative influence even for the marginalised. This is reflected in the sphere of public health as well [Qadeer 1999 and Priya 1996]. Ironically, it is not within the individual rights framework that a fight is put up against this international hegemony. Collectivities with a nationalist or community identity may usually catalyse such struggles.

If we accept that this analysis of the current international impact is even partially valid, then we face a dilemma because there is no one perspective or value framework that we can consider 'the best' and use as a reference point for evaluating the impact of qualitative research on processes of social change.

Is it then ethically justifiable to impose research and analysis from a certain perspective on a study group or community with a predominantly divergent perspective? Certainly this question cannot mean that researchers should not question community value positions. How do we resolve this?

We can turn to anthropology that has long dealt with the issue of diverse value frameworks for some methodological ways of dealing with this ethical problem. One is the whole debate of the emic (the 'insider' view) vs. the etic (the 'outsider' view). The emergent understanding [Bose 1995] was:

That the researcher cannot become an 'insider', but can attempt to understand the study group's worldview.

- To do this the researcher must contextualise in great detail the collective process and the specific case studies and then interpret them in relation to the group's worldview, and
- The researcher must not stand in judgement about the study group but only attempt to explain their behaviour and perceptions by understanding their logic.

A conceptual study design, which allows contextualising of findings on a specific subject is important here. For instance, studies showing greater recourse to the private sector and services for payment even by the poor could be interpreted to justify user fees and promotion of the private sector because the treatment seeking was not placed in the context of the condition of the public sector or the degree of indebtedness of these groups due to spending for



treatment. Similarly, analysing the sexual behaviour of those with multiple partners within the context of the norm of the whole group provides a very different perspective to the problem of AIDS from the high risk group approach espoused by the AIDS control programme. Analysing the factors leading to the norms can also provide directions for a more effective AIDS control strategy [Priya 1999].

However, this alone has not been found to be adequate in safeguarding the study group's interests. Given the ramifications (of conflicting social values and perspectives as well as conflicting material and power interests) related to the qualitative research in public health, three ethical issues arise:

- How does the research represent the needs and views of the marginalised within the study group as against the dominant groups?
- How does the research represent the needs and views of laypeople (which may include the community's dominant view but not the minority view within the community) as against the technocratic view?
- How does the researcher mediate between the possible positive and negative consequences of the liberal technocratic perspective and of the study groups' perspective?

The basic issue would be the right of the community - and within it of the marginalised - to decide if they want to participate in such research, to be given information up front, and to be fed back the findings. This also requires ensuring an environment in which the study group feels free to call upon and articulate its own value positions.

In addition to the methodological solutions provided by the anthropological debate above, some possible checks could be:

- A self-critical assessment to see if the researcher's agenda and reference point is the local context or the international dominant discourse.
- A mechanism for dialogue between the researchers and the community about objectives of the research, its findings and their interpretation of it.

This dialogue is the ingredient for finding the common ground of researcher perceptions and study group perceptions. It also allows the researcher and the study group to maintain their own value positions even while they examine them critically and may be even modify them. However, for this to occur there must be a respect for the others' value frame so that the exchange can occur on an equal footing. This may require a self-reflective exercise by the researcher.

The best way to really put all the above ethical requirements into practice may be by the researcher being in constant interaction with the study group over a long time in diverse situations. Acquire friends with whom to share laughter and tears, with whom to fight, and from whom to learn. Respect the collective wisdom of the community and yet debate with it. Such ethical research in public health would certainly be a demanding exercise but also a rewarding one.



V

# **Research on Mental Health**



# 9

## **Ethics and research on mental health**

**Soumitra Pathare  
Bhargavi Davar**

Mental disorders are caused by a complex interplay of biological, psychological and social factors. There is a justifiable research interest in unravelling the social origins of mental ill health. However, research, involving persons with mental disorder, pose unique ethical problems for social scientists. The case of the mentally ill is unique for two reasons. Firstly, due to the very nature of the disorders and their effects on those suffering from them. Secondly, due to the social stigmatisation of sufferers caused by the overall lack of support from the community, legal, service and policy frameworks in India. The purpose of this article is to highlight the dilemmas of making ethical decisions in this field and to encourage discussion and debate on some of the contentious ethical issues in the field of mental health research.<sup>1</sup> We focus specifically on the issue of informed consent in order to show that there are difficulties in simply treating ‘mental disorder’ as yet another type of health issue. We stress the need for a separate forum for discussion about social science research (and practice), and the role of ethics in mental health.

### **Social sciences, ethics and mental health**

Any discussion in the areas linking the social sciences, ethics and mental health will have to be done against the background of at least the following:

*Rationalism v/s post-modernism:* Following the copious work by the post-structuralists in the philosophy of the social sciences [eg O'Neill 1995] and the branching out of purist epistemologies into more fuzzy frameworks, there is an overall ‘post-modern’ suspicion about rule following of any type, and about any ethicism or humanism in social science (research and intervention).

Accepting any version of morality or ethics is being seen as dogmatic, authoritarian, fascist or androcentric. However, we agree with scholars who aim to invigorate the rationalist arguments in professional ethics, as Prilleltensky (1997) does, to claim that ‘the aspiration to be ethical’ and ‘the search for justifiable values’ are not just valid, but are definitively human endeavours.

*Ethics v/s Pragmatics:* To adopt a set of ethical principles means that, prima facie, they are accepted as axiomatic and valid unconditionally in any possible world. Arguments against a particular set of ethical principles could be on the basis of a conflicting, but equally objective, value system. However, the invalidity of any (or a set of) ethical principles cannot be because it cannot be actualised in this particular world or in any particular context. Accepting ethics is about accepting certain first principles as values. It is not about whether or not those values are ‘practical’. Making values work in research falls in the realm of the pragmatics of research, not ethics.

*Mental Health v/s Health:* The discourse of ethics in health care research and the role of the social sciences in this research cannot, without sifting and sieving for sameness and difference, be automatically transferred to the area of mental health. Unlike defining health or ill health even the definition of mental disorders are far more difficult to resolve (a fact acknowledged by the WHO in its International Statistical Classification of Diseases and Related Health Problems, 10th edition as well as the American Psychiatric Association in its Diagnostic and Statistical Manual of Mental Disorders IV edition).

The term ‘mental disorder’ harks back to an era of Cartesian mind-body dualism, while currently available evidence points towards a more holistic viewpoint. The term appears to survive due to absence of a more adequate terminology to describe a group of disorders that affect the human mind. In clubbing together issues in mental health with health, we run the risk of treating mental health in terms of the analogy to the body, brain, etc. and losing out on the holistic view. In the case of mental health, unlike health, there is a special case of both cognitive ability and personal autonomy being compromised via the medico-legal process of institutionalisation. This fact is recognised by many international

instruments, such as the National Commission for the Protection of Human Subjects, 1978 and special safeguards installed for doing research with the mentally ill.

*Ethics v/s Law:* Before an ethical framework can be proposed for social science research in mental health, the inter-phase between law, society, and ‘madness’ should be critically, logically and systematically examined and challenged. A code of ethics (for research or intervention) is effective in so far as the domestic law is supportive and empowering of those with a mental disorder. The very fact that for example, while a diagnosis of diabetes does not automatically invoke the legal order, while a diagnosis of ‘psychosis’ does, shows that at the fundamental level of citizenship, health and mental health are incomparable. In India, the law is invoked not because of user rights to treatment and care, but because of state rights to control deviance, enforce involuntary treatment, and prescribe loss of civil liberty to persons with a mental disorder. For a smooth and integrated alignment to be made between health and mental health, there has to be a comparable advocacy platform of discussion and strategies of structural change. However, the legal literacy and activism, user assertion and social science activism that has inspired the health movement is sadly lacking in the mental health scenario.

The points discussed above highlight the reasons why mental disorder cannot be considered as just another health issue. The unique nature of problems associated with mental disorder need to be addressed in a framework, which take these into account. The current paradigm for understanding social science issues in physical health matters does not adequately provide this framework. Merely replacing ‘physical’ with the word ‘mental’ in the prefix to ‘health’ pays little attention to some of the important issues in the field of mental health and the unique needs of those suffering from mental disorder.

### **Competency and informed consent**

From the practitioner's point of view, it is often assumed that in almost all conditions subsumed under the rubric of mental disorder, there is a propensity that affects the decision-making ability of the affected individuals. It thus follows that mentally ill



are incompetent in general and therefore incompetent to give consent in particular. This is a major assumption underlying the debate on informed consent in the case of the mentally ill, and the far-reaching legitimacy given to proxy consent in law and in practice.

'Giving consent' is a time specific and task specific action and there is no necessary, logical or essential connection, between doing this action competently and mental disorder. An individual may be judged incompetent for a particular task (such as doing a complicated math) but at the same time may be judged to be competent to make decisions about another different task (such as give consent to a research study). Whether someone can or cannot competently accomplish a task depends on background skills, education and training. For example, a bank clerk may be highly successful with a complicated mathematical problem, but not poetry, and a school teacher may be highly successful with memorising and reciting poetry, but not in mathematics. The cognitive impairments in mental disorder do not necessarily and automatically invalidate all decisions made by mentally ill individuals about research participation. At the experiential level, professionals and family members who have been fortunate enough to have close contact with individuals with mental disorder will be able to certify that this is manifestly false.

The issue of competence should be arguably de-linked from a diagnosis of mental disorder, and it must be established independently of whether a mental illness is there or not. Ruth Macklin [Macklin 1983] writes: "It might be thought that a diagnosis of mental disorder in a person implies that that individual is incompetent to grant or refuse consent, but that general supposition has been rejected both by many psychiatrists and in courts of law". As Macklin argues, the fact of delusion in a person, for example, does not automatically rule out his competency to give consent and the causal or etiological relationship between the delusion and the consent giving capacity is difficult to establish. She shows the questionable relevance of available mental status tests to settling the issue of competence to give consent. As she argues, a diagnosis of mental disorder is neither a necessary nor a

sufficient condition for a judgement that a patient is incompetent to consent to treatment.

Mental disorder does compromise cognitive ability. It cannot however, be equated with incompetence. The lack of competence to make decisions today does not necessarily rule out the possibility of the individual being adjudged to be competent in the future. Individuals with mental disorders may indeed have varying degrees of impairment in their capacity to understand the purpose, potential risks and benefits of the research and thus make an informed choice about research participation. Such impairments may also adversely affect the individuals' ability to give valid informed consent to participation in research, which is a basic requirement of ethically acceptable research. This is not to suggest that all persons with mental disorder at all times are incapable of giving informed consent.

Impairments in decision-making ability can be crudely categorised into four varieties - fluctuating, prospective, limited and complete [National Bioethics Advisory Commission 1998]. Some individuals with mental illness have fluctuating capacity to give informed consent. Their decision-making abilities are impaired during acute episodes of disorder but return to normal during periods of remission. This is the case with individuals with depression, manic-depressive illness, and schizophrenia. Prospective impairment is characteristic of disorders where future deficits can be predicted based on the known course of disorder. An example of prospective impairment is an individual in the early stages of Alzheimer's disease who may have no current decision making impairments but who is likely to have progressive impairment as the disease progresses. Limited capacity is characterised by the presence of definite impairments in individuals' decision-making ability, which may render them legally incompetent, but they still retain the ability to consent or refuse participation in research. Finally, some individuals may permanently and totally lose all reflective abilities required for making a rational choice, as happens in late stages of Alzheimer's dementia.

The threshold for impairment is a matter of debate, that is, at what level of impairment a potential subject is considered incapable

of giving informed consent. It has been suggested that this threshold is a social value judgement rather than strictly scientific. Societies are likely to set the threshold based on the degree of importance attached to personal autonomy, with liberal societies tending to set the threshold at the lower end [National Bioethics Advisory Commission 1998]. Equally contentious is the issue of who conducts the capacity assessment, whether the researcher him/herself or an independent professional specially trained in carrying out such assessments, or with involvement of subjects' trusted friends and relatives. The result of this assessment should inform the process of seeking informed consent. There is a whole context of protocols, logistics and structural, institutional arrangements needing to be framed in this area.

It is, therefore, essential that the researcher, recruiting individuals with mental disorder carry out a thorough assessment of potential subjects' ability to give informed consent prior to attempting obtaining individuals' consent. The American Psychiatric Association has published guidelines for assessing potential research subjects' decision-making abilities [APA 1998]. Potential subjects should be able to understand relevant information, have the ability to manipulate information rationally, the ability to express a choice and the ability to understand the consequences of their choice [Appelbaum and Grisso 1988].

The researcher has a duty to give as much information as possible in the most appropriate manner to enable those with impairments to be able to make an informed choice about participation or non-participation in the particular research project. When individuals are assessed as being incapable of making an informed decision at that particular point in time, the researcher needs to consider whether the subject is likely to recover the ability to make informed decisions in the near future and defer the task of obtaining their consent till that time. Conversely, the researcher also needs to remain aware of the possibility of the prospective participant losing the ability of decision making during the course of the research and taking appropriate steps to ascertain that the subject is potentially able and consenting to continued participation.

As a first principle, researchers in the area of mental disorder must accept as a value that patients are competent to give consent,

unless proven otherwise. 'Informed consent' is more about how people are to be treated as human beings by researchers and professionals, rather than being an objective evaluation or a judgement about inner capacities. In non-therapeutic contexts, a researcher is interested in the 'competence' of an individual only to the extent of ensuring that the autonomy of the individual is not violated in any way by the research.

### **Competency and law**

The question of 'informed consent' is a matter for the law because the question of individual 'autonomy' is an issue here and the law is supposed to protect individuals from violations. Is the Indian law supportive of informed consent? Incompetence is a legal concept and requires legal adjudication [Dhanda 2000]. The question of competence is often foregrounded when a patient refuses consent, seeks voluntary discharge and involuntary confinement is sought by interested parties, often a relative. As in laws elsewhere, under the Indian law, Mental Health Act (MHA) 1987 competence is a matter for court decision. However, the court does not recognise shades of individual capacity, but only absolute capacity or absolute incapacity. A notion of 'variable competency' [Macklin 1983], that a person may be competent for a specific task, but may be incompetent for others, is not recognised. This is because of the discrepancy in the law between medical diagnosis and 'insanity'. As the MHA is a custodial law and not a care and treatment law, it is concerned more with 'insanity' than with mental illness. In the extant law, the paradox is that a person may give consent to treatment and be institutionalised as a 'voluntary' boarder, but once institutionalised, 'voluntary discharge' is not easy. That requires a court mandate or professional arbitration. The law makes a mockery of the whole concept of patient consent.

The voluntary nature of the consent is a sine quo non for ethical research. This demands that the potential subject is neither offered undue inducements nor coerced into consenting to participate in research. Inducements can prove to be problem in India with a paucity of services for mentally ill and the financial costs of obtaining such services. It is especially relevant when service providers are also involved in research activity. They thus have

the option of offering services, either medications or other therapeutic services such as counselling, which potential subjects otherwise have no access to, or providing services to potential subjects free or at reduced cost contingent on participation in research.

Undue influence would also include "actions such as manipulating a person's choice through the controlling influence of a close relative and threatening to withdraw health services to which an individual would be otherwise entitled" [National Commission 1998]. Individuals with mental disorder are frequently dependent on professionals and also their family members and may perceive their participation in research as necessary for continued approval of their caregivers [National Bioethics Advisory Commission 1998]. Furthermore, individuals with mental disorders may have special difficulties in refusing requests for participation especially from persons perceived to be in a position of authority, persons who command respect within their community or in certain physical settings such as a community centre or a hospital.

When individuals are assessed as being permanently incapable of making decisions, the researcher is expected to desist from attempting to obtain their consent. In such situations, it would be valid to ask if the research cannot be carried out with subjects who can give informed consent. If this is not possible, there still remains the question of justifying the necessity of the particular research project with subjects who are incapable of making informed choices about research participation. 'In devising a procedure for psychiatric research, a balance has to be struck between the autonomy of the individual mentally ill person and the larger social interest in promoting the research' [Dhanda 2000]. The 'larger good' however is a communitarian value while 'autonomy' is an individualistic one, and the question of balancing arises because of the basic conflict between the two. Accepting the legitimacy of 'informed consent' for research means accepting the validity of a philosophy of individualism. The action of taking consent makes moral sense only when one accepts that 'autonomy' and 'privacy' are sought-after values. In India, this itself is an issue for the

professional milieu, where a communitarian outlook has justified all types of violations of individualistic ethics in clinical practice.

If the research is deemed crucial to furthering the society's understanding of the particular condition, there remains the possibility of obtaining informed consent from a proxy for enrolling these subjects into the study. Under the Indian law, proxy consent is permissible in research. In fact, the only ethical context that the MHA has attended to, regarding the rights of persons with mental disorder, is under Section 81(2). This section requires that research may be conducted only with the consent of the patient. What it however goes on to say is that, where the patient is not in a position to do so, proxy consent may be taken. Proxy consent is essentially obtaining the informed consent from a 'significant other' such as a relative or caretaker of the subject for the subject's participation in research. There are numerous problems with this particular stance of permitting proxy consent with respect to the mentally ill. It conceptualises the ability to give consent as an all-or-none phenomenon, which, as we have shown above, it is not. Secondly, it does not stress the need for an objective assessment about individuals' ability to give informed consent nor does it provide guidance about how such a judgement is to be made. There are also moral and legal dilemmas to the use of proxy consent.

Proxy consent for treatment is based on the utilitarian principle of a theoretical possible gain for the patient from the intended involuntary treatment. It is difficult to justify proxy consent for research participation on this utilitarian principle because in nearly all research there is little prospect of immediate gains for the particular subject. To quote the National Bioethics Advisory Commission, USA (1998) "anyone who serves as a subject in a research protocol therefore is engaged in a form of public service that may involve risk and for which there may be no direct or tangible personal reward." The consent level has to be pitched differently for research and treatment [Dworkin 1992]. The law also does not appreciate the difference between experimental research and therapeutic research [Dhanda 2000] but this difference would also be the basis for evaluating what 'benefit' means to the patient. The patients rarely give consent on the basis of the inductive or deductive logic alone. It is not true that, if all options

are laid out before the patient, and 'the final good' is pointed out to him, he will choose that option. The essences of 'consent' is that he chooses what he wants and for his own reasons, irrespective of the 'final good' and irrespective of the 'rational choice'. In India the situation is even more complex, where all the options are rarely laid out before the mentally ill patient in clear terms. So unless the sociological practices in mental health relating to consent are changed, permitting proxy consent is riddled with difficulties.

It may be possible to justify proxy consent where there is congruence of interests between the community and the individual. In an enormously stigmatising social context, the conflict of interest between the community and the highly marginalised mentally ill need not be spelt out. There may be a conflict between the personal interests of the proxy relative and the interests of the subject and it does not necessarily follow that the proxy relative will put the interests of the subject above his or her own personal interests. Lay notions of 'insanity' leading to treatment or incarceration may be guided by community intolerance for behavioural deviance than a concern for individual mental health. Legal case work has shown that a 'diagnosis' of mental disorder at the community level, leading to institutionalisation, may be made based on evaluations of 'problem' behaviour such as, 'not eating properly', 'not doing any work', 'remaining silent', 'speaking at random or incoherently', 'laughing without reason', 'roaming', etc. or specific actions such as 'wearing underpants over pajamas', 'going to mosque wearing bullock necks' beads', 'dancing with a dog on the head', etc. [Dhanda 2000]. In this case work, the lay understanding of 'madness' is shown to be broader and diffuse than the delimited, criteria - based clinical diagnosis of mental illness.

It is true that 'a total embargo on therapeutic research' could well be construed as 'discrimination of the mentally ill' and denial of useful knowledge to them [Dhanda 2000]. But these limitations of the proxy consent, also enshrined in our law, give very little protection to persons with impaired decision making capacity, thereby unwittingly running the risk of providing justification for unethical practices in obtaining consent of impaired individuals. Proxy consent is a concept that needs much debate and clarification, and the creation of ethical frameworks and structures, before it

can be used in the Indian context. Under the present circumstances, proxy consent can be justified neither on the basis of an individualistic philosophy (because of the absence of legal safeguards protecting individual autonomy) nor on the basis of a communitarian philosophy (because of the conflict of interest with the 'community' and the 'family').

### **Who can be the proxy?**

Who is designated as the relevant proxy to give consent on behalf of the intended subject and the relevant procedure for obtaining such proxy consent are also a matter of some debate and various countries have different institutional structures in place to protect the interests of the subject when decisions are made by proxy. Researchers such as Dworkin (1992) suggest that even for doing proxies, consent must be obtained from the subject. The United Kingdom Mental Health Act 1983, requires that proxy consent for involuntary treatment is obtained from two independent medical practitioners and a qualified psychiatric social worker [each of whom can veto the decision of the other two] all recognised and appointed by the state for this purpose. Once again, this procedure is only meant for consent to treatment and not for consent to participation in research. The system adopted by the UK Mental Health Act for obtaining proxy consent might appear tedious and cumbersome at first sight, but there are important reasons to justify proxy decisions being made by independent proxies bound by rules of confidentiality and professional ethics and these powers are not necessarily devolved to nearest relatives, as done by the Indian Mental Health Act, 1993.

Another problem with using proxy consent stems from the issue of information sharing and breach of confidentiality. For the proxy relative to make an informed choice, he or she needs to be provided with as much information about the subject, the illness of the subject and the planned treatment. The process of sharing this information will necessarily result in violation of the subject's right to confidentiality and personal autonomy; this is especially problematic when the subject is unable to consent or object to such information sharing with their nearest relatives. Relationships in families having a family member with mental illness are



invariably complex and there is no guarantee that such information obtained during the process of proxy consenting is later not used by the relatives against the subject. This is not to accuse all relatives, families and caretakers of individuals with mental disorder of malafide intentions. On the contrary, as mental health professionals we are only acutely aware that families form the backbone of long term caring for individuals suffering from mental disorder and they expend considerable time, energy and resources for obtaining the best possible outcomes for loved ones. The commitment of families and other informal caretakers to the best interests of their near and dear ones with mental disorder is unquestionable; however this does not detract from the fact that problems of conflict of interest and confidentiality are not just theoretical possibilities.

A final issue with respect to proxy consent is the principle forming the basis of the proxy's decision to consent or object on behalf of the subject. The proxy can use the principle of 'substituted judgement', i.e., the proxy attempts to make the decision based on the known choices, likes and dislikes and ethical, moral and religious beliefs of the subject. Using the principle of substituted judgement, a proxy would be appropriate in refusing consent for procedures or treatments, which in the proxy's knowledge, the subject would have objected to, irrespective of the possible benefits from the such treatment or the possible harm to the subject from refusing such treatment or procedures. An example of substituted judgement is the refusal of proxy relatives of Jehovah's Witnesses for blood transfusions even in life threatening situations [Jehovah's Witnesses' religious beliefs prohibit blood transfusions].

The other principle which can form the basis of proxy decision making is the principle of 'beneficence' - that is the proxy consents or objects to procedures on behalf of the subject taking into account the possible risks and benefits of assenting or refusing to assent to the proposed treatment, irrespective of the prior wishes and beliefs of the subject. In practice, most proxies use a combination of the two principles and it is not always that the two principles are in conflict with each other. These principles are relatively easier to apply to consent issues in treatment settings rather than research. It is difficult to use the principle of beneficence with respect to

participation in research when there is little immediate prospect of direct benefit for the participants.

Prospective consents are a mechanism by which individuals anticipate future loss of decision-making capacity and make adequate advance provision for such an eventuality. There are three types of advance planning mechanisms: projection of informed consent, projection of personal values and projection of personal relationships [National Bioethics Commission 1988]. Projection of informed consent is a device by which, a competent person makes a decision for accepting or declining some specific treatment in future, because the person anticipates being impaired in decision-making ability when the treatment is required in future. This can also be applied to research settings where a person who is competent currently, may leave instructions for enrolling or refusing to be enrolled in a particular research project in the future. Projection of personal values is broader than the prospective consent, where a person provides guidance for proxy decision-makers to make decisions based on personal beliefs and principles. Projection of personal relationships is a broadest of all, where a person appoints and entrusts a particular person to take decisions on their behalf in future when the person may be incapable of making such informed decisions.

These mechanisms are useful and in many western countries are routinely used in clinical care and for research purposes. In these countries there is a professional consensus on the use of prospective consent and in many cases, legal backing for the use of such instruments for obtaining valid informed consent from impaired the individuals. In India however, we do not have broad social or professional consensus and the law appears totally silent on this particular issue.

### **Confidentiality, privacy and anonymity**

Confidentiality, privacy and anonymity require particular attention in research involving persons with mental disorders. There is significant stigmatisation of individuals with mental disorders as well as institutional and non-institutional discrimination against such individuals in our society. Under these circumstances, it is crucial that there are adequate safeguards against breaches of

confidentiality of material obtained as part of subjects' participation in research. Privacy, anonymity and confidentiality issues are especially problematic when conducting community-based research in the Indian context, where even the provision of secluded, private and confidential space for interviewing research subjects is usually difficult.

Persons with mental disorders are also more vulnerable to exploitation for research purposes due to a combination of factors such as their impaired abilities to refuse participation, easy availability and a subtle social perception of 'undesirability' of such persons. There have been instances where persons with mental disorders, especially institutionalised mentally ill, are used as control subjects in research about medical disorders, primarily due to their easy availability as a captive population. There is a real danger that mentally ill persons are used as research participants when the benefits of such research will accrue to a different segment of the population. This is equally applicable to mentally ill in institutions as well as those living in the community. In USA, the National Bio-ethics Advisory Commission specifically directs Institutional Review Boards to 'not approve research protocols targeting persons with mental disorders as subjects when such research can be done with other subjects'. This prohibition is also in line with the principles of individual and distributive justice in research. The Ethical Guidelines for Social Science Research in Health [NCESSRH 2000] also says that the "easy accessibility of the participants alone does not constitute a fair criterion for their inclusion in research".

### **Ethics: Impractical?**

A frequent complaint from the research community has been to point out the impracticability of strictly adhering to all the ethical principles and yet managing to do meaningful research. It has been suggested in the past that some of these contentious issues are best left to the conscience of the individual researcher [Beecher 1966]. As others have done before us, we would beg to differ for many reasons. First, ethical principles are too important to be sacrificed on the altar of practicality. This is not to deny the importance of necessity for research, however, adequate protection

of participants is equally, if not more, important. Through the ages, especially in the latter half of the last century, significant violations of personal rights and exploitation of subjects for research have been justified on grounds of practicality. Second, there is no inherent contradiction between the ethical conduct of research and researchers and conducting high quality research. We would argue that the satisfying high ethical standard is the defining criterion of quality research work. Third, as with war, research is too important to be left to researchers alone! As *The Ethical Guidelines for Social Science Research in Health* (2000) clearly states, “research is a social activity, carried out for the benefit of society”. To this we would add “and on society's terms for the proper conduct of this important social activity”. The challenge for the research community and society at large is to find a way of simultaneously satisfying these twin needs of ethical behaviour and practicality. It is important to build a consensus by involving all the stakeholders in this debate. We hope this article will encourage a debate on the ethical issues in research involving persons with mental disorder in India.

**Notes :**

By ‘research’, we mean not only ‘mainstream’ medical and clinical research, but also the entire range of ‘alternative’ knowledge building practices, such as ‘action research’, ‘documentation’, ‘participatory research’, ‘qualitative research’, etc.



**VI**

**Research on Sexuality**



# 10

## Sexuality research and intervention

### Some ethical issues

**Radhika Chandiramani**  
**Lesley Jane Berry**

This paper addresses some of the ethical issues encountered while working in the field of sexuality. It illustrates ethical challenges that arise in research and intervention in a country where the socio-cultural context is often inimical to the sexual and reproductive rights of individuals, especially of women. The paper is presented in five sections. Since this paper has been written as a background paper to the *Ethical Guidelines for Social Science Research in Health* prepared by the National Committee for Ethics in Social Science Research in Health (NCESSRH 2000) and coordinated by the Centre for Enquiry into Health and Allied Themes, it refers to the NCESSRH Guidelines where appropriate.

We have begun by outlining the meaning, scope, and need for ethics in the field of sexuality, followed by an analysis of specific ethical issues relevant to sexuality and sexual behaviour research conducted in India in the last decade. Issues of need for services versus competence of providers, and the concepts of confidentiality, privacy, and anonymity are discussed in the context of intervention, in the subsequent section. This is followed by illustrations on ethics in practice on a telephone help-line. Finally there is a review of the NCESSRH Guidelines and adds to it points from other codes of ethics to enhance its usefulness in the field of sexuality.

### **Ethics of relevance**

Ethics refers to codes of moral conduct that guide behaviour. Personal codes of conduct might be ill defined and unarticulated, but they still serve the purpose of guiding behaviour and influencing actions. However, many professional bodies have articulated and codified their guiding principles into codes of ethics that serve to guide and monitor their work. All codes of ethics are based on



ethical principles that may or may not be clearly stated but are implicit in each of the guidelines.

Codes of ethics are dynamic, i.e., they are responsive to change. Therefore, they require periodic re-evaluation to ensure that they are in keeping with the challenges associated with changing times. For example, with the advances in electronic data communication and storage and the parallel advances in 'hacking', it is important that ethical statements pertaining to storage of data include suggestions on the safe electronic storage of sensitive information.

Historically, ethical principles that guide professional activities have been present long before any formal declaration of human rights. The Hippocratic oath that enjoins physicians to 'above all else, do no harm', pre-dates the Universal Declaration of Human Rights (UDHR 1948) by many centuries. Ethics as a branch of philosophy has a long and rich history. However, it has been the horrors of the second world war and the excesses of the Nazi regime that finally pushed the world community to formulate statements to protect the human rights of all peoples. In turn, the concept of individual human rights has fed into the articulation that no research, whether physiological or psychological in nature, should violate the human rights of its subjects [Ringheim 1995].

Human behaviour has always been an issue of great interest for social science researchers. How human beings spend their money, how they bring up their children, what they eat, what motivates violence, all this and more, has been studied using different approaches. The fields of anthropology, psychology and sociology have distinct ways of looking at and interpreting human behaviour and life. These different fields have studied the sexual customs, behaviour, and relationships of people all over the world.

Sexuality has also been studied using medical and public health models. Though sexual behaviour has been a subject of study since the early 19<sup>th</sup> century, never before has it been studied with a sense approaching desperation as it has been since the AIDS pandemic hit the world. Perhaps few other subjects of social science research and intervention are as complex and challenging as is the study of sexuality, because of its enmeshment with individual and group identity, social customs and norms, religious beliefs, gender roles and expectations, amongst other factors. Sexuality is linked with

notions of purity and chastity, shame, possession, cultural pride, and even national identity and statehood. All this necessitates the exercise of utmost sensitivity and social responsibility while engaging in intervention and research in sexuality.

With the increasing understanding that sexuality is multi-layered, it currently lies at the intersection of many fields including those of psychology, medicine, public health, sociology, anthropology, queer studies, gender studies and other emergent, and as yet unnamed, fields. As a field of study and action, it is inhabited by professionals from different disciplines, as well as by non-professional volunteers. Therefore, it is not yet governed by a particular and articulated set of ethical guidelines but borrows from guidelines developed in established fields. For example, an anthropological study of sexuality would primarily use the code of ethics followed by anthropologists in designing and implementing a research project.

While conducting research or engaging in an intervention in the field of sexuality, it is also important to look at underlying theoretical issues and assumptions. An excellent resource on this is the work of Carole Vance (1999) and Gayle Rubin (1999). Unexamined assumptions may serve to perpetuate particular constructs and in the long run be harmful to the well-being of certain groups of people. For example, Ericksen and Steffen (1996) found that the surveys of sexual behaviour they reviewed reflected dominant constructs of gender differences in male and female sex drive and behaviour.

In India, as in other parts of the world, most efforts to study sexuality (whether from an applied research or an intervention angle) are motivated either by a public health or family planning goal. Whatever be the underlying reason for undertaking research on sexuality, there must always be a valid, justifiable and clearly stated reason for doing so, or else researchers might exploit and damage other human beings and be accused of having political, voyeuristic or other pernicious motives.

Often one of the implicit goals of conducting research on sexuality is that of research findings and insights leading to the development of strategies that facilitate behaviour change, especially with regard to safer sex practices vis-à-vis HIV and other

infections, and, unwanted pregnancy. In this context, there is a need for in-depth research that yields accurate information concerning sexual attitudes, negotiations and practices in order to build a holistic strategy for prevention. Vance (1999) emphasizes this with regard to the fact that at present the majority of HIV research occurs within the biomedical sphere. This perspective not only fails to adequately address complex issues of sexuality, but also serves to obscure them due to its underlying assumptions concerning the nature of sexuality. Therefore, getting back to ethics, it is important to consider the ethical soundness of conducting research that explores issues of sexuality, both in terms of the 'depth' of data obtained, and the research experience of the participants (e.g. extent of rapport, safety and ease experienced).

Issues linking the goal of research to the methodology used are also significant. As Renu Khanna (1996) points out, "where empowerment of women and helping them gain control over their bodies is an aim, the research model itself needs to be a focus of attention. Participatory and action research models are better suited to facilitate empowerment as well as yield the good quality data we need. Research methodologies which draw on feminist principles of 'personal is political' and woman-centredness are also to be preferred while doing research with women on sexuality, gender and health". In line with this view, Holland et al (1999) provide an interesting discussion of a feminist investigation of young people's sexuality and illustrate how the researcher's feminist assumptions informed the process of research right from its conceptualisation to its interpretation.

Ethical principles are concepts that underlie the specific guidelines that are spelt out in codes of ethics. Codes of ethics attempt to, but realistically cannot address all possible ethical dilemmas that may arise in the course of work. Ethical principles contain the essential values or core concepts that can guide the resolution of ethical dilemmas.

Ringheim (1995) makes a strong case for using the principles laid down by the Council for International Organisations of Medical Sciences (CIOMS) that apply to bio-medical as well as to social science research, to also guide research on sexual behaviour. The ethical principles are:

- *Respect for persons*, which includes autonomy and the protection of persons with impaired or diminished autonomy
- *Beneficence*, which means maximising benefits and minimizing harms or wrongs
- *Non-maleficence*, which means ‘do no harm’, and,
- *Justice*, which prescribes equal treatment for all.

After reflecting on the meaning and significance of ethics for the field of sexuality in the previous section, the focus is now on some specific issues that arise in the course of conducting research on sexuality. These issues have been chosen because of their relevance to the current social and temporal context and are by no means the only issues that arise. The studies cited in this section are being used as examples to illustrate specific issues. All examples used in this section, are sourced from an annotated bibliography of research studies on sexuality and sexual behaviour conducted in the last ten years in the Indian context [Gurbaxani and Khanna 2000].

Sexuality is a multi-disciplinary field of study and can be approached in diverse ways. Training in sexuality research as in training on research in any field requires training in how to conduct good research. This necessitates training on all aspects of research including research design, methodology, data collection and analysis skills, and ethical conduct. Additionally, it requires researchers to be sensitive to the issues that they study. Clearly, interviewing participants about their sexual practices is different from interviewing them about eating habits.

Researchers involved with a project that explored rural women’s perceptions and experiences of marital sexual relationships, participated in a month-long training programme in order to instruct them on the in-depth interview method and to “desensitise them on topics pertaining to sexual behaviours and practices” [Joshi et al 1997]. This was followed by a preparatory series of trial interviews in a different village. This is an important ethical consideration: researchers should be adequately trained for the specific nature of the research that they are conducting, as poor interviewing techniques regarding intimate subjects could

potentially cause distress to participants. The training of researchers must include provisions that explicitly address these issues.

This study demonstrates methodological awareness of the need for sensitive, competent researchers to work with people participating in sexuality-related studies. Clearly, this is a major ethical consideration when designing projects, especially within local communities.

### **Participant Recruitment and Informed Consent**

An ethical consideration concerning methodological techniques is the methods that researchers use to select participants. In a study conducted in a community, George (1997) states that local non-governmental organisations (NGOs) were requested to identify and mediate with community members suitable for the study. One NGO that facilitated this process was a marriage-counselling centre with clients in the area, which gave George “a list of people, former clients and other contacts whom we could meet and request them to participate in the study” .

Although the disclosure of clients/contacts of local NGOs is a matter for their discretion, it is important to consider the confidentiality rights of individuals who are approached. As there is an inherent imbalance of power between the researcher and participant which may inhibit a potential participant’s ability to refuse participation it must be considered by whether this factor is enhanced if the researcher states that a specific individual or organisation known to the person recommended them for recruitment in the study. This initial request alone, or if a participant has a negative experience of any form during a study, may affect individual or community relations with the NGO associated with the study.

Therefore, in the event that an NGO wishes to assist a researcher in contacting potential participants, it might be useful for the NGO to first reflect on issues of contracts or assumptions of confidentiality that they might be operative in the minds of the people they work with. Maybe the NGO can itself initially contact potential participants to check whether they consent to having their identity revealed to the researcher and to being approached by the researcher. In the case of George’s research, this appears to have

not mattered too much as participants felt free to either drop out or continue with the study 'and some later confided in the researchers that they were 'not in agreement with the NGO person who was the via media'.

Associated with the issue of participant recruitment are issues of how consent is obtained. Is it free and informed? Quite obviously if participants are recruited through other agencies that offer them services, it has to be made clear that their participation or non-participation in research will not affect service provision. In some cases, where individuals may not be regarded as autonomous beings, the issue of consent becomes murky. For instance, if the village leader gives consent does it automatically mean that all the inhabitants of the village are agreeable to being research participants? Do they really have the choice to refuse? In this context, Gostin (1991) makes distinctions between individual consent, permission and community consensus in the context of culturally appropriate agreements to participate.

In a study conducted by George (1997), at times female respondents seemed uncomfortable during interviews held within their homes (because sexual matters were discussed) due to their mothers-in-law's presence in the house or the chance of their husbands returning home. This is a common illustration of the issue of privacy and confidentiality that must be considered when researching sexuality and sexual practices. Basu (1994) states that an ideal scenario would be to ensure that knowledge of an individual's participation in a study be kept from family members, both to avoid the "fear of disclosure syndrome", and to minimise spousal/family interference. Given the structure and functioning of Indian families and the life circumstances of people, this may not always be a viable option. Therefore, researchers need to consider the location of prospective interviews in order to minimise the discomfort experienced by participants, and also to anticipate and guard against any negative consequences for participants arising in the family.

Having said this, it is important to also point out that concepts of privacy are variable. This calls for researchers to be aware of privacy needs of people within local communities and be able to adapt to local requirements. Participants may sometimes surprise

researchers by requesting that others be present during an interview. Flexibility of methodology and consideration for the ease of participants is evident in a study on rural women's experiences and perceptions about marital sexual relationships, conducted by Joshi et al (1997), in the fact that when respondents (17 out of 69) requested it, they were interviewed in the company of their husbands or friends. This was accommodated within the methodology by adopting a 'paired interview' technique and was not automatically dealt with as restricting research outcomes. Furthermore, personal interviews were also not tape recorded as some participants raised objections to this.

Closely related to the aforementioned issue is the consideration of confidentiality of information when crosschecking responses of research participants. This is especially important with regard to those studies that address sexual attitudes or practices of married couples.

In such studies, researchers consider it necessary that the statements of married men be corroborated with those of their wives, in order to gain a higher level of accuracy and sophistication of data. This means that women are often interviewed after their husbands have become fully aware of the nature of the study. Can any specific methodology be employed to ensure that women do not become open to suspicion from their families with regard to the sensitive information that they are disclosing about their husbands? Several studies cite statements from male respondents indicating that they consider it inappropriate for women to initiate discussion regarding sexual matters. This suggests that caution should be exercised when approaching women to discuss these issues, and in disclosing to men that their wives have or will be interviewed on these matters.

### **Corrective Information for Participants**

Ingham (1990] notes that when investigating sexual and HIV-related knowledge, attitudes, and practices, it is important to ensure that research methodologies that test empirical knowledge, e.g. in 'true/false' questionnaires, provide adequate opportunity for respondents to have access to corrective information on completion of the study. This issue is relevant with regard to both mailed and

reader-response questionnaires, and with a range of interviewing techniques. In addition, Holland et al (1999) state “There were occasions when we were unwittingly doing sex education simply by asking questions”.

This issue applies to several studies. For example, a study conducted by Savara and Sridhar (1994) which seeks to establish respondents’ perceptions of the links between sex and sickness incorporates a Yes/No response to the questions ‘Do you think you can get sick because of sexual intercourse?’, and, ‘What type of sickness can you get: weakness/fever/STD’s?’. The study does not mention whether participants had access to corrective information although it stated that, “few respondents felt that sex leads to sickness”[Savara and Sridhar 1994].

Similar concerns arise with studies that investigate sexual behaviour/activity through questionnaires published in national magazines. Should it be considered necessary that a follow-up article be published in the magazine giving results of the survey? This could serve the function of exploring the topic in further detail, therefore addressing particular themes or common misconceptions that respondents may have raised, or that may be apparent from data analysis. Details of organisations that readers may contact for further information or help could also be included. Have the researchers made any provisions for readers to contact them with queries? After interviews are over, the interviewer can leave with the interviewee contact details or some written material on the topic, if appropriate, for further information, and can clarify obvious misconceptions.

Ingham (1990) also raises the issue of ‘ownership’ of data in the context of researchers working on a temporary basis in different localities and countries. This addresses the ethical connotations of taking knowledge ‘out’ of a specific locality or country with minimal regard for reciprocity issues, particularly if the information generated has practical value for the population involved.

An example of considering reciprocity is a study conducted by George (1997). After the study, she used findings generated from a community-level study of AIDS and risk perception to conduct AIDS awareness programmes with two local NGOs in the area where the study was conducted. She noted that in asking community



members to participate in the study their most common question was ‘what will I gain from this?’. The formulation of the awareness programmes was one way that George used to actively address this issue.

### **Scope for review panels**

The issues of ethical accountability with regard to non-locals or non-nationals conducting and using research, where relevant, could perhaps be raised with review panels or boards. The NCESSRH Guidelines state that peer review should be sought at “various stages of research” (III.2.9), and that peer review and refereeing “improve and advance of research” (V.1). It also recommends that there be appropriate organisational mechanisms (VIII) to ensure that research is conducted ethically. Review groups or panels could be set up for this purpose. These would be particularly useful in situations where researchers are exploring uncharted waters, for example in working on issues that are likely to affect local sentiments (incest, adolescent sexuality, etc).

Therefore the role of review panels could be specifically formulated to monitor the ethical content of studies in their preliminary stages, to some extent during the study, and especially during the publication and dissemination stages. While working with local communities, it would be wise to have a member of the community on the review board. This would not only ensure that researchers respect community sentiments at all stages of their work, but would also make the community more receptive to surprising findings, if any. The matter of presenting research findings back to the community from which data is collected is a serious issue that can result in unanticipated consequences. The manner in which findings are presented to communities must be sensitive to public sentiment and community needs. The review board would also have some influence in ensuring that findings from completed studies are used to the maximum benefit of any groups or organisations to which they are considered applicable.

### **Intervention and ethics**

Interventions that seek to directly or indirectly affect people’s sexual and reproductive health also touch many other parts of their

lives. Conversely, people engaged in interventions that initially had apparently nothing to do with sexuality find themselves having to grapple with the issues. For example, a programme addressing Panchayati Raj issues with rural women may need to address issues of sexual and domestic violence or be privy to information illustrating the links between sexuality and politics. Clearly, it is not possible to anticipate all the places where sexuality might rear its head, but certainly those working in areas that have a high likelihood of this occurring must equip themselves for this eventuality. And those whose work necessitates their dealing with issues of sexuality, for example those who work on issues of HIV/AIDS, reproductive health, and domestic violence, must be familiar with the ethical principles as well as with other issues that derive from those principles.

There are no clear-cut boundaries to demarcate ethical practice while working on sexuality issues with communities. There might also be competing forces at work that serve to further confuse issues for service providers. Cultural and social sensibilities are easily offended and any links with women and sexuality all too often exploited by political and fundamentalist forces to meet their own nefarious ends.

The culture argument is often used in opposition to the assertion of individual rights that include sexual and reproductive rights. The legal machinery does not always keep pace with the rights discourse. For instance, marital rape is not yet recognised in the Indian legal system. Dominant social norms and values may be inimical to well being and they pose a tremendous challenge to NGOs and others seeking to address vulnerability and oppression [Chandiramani 1996].

Given the complexity of working on this issue, it is crucial that work in the area of sexuality be above reproach or allegations of ethical violations. Because the field of intervention is wide-ranging in terms of the kinds of intervention that are made, and has fuzzy boundaries, it is perhaps not possible to delineate statements of ethics that can apply to all the work that is done. Nevertheless, it is important to be aware of over-arching principles that apply to all types of intervention.

The NCESSRH Guidelines focuses on research, not intervention. Some of the ethical guidelines for research apply equally well in the field of intervention, e.g. informed consent. Interventions in the area of sexuality take many forms, including support groups, help-lines, policy advocacy, public information dissemination, consciousness-raising, counselling, peer education, provision of clinical services, and so on. In this section we take a conceptual look at some of the core ethical issues pertinent to intervention that uses a counselling or allied approach.

### **Autonomy, Confidentiality and Competence**

*Autonomy* : All individuals are capable as moral agents of making decisions about their own lives. This principle is a corollary to the principle of respect for all persons and is what lies behind guidelines on informed consent. That all individuals are autonomous agents means that they have the ability and the right to decide for themselves what they wish to do, including the right to refuse to take a particular course of action. Autonomy also implies that NGOs and others cannot barge into people's lives with a 'we know best' attitude. Intervention in people's lives carries with it implications of unequal power - whether it is the power of expertise, medical authority or social power – and its potential of causing harm. In cases where the competence of people to make their own choices is questionable, as in the case with people who are mentally challenged for example, careful consideration has to be given to the question of whose interests are being served by a proposed course of action.

Respect for persons also demands the exercise of being non-judgmental. It means not judging people according to one's own value system. Being non-judgmental does *not* imply being value-free. There may be instances in the course of one's work where one's values must be clearly voiced. While dealing with a perpetrator of sexual abuse, for example, if the values of choice and consent are not stated, the perpetrator might perceive silence as sanctioning abusive behaviour.

*Confidentiality, Privacy, Anonymity*: Confidentiality refers to the communication of private information from one person to another in a setting where it is expected that the recipient of the

information will not ordinarily, disclose the information to anyone else.

Confidentiality refers to not divulging information shared by an individual. Anonymity refers to the identity of a person not being known. The difference between the two concepts lies in the fact that in the case of the former, the person's identity is known whereas in the latter the person's identity is not known. These concepts derive from the principle of beneficence. In the interests of serving clients better, confidential information might be shared with team members or with other professional colleagues with the understanding that it is confidential and is being shared for a specific purpose – e.g. making a referral, seeking supervision or peer support.

Confidentiality, especially in the context of material with a direct or assumed sexual content, cannot be emphasised too much. Because sexuality so easily evokes shame and guilt, and is tied in with social and cultural proprieties, it is essential that community workers, peer educators, counsellors, and others take all precautions to ensure that confidentiality is maintained. Breaking confidentiality can result in the client or participant experiencing discrimination and stigma. This is especially crucial in the context of HIV/AIDS related issues. The possible consequences of breaking confidentiality may include social ostracism. Social ostracism in turn, can lead to a lack of financial, emotional and medical support and consequently even death caused by the hastened progression of the illness and lack of adequate medical care.

Careless storage of documentation, other people overhearing conversations, inadequate privacy during a counselling session, naming clients, etc are some ways in which confidentiality may be jeopardised unwittingly.

Privacy and confidentiality are related but different from each other. Privacy means having conditions conducive to engaging in a private act or conversation, something one does not want to do in the presence of others. Confidentiality requires that the contents of the interaction not be divulged. Adequate privacy does not automatically translate into confidentiality. Also, most often people need to be reassured about confidentiality and if there are limits to confidentiality, this must be made clear to them. Issues of privacy

often take a backseat while working in community setting and even in public hospitals where space and time are at a premium. For example, people are usually not comfortable talking about their sexual lives in situations where others can happen along, as in interviews held in corridors or in a crowded room. Privacy does not require large rooms it requires the exercise of common sense and sensitivity. The precautions of taking the person to a quieter and less crowded place serve to enhance feelings of safety and comfort.

*Competence* : Ethical practice demands that individuals receive the best quality of care possible in a given situation. This implies that services must be provided by those who are competent; and who work within the limits of their competence. Competence demands skills and training. However, in the resource-poor settings of developing countries, the immediate demands of communities have to be met by using whatever resources are available. Consequently, interventions are often made by NGOs that do not have the resources to secure the services of trained professionals and/or do not, for various reasons, engage in undergoing professional training. Ideological differences also contribute to NGOs not undergoing professional training in certain areas like counselling. Some people believe that professional training serves to perpetuate empires of expertise and increases the power imbalance between the 'expert' and the others.

That the issue of competence can be a major problem is clearly seen in the area of counselling. Counselling is a word used loosely in the NGO as well as the government sector. It is often misused as a synonym for giving information to, advising, guiding and motivating people. Counselling, in a mental health context, has a specific meaning and is a skill. In simple terms, it is the process of facilitating people to find what it is that they want to do, the process of enhancing the autonomy of the client. Activism and counselling are different processes, informed by different but sometimes overlapping perspectives and require different sets of skills [Vohra 1998].

One of the main areas of disagreement between professional and lay counsellors is the topic of boundaries between client and counsellor. Lay counsellors feel that boundaries are artificial and

serve to increase the distance between counsellor and client, and they perceive this as being a bad thing in itself. Professional counsellors, on the other hand, view boundaries as an inherent part of the counselling process that enables the enhancement of self-hood or autonomy of the client. Whatever the ideological merits and demerits of the two, often conflicting, positions, the practical implications of an absence of clear boundaries have ethical ramifications for work on sexuality. Without clearly drawn boundaries, the counselling process might engender dependency and unrealistic expectations in the client, leading to resentment and a sense that counselling has not 'solved' the problem. Worse it can also lead to emotional and sexual exploitation of the client.

Counsellors and caseworkers may not be immune to obtaining vicarious gratification from their clients' accounts. A lack of clarity and discipline about boundary issues can result in psychological damage and/or sexual exploitation of clients. It can also result in a confusion between the counsellor's own needs and those of the client. End result: the client's issues are no longer of paramount importance because neither counsellor nor client knows where one begins and the other ends. This is a simplistic but accurate portrayal of what can and often does happen when well-meaning but inadequately prepared individuals engage in 'counselling'.

*Ethics in practice* : Familiarity with ethical principles and guidelines is no guarantee against ethical dilemmas. In fact, along with a deeper understanding of the subject matter there is a greater appreciation of situations that present themselves as challenging notions of what is the most appropriate and ethically sound response. In this section we share some insights that we have developed from practice.

In sharing some of our ethical dilemmas and insights we hope to illustrate the tension between various competing forces that affect intervention in the area of sexuality. TARSHI (Talking About Reproductive and Sexual Health Issues) is an NGO that believes that all people, whoever they are, have the right to a life of dignity encompassing their right to sexual well being, to a healthy, enjoyable and self-affirming sexuality. As part of working towards making this vision a reality, TARSHI runs a telephone help-line that provides women and men information, counselling, and referrals on sexual

and reproductive health concerns. Since 1996 TARSHI has received calls from thousands of women and men between the ages of 10 and 70 years. Trained phone counsellors handle calls on the help-line. All calls are documented for analysis so that findings can be used to ensure quality services and inform others working in the field. (For a fuller description of the functioning of the help-line and kind of calls received please see Chandiramani 1998). Services are in Hindi and English, free, confidential, and callers are guaranteed anonymity.

In the section below we share with you some of the ethical challenges faced at TARSHI. In the interests of brevity we are sharing only those issues that have not been dealt with in earlier sections and those that provide a special illustration of an ethical guideline.

*Research v/s services* : Given that there is a dearth of information on the sexual practices of individuals and that the help-line methodology offers a window into intimate areas of people's lives, there is a pressure to find out more about what people do sexually, with whom, in what circumstances, influenced by what factors, and how. There is a seduction in being in a position of being able to probe into people's lives, where both they and the counsellors are unknown to each other and yet are in a relationship of intimacy where callers can say things that they probably cannot say to anyone else. This calls for great discipline on the part of counsellors to stay tuned to callers' needs and only ask questions that are relevant to callers' concerns, and not to counsellors' research interests or voyeuristic impulses.

TARSHI has had to reflect on its priorities, and we have asked ourselves whether better methodologies of research would interfere with the nature of help-line work. In very simple research terms, if we had data about the marital status of all callers for example, we could perhaps use this consistently as a variable in our analysis of data. Yet as matters stand, as a policy we do not ask about or assume marital status (unless it is directly relevant to the caller's stated concern), because of the moralistic and heterosexist connotations attached to linking sexuality with marital status that would jeopardise callers' sense of safety and ability to freely share their experiences and concerns.

*Anonymity* : The TARSHI help-line ensures anonymity to callers, i.e. it does not require callers to provide any personal identifying details about themselves. However, in order to make appropriate referrals to health care services, callers may be asked which part of the city they live in so that they may be referred to a facility close to their homes. Callers likely to call again are given code numbers for identification on subsequent calls. The principle of anonymity precludes us from receiving messages on an answer-phone that might require us to call people back. This means that we 'lose' many calls from those who might have tried after our office hours or when the lines have been busy. However the reason we do this is that in addition to shifting the responsibility for the call to the help-line and not the person in need, it would also jeopardise the anonymity of the caller. Calling people back has the potential of arousing the suspicions of family members as to why the person is receiving a call from an organisation that works on sexuality issues.

In a lighter vein, the principle of anonymity also means that no caller identification technology is used despite the temptation to do so especially with obscene and abusive callers!

*Responding to media requests* : As a help-line that responds to people's concerns it is important that people know about TARSHI so that they can use the services offered. Media coverage is a good way of increasing visibility and credibility. However, we have had to exercise great discipline in our dealings with the media and anticipate the possible consequences for callers and the helpline that might result from careless media coverage.

Media requests for 'case studies' that illustrate a particular trend or phenomenon are always treated with caution at TARSHI. Information about calls that is given to the media is always about generic data, never about specific calls that callers might recognise as being their own. Media representatives sometimes want 'real examples' that would make their media reports stronger, and dangle the carrot of increased and free publicity of our efforts; we respond by explaining that our giving in to their requests would damage callers' trust in the service. Sexuality also being a subject that easily lends itself to sensationalism, we have to be very careful in making sure that journalists understand what we do and why we do it.



*Counsellor identity and protection:* Just as callers are anonymous, so is the identity of the TARSHI counsellors protected. This is to ensure that boundaries are in place and that the possible abuse of counsellors by crank and obscene callers is kept to a minimum. Code numbers given to callers for identification also serve to identify which counsellor they usually speak to. Counsellors give no personal information about themselves on the help-line. Counsellors are trained to deal firmly but politely with abusive callers. Abusive callers are people who have problems and need help, but this does not merit counsellors having to suffer verbal and emotional abuse.

Preventing counsellor burnout is another issue that is part of nurturing well-being of the staff and ensuring that no damage is done to those who provide services.

### **NCESSRH guidelines and other codes**

The NCESSRH Ethical Guidelines offer broad and general guidelines to those undertaking research or intervention in the field of sexuality. It is a commendable first step in the multi-disciplinary field of sexuality where the intermingling of various disciplines and approaches can often result in confusion for many.

Because the Guidelines have been formulated to address ethical issues that fall within the purview of social science and health research it is comprehensive in its coverage of a range of issues. This necessitates a deeper examination of certain issues of particular relevance to the field of sexuality. As work in this field grows, hopefully there will be greater discussion of ethical dilemmas and their resolution.

Those who work on issues of sexuality might wish to examine Codes of Ethics from other fields and borrow from them to add to what is in the NCESSRH Guidelines. Summarised below, with reference to specific NCESSRH guidelines, are guidelines from other Codes of Ethics that add to or clarify special points.

*Respect and protection of autonomy, rights and dignity of participants (NCESSRH Guideline: II.4):* The American Sociological Association's (ASA) Code of Ethics states in its General Principle on Respect for People's Rights, Dignity and Diversity, that sociologists strive to "eliminate bias in their

professional activities, and they do not tolerate any forms of discrimination based on age; gender; race; ethnicity; national origin; religion; sexual orientation; disability; health conditions; or marital, domestic, or parental status. In all of their work-related activities, sociologists acknowledge the rights of others to hold values, attitudes, and opinions that differ from their own” (Principle D).

This sentiment suits the range of research, counselling and applied activities within the field of sexuality that the NCESSRH Guidelines aim to encompass. The current statement under II.4 is directed specifically at researchers with regard to participants, and includes no specific reference to individual or group values or attitudes that may be particularly relevant within a counselling/ NGO context. The ASA principle is of particular relevance while conducting research with marginalised and disadvantaged groups.

*Accountability and Transparency (NCESSRH Guideline II.9 & III.7.2):* The American Political Science Association (APSA) states in its ethical guide aimed at scholars and professors (it is not research-participant centric) that, “With regard to any public scholarly activity including publication of research the individual researcher: Should disclose all relevant sources of financial support; (5.2) Should indicate any condition imposed by financial sponsors or others on research publication, or other scholarly activities. (5.3) Scholars have an ethical obligation to make full and complete disclosure of all non-confidential sources involved in their research so that their work can be replicated or tested (6)”.

Section II.9 of the NCESSRH Guidelines (Accountability and Transparency) refers to researchers being amenable to a financial review of their research. While the guidelines do not refer to aspects of sponsor conditionality, that might be important keeping in mind that sponsoring agencies might seek to push dubious agendas, the whole of Section VII is devoted to the rights and responsibilities of funders and sponsors.

*Anonymity (NCESSRH Guideline: IV.3):* The American Anthropological Association (AAA) Statement on Ethics specifies that with regard to anonymity within research, “It should be made clear to informants that anonymity may be compromised unintentionally (1d)”. Section IV.3.2 of the NCESSRH Guidelines explicitly states this possibility which is very real especially while

working in community settings where despite the best intentions, there may be no guarantee of protecting anonymity.

*Consent (NCESSRH Guideline: IV.2.3 (vii))*: This section states that all informants should be made aware of the possible future use of research or records as secondary data and for unanticipated uses. The University of Wollongong Human Research Ethics Committee (WHREC) Guidelines make the further provision that, “Secondary or subsequent analysis of data beyond that agreed to by participants requires the specific permission of participants (for identifying data)” (p.2).

*Media (NCESSRH Guideline: III.5.4)*: This section advises that when findings are disseminated through the popular media, care be taken to ensure that they are understood in the context of their limitations and implications. The APA Ethics Code (1992) produced by the American Psychological Association (APA) also cautions its members to comply with ethical practices when involved with media presentations in a professional capacity: “When psychologists provide advice or comment by means of public lectures, demonstrations, radio or television programmes, pre-recorded tapes, printed articles, mailed material, or other media, they take responsible precautions to ensure that (1) the statements are based on appropriate psychological literature and practice, (2) the statements are otherwise consistent with this Ethics Code” (3.04).

*Role of Funders and Sponsors (NCESSRH Guideline: VII.3)*: In the WHREC Guidelines for the assessment of research proposals, committee members are asked to consider “What is the relationship between source of funding and the aims of the project? Does that relationship have implications for the ethical conduct of the project, especially the recruitment of participants and the character of information sought?”

*Organisational Mechanisms (NCESSRH Guideline: VIII)*: The Commission to Review the AAA Statements on Ethics (1995) presents an analysis of factors necessary for a body to successfully adjudicate charges of unethical practice. This includes the ability to: Ensure due process, which involves collect of data, interviews, hearings, etc. Have the ability to impose meaningful sanctions. Have

moral, if not legal standing. Be willing and able to take on all appropriate claims. Be able to deliver what it promises. (B.2 p22)

Because the AAA Statements on Ethics had no legal standing and a weak adjudication mechanism, the Review Commission recommended that the AAA: Direct its energies and resources into establishing an on-going aggressive ethics education programme and offer advice to persons who are faced with ethical dilemmas and to persons who are considering bringing a claim of unethical behaviour in another venue.

Since this appears to be very similar to the situation that those working in the social sciences and particularly in the field of sexuality experience, maybe there are some lessons for us here. Of particular interest and applicable in our situation are the recommendations that the Commission made for an educational programme in ethics.

*Recommendations of the AAA Review Commission for an educational programme :*

- Produce and periodically update a publication of case studies of ethical dilemmas researchers, teachers and practitioners might face, suitable for use in graduate training, postdoctoral training, and continuing education.
- Provide departments technical assistance in establishing educational offerings in ethics. Conduct ethics training workshops.
- Seek a grant....to develop a basic ethics training module, ....which could be supplemented with training specific to the discipline....Develop broad guidelines to help departments determine the appropriate minimum of ethics training which should be offered to different levels of students.

These recommendations are very useful with regard to the NCESSRH Guidelines, and could help in determining its scope and possible routes of expansion in the future.

The AAA Statement on Ethics also states, “Anthropologists may choose to move beyond disseminating research results to a position of advocacy. This is an individual decision, but not an ethical responsibility” (C, 2). With reference to the NCESSRH

Guidelines, perhaps a Review Committee could be a source of advice (or recommend relevant contacts) for the ethical application/development of advocacy strategies if an individual or the group requests it.

**VII**

**Research with Women**



# 11

## **Ethical dilemmas in research with women**

Case studies of survey  
and qualitative research

**Neha Madhiwalla**

Conventionally, one conceptualises research relationships as that existing between two sets of free agents - researchers and participants, who may, of course have very different levels of control over the research process. Research with women, involves additional dilemmas that arise from their lack of autonomy.

Every researcher and participant is entangled in a network of power relations. Funders, the state, employers, landlords and politicians, among others, inevitably influence and control the direction of scope of the research and guide the actions of the researchers and participants. However, in most cases, they influence the direct players as a class. And thus it may be possible to engage with them as a class (participants may collectively ignore a ban imposed by the employer or an entire village may boycott a survey). In the case of women, however, even in the absence of any overt sign of hostility, each individual woman must negotiate with their individual households, as must the researcher. In a sense, it is implied and understood that women must seek the consent of the households. To define intelligent adult women as having gatekeepers even when they are not living in closed institutions is unthinkable. But in real life, is it not what we always do? Most often, one is caught between legitimising the authority of men or older women to dictate the actions of women on the one hand, and ignoring or resisting their control even at the risk of retaliation on the other. While the ethical response for the individual researcher in a specific instance may be the former, can we deny it is the second option that represents the truly ethical stand truer to the commitment that we make to women's empowerment?



Both women participants and researchers are always engaged in a process of building alliances with men. Women will very pointedly involve strategic male members in the research process as a means of protecting themselves from the danger that may be posed by the researchers. Alternatively researchers may approach men and legitimise their authority in order to gain access to women and ensure their safety and also ensure that there will be no disruption or opposition later on. However, having once involved men the situation is not easy for women participants to control it. The research process then involves a continuous process of negotiation and bargaining, in which women participants are particularly vulnerable. However, for either group, this strategic move foregrounds patriarchal subordination and reinforces the existing power structure.

The lack of autonomy also relates to the setting of priorities in research. In the context of women's health research, another important issue relates to relevance and control over knowledge. Women have suffered as much as they have benefited from social research. On the one hand, perceptive studies have exposed how little women have gained from development and why women and girls continue to suffer poorer health and higher mortality than men. On the other hand, so much health research has gone into improving the acceptance of undemocratic contraception programme and effecting behaviour change among disempowered sex workers and poor mothers. This is not to deny that family planning and safe sexual behaviour or more informed childrearing practices are admirable goals. However, these processes are meaningful in a context where women can exercise their free will and do not have to make choices under duress. Thus research which aims to change women without changing their context is not relevant unless it examines the pressures and constraints that may prevent women from acting in ways beneficial to themselves, even against their better judgement.

Not only are women unable to exercise control over their community, they also have very little control over the researchers' knowledge. As a group, women have limited access to education. Marginalised women are even more disadvantaged. They are isolated not merely because they are poor and uneducated, but also

because they are women, unable to travel far from their homes and too intimidated of office environments. Researchers gain legitimacy from the fact that they are able to speak a language that is comprehensible to those in power. They are thus able to speak for women. On the other hand, women do not possess the means of using and understanding the knowledge that *they* have helped produce. Education teaches people how to use this language of knowledge. Those who are deprived the right to education (as many women are) do not have the language to use or understand the knowledge that scientific inquiry produces. It must be debated whether it is not the ethical responsibility of the research community to bridge the knowledge gap between the participants, and themselves. This issue relates to the politics of research assuredly, but also to the ethics in an indirect way. Many of the areas, which we consider unexplored, are so deemed because there is no written account of them. By gaining access to the written word, not only would the participants be able to judge what is produced on them, but it would also allow them to counter the monopoly of researchers to speak for them. This may very fundamentally alter relationships between researchers, policy makers and the community where the imperative to heed the voices of women may become very compelling indeed.

Against this general background, I reflect on two experiences of research conducted while working in a structured research organisation. These experiences illustrate the manner in which ethical dilemmas related to women's research emerged and our attempts to resolve them. The resolution of these problems was not complete, nor ideally accomplished. However, we attempted within our limited capacities to deal with them with some measure of integrity.

### **Household Survey On Women's Health**

Apparently, survey research poses fewer ethical questions due to the structured nature of research methods as well as the interaction between researcher and participants. However, the *impersonal* nature of the survey itself poses other ethical dilemmas and issues.

In 1996, we conducted a household survey in Nasik district, of Maharashtra, to document illness, utilisation of health care and health expenditure. Although information was collected on all family members, there was a specific focus on women. We therefore, introduced probing (a list of symptoms) in order to record morbidity that is perceived but not reported. The fieldwork team was entirely female, consisting of investigators, young women between 18 and 25 years, research assistants and three researchers. Our investigators were living in Nasik and Bombay and had about 10-12 years of formal education. Their fathers/husbands were largely industrial workers, petty traders or in the lower rungs of the service sector (office assistants, bus conductors, etc.).

The survey covered rural areas of Igatpuri taluka and Nasik city. The households were randomly selected from the selected villages and urban clusters. They represented a cross section of the population of the district. In the rural phase, researchers visited the selected villages, established contact with the local leaders and women in the community. We also conducted key informant interviews with women and men in the villages. This initial visit was also used to fix the time and date of the survey. Usually, there was a gap of three or four days between the first visit by the researchers and the arrival of the research team. This time was sufficient for information to spread by word of mouth that such a survey was being planned. In almost all villages, we also held a public meeting for women in the *balwadi* (creche), *samaj mandir* or temple to give information about the study, its objectives, the date and the process involved (mapping, sampling, and interview).

This process continued simultaneously with data collection. Thus, while the survey was going on in one village, the researchers would establish contact in the next village. Often, women from one village would have natal homes in the next sampled village. This network of relationships was very useful in reaching out directly to women and households without the mediation of the established leadership (*panchayat*, health workers, and police *patil*).

On average, each interview took an hour and a half. This included the time spent by the investigators in introducing themselves and the study. A pamphlet had been prepared stating the full details about the organisation, the objectives of the research,

the use that the data would be put to and the rights of the participants (to withdraw from the survey, to refuse to answer specific questions and the right to confidentiality) and the names of the individual researcher involved in the study as well as the organisation head (co-ordinator). This pamphlet was signed by the researchers and the co-ordinator and hence, represented a written endorsement of all of the above. This was read out and given to the respondent prior to the interview.

The same process was followed in the urban areas. The only difference being that in the clusters of bungalows and apartment blocks, no community meetings were held. Each household was approached individually.

Typically, surveys concern communities rather than individuals and hence in this study too, we approached the 'community' before starting the survey. The idea was to obtain 'informed consent', not merely from individual respondents, but from the community. Of course, it is very difficult to define what constitutes the community's consent. We resolved this problem by holding public meetings prior to the survey where we explained the nature of the survey, its objectives, the method of sampling and the interview. We took care to ensure that more than half of the participants in these meetings were women. We also held as many meetings as required (in different lanes and quarters of the slum/villages, settlements) to ensure the participation of women of all the identifiable groups in that community (including dalits, the different tribal groups, minority communities and migrants). We invited questions in these meeting and clarified doubts. The community meeting was a way of indicating that we recognised the existence of the collective and, apart from individual women, were also accountable to the collective. A meeting is a public space, where women felt more secure in raising doubts and reservations, because they could rely on other women for support. It also indicated that we were willing to face them as a group. If we felt that the group in general, was not convinced or that they had not entirely grasped the information, we held a meeting again after a couple of days just prior to the survey. If we felt that there was insurmountable opposition to the exercise, we did not conduct the survey in that particular community at all.

Needless to add, the consent of the elected representatives and the local leaders was also sought, not only for ethical reasons, but pragmatic considerations as well. However, at no point, did we use their consent as a proxy for the consent of the actual participants.

*Facing Refusals:* In two instances, in spite of the exhortations of the *sarpanch* (village head) to conduct the survey, we did not do so because we surmised that the actual respondents did not want it. While we decided that this was the only ethical position that we could take, the other side of our actions must be very clearly understood.

When we tried to examine why did an entire community refused to participate in the survey, we found that in both cases, the women were particularly vulnerable within their own communities.

In one instance, the village was a remote tribal village, facing large scale take over of land by a private investor, where there was seasonal out-migration of men and a noticeably higher incidence of bigamy and, most definitely a marked deprivation in terms of health and absolute poverty. In the other instance, the village bordered an artillery range and had a very large number of young widows whose husbands had been killed while foraging for scrap metal inside the range. The entire community straddled a precarious balance between observing the law and ensuring survival. It was evident that the women were paying a heavy price for this as well. Under these circumstances, they seem to be more likely to withdraw from contact with outsiders. They probably perceive the possibility of such an interaction as one more threat giving rise to a new situation with dynamics that they can neither perceive nor feel competent to handle, and thus be wary.

## **Relationships amongst researchers**

*Unprepared for pressure:* Among the other significant issues relating to this research study was the relationship between the main researchers and the investigators. It was understood that unless investigators had internalised the methods of the research and its objectives, they would not be able to do justice to the study. Thus, they were trained rigorously, especially with the intention of making them sensitive to the issue and receptive to women. However, although the training equipped our team intellectually and

ideologically, we ourselves had not anticipated the emotional burden that the investigators would have to carry. The survey was a large-scale exercise, involving a large team of 20 people and considerable material resource. The pace of the survey was guided by logistics as well as the imperative to interview all the households within the same season. Thus, as the survey progressed, the pace became more and more punishing as we attempted to make up for unforeseen delays and days lost due to bad weather. Typical to the survey are short sporadic interactions with participants, who have been chosen merely because their house has been randomly sampled. However, the nature of this interaction itself can become particularly distressing.

Each set of two investigators encountered, on average, four to five households a day and met ten or twelve women. Each day brought its store of traumatic stories of death, suffering and loss. Women broke down and cried and it was not unusual for the investigators to join them. Even the most experienced of our investigators found her-self getting involved in the life of the woman she interviewed. As the leaders of the team, however, it was our duty to keep the work moving. Often, we had to goad reluctant investigators out of one house and into the next. The fear was not merely that precious time would be lost, but also that the investigators would spend enormous amounts of physical and emotional energy generating information that we were not capable of using. Our investigators, justifiably, got angry at our attempts to put the research above the natural impulse to listen, console and counsel. The brevity of the contact itself became the source of much distress. The result was sporadic bouts of utter scepticism about the entire exercise and a marked reluctance to continue working in this way. Things were not made easier by the fact that investigators continuously faced questions from participants about what was to be gained by this exercise. While they had been trained to explain the long-term objective of gender sensitive research, it is easy to see why they often did not believe their own answers.

A coping mechanism, which they (and certainly we ourselves) developed, was a feeling of being anaesthetised. Also, after the third or fourth week of fieldwork, all the stories sounded vaguely familiar. Therefore, it was very necessary to evolve a more creative

way of coping with this situation. A way out that would allow us to continue working without feeling burnt out but still prevent us, from becoming mechanical and our response synthetic.

We therefore institutionalised the evening team meeting. It was held in any place that was private, mostly at our headquarters in Nasik, or in the jeep or a restaurant on the way back. The meeting was held to take stock of the work accomplished and the problems encountered. The investigators typically spent hours relating what various women had told them and what they had experienced themselves. The meetings were cathartic. They helped all of us to release the pent-up frustrations and articulate our sense of anger and helplessness. We realised how important it was for even the most junior member of the research team to be able to distance herself from the issue and view it within a perspective. All of us also brought our share of personal problems and experiences that made the fieldwork even more difficult. This space was used to resolve those issues. Typically, the meetings were never entirely professional, but involved a lot of personal sharing of physical contact, of expressions of concern and affection and annoyance and irritation as well. It is largely on account of these meetings that we were able to complete the survey successfully and divert some of our frustration creatively into writing of field-notes and diaries (which all of us did).

*Hierarchy:* Apart from the ethical issue of exposing the juniors in the team to experiences that they may not have been prepared for, the larger issue relates to the relationship of the researchers itself. It is difficult to argue against the existence of a hierarchy in the research team itself. One recognises that there is need to reiterate that researchers have different roles. However, it is still important to question why certain ways of writing legitimise research more than others. This is particularly relevant in the field of women's research where qualitative techniques are used extensively and very sensitive issues are probed in detail. The depth and richness of the data itself lends much to the quality of the research and, thus, investigators and assistants who conduct the actual interviews and group discussions in many cases are very important players. Their sensitivity, understanding of the issue and a high level of skill are pre-conditions for good data collection. Not only are they involved

intensively in this phase of the research a participatory mode of functioning may actually equip them with additional skills. Our own experiences indicated that the meetings and discussions imparted certain skills to investigators that are normally associated with research writing. They learnt how to abstract, how to generalise and how to analyse situations from what we would understand as a 'sociological' point of view. Their skills of writing were admittedly poor because the level of education was generally quite low. However, these are skills that can be acquired with effort and inputs. While our investigators may have been too junior and ill – equipped to manage all the phases of research, it is quite possible that investigators who have much more formal education and some training may become capable of doing research independently and quite competently. It is important that designation does not define roles and space is created for junior members to share in the writing. However, are our institutions open enough to absorb people who may raise themselves from below? This issue is quite distinct from sharing research with participants, as is the norm in 'participatory research' where they have a say in designing the methodology and the conduct of the research as well as in the use of it.

While participants share the gains of the research largely through changes, which result in the community after the research (by an improvement in the Public Distribution System (PDS) for example), junior researchers would share the professional gains and prestige associated with research. It would involve changing the policies of institutions and implement measures that seriously challenge the existing hierarchies in institutions. The material gains too would be distributed and serious questions would be posed about the social structure of research organisations and the class structure that they reflect.

### **Qualitative Study**

The ethics of research in qualitative studies poses contrasting challenges. In general, the interaction with participants is of longer duration and more intense. Qualitative data collection also tends to isolate researcher and participant because of the nature of the inquiry. Thus, the issues revolve around sustaining relationships, terminating them meaningfully and coping with the intensely



personal nature of the exercise. It becomes important for the researcher to be able to step back from the individual experience and view it from a more objective point of view.

The second study involved the extensive use of in-depth interviews. Fortunately, for us, broaching the subject and openly selecting women for interviews was not problematic. The objective of the study was to document changes occurring in the living environment of women on account of changes in the economy, which affected their work, employment and access to services. We were also interested in establishing links between these changes and women's health situation. The study was based largely on in-depth interviews with 40 women. The method for selecting these women was a matrix of five variables - age, marital status, work-status, duration of stay and community. We selected two slum settlements and obtained this information for a large number of women and classified women into this matrix. Following this, we selected two participants from each cell of the matrix.

## **Issues**

*Rights of Minors:* As we were largely concerned with issues of livelihood and work, it was not difficult to gain the consent of the participants of the study. The fact that our sampling design was also quite straightforward and the selection of the participants was based on very commonly known details –there was no difficulty in explaining why some women were chosen among the many. However, protecting the privacy of the selected participants and their confidentiality was still problematic. Most problematic was gaining the consent of the minor girls (14-18 years) and interviewing them in such a way that they were not stigmatised. We were interested in including adolescent girls because we were convinced that their domestic roles were very similar to adult women and they shared similar problems, which was never acknowledged. Nonetheless, the selection of these girls, who in the general understanding, did not really qualify as women aroused a lot of curiosity and suspicion. In spite of allowing us to interview them, there was a hint of reluctance from their families itself, who feared that these girls might complain about them or speak ill of them. Invariably, their mothers or others in the household would want to

know what they said. The girls themselves were very edgy about speaking to us in the community, especially in the presence of their family members. We were caught in a double bind. On the one hand, we wanted to interview them in full view of the community, in order to assure them of the innocuous nature of the exercise, on the other, the girls wanted to speak in place where no one could hear them or be seen. However this was difficult physically because the girls hardly ever went out of the community on their own, unescorted. We tried to strike a balance between the two and made sure that the girls' privacy and confidentiality was never violated, even as we ensured that we did not arouse unnecessary suspicion.

Thus, doing research, involving minors, is not easy. We used reasoned ways to ensure the rights of the minors as participants of our study, as described above. No one heard (including their parents), what they said to us and we did not divulge anything that they said. However, occasionally a mother would come and sit and we did not prevent her from doing. We never interviewed a girl without her parents' permission. With minors it is necessary that we acknowledge the authority of someone (whom we trust) and at the same time acknowledge their own autonomy. Negotiating power relations between adolescent girls and their parents is quite a complicated affair. Not least because, there is usually a long term struggle for more independence underlying their relationship. While it is important that as 'almost' adults, we take a stand positively in support of girls, who are disempowered both by their age and the sex, it is still necessary to acknowledge that their parents are not only legally, but also emotionally and socially indispensable for them.

*Ethical issues associated with the researchers' community:* An important issue that this study brought to the fore was that of identity. It is common practice in research and development work to look for people who share some cultural ties with the community where we intend to work. While knowing the language and the customs of the group/community does resolve certain practical difficulties, there is also a certain intangible gain from the psychological feeling of comfort that participants derive from interacting with an 'insider'. To establish this insider status, it is never necessary to overtly announce one's caste, religious or

linguistic background. In a complex social context as in Mumbai, most people are adept at guessing these from the smallest signs in the name, dress and speech. Sometimes however, these signs can be misleading.

My name and appearance does not immediately suggest to people that I am Hindu, which is the religion into which I was born. Because I happen to be Gujarati speaking and not a community with which this particular group is very familiar, it is all the more difficult to guess that I am Hindu. As it was assumed that I do not look like a Hindu, it was decided that I must be Muslim. The first indication that I received that the Muslim households in the community may have misread my origins came when people would say, for example, so and so belongs to our kind (*apni jat*). As we progressed further, I realised that this perception may be more widespread than I had imagined. By the time, I began to clarify that I was not Muslim, a certain trust had already been built. It no longer mattered to people that I was not a co-religionist. This episode involves not so much ethical issues as political ones. While one may consciously deceive participants by 'claiming' to be something, which one is not, this was certainly not such a case. However, the fact that people immediately want to place you in a grid of social identities is well known to us. The fact that it contributes, even if only sub-consciously, to the building of relationships is also something we all acknowledge. Our religious identity may not be important to ourselves, but it works in very subtle ways to draw people towards us and away from us too.

It is clearly unethical to manipulate identities, especially those that we ourselves do not acknowledge (even though they may not be false), for the purpose of research. Often participants are led to believe that they may share certain interests or certain histories in common and they react accordingly. For those of us, who can clearly shift identities easily, it is tempting indeed to do so in order to make every participant feel that they are speaking with an insider. One is always emphasising certain identities, while obscuring others. Thus, being a woman is more relevant than being Hindu. Our ideological positions are not much more than the prioritisation of these identities. While they may all co-exist, what I value must be fore-grounded. It is equally important to state our ideological

stance, at least, on relevant issues, as it is to brief participants about the objectives of our study. Especially when we study political affiliations, social prejudices and other such issues, it is our responsibility not to keep the participants in doubt about our own beliefs. No doubt, this problem can be fairly complicated in the instances where we are ideologically opposed to the participants and the interests they represent.

*Reporting research:* Another issue which dogs ethnographic studies done with very specific individuals or distinct communities is the matter of revealing names and leaving markers in the text that makes it possible to identify the individuals involved in the study. One has to strike a balance between maintaining anonymity and yet making the context of the study clear. This is a problem that we confronted in our study. As the focus of the study was the living environment, identifying the exact locations of the settlements lent a strong sense of credibility. However, it also made the communities identifiable, especially to those who are familiar with the area. This problem was particularly important to resolve because we were committed to return findings of the study to the participants. When we started preparing the report in the vernacular, we realised that let alone names, even details of the women's narratives could not be included. Initially, we had a plan to develop fictitious narratives, but we soon realised that even that would lead to a misunderstanding. Secondly, some of the findings of the study clearly indict the community's own actions as being responsible for its problems. Most of these relate to the hierarchical nature of the community leadership and their role in perpetuating the subordination of women. While it would be honest, in some form, to return even these findings to the community, it would be irresponsible to do so merely by disseminating the report. Do we have the right to sit in judgement of people's intentions and actions, when we do not wish to share their predicament and work with them towards resolving their problems? This, inexorably, draws us towards the realm of activism or, at least, intervention. While, it is undeniable that research should ultimately lead to progressive action, how feasible is it for individual researchers or teams to get involved in a process of this kind.

We ourselves have still not resolved this dilemma. However, there seems to be a clear indication that returning findings to this community will involve a prolonged and gradual process of discussion, debate and self-reflection. While we hardly endeavour to instruct the community, we can be quite certain that such a process will throw up insights that we may have missed earlier and a better understanding of the limitations and predilections of either party will be revealed.

## **Conclusions**

In the previous sections, I have outlined the nature of ethical dilemmas that we confronted while conducting two studies. While some of these issues are gender specific, some are of a general nature. The teams involved resolved the ethical dilemmas by responding to problems, as they arose evolving a consensus through discussion and self-reflection. The utility of ethical guidelines would largely lie in pre-empting these problems and allowing researchers to devise strategies with the compulsion imposed by the being in the midst of an unfinished process that can neither be reversed nor stopped. The guidelines would also facilitate discussion between different team members who may not share a similar perspective. The guideline also represents the basic minimum, which each strategy must adhere to and beyond which compromise is not acceptable.

It is however, necessary to contextualise these guidelines where research with women is concerned. The universal principles apply, but the specific indicators may be difficult to identify. Just as in any other field, it is difficult and, at the same time, imperative to separate the interest of women from that of the household/community.

Thus do we define consent of the household as consent of the woman? Does gain accruing to the household amount to gain accrued to the woman. Is sharing the knowledge with the community in a written form in front of the elders and community leaders enough? What will women do with knowledge that they are not empowered to use? What stand should we take when women try to set up a system of checks and balances between the researcher and

the authority figures, who are conventionally bound to protect her. By accepting their legitimacy, one automatically endorses their right to share the knowledge resulting from the research. Does this compromise our commitment towards women who are the rightful recipients of that knowledge? How does one then confront the same authority figures?

Finally, one must address the problems within. An important agenda for women's studies has been the widening of the definition of knowledge and challenging the norms governing the hierarchy of knowledge. There is an assertion of the legitimacy of women's voices, oral cultures and lay knowledge. However, as women's studies get recognised and institutionalised, new hierarchies are being established in new institutions. Research in women's issues, especially women's health is not confined to activist groups and dissidents among the academic community. Apart from the state, which continues to conduct research *on* women, it involves large research institutions in the mainstream, large non-governmental organisations and multi-lateral agencies, many of which claim to be conducting research *with* women. All these agencies are spread across a wide ideological and political spectrum. Nonetheless, is it sufficient to claim that women participants are partners? What about the woman research investigator (who also forms the informal sector of the research industry, indispensable and yet highly substitutable), who should legitimately share the direct gains of research, both material and social?

[This paper draws on the experiences of two research studies conducted while I was working at CEHAT. I would like to acknowledge the contribution of my team members to the discussions that led to the writing of this paper in particular. Roopashri Sinha and Padma Deosthali, with whom I not only discussed but also lived these experiences and to whom much of the credit for this paper should legitimately go. However, the views expressed in this paper are mine only.]

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## Abortion research

### Ethics in practice

#### Sunita Bandewar

The Ethical Guidelines for Social Science Research in Health [NCESSRH 2000] offers a concrete framework for researchers while conducting social science research, especially on health related issues. The evolution of such guidelines, however, does not imply that ethical principles of research were disregarded earlier, nor does it mean that all research hereafter will be ethical. In the past too, individual researchers have grappled to resolve various ethical dilemmas faced while dealing with the various complex field situations, and issues of research. The present communication is to share with the readers the ethical issues of the two of research studies, amongst those that I have been involved with while at CEHAT.

At the outset I would like to mention that my concerns about such 'difficult to resolve issues' found an expression at CEHAT. CEHAT has been striving to conduct quality research without sidetracking or ignoring the ethics of research. Not all environments allow researchers to voice and address their ethical concerns. Institutions need to cultivate, nurture and develop an atmosphere and culture that is conducive to encouraging rigorous work, in terms of both research and research ethics. Team efforts and convictions are absolutely essential to conduct research in a manner that is ethically informed and sound.

One of the studies discussed in this paper was a community based qualitative abortion research to understand women's perceptions of abortion and abortion practices. The other one was a health care facility based study, to assess quality of abortion care using a mix of quantitative and qualitative methodologies.

Research with women using qualitative methodologies on sensitive issues was bound to throw a range of ethical challenges, often difficult to be addressed and resolved. On the other hand,

research with 'exploiters' or 'oppressors' having an upper hand in a provider - client power relationship threw challenges to be faced necessarily on account of their simultaneous identity as 'respondent'. We, while pursuing our abortion research and advocacy agenda, have been dealing with these two constituencies as respondents, during research and as population to be influenced.

Our efforts were intended to generate information and insights into the abortion issue from women's perspective and to understand the socio-cultural, legal, medical and political context of abortion. Giving women information and making them aware of the legal provisions of abortion care available to them, facilitating their understanding of the broader context of abortion and introducing them to a woman-centred perspective on abortion needs, were some of the goals of our abortion research and advocacy initiatives. As regards service providers, making them realise their responsibilities towards women for providing safe and legal abortion care was one of the major goals. It is obvious that we were working with two constituencies having conflicting interests constituting an exploitative power relationship. This particular nature of our research gave rise to very peculiar ethical dilemmas.

The following sections are a documentation of the ethical issues and dilemmas experienced, and the reasoning that went into taking decisions about the ways and means to handle them. It is hoped that this would facilitate in evolving better ways to deal with ethical dilemmas in a similar situation with required adaptations. The discussion is organised along the major research phases that we traversed.

### **Community-based Abortion Research**

This study was undertaken to understand women's abortion needs and practices and get insights into the socio-cultural context of abortion which influences their abortion seeking behaviour. The specific ethical issues and dilemmas were primarily because of the sensitive and tabooed subject of research. However, ethical dilemmas also stemmed from various other sources. For instance, the fact that the study was community based abortion research, added various dimensions to our ethical dilemmas. Moreover, the



use of qualitative methodology and women respondents, further complicated certain issues.

*Selection of the research area:* We faced a major ethical dilemma right at the beginning of the study, while selecting the study area for our research. The research topic and the overall methodological approach that we had in mind demanded an excellent rapport with the community and with the women. This obviously directed us to consider a research area where some developmental activities through outside groups were on and that these groups were at good terms with the community. The purpose was that we could then introduce ourselves to the community in a better manner, with fewer difficulties and with less scepticism on part of the community and individual women respondents. Implied in it was that we 'capitalise' on the credibility of the developmental agency for conducting our research. This could also be interpreted as us using the area as an experimental laboratory to do research on humans. We needed to simultaneously consider all these aspects while selecting the area for our study. This was a difficult issue to resolve.

After much thought and after exploring other options we decided to go ahead with the community with which one of the researchers on our team had been working with since five years. She had lived with the community and had been establishing participatory processes for the community's, and specifically women's, comprehensive development. The thrust of these interventions was health, small saving self-help groups and some income generating activities. An organic relationship had developed with the community over this period. The group's feminist perspective on women's health issue reflected in their methods of working, looking at the issues and developing the processes. This could be felt and sensed even by outsiders.

Even though we selected this community, we decided against directly entering the community on the grounds of the credibility of the group and the person who constituted the research team. Instead, we held rounds of discussion with the other members of the group, trustees and the members of the executive committee (the body which was responsible to execute decisions taken by trustees and Ethics Committee (EC) in consultation). The

community members were also part of EC. This exercise was undertaken to explore and anticipate how the community would receive the study and what could be the possible implications of such a research for the community as well as for the group in the future. We explained to them the nature of the research and the kind of involvement that we anticipated and hoped for from the community. We also shared with them the constraints that we felt while seeking the co-operation of the community in a research activity. The community members of the EC made efforts, along with others, to understand the implications of such a study. Not only did they raise issues but also actively participated in the discussions. This exercise helped us a great deal in addressing the dilemmas that we were facing.

The group appreciated both the social relevance of the research and the dilemmas that we were facing as regards using the intervention area as experimental laboratory as explained earlier. We sought to resolve our ethical dilemma by educating women on women's health and especially the issue of abortion as a token of gratitude for their prospective participation. The idea was to make the research activity of mutual gain, especially in terms of increased awareness and offering women an exposure to issues that concern women and yet they are less touched upon. The EC also felt that this could facilitate and strengthen their own processes for addressing women's health issues. It was thought that it would complement their expansion of activities by understanding women's perspectives.

*Seeking informed consent:* Our experiences during this research proved that operationalisation of the concept of seeking informed consent of the respondents needs to be dealt with creatively and in an innovative way to make the process culturally sensitive and meaningful.

Not all the women with whom we interacted with were able to read and write. People have been known to have a serious discomfort when it comes to signing papers (in this case - for informed consent). This was reaffirmed in our study. Women's dependence on decision-makers in their families in such matters was an additional obstacle. This emerges from women's status in the family and the social structures dominated by the patriarchal

value system. Thus anything that required women to sign papers, to meet the requirements of ethically sound research, was out of question. An alternative needed to be evolved. We thus had to weave the process of seeking informed consent within our methodology. The following discussion would help understand as how it was achieved.

We sought the involvement of two women as ‘resource women’ from each of the villages that were included in the study. By inviting such an involvement of women from within the community, we sought to bridge the gap between the community and us. We made conscious efforts to share with them the perspective that we had on abortion. This included abortion as both, a public health issue and a women’s rights issue in the context of women’s health and rights perspective. We had monthly meetings with them in one of the villages or the centrally placed office of the organisation in the study area itself. The purpose of these meetings was primarily to share with them the progress of the work and the issues that we had faced during the month. We discussed our field approaches with them before implementation, thus enabling them to play a key role. This was done in order to understand and appreciate the different voices and responses of the community, and of women respondents in particular, by receiving feedback from the resource women. This helped us pre-empt any problems as well as understand the pulse of the community, which in turn enabled us to be sensitive in our approach. Future plan of action and strategies were evolved during these meetings. We also used this platform to orient them on the issues in the during the subsequent phases of fieldwork. Groundwork to be done by them before we as researchers went into their villages was also planned. They gave us community’s feedback – reactions and responses. This entire process played a key role in making community *informed* about what we were engaged in.

We mainly used focus group discussions followed by in-depth interviews with women and men in the study area. The above mentioned process of making community informed about the subject matter not only served the purpose of being transparent with them but also enriched the group discussions. Thoughtfully planned series of focus group discussion, which continued for about

six months, facilitated the identification of the women to be considered for in-depth interviews. It also created an environment that was conducive for conducting the in-depth interviews with women. During this process they were exposed enough to the subject matter and our pursuit for such a research. Eventually, we spent time with individual women to share with them the purpose of conducting in-depth research. Our contact women also played a significant role in these efforts. Women were also told about their right to withdraw their participation at any point of time during research. Thus seeking informed consent was not a one-time activity. Instead, it was an ongoing process during the entire project period.

*Strategies to maintain privacy:* Maintaining privacy in a community setting is not an easy process. The strategies that we evolved for maintaining privacy for focus group discussions and for in-depth interviews with women and men were different. During focus groups, we had to make sure that the men were not around to enable the women to share freely. We did not want men to be around to hear what women would share in these. Initially, we did begin with loosely structured meetings for which though men were not invited, they were also not restricted from sitting around. The purpose of these meetings was to talk about general health issues and concerns of the community and to introduce ourselves to the community.

Eventually the groups were constituted; these we treated as focus groups. Rural life style and women's work schedules going on till late evenings left the space for such focus group meetings only after 9 p.m. Women used to feed their families and put the children to sleep before they came for these meetings. Once the women got interested in these meetings, they wanted to have them at someone's place rather than having them conducted at any open or public space, such as, village temples, *samaj-mandir*. This provided women the privacy they wanted to have during such meetings. Men in the families, whose houses were used for meetings, recognised and respected women's need to have the space for themselves. They often used village *mandirs* to either spend time chatting with other villagers or slept there. The rapport that the researchers developed over time played a significant role in

smoothing all edges. It is to be noted that we as researchers lived in the villages with the families of our contact women. This helped us to build close bonds with the families of our hosts as well as the community.

The in-depth case interviews with women took about three to four sittings per woman, each sitting lasting for about three to four hours. Women could not spare time exclusively for us. It was preferred by them and us that we conduct the interviews either at their homes or fields, while they continued working. This provided a great deal of privacy and comfort to women while they talked about their intimate feelings, domestic and family dynamics and a range of other personal matters. During this phase, the fieldwork smoothly became anthropological in nature and was no more only sociological. The researchers spent time with women's families and assisted them in their household and fieldwork. When women wanted to speak with us about their intimate matters, we did not stop them. The research process as it evolved, provided us with not only sound data, but more importantly, it enhanced the comfort felt by the women as a result of the privacy maintained.

*Compensation for participation:* Another closely related issue was the mode and form of compensation for the respondent for sparing their time and energy for participating in the research. It was not easy to resolve this issue. We had two sets of respondents involved in the study. One, there were two resource women from each village who played a crucial role in the way the research eventually evolved. We made formal arrangements for paying them honorarium and bearing the cost of their travel to places for monthly meetings with the community members. The honorarium given was commensurate with the wages that the NGO offered to the grassroots level workers. Some of the local resource persons were in fact already a part of the NGO's health team working at the grassroots.

The other respondents were the women and families who actually participated in our study either by being part of our case studies and/or by participating in the focus group discussions. We faced a number of dilemmas when it came to compensating this group of participants. Would incentives or compensations affect the quality of responses? Would such compensation have

implications for any further research activities that may be conducted in the area? Would 'not offering any incentives or compensation to the participants' amount to exploitation? Such dilemmas arise in any other research situation. They became more complex in view of the fact that we as researchers were drawing salaries much higher than the average income of the people in rural areas. With all the rationale and essentiality of taking up such research, one cannot ignore the fact our engagement in this research was also the means to our own livelihood.

Not offering incentives to the participants in the form of compensation to participants, is one of the stands held among researchers in general. It has been argued that research may or may not give anything tangible to the participants, since the purpose of research is to further knowledge – which would then benefit people the long run. To me, this perhaps would have been a valid argument had research, interventions and service provision to people continued to be done and given in the spirit of charity – as it used to be at one time. However, the contradictions arise now, as there is visible shift over the time from people engaging in such activities as a charity, to they being compensated for in terms of salaries as researchers or action researchers. The intentions is not so much to highlight or resent this shift, but to bring to the forefront the need to re-look at the position on offering incentives to the participants.

Linked to the issue of incentives was the fact that the researchers and the organisation itself get additional incentives - in terms of publications on their names, credibility amongst peers, career advancement, additional funds for continuing research and related activities. If so, it is essential to ponder over different mechanisms to deal with the issue of 'compensation' or token of gratitude for the active participation of individuals from the study population. With these dilemmas coupled with the changing purpose and nature of research, we had to address the issue of offering incentives. If yes, then in what form and at what stage of the project? We devised various means to resolve this issue. Towards the end of the fieldwork, we organised a daylong get-together for all the participants. The idea was to share with them the findings of the study through a presentation, express our gratitude for their warm co-operation and to provide them space to speak about their

experiences while being part of this research activity. We organised some entertainment programmes for our women, who otherwise hardly get any such opportunities to interact with their fellow women and exhibit their talent. We also offered them small gift items.

During the fieldwork phase we extended our assistance to villagers in whichever way they perceived that we could. Most of the times it was sought with respect to health care services. This led us to another dilemma. None of the researchers were medical professionals. We could not meet their requests for health care services on our own. We thus assisted them in accessing safe and affordable health care services. Accordingly, we either referred them to the secondary or tertiary public health care facilities or to the Loksewa Aushadhalaya, a rational drug counter being run by the local NGO, depending upon the type of need. At times, we accompanied the women, when they wanted us to do so, while seeking health care services at taluka (District sub-block) or district level.

*Documentation:* The writing pads and pens in our hands were initially slightly frowned upon. However, with time the women got used to it. The in-depth case studies of women started about 8-9 months after we started interacting with the community as part of the research activity. By then, not only women, but also the community had enough confidence in us to make it possible to take notes while conversing with our participants. We documented our interactions with women in detail on the same day, which often meant sitting through nights.

When women told us that we should not document a particular piece of information, we respected their wish. We also refrained from using electronic recorders for case studies since we were talking about a sensitive issue and women shared with us very intimate views and experiences. We did not even explore the option to find out how the women would respond to such a request, as we ourselves were not comfortable with it.

*Sharing research findings:* What purpose does it serve to share the research findings with the respondents? One is to confirm with the respondents that the findings and their articulation by researchers are not objectionable from respondents' point of view.

It is also to seek respondents' consent and approval to share their perspective with the outside world. Another is to share with them, in a comprehensive manner, their own perspective that emerged from our analysis. This, we thought, could enhance their knowledge and enable them to be better informed and maybe even empowered.

The qualitative methodologies used for data collection to understand women's perspective made us ponder over the manner in which we could share the findings. We mostly relied upon case studies of women who had undergone abortion in the past. At times the information the women shared with us went beyond the scope of our study. These we had documented them at length to capture the nuances, dynamics and processes. Thus the nature of the data was such that it had tremendous potential, if manhandled or treated insensitively, to cause harm and distress not just to the woman and the family, but to the community itself. However, we felt that it was our ethical duty to share our findings. We needed to achieve the delicate balance to tackle this dilemma – of sharing findings without compromising the protection of our participants. Moreover, what complicated the issue further was the ethical challenge of describing case studies. This could lead to a disclosure of identities as well as reflect on the culture of the community. This could prove disastrous for the community since the research dealt with issues related to people's sexual behaviour, the extent of promiscuity and indulgence etc. We thus tried to strike a balance among many factors keeping the sensitivity of the issue in mind.

We chose to prepare a slide set and a booklet in Marathi the local language on abortion. They were based on the perspective gathered from this study. While preparing slides and the booklet, we had two rounds of discussions with the respondents on the draft of these materials. The drafts were discussed for content, form, illustrations and presentations. Their feedback was incorporated in the final draft. The slides were prepared in the form of a story and raised a range of issues associated with abortion. These stories represented various abortion situations that women face and about which common people as well as women are aware of. The booklet on the other hand used the question-answer form. It dealt with abortion issue in the wider context of issues related to women's health, reproductive health and rights. We felt that such a



presentation style would provide the viewers the broader perspective on abortion and women's abortion needs, thus helping to remove stigma attached to abortion. These two productions have proved very useful resource material at various levels. They have been used to educate and sensitise people.

The material prepared to share with the peers carried the same perspective. However, the form and means were different. We wrote research papers and articles for academic journals and the popular press, both in English and Marathi (the vernacular language).

### **Assessing Quality Of Abortion Care**

In the second study, which was an institution-based research, ethical dilemmas arose as a result of a myriad of facts. For instance, non-medicos were conducting an assessment of the quality of abortion care that involved medical aspects and dealing with medicos. Moreover, a profit making 'community' was being assessed. Some of the aspects of quality of abortion care were difficult to understand unless we had used intrusive methods of data collection, such as, observation. Besides, we had an in-built component of advocacy for improving women's access to safe and legal abortion care. For this we had to deal with the medical fraternity and the state administrator and bureaucrats. The thrust of our advocacy efforts, within our limited resources, was to bring about changes in the state level Rules and Regulations of the Medical Termination of Pregnancy (MTP) Act, 1971, to facilitate registration of MTP facilities, to provide the required information to the members of the concerned constituencies in a systematic manner, and to sensitise the medical fraternity about various aspects of the issue.

*Methodology used:* The thrust of the study was to assess quality of institutional abortion care service provision. It did not look into quality of abortion care provided by local abortionists. The objective was to capture the overall trends with regard to quality of abortion care, though not statistical generalisation. The study required us to cover a much wider geographical spread compared to what we covered in the community-based research done earlier. In order to understand the overall scenario we needed to include urban and

rural based abortion care facilities; public and private abortion care facilities; as well as registered and non-registered ones.

In order to assess these services, we devised a model that had three major components namely, 'structure', 'process' and 'outcome' of the service provision. Structure refers to physical access, physical standards and human power. Process refers primarily to provider-client interaction, competence of the provider, screening of the client and management. Outcome refers to post procedure bio-medical indicators in terms of women's health status and socio-behavioural indicators such as a woman's satisfaction and perceptions about the services she received. Of these, 'process' and 'outcome' required in-depth case studies of the health care facilities and of women coming to these facilities to seek abortion care services from there. We therefore used both a quantitative survey followed by qualitative in-depth case studies of the sub-sample of the health care facilities engaged in abortion care service provision. This was necessarily because of the limitation of a quantitative survey to provide us with an assessment of 'process' and 'outcome'. An enumeration of health care facilities was necessary to locate abortion care facilities before we began the quantitative survey.

### **Seeking Informed Consent**

*Provider respondents:* 'Exploiters', 'oppressors' constituting the respondents pose different set of ethical dilemmas. In the present study we were quite sceptical about the willingness of the heads of the institution providing abortion care and abortion services (now onwards they both together would be referred to as providers), to participate in such a study. The fact was that we were to assess the quality of care provided by them. It was highly likely for the respondents to perceive this assessment as a 'scrutiny' by outsiders, who by no way were bestowed upon with such authority, at least not in the capacity of state's representative or administrator. We could thus visualise the problems that would arise during the process of seeking informed consent. The other major obvious concern, and in fact an anxiety that we felt all through the field work, was whether we would be able to include those institutions which were not registered under the MTP Act. The ethical principles of research

that we believed in required us to be transparent with them about the objectives of the research. This implied probable poor participation of the providers. In addition, the situation also had a potential to exert pressure on field researchers to abstain – perhaps quite without their knowledge from revealing the objective of the research, especially if the respondents were suspicious of the purpose of our research. The challenge was to optimise participation without compromising respondents’ rights. This practically meant that we strategised (*not* manipulated) our content of communication with them, especially the one during the initial visits.

Thus, while communicating to the respondents we opted to articulate the issue more in term of systemic issues, problem, failures etc., rather than in terms of individuals indulging in such practices, knowingly or unknowingly. We highlight those aspects of our research objectives, which were related to understanding the problems emerging from the systemic failures. We found this was a more amicable approach that neither compromised ethical requirement of the research, or communicating the purpose of the research to the prospective respondents nor did it offend them. It was important to give them the confidence that we were there as representatives of the people to understand the ground realities-systemic problems and their reflections at the level of individual health care facilities, which have bearing on the various aspects of quality of care and other related matters. The intentions and objectives of the research was not to expose them.

*How was it done?* With these ethical concerns in mind we yet again evolved a mechanism to seek informed consent, integrated within the methodology . The enumeration of the health care facilities in the study area involved visiting every health care facility regardless of whether it was engaged in abortion care service provision or not. We aimed at achieving two things during this round. One was to obtain some basic data about the institutions including whether a particular health care facility was engaged in abortion service provision and qualification of the head of the institution and abortion service provider. Two to inform them about the subsequent quantitative phase of the research and seek their participation.

The mode of introduction we used, the amount of time we were willing to spend for the introduction of our institution, its thrust areas in general, and of this research, in particular and most importantly, the extent to which we were equipped to answer their queries on the subject matter, was very critical. It was a question of our credibility to conduct such types of research with the medical community. We were prepared to spend the necessary time during this phase. We opted to give our respondents a written mode of communication—a short and yet a comprehensive note, that introduced us, the institution, our overall objectives and the nature of work, the specifics of abortion research, and advocacy.

The respondents had a lot to ask, ranging from the details of the study to the philosophy of the institutions and usefulness of the type of research we take up. This, therefore, required that the field researchers were thoroughly oriented not only about our perspective and the work on abortion but also that of the institution. The field researchers were required to have certain flexibility on this while dealing with the respondents in the field. However, the ground rule was to share with them in a manner that they comprehend, as to what their participation implied. We told them that it would involve assessment of various aspects of quality of care, observation of interactions with their clients and an access to their premises to the extent that it would allow us to move around along with their staff, which would enable us to make an assessment of the physical standards.

We had anticipated a large proportion of denials to participate in the study. However, this proved to be rather unfounded, as by and large respondents were willing to co-operate and participate, though there was some scepticism among them. The results of the study indicate that it did not hamper our data collection nor affect in any way its quality.

We did not seek a written consent of the head of the institution. Instead, their verbal consent and their willingness to participate in the quantitative survey phase was recorded.

*Woman respondents:* Seeking informed consent from women was complex for various reasons. *One*, providers were not always in a position to understand the significance of taking consent from women despite we spending time to orient them. What thus

happened was that the providers would seek women's consent on our behalf or assumed that their own consent implied consent by women. The latter were difficult to deal with. This is because women, or for that matter anybody seeking health care, would often be in a vulnerable situation. They also tend to trust the providers and tend to be less sceptical about that the providers tell them. And this is regardless of whether they seek health care services regularly or not from a particular health care facility. Thus, it is a characteristic of any provider-client relationship in general. Providers' assumptions of this type are primarily reflections of hierarchical provider-client power relationship. We were required to strike a balance between respecting the providers' initiative and willingness to co-operate with us on the one hand and not compromising on fundamental ethical principles of research in terms of essentiality of ensuring voluntary participation and informed consent of the participant. This also reflects upon the lack of recognition on the part of the providers about client's ability to comprehend and take a decision to participate. Two, for some of the providers, women seeking abortion care indicated their 'sexual indulgence'. Accordingly, they did not deserve to be asked for participation, i.e., they did not deserve any such 'niceties'. Three, they also had developed a misperception about us that we were there to record 'illegitimate sexual relationships' in the society and to expose these women. In that sense we were considered as their allies. Four, the practical difficulty in acquiring informed consent was that, that neither the provider nor the field researchers would know about which women from the waiting room were there to seek abortion related services. Practically speaking, the process of seeking informed consent could be started only after a woman entered the consulting room and expressed her need for abortion care.

Keeping these complexities in mind we conceptualised a two-step mechanism to seek consent from the women. We first requested the abortion service providers to interact with women seeking their consent before we began our interaction with them. We then sought her consent again independently. This gave us some anxiety, since we were not in a position to know what communication takes place between the provider and client as part of 'seeking informed consent'. This was one of the most difficult situations to resolve.

We visualised that practically, when we would be allowed in the consulting room to observe the pre-procedure interactions, we would do the required communication with women right there in the consulting room. This would mean that the provider might spend almost double the consulting time for seeking consent. It also implied in commercial terms that they would lose that much consultation time and in turn their earnings. The situation had tremendous potential to exert pressure on the field researchers to be brief with women. The pressure could also be on women since they were in an unequal power relationship vis-à-vis the provider and probably even the field researchers. This left us with little space to 'negotiate' with the providers on this issue.

With this understanding of the situation we requested all the respondent providers to introduce the subject matter to begin with and then introduce our field researchers to the women. With this, when the situations allowed we sat through the consultation to observe pre-procedure provider-client interactions. However, providers did not involve us in the process of seeking informed consent of women. Instead, they called us into the consulting room to interact with women and introduced us to women in brief. We then shared with the women the objectives of the study and significance of their participation in the study. We put considerable emphasis on their right to decline participation at any stage of their study. Not many providers allowed us to be there in the consulting room. Later on, when we first interacted with women outside the consulting room, we spent adequate time with the women giving them the details of the research, including objectives and probable outcomes of this particular research initiative. Women were also told about the time that they would need to spend with us as well as the nature of questions that would be posed in two subsequent phases. This was done in Marathi.

We allowed flexibility to the field researchers with regards to the method of communication and the extent to which the nitty-gritty were to be included in the communication, etc. We did not use written note, like we did in the case of providers, to facilitate the process of informed consent of women. This was because (a) we did not want to exclude non-literate women from the process and thus from participating in the study, and (b) we did not feel

very confident about its usefulness to meet the purpose in those particular situations of women.

We would like to share with the readers the feelings of the field researchers about women respondents' non-verbal response to the process of seeking informed consent. It was felt that the women did comprehend the communication but their body language and facial expression gave us an impression that they were experiencing a mix of amazement and confusion. We also got the impression that they had not understood the fact that they had a real choice to say no if they so wanted. In such a situation, the responsibility of field researchers was all the greater to ensure that the women were not forced to participate. We also recognised our limitation of the extent to which we could ensure this.

*Privacy:* There were a number of issues with regards to privacy: (a) not all the providers were particularly wanting to have privacy; (b) the information that we were gathering through the interviews were less personal and not sensitive; (c) in addition, pragmatically it was too ambitious to expect to have privacy in the absolute sense for a couple of hours with the providers; (d) in reality, we did have quality time with providers, which we attributed to the fact that providers were in control of the situation and could do so depending upon the extent to which they were interested, and (e) there was less scope for anybody to intervene given the fact that they were the 'rulers' in their situation. However, there were difficulties that we faced were while interviewing the women providers, and especially when their partners and/or relatives (for example, in-laws) too were practising and sharing the same set up. In certain cases they sat through the interviews. We will not deny the contamination of the responses of women providers in these situations. It may have happened regardless of intervention by their partners. The field researchers did try to communicate that the respondents needed to be left on their own in private with the interviewers. We sensed that the women respondents had less control over the situations even if they agreed with us.

Besides, there were some practical difficulties, such as, women's (who have approached to seek abortion care), immobility after the procedure, the presence of other users of the services either in the ward, consulting room or waiting room; presence of her

relatives and the hospital staff could be helped little. Despite this, the field researchers tried to maintain privacy during this communication. They had to devise strategies on the spot. It led to prolonged interaction with women with some pause in-between. In general it required a good deal of maturity on the part of the interviewers to be able to capture the subtle and sensitive communication during the interviews.

### **Methods and tools of data collection**

*Interviewing women at the health care facilities:* While designing the methodology we had a major debate over whether it is methodologically and ethically appropriate to interview women in the health care facility while she seeks abortion care. There would be some pressure because being treated by the providers and feeling obliged towards them for bringing them out of ‘ill health status’. Our scepticism was whether women would be in a position to assess objectively the quality of care they received. Even if they could, would they be able to express their dissatisfaction about the services if any, in that atmosphere, immediately after undergoing the procedure. Also, making her sit through the interview in the hospital itself, may potentially be taxing for her either physically or maybe even emotionally.

We had earlier identified these as areas of concern. The alternative methodological option was to follow up women in the community after a certain period. This would have had the advantages of conducting interview in her own setting assuming that she was comfortable to talk about the abortion care she had received.

We decided against the latter because the ethical compromises that would have had to be made were of a different nature and of a larger magnitude compared to the former. We had yet another option. We could completely drop women’s interview from the study. This meant dropping an assessment of the two major components of quality of care, namely, ‘process’ and ‘outcome’. We decided to go ahead with the interviews. It was less compromising ethically keeping women’s interests and concerns as our deciding factor. In the process, the superiority of a particular option (in methodological terms) was considered secondary.



Besides, we consciously kept in mind these limitations of the method while reading, analysing and interpreting the data obtained. We also spent adequate time with women and listened through what she had to share with us without really getting worried about the time we had to spend in doing so. We took care that only the relevant information was recorded from the free flowing conversation.

Now that we are in position to understand the worth of insightful data that came from women's interviews and observing the provider-women interactions, we feel that it was an appropriate decision. The information that we could obtain through these is of tremendous importance to women's health care. It unsheathed the ruthlessly exploitative and insensitive medical practice at the cost of women and their health. We could understand in great detail the dynamics that function and could see how providers' perspective get translated while interacting with women in the course of providing her abortion care services. We could actually watch the pathways of how patriarchy that we all live with and live within (and some practice – knowing or unknowingly) influences providers' perspective about women' abortion needs on the one hand and interpretation of the MTP Act on the other; and further how all these together translate into the way they treat women seeking abortion care services. We would have lost this understanding had we dropped the women's interviews.

*Observation:* Observation guide was one of the most extensively used tools in this study in both the quantitative and qualitative phases. By its very nature it is one of the most intrusive methods for obvious reasons. As stated elsewhere we preferred to observe the provider-woman interactions instead of collecting such information by posing women the questions. In the study we used the mix of it depending upon the circumstances. To be in position to assess 'process', a major component of quality of abortion care, one needs to do this exercise during before, after and during the procedure too. Of these, we consciously decided not to assess 'intra-procedure' aspect of the process, despite its significance. This was for two major ethical considerations. One, it meant completely encroaching on a woman's privacy. Also, the fact that women, and in general users of services, tend to be 'obedient' to their service providers because of the very specific nature of the relationship

and the conditioning. Two, we as non-medicos did not find it legitimate to assess the medical competence of the service providers.

*Field researchers:* Primarily, field researchers conducting such type of data collection need to have the firm belief in respondents' rights, respect for them and the ability to read them. Only two sensitive researchers conducted the qualitative phase. One of them was working on the abortion issues in our institution for about three years and was trained in anthropology. The other one was with us though comparatively for shorter period of time but has been involved with the quantitative phase of the project, which preceded the qualitative in-depth studies. Her participation in that phase, orientation and sensitisation of the entire team helped her get insights into the subject.

The need to have a well equipped team sensitive to women's issues was important. However, the deviation, if at all any, could be the fact that comparatively senior researchers conducted the fieldwork.

*Expressing gratitude for respondents' participation:* We believed in offering a token of our gratitude to the respondents for their participation beyond a mere acknowledgement in our reports etc. As was the case with the community based study we presented some of our relevant material to both the providers and the women.

In addition to this, in case of women respondents, we could recognise that they would appreciate if we heard their story of sensitively and patiently. It is found that pre and post abortion counselling offered to women and her companion helped them to relax and relieve of the mental and physical stress that they undergo. It was imperative that the women trust us. The fact that once, we started the communication with women they generally went on smoothly testifies that field researchers could do it. We felt that we were empathising rather than counselling.

*Sharing research findings with the respondents:* Once again the respondents' generic identity as 'oppressors' exerted a pressure of its own when it came to sharing of research findings with representatives of the respondents. The pressure was also because the research findings clearly revealed the abysmally poor status of health care facilities in general and abortion care service delivery in particular. In fact, there was little that we could do to underplay

the pathetic state of affairs. We feared a backlash from the respondents (the medical community) for sharing such findings. The findings had the potential of making the respondents pressurise us not to disclose or publish them. Had this happened, it would have posed a difficult ethical dilemma.

Anticipating such a situation, we preferred to strategise the mode of sharing of the research findings. At this juncture, it needs to be mentioned that we had also got involved in advocacy on abortion. This involved, working with the members of the medical association, representatives of the state administrators along with representatives of some other constituencies. We had by then organised (this, before we started the quantitative survey) a state level consultation to discuss the issues and concerns as regards access to safe and legal abortion care services. We, therefore, decided to share and disseminate the research findings in a similar manner by organising a workshop. Both, strategically and otherwise, the problems regarding poor implementation of the MTP Act were to be addressed. We had gathered substantial information through the study about the range of problem areas that the medical fraternity was facing vis-à-vis registration procedure, access to relevant information, their awareness about the act, etc along with information on various indicators of quality of abortion care. We decided to present the findings of the quantitative survey, which included primarily the physical access and physical standards, in addition to the above-mentioned data at this workshop. The members of the medical fraternity, including representatives of the respondents; members of Federation of Obstetricians and Gynaecologists' Society of India (FOGSI), representatives of the state administration were invited and to this workshop. In the meanwhile a bilingual booklet was prepared to meet information needs of the medical fraternity and state administrators as regards MTP registration based on our insights during the fieldwork and from the data obtained. It was also to generate support to bring changes in the state level rules and regulations, which were obstructing the process of registration. To one's surprise the findings were well received by all the constituencies, including the medical fraternity and the respondents themselves. Retrospectively, this could be because (a) the data were presented in an aggregated

manner across the three analytical categories; (b) the individual identities were not revealed; (c) the systemic problems were taken note of and (d) the booklet was intended for their benefit. We were thus not only able to share and disseminate the research findings, we were also able to seek feedback on the booklet and draft the recommendations for amendments to be forwarded to the Directorate of Health Services (DHS) and secretariat at the state level.

However, the challenge remains, since the respondents (medical fraternity, including the heads of facilities) might not always receive the findings in such a spirit. It might also be possible that the researchers might not have the scope to adopt such modes of sharing of the research findings.

### **Events to remember**

One of the field researchers, during the pilot testing of the facility survey tools happened to have observed the abortion procedure. Myself, as a facilitator of the research team, was terribly upset with the slip. It forced on us an introspection about where we fell short in orienting and sensitising the team members. The person was excited and thrilled while sharing it with the rest of the team. We knew that it was not ill intended and yet we could not share her excitement. It was a learning experience for all of us and prevented us from indulging in such acts during the fieldwork. In case there are any ethical doubts, there should be space for discussion, even if it means one less interview.

In both the studies, we had a couple of instances where the respondents decided to back off from participation. In the latter, it was generally the intolerance and a kind of irritation about the interview as she was feeling bothered physically and even perhaps mentally after undergoing the procedure. Of those two, one woman was feeling the pressure of her partner and nurse being around. The woman from the community-based survey who withdrew had had multiple sex selective abortions. Her husband perhaps found us too intrusive. These are our assessments of the situations and not their reasoning. We respected their withdrawal.

The ethics committee had a consultative role. Thus it was our responsibility to keep them informed and involved in the process. It will be erroneous to claim that we could do this. The reasons could be that it was a comparatively fresh idea and pragmatically it demanded much more time management and co-ordination. Neither the committee members nor the researchers were tuned to its operational details adequately. After the initial meetings with the members, especially the ones before entering the field, to discuss the methodologies the interactions were sparse. Within the team and with some of the peers within the institution we discussed the dilemmas with rigour. Our internal mechanisms and structures do demand peer discussion and provide space to seek critical feedback at completion of various phases in the project.

The other constraint may have been [as we realised only retrospectively] the fact that we invited consultation of both members of consultative and ethics committee together. The rationality and scientific rigour of the research remained the prime concerns during those discussions. We feel that inviting separate meetings to debate the ethical issues would force researchers and committee members to concentrate and focus attention on them providing space of its own.

Despite these constraints and shortcomings on our side, I feel that we could maintain the ethical rigour in both the studies because it was self-imposed out of our own convictions. This is not to claim that all our decisions were ethically correct. We did, however, spend adequate time and give adequate space for airing dilemmas and debating ethical choices.

## **Highlights of ‘ethics in practice’ in abortion research**

### *Selection of the study area:*

- Community based abortion research, which involves qualitative in-depth case studies necessitates that either researchers or mediating entity (institutions/ individual) has good rapport with the community.
- In the community-based research, there should be a concrete plan and commitment on part of the researchers and/or the mediating agency for ‘after-project’ phase.

- These concerns would have bearing on selection of the study area.

*Seeking informed consent:*

- It is a process and not a one-time event, especially in studies conducted using qualitative methodologies.
- It is the responsibility of researchers to ensure that the process takes place.
- The field researchers need to have flexibility. In the facility-based study consent of providers/any other person cannot be proxy to the consent of the woman herself.

*Expressing gratitude for respondents' participation:*

- It needs to be beyond the words of acknowledgement in the documentation that we do which would be of their use.
- Their identity could be revealed if they wish, while expressing the gratitude in any research-based documentation.

*Sharing of the research findings:*

- Strategies need to be laid down with much caution, care and sensitivity regardless of whether respondents are 'underprivileged/oppressed' or 'oppressors', although they would differ in these contrasting situations.

The methodology that we choose plays an important role in allowing the space to take care of ethical issues and concerns. Consequently, ethical concerns shape the methodology that we choose.

**Conclusions**

It is difficult to 'conclude' communications of this nature, which leave not only the readers but writers, too, with a lot of dilemmas to ponder over and think afresh. We are left with more issues than resolutions, more questions than answers. However, such sharing facilitates the debate on issues of concern, keeps the researchers informed about what kind of attempts are being made, and above

all it makes one's research transparent and open to peers for constructive critique.

It is necessary that we debate and discuss with those outside the research team the dilemmas that we face and the resolutions thought out. The entire team, including the field-investigators needs to be educated and sensitised on the principles of ethical research. Efforts are required to ensure that the field investigators are trained to view field situations from the point of view of the respondents, and that regular dialogue and discussion takes place between the researchers/team leaders and the field investigators. In general, the challenge lies in sound operationalisation of the ethical principles or guidelines that we lay down. They need to be adapted to specific situations and areas of research. There perhaps lies a weak line between such an operationalisation and compromising on ethical principles under the pretext of difficulties in actual implementation. This raises additional issues. One such important issue is the extent to which one is allowed (takes liberty) to compromise ethical principles in a particular context while conducting research. This is not an easy question to answer. The high degree of subjectivity involved in it makes it more complex. And therefore it is all the more important to be self-critical and vigilant about the way we conduct research.

( The articulation of the ethical issues presented here is based on the discussion that took place during the tenure of the projects within the team and institution and with members of the consultative and ethics committee at various points of time. The rigour in those debates over various issues made it possible for me to put them on the paper. Manisha Gupte, the team leader of the community based project, played a key role in educating and sensitising us on these matters. She facilitated valuable discussions and provided the ethical perspective we needed to conduct the study. I would also like to acknowledge the contribution made by Hemlata Pisal during those discussions. I wish to thank Manisha for going over the present draft and for her valuable feedback. Mahuri Sumant, my colleague on the facility-based study, also went over the draft and added her valuable insights based on her field experience. I must add that although I am greatly benefited from all those mentioned above, the errors and omissions in this communication are my own.)

**VIII**

**Publishing Findings of Research**





# 13

## **Ethical responsibility in academic publishing**

### **Role of editors, journalists and peer reviewers**

#### **Padma Prakash**

Ethical codes of conduct cannot be effectively implemented in isolation and may be enforced in several different ways. One is to conscientise members of the profession to observe the rules. Second way would be to effectively police the system, and a third to create links with associated disciplines or community of practitioners who together can form a network of conscience keepers. Journals and publications can play this supplementary role in ensuring adherence to codes of ethics.

It is hardly necessary to point to the crucial role that publications and journals play in disseminating products of research. In so far as the process of research today is increasingly enriched by, even dependent upon, the articulation of the findings of research and their communication to the rest of the academic community and to the people at large, there can be no research without its publication. Thus, journals are portals through which research activity and, one might say by extension, the research community finds a voice.

The primary and major responsibility for ensuring that ethical norms are followed in the social science research lies with the researcher(s). All others who are touched by the research and are involved with any stage of it - institutions, journals, peer reviewers, editors, popular media - may play only a supplementary role. Journals and their editors can be seen to be conscience keepers for ethical research. However, in so far as they are also members of the press, their conduct must adhere to the codes of conduct of their profession. Journals play an important role expanding and fine-tuning ethics in research and in journalism. Editors of academic journals are doubly accountable.

There are, however, severe limitations to this role. For instance, should editors be whistleblowers? Should journals become a clearing-house for ethical misdemeanours? Given that they are the portals through which all research must pass in order to be accredited and acknowledged, should journals attempt to locate, separate and make complaints about and keep track of unethical conduct?

Journals cannot take on the responsibility of policing social science research. Firstly, they neither direct nor administer research. They are players only at the last phase of research. Secondly, their project is different - it is not the creation of knowledge, but its dissemination. While the manner in which the knowledge accumulation takes place is of importance, the journal's concern is with its readers, its contributors and with the expansion of knowledge base in the discipline(s). Thirdly, material published in a journal has to satisfy many criteria and not just in matters of ethical conduct of research. However, insofar as they receive a wide range of research contributions, they may be able to keep a finger on the pulse of research and its conduct. Essentially, the role of academic journals is to nudge researchers and research institutions towards ethical conduct. But this role is entirely dependent on their interaction with and their significance for researchers and research establishment. A journal of repute may be better able to play to play this role than a new journal or that has not for one reason or other gained a large readership in the academic community. This may be facilitated by creating a consensus among research journals on such issues as ethics in research.

### **Some realities**

In India, journals that are not run by professional associations are few. The latter are bound by the codes of conduct of the association as much as by publishing ethics. To that extent it is easier for these journals to formulate norms and procedures that ensure that unethical social science research does not get published and disseminated. However, independent journals need to evolve codes, which draw from several disciplines. While these may not clash, the application of one set of 'dos and don'ts' may not be advisable for another. The criteria for selecting and accepting papers

are different for different journals. But in all circumstances the decision rests with the journal.

Not all journals are entirely peer-reviewed. This may be because journals may have on their core staff, professionals from various disciplines. Or it may be because the periodicity of these journals and the number of papers they receive is such as to make the peer review process for all papers impossible. It could also be because, they include sections devoted to current affairs, where peer review cannot be a norm.

It is important to acknowledge that most academic journals are short staffed! Like a teacher confronted with a pile of term papers, editors too resort to ways and means of making their work faster, and more interesting. One practice followed universally is that the inarguably better presented and very evidently, better-organised paper gets picked first, from the lot of papers received more or less at the same time. It is important to remember this, because editors/peer reviewers are not infallible, nor can they play god. However codified are the norms of ethics, there is room for slippage.

The time period between the receipt of a paper in a journal and its publication varies widely among journals and for disciplines depending on various factors including periodicity of the journal. It may be as little as two weeks or as long as a year. It is not widely known that the publication of an article is dependent on a number of factors: its topicality, its shelf life, length of the paper, subject of the paper, and so on. Several considerations also operate when processing a paper submitted for publication. How interesting is the topic of research? Is it of relevance - to the discipline, to society? What purpose is it supposed to serve? Is the construct of the hypothesis mischievous, deliberately biased? How good is the work being presented? Is it academically rigorous? Is it scholarly? Has there been adequate literature survey? Does it academically, reinvent the wheel? Ethical issues pop up within all these considerations. It has been said many times that bad research is also unethical. So a paper rejected for lacking rigour may well have not followed ethical practices. On the other hand all research that follows ethical norms may not necessarily be found acceptable by a journal for other reasons. However, the time between the submission of a paper and

its processing is determined by fewer factors and typically, an author gets to know the status of a paper in some months.

### **Ethical issues**

*Plagiarism:* The term originates from the Latin word 'kidnap'. In the broadest sense plagiarism deals with the lifting of text/data from a source without crediting the source. However, the issue of plagiarism abuts on issues of copyright. Codes of several professional bodies have very specifically dealt with plagiarism and have defined it in different ways.

A journal or a publishing house plays a crucial role in ensuring that authors do not get undeserved credit for work that is not their own. In due process, plagiarised text is not very difficult to identify. Normally in any journal or publishing house, the manuscript submitted for publication is read by a person who is in touch with the work in that field.

Even so, while plagiarised writing may be relatively easy to spot, it is far more difficult to spot plagiarism at the research end. Has the data been lifted from earlier documents? The Ethical Guidelines for Social Science Research in Health [NCESSRH 2000] addresses this fact:

Researchers should ensure that there is no fabrication, falsification, plagiarism or other unethical practices at any stage of the research; and that the findings of research are reported accurately and truthfully.... (III.2.6).

There are other questions - have arguments evolved and presented included in the text without acknowledgement? This sort of detail is far more difficult to spot. And with the rapid expansion of academic activity and the number of sub disciplines it has spawned, this could be a problem. One way to deal with it is to send the manuscript to more than one referee, so that the likelihood of plagiarised text coming to light is enhanced.

What is the responsibility of the journal and its editors once a case of plagiarism is spotted? Other than sending the paper back to the author, does the journal pursue the matter and make the information known generally? Does the journal inform the author of the reasons for rejecting the paper - that the journal has recorded

that material has been lifted from other source without acknowledgement? Does it inform the original author of the attempt to plagiarise if her address is available? In other words, apart from ensuring that plagiarised material does not appear in its pages, can the journal ensure that the paper does not appear anywhere? Should it take on this role at all?

For the present there is little the journal can do but inform the author of the paper the reasons for the rejection. But there is no supervisory body to which it can send a general alert. Nor do professional associations in India have a 'clearing house' or adjudication process for such issues. Nor is it possible to send information to the original author systematically or routinely. And then again, the journal has insufficient information to sit in judgement. For instance, it could possibly emerge that the first author had in fact lifted from the second paper, but due to a combination of circumstances, the first got published earlier. For this there has to be a process that compares the two papers and arrives at a decision. We do not as yet have such a process in place.

Sometimes though, especially in periodicals, which have sharp deadlines to keep, plagiarised papers do get into print. What happens then? Usually, such a paper is spotted within weeks of publication. And the journal may be informed of it either by the original author or by another reader. In such a case there would be copyright violation and the journal itself stands to be charged with it.

*Copyright:* The Indian Copyright Act was first promulgated in 1911 and subsequently amended in 1957 incorporating the requirements of the Berne Convention, which India signed in 1927. A separate treaty under UNESCO was signed by the US and the former Soviet Union in 1952, which granted protection of only 25 years in contrast to the Berne convention, which ensured lifetime protection to the author, plus 50 years. The Indian act ensures protection for lifetime and 60 years after. With the signing of TRIPS in 1994, these conventions became infructuous. Amendments in the act in India in 1992 have been made including the right to formation of societies for monitoring copyright violations. While plagiarism is not mentioned directly in the act, it is covered in section 13(3). The problem is the issue of plagiarism has not come up for open discussion in the Indian academic community. This

does not mean that plagiarism does not occur both in the mass media and in the academic media.

Today with the expansion of the media and seamless communication, it is far more difficult to monitor such offences as plagiarism. There is an urgent need for academic journals in India to get together on this and several other issues impinging on academic freedoms and un-freedoms.

*Simultaneous publication/submission for publication:* Several professional associations in the west have specific cautions against simultaneous submissions. The American Sociological Associations (ASA) Code of Ethics for instance is the clearest in this regard and stipulates:

16.01(b) In submitting a manuscript to a professional journal, book series or edited book, sociologists grant that publication first claim to publication except where explicit policies allow multiple submissions. Sociologists do not submit a manuscript to a second publication until after an official decision has been received from the first publication or until the manuscript is withdrawn.

In India, the notion has clearly not caught on. Sometimes, though rarely, authors submit papers for publication to two journals, without mentioning that information in either submission. This is a serious offence and must be considered to be so because it can lead to simultaneous publication of the paper leading to copyright infringement.

However, there is genuine confusion amongst academics on this matter. Is it incorrect to submit material for publication to two publications, one a condensed version and another the longer paper? Is it wrong to offer a paper to two publications one of which is a small circulation journal with possibly a specialist readership?

There can be few blanket rules here. Overall, simultaneous submissions are to be avoided. However, there could be an extraordinary reason why a paper or a part of it be submitted for publication to two journals. It could be because the publication of the full paper may take some time in an academic journal, while the content of the paper needs to be available for wider dissemination immediately, either through the mass media or

through specialist journals or as a pamphlet. In all these cases, the author should inform the editor of the circumstances and seek permission, which may be given at the discretion of the editors in the interest of wider dissemination. Ways and means may be sought to overcome copyright problems. But in any case it is the responsibility of the author to inform the editors of the act of simultaneous submission.

*Authorship and publication credit:* Currently while some journals prescribe the manner in which authors' names should be presented, there appears to be no norms for ensuring, at the time of publication, if indeed credit for work has been apportioned justly in the taxonomy of contributors in a particular article. The NCESSRH Guidelines (2000) sets out the issue in broad terms lays down elaborate guidelines for authorship (III.5.3).

However, presently, the Indian academic community appears unaware of these issues. Authorship norms vary among institutions. More often than not, authors are listed on the basis of seniority in the department rather than on the actual work done. Unless journals ask, as the Lancet does, for details of contributions of individuals, it is impossible to right a wrong in this matter. For example, it is well known and accepted that if a paper uses the work of a student, then the student should be the main author. This is not universally followed. Since this is easy enough to determine because of citations of the research work of the student, what should journal do in these instances? Currently in the absence of such codification in professional associations, journals have no grounds for suggesting a change in the order of authors' names, exposing a students research open to exploitation.

These above are patent and obvious problems for dealing, for which there is sufficient documentation and even codification. Just what procedure one adopts can only be left to the journal. There are, however, a number of other issues, which impinge on un-ethics, but may well get dealt with if the academic standards sought by the publication are stringent enough.

There are other issues with regard to indifferent research, which impinge on ethical practices.



## **Lack of rigour affects ethical conduct**

*Issues with regard to data:* The database in any dissertation, especially in one that is an empirical exercise, determines by and large the quality of the analysis.

Poor data may be a result of genuinely poor research expertise. But insofar as poor data carries with it the potential to give rise to misleading information and understanding, it must be regarded as a matter of ethical consideration. Editors/referees cannot ignore the following. For example :

- Random sampling, which is not in fact random, and is deliberately biased
- Either too many discrepancies within the body of data gathered, or too few, matching all the expectations of the study perfectly
- Use of old or obsolete data for comparisons, when later sets are available
- Inappropriate time frames for gathering data, e.g. data on illness episodes draw on only in one season used as universal data and overall conclusions drawn.

This is poor research, which is also unethical.

*Informed consent:* Often papers do not indicate whether or in what manner the population under study has been informed about the study. Nor if the researchers have ensured that people concerned do not have any objection. Presently, this is perfectly within the contours of a good paper, which does not necessarily state that each and every ethical norm has been observed. This being the case, while it is important to ensure that the work submitted for publication has abided by the norms of ethical research, it is difficult to be certain that it has. The best a journal can do is to look for associated indicators of good ethical practice (see below). However, papers do sometimes mention that the issue of obtaining consent from a population or group under study has not even been considered. Then it is useful in the interest of ethical research that the journal seeks information about it. Whether or not research that violates some norms of ethical practice should be accepted for publication on the strength of its research content, for the new understanding that it brings to bear on a certain area of study is an

issue that needs to be discussed within the community of academic journals.

*Checklist for editors/referees:* In considering a paper for publication, it is not always possible; as we have seen, to identify unethical practices, leave alone ensure that norms of ethics have been respected. While ethical guidelines may make the task easier, researchers are not bound to submit any assurance that the research has been conducted as per the norms of ethical practice. But it is often possible to look for indicators of good practice, and editors often do. For example, papers coming from certain institutions prompt a more positive reception than others, often perhaps because the institution has a reputation for undertaking good research (which refers to good quality as well as ethical research). If journals have a check list which covers some of the major considerations in ethical research, this may, over a period of time encourage research institutions to not only adopt ethical guidelines but also to codify norms and practices for the institution with regard to the conduct of research and its presentation. The checklist is however just that - it is not a decider. A first such checklist is given below:

- Has any attempt been made to disseminate the results of the study to the study population?
- Has care been taken to ensure harm<sup>1</sup> has not accrued to the population as a result of the research?
- Does the institution under which research has been conducted; has in place a research ethics committee of any kind? Is it operational?
- Are peer review processes in place in the institution? In particular, is publication submitted for publication subject to peer review?
- Has the paper taken adequate care to ensure that the participants in the study have not been identified by the use of markers or other means? <sup>2</sup>
- Have the people affected by the research understood and consented to the research? Or, does the institution have the practice of obtaining such consent for its research?
- Principle of exclusion: As a thumb rule which gives some indication, who has been excluded in the study? Which

population group has been deliberately included? Is there a reasonable explanation offered for this? <sup>3</sup>

- If the research is independently done, outside institutions and is privately funded, has the author offered information on ethical considerations followed? Or has the funding agency adopted codes of conduct for research?
- Language: Does the paper use abstruse and convoluted language or jargon when the same would have been conveyed in simpler language? <sup>4</sup>
- Are there too many gaps in referencing? Are the citations incomplete? <sup>5</sup>

### **Popular press**

The paper would be incomplete without some reference to the popular press. There is a wider gap between the popular press and the academic terrain, and presents far more issues, which need to be discussed in both communities of professionals.

Many of today's senior journalists in the press are academics who by their training and more often than not, their years of work, are as much members of academic community as they are professional journalists. This puts a double burden of responsibility on them. And there are manifest tensions between the immediate objectives of the academic community and the press. An accepted norm within natural science and technology disciplines is that 'discoveries' and research outcomes are not revealed to the 'general' public before they are presented to the relevant academic community either through papers presented at seminars or published in disciplinary journals. In the social sciences this distinction is not so clear. In fact on the face of it there seems to be very little room for observing such a practice.

However, it must be stressed that the publication of research outcomes of social science research, and especially in health and health care, which has not been subject to peer review or the scrutiny of the population under study can be harmful, misleading and may even be dangerous and certainly unethical. Journalists and editors working in the popular media have a special responsibility to ensure that there has been adequate opportunity for research results to have peer attention.

It needs to be widely emphasised, especially with the growth of social science research especially in health impinging on policy and affecting the lives of people, that research often needs wider dissemination even before they are published in academic journals. The NCESSRH guidelines put great weight by dissemination of research results to the affected or involved population (III. 4.4).

With the easy availability of international academic journals on the World Wide Web, there is an increasing tendency, especially in health and medicine, to cull information from published academic papers. It is best in fact to allow for discussion to develop within the academic community on particular papers before reporting the research in the popular press (unless of course if there has been a press conference and even then journalists should check if there has been adequate peer review). In the event of there being an urgency to report the research, then it is imperative that the journalist should conduct an independent 'peer review' of sorts eliciting the opinion of other academics in the field. Today with modern means of communication, this is not at all difficult.

Similar cautions should be exercised in writing up interviews. Crosschecking facts/data with the interviewee is necessary in all disciplines not only in the natural sciences and technology.

In India there are associations of journalists specialising in science or in environmental issues. But they have done little towards the clarification of some of the issues mentioned above.

### **Role of editors in cyberspace**

The vast communication media opening up through the Internet is completely uncharted, with few signposts. There is very little in the form of legislation and copyright laws are being tested severely. In social sciences there at least three academic social science journals which are entirely on the Internet. While they have processing norms for papers, giving that the medium allows for a more rapid turnover and response rate, it gives rise to a number of problems in publishing. These are only now being even defined.

Moreover, there is little clarity on the norms for individual researchers to 'publish' papers, articles and even books on the Internet on their personal web pages. Who governs this kind of publishing? How does the process of peer review apply here? Is

this sort of publication itself in a manner of speaking, an opportunity for peer review? How do copyright laws apply? We need to recognise the fact that all this may make it more difficult to apply copyright laws. And while copyright laws are being evolved and codification is under way, it will take a while for norms and conventions to develop.

### **What needs to be done?**

Evidently, there is an urgent need to formulate code/s of ethics for academic publishing. A first step is in fact to build a consensus for evolving such a code. The code of ethics, however rudimentary, evolved by the various press associations could be a starting point and may in fact play a lateral role in reviving interest in strengthening a code of conduct for journalists as well.

An attempt must be made to create a space for communication among academic journals and their editors. So far academic journalism in India has been at a rudimentary level. Indian social science journals do not as a rule attract serious academic attention abroad for many reasons. One of these reasons is the uneven quality of academic presentations in these journals. If good, ethical and effective social sciences as academic disciplines are to grow, then social science journals need to review their performance. With increasing research output within India and on India and South Asia, there is a potential for specialist academic journals to expand their publications and encouraging ethical research. Without a forum such as this, it would be very difficult to emphasise and encourage rigour in academic research.

Moreover, it must be kept in mind that in India there is a tradition of remarkable academic research in social sciences being undertaken by groups and bodies and individuals who have no affiliation to large academic bodies and who may be part of activist and political groups. While such research has played an important role in the continued vitality of the social sciences, there has been much discussion about its academic rigour and such issues as bias. This is a significant tradition, which often challenges dogmas and dominant paradigms within academic circles. If academic journals are to allow space for these while at the same time not fall into the

trap of publishing 'biased' research or studies without adequate rigour, then we need to have a forum for discussing such issues and arriving at broad guidelines.

It should be apparent that codes, guidelines and norms do not in isolation make for good, ethical research. To quote the Tri-Council Code (1997)

Good ethical reasoning, like good reasoning in research, must be more than a matter of mechanical and dogmatic application of rigid rule to fact situations. Ethical reasoning requires thought, insight and sensitivity. As in research peer judgement is important. In the case of ethics, peers include more than fellow research participants. Ethics peers include the larger intellectual community and society at large, including research participants.

Editors comprise this larger intellectual community and should play their role responsibly.

### **Notes**

1. There are many definitions of 'harm' in the different codes. Essentially, as far as journals are concerned they need to ask if any immediate and visible harm done because of the study.
2. The Code of Ethical Conduct for Research Involving Humans (Code formulated by the Tri-Council Working Group) in Canada for instance specifies: "Researchers should not publish any part of their research that could lead to inadvertent identification of individuals." Other codes also specify such practices.
3. The Tri-Council Code suggests that "women should be represented in proportion to their presence in the population affected by the research" which rule may apply to other groups and communities within the study population.
4. Language is used sometimes to cover up indifferent research and lack of rigour and is a good rule of thumb, though it cannot be a decider. Also since the business of a journal is dissemination, there is reason to be sensitive to convoluted language.
5. Incomplete referencing should prompt a doubt in the editor's/referee's mind that the author may not know the work cited very well. This also applies to text that is incomplete or in obvious ways misquoted.



**IX**

**Ethics Review in  
Social Science Research in Health**





## **Institutional ethics committees**

Experience of CEHAT, 2001-02

**Neha Madhiwalla, Anil Pilgaonkar,  
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Sporadically the issue of importance of ethics in professional practices comes into focus only and more often than not, after a catastrophe. The Nuremberg Trial revealed the atrocities committed by doctors, and from that emerged the Nuremberg Code (Nuremberg Military Tribunal, 1949). Since then, various medical research codes point out that there is a recurring need to sharpen understanding and update codes in order to make medical research humane and meaningful and most importantly fair and dignified. There was a considerable time lag between realising that a catastrophe has taken place and the actual events because basic norms related transparency in professional practices were blatantly violated, because of several external factors as well as malafide intentions of the researchers.

Unfortunately, one gets a feeling that in India there is general perception among social scientists that ethical scrutiny is important to the practices in medicine and that research in the field of social sciences need not be burdened with requirement of ethical scrutiny because it does not involve any direct intervention on individuals and does not apparently have any serious effects on them. This could have dangerous repercussions particularly because the latency period between the cause and effect is far greater, since it potentially leads to social scientists and society to often become oblivious of consequences. If we mean to learn lessons from past catastrophes it is important to ensure that events leading to catastrophes are nipped in the bud, be it any kind of research (medical or social science).

Since its very inception in 1994, CEHAT has earnestly worked to generate a rigorous and sustained debate for evolving standards of practice of ethics in research work. CEHAT has, as we see it, believed in sharing its work with larger audiences for critical

feedback because it believes there can be no room for complacency ever. Taking a cue from this we, as participating panellists, in (or members of) the Institutional Ethics Committee (IEC) of CEHAT, have taken this opportunity to expand the debate in the public sphere. It is important to note that while the text portrays our understanding and views on the subject, it has not gone through the intense scrutiny of the entire IEC. Hence it must be read in that light. The report of the first year of the IEC has been published and gives a detailed account of its functioning, problems and an evaluation of its work [IEC 2002].

An institutional mechanism to consolidate ethical conduct in research is a necessity for several reasons. For one, it signifies the formal commitment of an organisation to adhere to an ethical code or guidelines and to subject itself to external review through a structured and institutionalised procedure. Secondly, a review process that is regular and systematic helps to make ethics visible to all those who work in the organisation, it encourages and impels them to understand its concepts and, over time, ensures that the observance of basic norms of ethical conduct of research become universal and automatic in the functioning of the organisation. However, the process of establishing an Institution Ethics Committee requires considerable planning, reflection and effort. IEC of CEHAT is one of the first attempts by an independent non-governmental organisation, engaging in social science research to establish a structure and standard procedure for ethical review of research projects.

### **What triggered the constitution of IEC?**

CEHAT undertook the task of co-ordinating an initiative to develop ethical guidelines for social science research. For this purpose a National Committee for Ethics in Social Science Research in Health [NCESSRH 2000] comprising of individuals from different social science disciplines working in different settings such as universities, NGOs, academic journalism and government institutions, was constituted. These guidelines were shared in different institutions through meetings and workshops. The feedback received was incorporated, leading to the finalisation of the guidelines. One aspect on which there was inadequate discussion

was the institutional mechanism for implementing the guidelines. CEHAT took it upon itself the task of constituting institutional ethics review mechanisms. Towards this end, the institutional ethics committee was constituted for the first time in 2001. The first meeting of the IEC was held on February 7, 2001.

### **Preparatory time and process involved**

There being a lack of trained ethicists in India, CEHAT had to think of alternative ways of constituting an IEC. It was assumed that the IEC should represent the interests of all the different players involved in research. While the primary objective would be safeguarding rights of participants, the IEC would also play a role in fostering an ethical environment within the organisation. Ethical practice needs to become integral to the organisation's functioning. Thus, the criteria for the composition of the IEC were that: it would be autonomous, multi-disciplinary and representative of society, enabling a more comprehensive ethics review. The present committee therefore, has members with backgrounds in philosophy (the foundation discipline for ethics), medical ethics, psychiatric ethics, health, human rights and law. There was also one member who, though she has a fair understanding of research, can represent the view of the participants as a laywoman. Thus, constituting the IEC was a dynamic process of identifying relevant disciplines and people with experience in research or in the practice of ethics.

The multi-disciplinary composition was consciously decided keeping in mind the role that the IEC was expected to perform in CEHAT. Usually, an Institutional Review Board (IRB) essentially exposes itself to research projects in 'pulses' [i.e. periodically]. Changes then are readily seen - than if continuous contact is maintained with research projects. On the other hand, an ethics committee is required to concern itself with *practice* and must be 'there -ready at hand' for consultations, ethical conflict solving and arbitration. CEHAT's requirements included elements of both an ethics committee, as also IRB, hence having both internal and external members was necessary. Internal members (staff) have very important role to play in (a) pre-empting actions and designs in research projects and other programmes that could later prove to be problematic in terms of ethics, and (b) in nurturing an enabling

climate within the CEHAT to foster a positive attitude for ethics as an integral part of any activity. Hence, it was decided to establish an institutional ethics committee, rather than merely a review board.

A total strength of eight members was decided upon keeping in mind the multi-disciplinarity of the exercise. Of these, three would be internal members, in order to function as a bridge between the external members and CEHAT. Five are external members. Two of the internal members run the IEC Secretariat.

*a. Tenure:* The tenure of the IEC is of two years. After discussion it was felt that there should be an overlap in the tenure of the successive IECs to provide continuity. Hence, it was decided that some external members from the first IEC would remain in the successive IEC.

*b. Schedule:* Looking to the requirements of the urgency of the projects on the one side, these IEC members can at the maximum commit to 24 days of meetings in two years (an average of 1 day a month). It must be borne in mind that an equivalent number of days these members spend towards preparatory work for meetings. Of the 24 days, one day every six months is devoted exclusively to self-review and self-evaluation exercise done by IEC. All meetings are scheduled by mutual agreement within members of the IEC by the Secretariat.

*c. Overlap with other structures of CEHAT:* In CEHAT, there are several bodies that are responsible for addressing different aspects of the functions of the organisation. These include a Working Group (WG), which is an elected body consisting of staff members and the co-ordinator, and is responsible for all executive functions in the organisation (including monitoring of projects, approving new projects/budgets, recruitment, evaluation and promotion of staff members). Personnel related matters and interpersonal problems (including cases of sexual harassment) are referred to a grievance redress panel, which is a body appointed by the working group, also consisting of staff members. Methodology and content related issues are reviewed by a scientific review committee, which is made up of all the senior researchers in the organisation (seniority being determined by designation).

IEC performs its role within this larger framework. In order not to violate the dignity and integrity of these bodies, IEC has

consciously stated that it will not take up issues (which have a bearing on ethics) that lie within the purview of these committees. However, if these bodies or the organisation refers these matters to the IEC, the IEC will then address the issue and respond appropriately.

*d. Roles, Responsibilities and rights of IEC:* In view of the above background The IEC has the following responsibilities:

*Review:* The IEC reviews research projects at various stages viz. (a) before submission to Funding Agency, (b) after PRC (peer review committee) evaluations and before starting the project, (c) midway through the progress and (c) at the end but before publication. All research projects must be presented for ethical clearance at the appropriate stages. Research initiatives emerging in action projects due to the requirements of the field situation may be reviewed at the earliest feasible time.

The IEC certifies research at the above stages. It has recommendatory powers and suggests modifications and advice as and when necessary.

Apart from research projects, CEHAT undertakes a number of projects, which are based on advocacy, training and intervention. There was considerable discussion about ethical review of such projects. It was felt that there is a large amount of unpredictability in these projects, unlike research, where the research agency has relatively more control. Moreover, there were no guidelines, which could be used as a framework to review this work. The IEC felt the certification of such projects would be difficult because of the nature of the work itself, which was changeable and required prompt decision-making. Hence, it was decided that the IEC would review the work of action projects, offer advice, document the process of ethical review, but will not certify such work.

*Report:* IEC submits its report on matters placed before it to CEHAT *after* the end of every year. It makes its report to the people and CEHAT is obliged to make sets of these available to pertinent requests from people.

*Rights of IEC in order to maintain its autonomy:* Although the recommendation of the IEC are not binding, the IEC is entitled to an explanation if its recommendations are not fully implemented or if they are partially or fully rejected by the project team or

CEHAT; and can use its discretion to bring this debate in the public domain. IEC members have access to all the relevant material/documents about the project (CEHAT has responsibility to provide the requested material to the IEC).

IEC has the right to appoint a sub-committee of the members from within IEC to review a particular project, depending upon nature and scale of the project. IEC has the right to select and invite experts whenever needed for the work of IEC. For this, CEHAT will meet the necessary infrastructure, logistics and payments (if called for). IEC has right to seek explanations and clarifications that are needed from time to time for the purpose of its work from researchers / institution.

IEC has the right to decide which debates and deliberations to reveal to the larger public. It would use its own discretion about making information and discourses available for public use. The IEC has the right to call for a consultation with the larger body of staff within CEHAT. The IEC members should be invited for the public peer workshops organised by CEHAT to report on the work, which has been reviewed by the IEC.

*e. Review of research projects:* Prior to the establishment of the IEC, each project within CEHAT involving fieldwork had a project ethics committee. In some cases, the expert consultants committee doubled up as the ethics committee. Largely, the initiative for discussion of ethical issues was dependent on the team. However, as a norm, ethical issues arising in the project were discussed and reported in the research report. The IEC represented a move forward in three ways. Firstly, the same committee deliberated on ethical issues in *all* projects, with a view to increasing uniformity in assessment and consistency. Secondly, this IEC used the guidelines developed by the NCESSRH, which signalled the continuation of the exercise of the national committee. Thirdly, the review process was made more structured with the establishment of rules about phases of review, process of review and a structured standardised format for giving information about the projects to the IEC. This made the process of ethical review more systematic and rigorous.

At the point of the IEC's formation, there were several projects at different points of completion. It was consciously decided to

refrain from certifying such ongoing projects and only new projects were accepted for the review and certification.

*f. Review of action projects (projects involving service delivery, training and advocacy):* As noted earlier, certification is limited to research projects alone because by definition research is elective completely planned. Hence, there is scope for incorporating suggestions and recommendations made by the IEC. Action projects, on the other hand, by their nature, respond to external circumstances beyond the control of the institution. Thus, in this situation, the IEC's role is limited to being sounding board on pitfalls and possible strategies. A checklist for action projects was one of the outcomes of the above discussion.

### **Nurturing ethics within organisation**

*On the job training:* Recognising that none of them were formally trained ethicists, the members of the IEC felt that it was necessary to train themselves on the job. A conscious decision was taken to use the meetings for extensive debates, in addition to the review of projects. At least two meetings in the year were specifically devoted to the review of the work output and discussion on issues concerning the organisational aspects of the IEC. Detailed documentation of all the relevant debates was done. This served two purposes : Firstly, it served as a basis for exploring areas needing improvement within the IEC's functioning. Secondly, it also serves as a material basis for subsequent IECs to build on - providing information on precedents, positions taken by the IEC on different issues and the rationale for the decisions taken.

After a year of its work, IEC took on the task of self-evaluation of the work output. The evaluation was done on four parameters : (1) Overall functioning of the IEC; (2) effective and optimal utilisation of resources made available; (3) impact of IEC on the staff, and (4) quality of review. The evaluation also included feedback from the teams who had interacted with the IEC.

*Facilitating education of staff on pertinent issues related to ethics:* The process of review consciously included discussions with the researchers representing project/proposal on larger ethical issues relevant to the project. In addition to the mandatory review process, the IEC interacted with teams when requested to share the



team experiences and highlighting the ethical content in the project. At the end of one year, it was felt necessary to conduct a formal orientation workshop on ethics for the entire staff. This was organised by the IEC in July 2002.

In addition to this general training, the IEC has conducted orientation workshops prior to fieldwork and debriefing sessions following field work with individual teams. The emphasis in these meetings is more akin to the role of the conventional ethics committee, which is to find a resolution to specific ethical problems and discuss ethical dilemmas specific to that project.

*Integrating ethics Social Science Research:* It is hoped that the IEC of CEHAT will provide a prototype for other organisations, which decide to establish an IEC. Towards this end, the IEC has decided to document its own experiences, attempt some amount of formulation of specific rules on basis of the guidelines and publish its report in the public domain in various forms. While ensuring that the confidentiality of participants and research teams is not violated, the IEC would like to share its experience, including the problems encountered with others. While one year is too short a period to complete the task of transforming the broad guidelines into rules, the work of successive IECs, hopefully of IECs of several organisations, will generate enough evidence and experience for such an exercise. In order to maintain confidentiality, in the report to the people, the names of individuals are not used. However, even the guidelines themselves are not eternal and may be subject to review based on experiences.

## **Learning from experience**

The experience of the institutional ethics committee has been largely positive in CEHAT; certain issues emerged during discussion and during the functioning of the IEC.

*(1) Appointment, autonomy and continuity of IEC:* There was considerable discussion on the mode of selection and appointment for the IEC. In this case, the organisation's main executive body (Working Group) proactively constituted an IEC with the knowledge of its parent body, i.e. the governing board, Anusandhan Trust. However, the Working Group members are themselves subject to the scrutiny of the IEC (as members of individual project

teams). This led to a paradox. Should those who are part of the review process have the prerogative to appoint the IEC? What implication does this have for the autonomy of the IEC? Although there was no disagreement over the composition of the IEC between the working group and the governing board, it was decided that the governing board formally appoint the IEC. This was decided as good practice because it ensured that the IEC was completely autonomous of the internal structures of the organisation. Thus, the IEC also by implication is answerable directly to the governing board, ensuring that there is no interdependence between the working group and the IEC.

During general discussions, another allied but important issue that emerged was that of financing the IEC. It was strongly felt that the expenses of running the IEC should be met directly by the institution and not be dependent on short term or ad hoc funding (i.e. project funds). This would ensure that the IEC continues to function consistently and does not owe its existence to any particular team or project or to the discretion of the executive body. This also implies that the IEC's existence will not be linked to the tenure or financial condition of projects, but that it will be sustained throughout the existence of the institution.

Another unresolved issue was that of avoiding conflict of interest. It is technically possible (in fact, quite probable) that the organisation may want to utilize the services of an individual serving on the IEC as a consultant or for a particular assignment. Should it be allowed? If yes, will it affect the judgment of the person when reviewing the project with which s/he is concerned in the IEC? Quite apart from direct involvement, certain issues and subject may be of interest to the IEC member due to his/her professional work. For e.g. the study under review may be exploring an area in which the IEC member is himself/herself active and involved. These issues are difficult to resolve because there may not always be malafide intentions behind individual actions or any direct or material gain to the IEC member.

The most important safeguard for preserving the independence of the IEC is transparency. It was felt that transparency was important to ensure that there are checks and balances maintained. Hence, ensuring that the work and the performance of the IEC are

accessible to the public and open to scrutiny is important. This creates a system of checks and balances, while the IEC should be as autonomous as possible from the organisation, it should be equally accountable to the larger society. This is possible when the IEC puts as much as possible (within the limits of respecting confidentiality of persons and institutions) for public review through its reports and writings.

(2) *Is an IEC an improvement over ad hoc, temporary project based ethics committees?* As stated earlier, in the earlier phase of CEHAT, each research project appointed an ethics committee in addition to a committee of subject experts (consultants). This procedure was followed by for two large projects between 1995 and 1998. Later, an ad hoc decision was taken to merge the two committees namely to request the experts' committee to also look at ethical issues in the project.

There were several problems encountered in both cases. Firstly, having a separate ethics committee for each project led to large amounts of paperwork for the organisation. Also, a single project generated only limited issues and discussion. Thus, there was no system in place for either the committee or researchers to have streamlined ethics review process and the effectiveness of the ethics committee was entirely dependent on the initiative taken by the research team. There were no guidelines, or specified phases of review. Some did approach committees more frequently than others. In absence of any exposure and/or systematic understanding of ethical issues in research both for research teams and members of ethics committees it was hard to maintain the rigour of ethics review process. After combining the experts committee with the ethics committee, the review process became fairly regular. However, the priority was always on the scientific aspects and ethical issues were rarely centre-staged. Setting up of ethics review committees for individual projects has become fairly common in many organisations not having an IEC because of the requirements of certain funding agencies. The experience of CEHAT is important in understanding limitations of such practices. In the case of CEHAT, this experience created background for establishing the IEC.

The IEC was a substantial improvement over the ad hoc project based committees because it led to the standardisation of review

across projects. An institutional committee which reviews several projects, is able to generalise across projects and apply similar standards. For e.g. the manner in which informed consent is taken. The strategies adopted by one team become a precedent for the following teams. A single committee which meets at periodic intervals, is able to make more optimal use of the time available. Since the IEC reviews several projects within the same organisation, it is also able to observe, and to some extent direct, the internalisation of ethical practice. The IEC, because of its more consistent exposure to the organisation, also develops a better understanding of the context in which the organisation works. This, undoubtedly, also creates the possibility that the IEC begins to identify with the organisation and this may affect its objectivity. However, given that the IEC is reconstituted every two years reduces this risk to a great extent.

An important advantage of having an institutional ethics committee is that there is a standardisation of procedures and across projects. However, even with an institutional ethics committee, a lot depends on the team's initiative and ability to articulate ethical issues and bring them forward for discussion. Because the exposure of the ethics committee is limited to the time spent in the review, it is incumbent on the team to detail situations and problems that the team has observed and experienced. Having an institutional ethics committee is advantageous because it creates a safe forum to which researchers can bring their doubts and dilemmas. Thus, for teams to understand and for the IEC to mould the review process into a learning exercise is extremely important. Detailed documentation of the discussions and decisions, as well as the actual practice of ethics in the field is extremely important because it creates a body of literature, which the researchers can turn to for guidance.

Unlike other ethics review boards, the IEC meets with the team representatives at the time of review. This meeting serves the purpose of clarifying issues, ascertaining the views of the team as well as educating researchers about ethics. In the present situation, where ethics review are relatively new, researchers are often confused about the ethical issues in their projects and may not be able to articulate ethical dilemmas very clearly. Hence, the educative function of the IEC is very important. The researchers reportedly

found the face-to-face interview of the team representative (in some cases the entire team) with the IEC very beneficial.

(3) *Is the IEC responsible for scientific reviews:* A recurrent problem that crops up in ethics committees have to face research that is not sound methodologically and has been insufficiently peer-reviewed. Badly designed research, which is brought for ethical review poses several problems. The cardinal principle of research ethics is that bad science is *per se* unethical. Hence, it would be wrong for the IEC to ignore methodological problems in the study. However, this often would lead to an overlap with the peer review committee (PRC). As long as the IEC and the PRC concur and the PRC endorses the views of the IEC in retrospect, there are fewer problems, apart from the delay that may result. However, if they happen to disagree over a certain issue, whose judgment should be held paramount?

An allied but important issue is developing an effective mechanism for peer review in small organisations. Most often, faulty research designs are the result of the lack of expertise, rather than any malafide intention. However, a mechanism has to be developed to do rigorous scientific review of research. This could be achieved by inviting external consultants to be part of the peer review or by utilising the intellectual resources of a larger academic or research organisation. Ensuring that the capacity to design and conduct studies with sound methodology is important for many different reasons. Firstly, any research endeavour requires resources. These would be optimally utilised if the research effort results in the collection of relevant and valid information. Secondly, by building the research capacity of small organisations, one can create a counter-point to the mainstream research emerging from academic institutions and large organisations. However, to create a peer review mechanism in small organisations could prove difficult, given the paucity of professionally trained staff. But such an effort should be undertaken seriously for both ethical as well professional reasons.

Another problem that often confronts IECs and organisations is the ethical review of student research and assignments. Very often, students from various disciplines ranging from medicine, to administration, to social work and law are placed for internship

with voluntary organisations for periods ranging from one to three months. Very often, organisations find it useful to utilise this human-power to conduct studies, which they may feel may be useful for their work. Since they come for very short periods of time, and are not part of the regular staff, often their work may escape notice. However, it would be worth considering whether even student research should be reviewed by the IEC.

After considerable deliberation, the IEC opined that all student research should be reviewed. Since students are at the beginning of their career, it is extremely necessary to expose them to the concept of research ethics and put them through the experience of ethical review. Also, as students who have even less exposure to research than older trained professionals, they need even more guidance to ensure that their actions protect the confidentiality of the participants and that they seek genuine informed consent. Also, it is important to remember that the ethical risks do not depend on the scale of the study, but rather its subject matter, methodology and field situations. Hence, to argue that since research by students is usually short-term, small scale and sporadic, it should be left out of the purview of the IEC would be wrong.

*(4) Does the institution of the IEC make the practice of ethics mechanical?* One of the questions that the IEC gave serious thought to was the danger of ethics becoming ghettoised in the IEC. Prior to the institution of the IEC, the teams were largely dependent on their initiative for raising and resolving ethical dilemmas. One of the primary aims of institutionalising an ethics committee is to make ethical practice automatic. This would be enabled with the training of researchers, continuous debate in the organisation on ethical issues and constant perspective building. It is hoped that the presence of an institutional ethics committee would provide a catalyst for this process. However, the opposite could also happen. That is, ethics review because it is mandatory, will become another bureaucratic hurdle to be overcome.

This possibility is increased if simultaneously with the review process training of the staff is not undertaken. An overall environment has to be created for nurturing ethical practice. Thus, it is important that the staff does not receive conflicting signals from the different structures of the organisation. For example senior

staff should constantly emphasise the importance of ethics, otherwise the general impression would be to look for strategies of satisfying the IEC, rather than engaging in a frank and open discussion.

It is also important for other structures in the organisations to complement the role of the IEC. In fact, the functioning of the IEC would be optimised if ethical problems were pre-empted and resolved even before the project came up for review before the IEC. This is possible during the peer review process or even by ensuring that the internal members are actively consulted during the process of developing the methodology. When ethics becomes part of the general intellectual discussion in the organisation, the staff will be able to articulate ethical problems clearly as also find resolutions for the problems posed.

It is extremely important to ensure that having constituted an IEC the organisation renews the consensus in the organisation. As new staff are bound to join in and older ones leave, rebuilding the understanding of ethics and the need for ethical review should be constantly undertaken. This should ideally be done, not merely by the internal members, but by all the core staff in the organisation. Similarly, it is important for the professional development of the researchers, that they read and increase their own grasp of ethics, rather than pay attention to ethics only at the time of the review. Ghettoisation of ethics within the IEC would be dangerous because it could lead to research teams claiming credibility on the basis of the review process, without applying their minds to internalising ethical practice.

(5) *How to make the IEC work:* An important issue relates to the selection of members for the institutional ethics committee. As ethics as an academic discipline does not exist in India, there are few trained ethicists in the country. Thus, the choice of members is made largely based on their reputation as professionals then conduct as professionals and their willingness to train themselves as ethics committee members. There is inevitably a degree of subjectivity about the manner in which ethics committee members are selected, with the organisation seeking those whose ideological positions largely conform with those of its own. Also, an organisation would try hard to ensure that there is compatibility among the members

of the IEC itself to ensure smooth functioning. In such a situation, it is important for IEC members consciously assume different roles and hold different positions to encourage debate and reflection. Nonetheless it is important to ensure that there is some synergy in the IEC to ensure its efficiency.

The experience of the IEC has been that despite varied viewpoints and marked differences in approaches, if the extent of involvement of its members in the work is high, there is much debate, but consensus building is also facilitated. The IEC quite consciously and repeatedly brought itself back to the task of reviewing the research and ensuring that an objective and fair decision was taken, despite differences of opinion within the IEC. Rarely was any issue decided by vote rather than consensus. This is not to suggest that the IEC was casual about its work, but rather that the IEC members kept in mind that the first priority was to arrive at a judgment that assists the research endeavour to move forward.

Another vital issue is about creating and sustaining an effective IEC. Since IEC is comprised largely of outsiders, commitment of time by the IEC members is of vital importance. The review process can be seriously hampered by the absenteeism of IEC members or their inability to devote enough time to scrutinising the material sent to them. Insufficient preparation for the meeting could result in waste of time as well as oversights. Since, IEC members are likely to be busy professionals and academics, co-ordinating the meeting of the IEC is not an easy task. However, this problem can be largely resolved by pre-deciding the dates of the review meetings and ensuring that all members attend the meetings regularly.

Maintaining an objective distance from the organisation's predicaments becomes vital. One of issues that the IEC pondered on related to the fact that most of the members had consented to be on the IEC out of solidarity with the organisation and its mission, rather than any monetary or career-growth considerations. One of the primary decisions taken by the IEC was that they would play a facilitative role rather than a supervisory role. Hence, the review of projects itself was lengthy (a discussion of two to three hours each) and there was an extensive exchange of ideas and suggestions. The IEC went out of its way to suggest strategies and changes on



to the teams. A question arises whether this process of facilitating research could lead to undue compromises. Equally, certain practical difficulties of the organisation – e.g. related to lack of personnel or resources or time, could enter into the judgement of the IEC leading to a dilution of standards.

Finally, the most important component of making an IEC work is the commitment of the organisation to ethics. This commitment is important in both letter and spirit. The ideal situation would be to make the ethical clearance statutory with the organisation voluntarily agreeing to suspend research studies, which are not cleared. This gives the IEC a secure position within the organisational structure. However, it also implies that the judgement of the IEC can have serious impact on the fate of research, researchers and teams, and hence the level of responsibility expected from them would be greatly enhanced. On the part of the organisation, it will become incumbent to ensure that the independence of the IEC is protected. The governing board, which institutes the IEC, must vigilantly monitor its function to ensure that it remains unbiased and that hierarchies within the organisation do not permit any team to evade review or subvert the review process.

Simultaneously, it is important that the researchers become aware of and actually experience the advantage of ethical review. This is possible only when there is a high degree of internalisation of ethics within the organisation. This requires constant effort and reflection on the role of ethics within professional practice. The response of researchers to the ethics committee is unlikely to be very positive in the initial stages when researchers find that their proposals are being rejected or that the committee is asking them difficult questions for which they are not prepared. This is an inevitable phase till the organisation becomes habituated to the procedure of review. As researchers begin to reflect more on the ethical issues in their work and learn to articulate ethical issues, rather than evade them, the interaction with the IEC becomes more productive and less frustrating. Gradually there should be a voluntary effort to seek review with the understanding that this enhances the quality of their work, rather than simply an effort to stay within the rules of the organisation.

In conclusion, institutionalising ethics within any organisation requires at various times, the use of regulations and authority as well as constructive dialogue and consistent education of the staff. Without complementing one with the other, the internalisation of ethics is difficult because neither pure coercion nor pure voluntarism is practicable. Ethical review can become a very rewarding process for researchers, enabling them to reflect on their role as social players and the consequences of their work. It can provide a starting point for developing sensitivity and perspective in the organisation's staff, which can only enrich their work.



**X**

## **References**



# References

- Ahmed M, "Smithkline-Beecham mulls clinical data management centre", *Business Standard*, Calcutta, February 24, 1998.
- AIDS Treatment News*, June 18, Issue 321, 1999.
- Alberti KGM, "Local research ethics committees", *British Medical Journal*, 311, pp: 639-41, 1995.
- Altman D, "Misuse of statistics is unethical", *Statistics in Practice*, London: BMJ Publications, 1982.
- Altman D, "The scandal of poor medical research", *British Medical Journal*, 308, pp: 283-84, 1994.
- American Anthropological Association, *Statements on Ethics*, 1986.
- American College of Epidemiology (ACE), "American College of Epidemiology Ethics Guidelines", *Ann Epidemiol*, 10, pp: 487-97, 2000.
- American Political Science Association, *A Guide to Professional Ethics in Political Science*, 1998.
- American Psychiatric Association (APA), "Guidelines for Assessing the Decision making Capacities of Potential Research Subjects with Cognitive Impairments," *American Journal of Psychiatry*, 155, pp: 1649-50, 1998.
- American Psychological Association, *Ethical Principles of Psychologists And Code Of Conduct*, 1992.
- American Sociological Association, *ASA Code of Ethics*, Approved by ASA Membership in Spring 1997.
- Angell M, "The ethics of clinical research in the Third World", *The New England Journal of Medicine*, 337, pp: 847-49, 1997.
- Angell M, "Investigators' responsibilities for human subjects in developing countries", *New England Journal of Medicine*, 342, pp: 967-68, 2000a.
- Angell M, "Is academic medicine for sale?" *The New England Journal of Medicine*, 342, pp: 1516-18, 2000b.
- Antia NH, Bhatia K, *Introduction to People's Health in People's Hands: A Model for Panchayati Raj*, Pune: Foundation for Research in Community Health, 1993.
- Appelbaum PS, Grisso T, "Assessing Patients' Capacities to Consent to Treatment," *New England Journal of Medicine*, 319, pp: 1635-38, 1998.
- Arora M, Banerjee JK, Sahni P, Pande GK, Nundy S, "Which are the best undergraduate medical colleges in India", *The New England Journal of Medicine*, 9, pp: 135-140, 1996.
- Arunachalam S, "How relevant is medical research done in India? A study based on Medline", *Current Science*, June 72 (12), pp: 912-922, 1997
- Arunachalam S, "Does India perform medical research in areas where it is most needed?" *National Medical Journal of India*, 11 (1), pp: 27-34, 1998.
- Bagla P, "India Creates Novel Brain Research Centre", *Science*, October 1; 286, pp: 25b-27b, 1999.

- Bagla P, "India acts on flawed cancer drug trials", *Science*, 293, pp: 2371-73, 2001.
- Balakrishnan R., "State Sponsored Health Care in Rural Uttar Pradesh: Grass Root Encounters of a Survey Researcher", *Sociological Bulletin*, 45(1), March 1993, pp 87 - 96.
- Banerji D, *Health and Family Planning Services in India - An Epidemiological, Socio-cultural and Political Analysis and a Perspective*, New Delhi: Lok Paksh, 1985.
- Banerji D, "A Fundamental Shift in the Approach to International Health" by WHO, UNICEF, and the World Bank - Instances of the Practice of "Intellectual Fascism" and Totalitarianism in Some Asian Countries, *International Journal of Health Services*, 29(2), pp.227-259, 1999.
- Barnes JA, *The Ethics of Inquiry in Social Sciences: Three Lectures*, New Delhi: Oxford University Press, 1977.
- Basu DP, "Appropriate Methodologies for Studying Sexual Behaviour in India", *Indian Journal of Social Work*, LV (4), pp: 573-588, October 1994.
- Bauxamana R, "The price of assistance: the family planning programme in India", *Socialist Health Review*, March; 1(4), pp: 148-159, 1985.
- Beecher HK, "Ethics and Clinical Research", *New England Journal of Medicine* 274, pp. 1354-60, 1966.
- Benatar SR, Singer PA, "A new look at international research ethics", *British Medical Journal*, 321, pp: 824-26, 2000.
- Bharat Seva Samaj, *Slums of Old Delhi, Report of the Socio-Economic Survey of the Slum Dwellers of Old Delhi City*, 1958.
- Bhattacharya S, Senapati S, "Sexual Practices of the sex Workers in a Red Light Area of Calcutta", *Indian Journal of Social Work*, vol. LV, No. 4, 1994
- Bhatnagar OP, *Research Methods and Measurements in Behavioral Sciences*, Agrical, New Delhi, pp 547-556, 1981.
- Blumenthal D, Campbell EG, Anderson MS, Causino N, Louis KS, "Withholding research results in academic life science: evidence from a national survey of faculty", *The Journal of American Medical Association*, 277, pp: 1224-28, 1997.
- Bodenheimer T, "Uneasy alliance: clinical investigators and the pharmaceutical industry", *The New England Journal of Medicine*, 342, pp: 1539-44, 2000.
- Bose A, *Population of India: 1991 Census Results and Methodology*, Delhi: B. R. Publication Corporation, 1991.
- Bose PK, "Research Methodology - A Trend Report", *Research in Sociology and Social Anthropology - Monograph 4*, New Delhi: ICSSR, 1995.
- British Medical Journal, "Journals fail to adhere to guidelines on conflicts of interest", *British Medical Journal*, 323, p: 651, 2001.
- Cassell Joan, Wax Murray L, "Editorial Introduction: Toward a moral science of human beings", *Social Problems* 27 (3), 1980.
- Cassell Joan, "Does risk-benefit analysis apply to the moral evaluation of social research". In Beuachamp, T., Fadesn R.R., Wallace, J., and Wallers, L., (Ed.) *Ethical Issues in Social Research*, Baltimore: Johns Hopkins University Press, 1982.

- Castro R, "The Subjective Experience of Health and Illness in Ocuiahuco - A Case Study", *Social Science and Medicine*, 41(7), 1995.
- Chalmers I, "Underreporting research is scientific misconduct", *The Journal of American Medical Association*; 263, pp: 1405-8, 1990.
- Chandiramani R, "Rights and Ethics in Interventions, Experiences and Research in the Field of Sexuality", Paper presented at the International Seminar on *Advances in Reproductive Health and Sexuality*, Mexico City, 1996.
- Chandiramani R, "Talking About Sex", *Reproductive Health Matters*, 12 (6), pp: 76-86, 1998.
- Chinai R, "Preventing HIV transmission", *The Times of India*, Mumbai, November 9 and 10, 1998.
- Chowdhury J, "Lab tests new drugs on human volunteers", *The Times of India*, Mumbai, October 10, 1995.
- Christakis NA, "Ethics are local: Engaging cross-cultural variation in the ethics for clinical research", *Social Science Medicine*; 35 (9), pp: 1079-1091, 1992.
- Commission to Review the American Anthropological Association Statements on Ethics, *Final Report*, 1995.
- Connor EM, Sperling RS, Gelber R, Kiselev P, Scott G, O'Sullivan et al, "Reduction of maternal-infant transmission of Human Immunodeficiency Virus type 1 with Zidovudine treatment", *The New England Journal of Medicine*, 331, 1173-80, 1994.
- Copans Jean, "Comments", *Current Anthropology* 40 (2), 1999.
- Coughlin SS, Beauchamp (Ed.), *Ethics and Epidemiology*, New York: Oxford University Press, 1996.
- Council for International Organisations of Medical Sciences (CIOMS), *International Guidelines for Ethical Review of Epidemiological Studies*, Geneva, CIOMS, 1991.
- Council for International Organisations of Medical Sciences (CIOMS), *International Guidelines for Biomedical Research Involving Human Subjects*, Geneva, CIOMS, 1993.
- Council for International Organisations of Medical Sciences (CIOMS), Revised Draft of CIOMS *International Ethical Guidelines for Biomedical Research Involving Human Subjects*, Geneva, CIOMS, 2002.
- Coutinho Lester, Raje Gauri, Bisht Suman, "Numerical narratives and documentary practices: Vaccines, targets and reports of the immunization programme", *Economic and Political Weekly* XXV (8 & 9), 2000.
- Das Veena, et. al, "Scientific and Political Representations: The Cholera Vaccine in India", Centre for Development Economics, "*Social Science and Immunisation Country Study*: India, Working Paper 5, 1997.
- Das Veena, "Public good, ethics and everyday life: Beyond the boundaries of bioethics". *Daedalus (Bioethics and Beyond)*: 128 (4), 1999.
- Das Veena, "The Act of Witnessing: Violence, Poisonous Knowledge and Subjectivity", In Das Veena (Ed.), *Violence and Subjectivity*, Berkley/Los Angeles/London: University of California Press, 2000.



- Davidoff F, DeAngelis CD, Drazen JM, Hoey J, Højgaard L, Horton R, et al., "Sponsorship, authorship and accountability", *The New England Journal of Medicine*, 345, pp: 825-6, 2001.
- Dhanda A, *Legal order, mental disorder*, New Delhi: Sage, 2000.
- "Discussion on Depo-Provera", *MFC Bulletin*, January-February; 214-215, pp: 12-16, 1995.
- D'souza M, "The ethical principles followed by vaidus", *Issues in Medical Ethics*, January-March; 7 (1), 1999.
- Dworkin RJ, *Research on persons with mental illness*, CA: Sage, 1992.
- Eckenwiler Lisa, "Moral reasoning and review of research involving human subjects", *Kennedy Institute of Ethics Journal* 11.1, 2001.
- The Economist, "Patient Capital. India promises to become a world centre for testing new medicines", *The Economist*, 354, pp: 77-78, 2000.
- Eichenwald K, Kolata G, "Drug trials hide conflicts for doctors", *The New York Times*, May 16, 1999a.
- Eichenwald K, Kolata G, "A doctor's drug studies turn into fraud", *The New York Times*, May 17, 1999b.
- Engler RL, Covell JW, Friedman PJ, Kitcher PS, Peters RM, "Misrepresentation and responsibility in medical research", *The New England Journal of Medicine*, 317, pp: 1383-89, 1997.
- Enserink M, "Helsinki's new clinical rules: fewer placebos, more disclosures", *Science*, 290, pp: 418-19, 2000.
- Erickson J, Steffen S, "What can we Learn from Sexual Behaviour Surveys: The U.S. Example", in Zeidenstein S and Moore K (Ed.), *Learning About Sexuality*, New York: The Population Council, 1996.
- Esteve G, "Development", in Sachs, W (Ed.), *The Development Dictionary - A Guide to Knowledge As Power*, Orient Longman, 1992.
- Fitzgerald John, Hamilton Margaret, "The consequences of knowing: Ethical and Legal Liabilities in Illicit Drug Research", *Social Science and Medicine* 43 (11), 1996.
- Forum for Women's Health, "The case against anti-fertility vaccines", *MFC Bulletin*, May, 218, pp: 1-8, 1995.
- Foundation for Research in Community Health, *Health Research Studies in India- A Review and Annotated Bibliography*, Mumbai: FRCH, 1994.
- Francis CM, "Medical ethics in India: Ancient and modern (I)", *Issues in Medical Ethics* October-December; 4 (4), pp: 115-118, 1996.
- Francis CM, "Medical ethics in India: Ancient and modern (II)", *Issues in Medical Ethics* January-March; 5(1), pp: 3-6, 1997.
- Ganatra RD, "Ethics of authorship of scientific papers", *Issues in Medical Ethics*, July-September; 4(3), pp: 78-80, 1996.
- Ganatra BR, Hirve SS, Walawalkar L, Garda L, Rao VN, "Induced Abortions in a rural Community in Western Maharashtra: Prevalence and Patterns", Pune: KEM Hospital Research Centre, 1996.

- George A, *Sexual Behaviour and Sexual Negotiation among Poor Women and Men in Mumbai - An Exploratory Study*, Baroda: SAHAJ Society for Health Alternatives, 1997.
- Gitanjali B, Raveendran R, "Teaching research methodology to postgraduates: Is dissertation the only method?" *National Medical Journal of India*, 11, pp: 23-5, 1998.
- Goodman KW, Prineas RJ, "Towards an ethics curriculum in epidemiology", in Coughlin SS, Beauchamp Ed.), *Ethics and Epidemiology*, New York: Oxford University Press, 1996.
- Gostin Lawrence, "Ethical Principles for the Conduct of Human Subject Research: Population-Based Research and Ethics", *Law, Medicine and Health Care*, 19 (3-4), pp: 191-201, 1991.
- Gostin Lawrence, "Informed consent, cultural sensitivity, and respect for persons", *Journal of the American Medical Association*, 274, 1995.
- Government of India, Ministry of Health and Family Welfare, *Guidelines for exchange of human biological material for biomedical research purposes*, November 19, 1997.
- Grillo Ralph, "Comments", *Current Anthropology* 31 (3), 1990.
- Gupte MD, Sampath DK, "Ethical issues considered in Tamil Nadu leprosy vaccine trial", *Issues in Medical Ethics*, 8 (1), pp: 10-12, 2000.
- Gurbaxani S, Khanna R, *Review of Research Studies on Sexuality and Sexual Behaviour in India (1990-1999): Overview*, Draft for internal circulation, Baroda: WOHRAC, MS University of Baroda, 1999.
- Hastrup Kirsten, Petel Elsass, "Anthropological advocacy: A contradiction in terms?" *Current Anthropology* 1 (3), 1990.
- Herzlich C, *Health and Illness: A Social Psychological Analysis*, Elsevier Science & Technology Books, 1973.
- Hill AB, Hill ID, *Bradford Hill's Principles of Medical Statistics*, 12th Edition, BI Publications, 1991.
- Hieu DT, et al, "31,781 cases of non-surgical female sterilisation with quinacrine pellets in Vietnam", *Lancet*, 342, pp: 213-217, 1993.
- Hobbes Nicholas, "Ethical Issues in Social Sciences" *International Encyclopaedia of Social Sciences* Vol. 5 & 6, London, 1968.
- Hoffmaster Barry, "Can ethnography save the life of medical ethics?" *Social Science and Medicine* 35 (12), 1992.
- Holland J, Ramazanoglu C, Sharpe S, Thomson R, "Feminist Methodology and Young People's Sexuality", in Parker R, Aggleton P (Ed.), *Culture, Society & Sexuality*, London: UCL Press, 1999.
- Hulley SB, Cummings SR, *Designing Clinical Research*, Baltimore: Williams & Wilkins, 1988.
- Illich I, 'Needs', in Sachs W (Ed.), *The Development Dictionary: A Guide to Knowledge As Power*, Orient Longmans, 1992.
- "India agrees for AIDS vaccine trial", *Indian Express*, Mumbai, November 10, 1998.
- "India okays AIDS vaccine trial", *The Times of India*, November 10, 1998.

- Indian Council of Medical Research (ICMR), *Policy statement on ethical considerations involved in research on human subjects*, New Delhi: ICMR, 1980.
- Indian Council of Medical Research (ICMR), *ICMR guidelines on responsibility for clinical trials of contraceptives conducted in India*, New Delhi: ICMR, 1994.
- Indian Council of Medical Research (ICMR), *Ethical Guidelines for Biomedical Research on Human Subjects*, New Delhi: ICMR, 2000.
- Indian Institute of Economics, "*Socio-Economic Survey of Hyderabad and Secunderabad City Area*", Hyderabad: Government Press, 1957.
- Ingham R, Memon A, "*Methodological Issues in the Study of Sexual Behaviour in the Context of HIV-Infection - An Overview*", Working Paper 90/3, Department of Psychology, University of Southampton, 1990.
- Institutional Ethics Committee (IEC, CEHAT), "*Moving Towards Institutionalising of Ethical Review: Report of the Institutional Ethics Committee, Feb 2001 to June 2002*"; Mumbai: CEHAT, 2002.
- International Epidemiological Association (IEA), Guidelines on Ethics for Epidemiologists (draft), Washington, D.C.: American Public Health Association, *Epidemiology Section Newsletter*, Winter, 1990.
- Jesani Amar, "Ethics of authorship", *Issues in Medical Ethics*, October-December; 4(4), p: 127, 1996.
- Jindel R, *Culture of a Sacred Town: A Sociological Study of Nathdwara*, Bombay: Popular Prakashan, 1976.
- Jones JH, "Bad blood, The Tuskegee syphilis experiment", New York: *The Free Press*, 1981.
- Jorgensen Joseph G, "Towards an ethics for anthropologists: On Ethics and Anthropology", *Current Anthropology* 12 (3), 1971.
- Joshi A, Dhapola M, Kurian E, Metha A, Rajeshwari M, Biswas S, *Rural Women's Experiences and Perceptions of Marital Sexual Relationships - a Working Paper*, Baroda: Operations Research Group, 1997.
- Kahn Jeffrey P, Mastroianni Anna C, Sugarman Jeremy (Ed.), *Beyond Consent: Seeking Justice in Research*, New York: Oxford University Press, 1998.
- Katz J, "The Nuremberg code and the Nuremberg trial", *The Journal of American Medical Association*, 276, pp: 1662-66, 1996.
- Kefalides PT, "Research on humans faces scrutiny: new policies adopted", *Annals of Internal Medicine*, 132, p: 513, 2000.
- Khanna R, "Dilemmas and Conflicts in Clinical Research in Women's Health: A Case Study of Sarthi", *Medico Friend Circle Bulletin*, pp 1 - 7, Jan-Feb, 1996.
- Khanna R, "Research and Intervention: a Woman-centred Approach", Paper presented at *Reconceiving Sexuality: International Perspectives on Gender, Sexuality and Sexual Health*, Rio de Janeiro, April 14-17, 1996.
- Kiss E, "Democracy and the Politics of Recognition", in Shapiro I, Hacker-Cordon C (Ed.), *Democracy's Edges*, 1999.
- Kleinman Arthur, "Moral experience and ethical reflection: Can ethnography reconcile them? A quandary for 'the new bioethics'", *Daedalus (Bioethics and Beyond)* 128 (4), 1999.

- Koenig M, Jeebhoy S, Singh S, Sridhar S, "Undertaking Community based research on the prevalence of Gynecological Morbidity: lessons from India". Paper presented at the *IUSSP Seminar on innovative Approaches to the Assessment of Reproductive Health*, Manila, 1996.
- Kothari S, Joshi K, "A Comparative Study of Delinquents and non-Delinquents with regard to some Personality Characteristics", *Indian Journal of Psychology*, 67(3&4), pp 87 - 94, 1992.
- Krishna KP, "Status of Psychological Researches in India: Issues and Perspectives", *Psychological Studies*, Vol. 36, No. 1, pp 39 - 47, 1991.
- Kusha, "Contraceptive research in India", *Socialist Health Review*, March; 1(4): 178, pp: 166-170, 1985.
- Lal A, "Pharmaceutical drug promotion: how it is being practiced in India?" *Journal of The Association of Physicians of India*, 49, pp: 266-73, 2001.
- Lee R, "Introduction", *Doing Research on Sensitive Topics*, Sage, London, 1993.
- Levine RJ, *Ethics and regulation of clinical research*, 2nd Edition, Baltimore, Urban & Schwarzenberg, 1986.
- Levine RJ, "Clinical trials and physicians as double agents", *The Yale Journal of Biology and Medicine*, 65, 1992.
- Levine RJ, "The Institutional Review Board", in Coughlin SS, Beauchamp (Ed.), *Ethics and Epidemiology*, pp: 257-73, New York, Oxford University Press, 1996.
- Lilford RJ, Edwards SJL, Braunholtz DA, Jackson J, Thornton J, Hewison J, "Ethical issues in the design and conduct of randomised controlled trials", in Stevens A, Abrams K, Brazier J, Fitzpatrick R, Lilford R (Ed.), *The Advanced Handbook of Methods in Evidence Based Healthcare*, London, pp.11-24, Sage Publications; 2001.
- Loue S, Okello D, Kawuma M, "Research bioethics in the Ugandan context: A program summary", *Journal of Law, Medicine & Ethics*, 24, pp: 47-53, 1996.
- Lurie P, et al, "Ethical, behavioural, and social aspects of HIV vaccine trials in developing countries", *Journal of the American Medical Association*, January 26, 271, pp: 295-301, 1994.
- Lurie P, Wolfe S, "Unethical trials of interventions to reduce perinatal transmission of the Human Immunodeficiency Virus in developing countries", *New England Journal of Medicine*, 337, pp: 853-856, 1997.
- Macklin R, "Philosophical conceptions of rationality and psychiatric notions of competency", *Synthese*, 57, pp. 205-224, 1983.
- Madan TN, "Political Pressures and Ethical Constraints Upon Indian Sociologists", in Gideon Sjoberg (Ed.), *Ethics, Politics and Social Research*, London: Routledge, 1967.
- Madan TN, "*Comments: The Relevance of Social Sciences in India*", in New Delhi: Institute of Economic Growth, Relevance in Social Science Research: A Colloquium, 1982.
- Madden JM, et al. "Undercover care-seekers: Simulated clients in the study of health provider behaviour in developing countries", *Social Science and Medicine* 45 (10), 1997.
- Marshall E, "Shutdown at Hopkins sparks a debate", *Science*, 293, p: 587, 2001.
- Mathiesen, Per, "Comments", *Current Anthropology* 31 (3), 1990.

- McCrary VS, Anderson CB, Jakovljevic J, Khan T, McCullough LB, Wray NP, Brody BA, "A National Survey of Policies on Disclosure of Conflicts of Interest in Biomedical Research", *New England Journal of Medicine*, 343, pp: 1621-26, 2000.
- MacIntyre Alasdair, 2nd edition. *After Virtue: A Study of Moral Thoery*, 2nd Edition, Notre Dame: University of Notre Dame, 1984.
- MacIntyre Alasdair, "Ethical dilemmas: Notes from outside the field", *AAA Newsletter* 34 (7), 1993.
- Mehendale S, "Ethical considerations in AIDS vaccine trials", *Issues in Medical Ethics*, 8 (1), pp: 13-15, 2000.
- Mehra P, "Of human guinea pigs", *Illustrated Weekly of India*, May 2, 1992.
- MFC team, Bangalore, "Medical research in Bhopal", *Medico Friend Circle Bulletin*, April, 112, pp: 1-4, 1985.
- Mudur G, "India concerned at export of genetic material", *BMJ*; 312, pp: 464, 1996.
- Mudur G, "India to control foreign research involving Indian patients", *British Medical Journal*, 314, pp: 165, 1997.
- Mudur G, "Doctor in India arrested over irregularities in trial of vaccine", *British Medical Journal*, 318, pp: 1308, 1999.
- Mudur G, "Indian doctors defend "unethical" anticancer drug trial", *British Medical Journal*, 323, pp: 299, 2001.
- Murthy RS, et al, "Ethical issues in medicine: an opinion survey", Paper presented at the International Conference on health policy: ethics and human values, New Delhi, 1986.
- Nagral A, "Research in public hospitals of Bombay", Paper presented at a meeting of the Medico Friend Circle, Mumbai, June 26, 1994.
- Narendranath KG, "MNCs rush for clinical trials in India: 24 applications filed in 1999-2000", [www.pharmabiz.com](http://www.pharmabiz.com) (Available from URL: [www.pharmabiz.com/archives/may2k/res27.asp](http://www.pharmabiz.com/archives/may2k/res27.asp)), May 25, 2000.
- National Bioethics Advisory Commission, *Research Involving Persons With Mental Disorders That May Affect Decision Making Capacity*, USA, 1998.
- National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research, *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, Washington, D.C.: U.S. Government Printing Office, 1978.
- National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research, *Research involving those institutionalised as mentally infirm, Report & Recommendations*, DHEW No. 78-0006, Washington DC, Government Printing Office, 1978.
- National Committee for Ethics in Social Science Research in Health (NCESSRH), *Ethical Guidelines for Social Science Research in Health*", Mumbai: CEHAT, November 2000.
- New Indian Express, "The Third World cannot be reduced to one big lab", *New Indian Express*, 26 April, 2000.
- Nundy S, "What can be done about Indian medical research?" *National Medical Journal of India*, January-February; 11(1), pp: 1-2, 1998.

- Nuremberg Military Tribunal, "Trials of War Criminals Before the Nuremberg Military Tribunal", Vol. 2, Military tribunal, case 1, United States v Karl Brandt, et al. October 1946 - April 1949. Washington DC: US Government Printing Office; 1950.
- O'Neill J, *The poverty of postmodernism*, London: Routledge, 1995.
- Pai M, Colford JM Jr, "Clinical trials sponsored by the pharmaceutical industry in India: a proposal for reforms", *National Medical Journal of India*, 15(2), 2002.
- Paine Robert (Ed.), *Advocacy and Anthropology: First Encounters*. St. John's: Institute of Social and Economic Research, Memorial University of Newfoundland, 1985.
- Pandya SK, "Why is the output of medical research from India so low?" *British Medical Journal*, 301, pp: 333, 1990.
- Pandya SK, "Hospital ethics committee", *Issues in Medical Ethics*, April-June, 4(2), pp: 51-53, 1996.
- Pandya SK, "Organising a public debate: ethical guidelines on biomedical research in humans", *National Medical Journal of India*, 11(6), pp: 294-295, 1998.
- Petersen A, Lupton D, *The New Public Health-Health and Self in the Age of Risk*, Sage Publications, 1997.
- Pels Peter, "Professions of duplicity: A prehistory of ethical codes in anthropology", *Current Anthropology* 40 (2), 1999.
- Phadke A, "An alternative view about Depo-Provera", *MFC Bulletin*, August-September; 221-222, pp: 10-13, 1995.
- Pilgaokar A, "Ethics in biomedical research", Unpublished paper presented at the annual meeting of the Medico Friend Circle, 1995.
- Pollack AE, Carignan CS, "The use of quinacrine pellets for non-surgical female sterilisation", *Reproductive Health Matters*, November 2, pp: 119-122, 1993.
- Prakash Padma, "Injectable contraceptives", *MFC Bulletin* May; 113, pp: 1-3, 1985.
- Prilleltensky I, "Values, assumptions, and practices: Assessing the moral implications of psychological discourse and action", *American Psychologist*, 52(5), pp: 517-535, 1997.
- Priya R, "Rethinking AIDS in Women and the RCH Package - Some Epidemiological and Social Considerations", in Centre for Social Medicine and Community Health, Jawaharlal Nehru University (Ed.), *Reproductive Health In India's Primary Health Care*, pp: 56-71, 1998.
- Priya R, "Dalit Perceptions of Health", *Seminar*, 428, 1995.
- Priya R, "Issues of Women and AIDS in India", *Political Environments*, 4, 1996.
- Priya R, "Public Health, Ethics and Tuberculosis", *Indian Journal of Tuberculosis*, 46, pp: 273-278, 1999.
- Perinatal HIV Intervention Research in Developing Countries Workshop Participants, "Science, ethics, and the future of research into maternal infant transmission of HIV-1", *Lancet*, 353, pp: 832-36, 1999.
- Porter JDH, Ogden JB, "Public Health, Ethics and Tuberculosis", *Indian Journal of Tuberculosis*, 46, pp: 3-8, 1999.
- Qadeer I, "Health Care Systems in Transition III - The Indian Experience", *Journal of Public Health Medicine*, 1999.

- "Quinacrine sterilisation still being done despite expert advice against it", *Reproductive Health Matters*, May 9, pp: 176, 1997.
- Quinn TC, et al, "Viral load and heterosexual transmission of Human Immunodeficiency Virus Type 1", *The New England Journal of Medicine*, 342 (13), 2000.
- Raghunathan S, "India launches AIDS vaccine programme", IAVI Report 1999; 4 (2): 15. Quoted by Mehendale S: Ethical considerations in AIDS vaccine trials. *Issues in Medical Ethics* 8(1), pp: 13-15, 2000.
- Rajagopalan A, "Medical research in India", *Current Science*, 73, pp: 397, 1997.
- Rao Mohan, "Quinacrine Sterilisation Trials: A scientific scandal?" *Economic and Political Weekly*, March 28, 1998.
- Rao Mohan (Ed.), *Disinvesting in Health: The World Bank's Perceptions for Health*, New Delhi: Sage Publications, 1999.
- Ravindra RP, "Reject the injectables", *Issues in Medical Ethics* 7 (2): 47, 1999.
- Reddy KS, Sahni P, Pande GK, Nundy S, "Research in Indian medical institutes", *National Medical Journal of India*, 4, pp: 90-92, 1991.
- Rennie D, "Thyroid Storm", *Journal of the American Medical Association*, 277, pp: 1238-43, 1997.
- Report of the women and Health Cell meeting, Wardha, January 4-5, *MFC Bulletin*, January-February; 214-215, 1995.
- "Research does not reflect global disease burden", *British Medical Journal*, 320, pp: 1228, 2000.
- Riecken Henry W, Ravich, Ruth, "Informed Consent to Biomedical Research in Veterans Administration Hospitals" *Journal of the American Medical Association* 248, 1982.
- Ringheim Karin, "Ethical Issues in Social Science Research with Special Reference to Sexual Behaviour Research", *Social Science and Medicine*, 40 (12), pp: 1691-1697, 1995.
- Robinson Ian, "Confidentiality for whom?" *Social Science and Medicine* 32 (3), 1991.
- Rubin G, "Thinking Sex: Notes for a Radical Theory of the Politics of Sexuality", in Parker R, Aggleton P (Ed.), *Culture, Society & Sexuality*, London: UCL Press, 1999.
- Saheli Women's Resource Centre, "ICMR draft ethical guidelines: A critique", *Issues in Medical Ethics*; 8 (1), pp: 20-21, 2000.
- Saheli, *Target practice: anti-fertility vaccines and women's health*. Delhi: Saheli, 1998.
- Sanwal AK, et al, "Informed consent in Indian patients", *Journal of the Royal Society of Medicine*, Apr 89(4), pp: 196-198, 1996.
- Sathyamala C, "Depot-medroxyprogesterone Acetate and breast cancer: a critique of the WHO's multinational case-control study", *MFC Bulletin*, July, 220, pp: 1-5, 1995.
- Savara M, Sridhar CR, "Sexual Behaviour Amongst Different Occupational Groups in Maharashtra", *The Indian Journal of Social Work*, LV (4), pp: 625, 1994.
- Scheper-Hughes Nancy, Lock Margaret M, "Speaking 'truth' to illness: Metaphors. Reification and a pedagogy for patients", *Medical Anthropology Quarterly* 17, 1986.
- Scheper-Hughes Nancy, "Three propositions for a critically applied medical anthropology", *Social Science and Medicine* 30 (2), 1990.

- Scheper-Hughes Nancy, "The primacy of the ethical: Propositions for a militant anthropology", *Current Anthropology* 36 (3), 1995.
- Schuklenk U, "International research ethics guidelines to be revised in nearly complete secrecy", *Monash Bioethics Review*; 18(3), 1999.
- Schuklenk U, "Ethics and AIDS vaccine trials: a response", Letter, *Issues in Medical Ethics* 8 (2), 2000.
- Sethi PK, "Orthopaedics in an unjust world", *Issues in Medical Ethics*, July-September, 1999.
- Sharma DC, "India tries to improve national system for handling clinical trials", *Lancet*, 357, pp: 1682, 2001.
- Singer Merrill, "Reinventing medical anthropology: Toward a critical realignment", *Social Science and Medicine*, 30(2), 1990.
- Singh Y, "Relevant Sociology: Some Conceptual Issues and the Indian Situation", in Doshi SL (Ed.), *Relevance in Sociological Research*, 1991.
- Smith Harmon L, "Ethical consideration is research involving human subjects", *Social Science and Medicine* 14 (5A), 1980.
- Special correspondent, "Foetal tissue transplant: ICMR clarifies", *The Hindu* (Madras), January 2, 1997.
- Srinivas MN, *Dominant Caste and Other Essays*, New Delhi: Oxford University Press, 1987.
- Srinivas MN, *Social Change in Modern India*, New Delhi: Orient Longman, 1972.
- Sriram TG, et al., "Opinion survey of physicians on ethical issues in medical research", *Journal of the Indian Medical Association*, July, 89(7), pp: 187-190, 1991.
- "Supreme Court of India bans import, manufacturing, sale and distribution of quinacrine in pellet form for use as a contraceptive", *The Hindu*, August 17, 1998.
- Sutton R, Schurman S, "On studying Emotionally Hot Topics: Lessons from an Investigation Of organizational Death", *Research in Organisational Behaviour*, 1999.
- Thorne Barrie, "You're still taking field notes: Fieldwork and the problem of informed consent", *Social Problems* 27 (3), 1980.
- The Tri-Council Working Group [appointed by The Medical Research Council (MRC), the Natural Sciences and Engineering Research Council (NSERC), and the Social Sciences and Humanities Research Council (SSHRC), Canada], "*Tri-Council Policy Statement: The Code of Ethical Conduct for Research Involving Humans*", May, 1997.
- United Nations, *The Universal Declaration of Human Rights*, 1948.
- University Of Wollongong/Illawarra Area Health Service, Human Research Ethics Committee, *Human Research Ethics Application Guidelines*, January 2003.
- Useem, M, Marx, G, "Ethical Dilemmas and Political Consideration", in Smith Robert (Ed.), *An Introduction to Social Research, Volume I, of Handbook of Social Science Methods*, London: Cambridge-Ballinger, London, 1983.
- Vance C, "Anthropology Rediscovered Sexuality: A Theoretical Comment" in Parker R, Aggleton P (Ed.), *Culture, Society & Sexuality*, London: UCL Press, 1999.
- Varmus H, Satcher D, "Ethical complexities of conducting research in developing countries", *New England Journal of Medicine*, 337, pp: 1003-5, 1997.



- Viswa D, *Sexual Behaviour Patterns in the Context of HIV/AIDS in India- A Review*, (Unpublished M.Phil. dissertation), New Delhi: Centre for Social Medicine and Community Health, Jawaharlal Nehru University, New Delhi, 1998.
- Vohra S, "Empathy and Sympathy", *Psychological Foundations: The Journal*, Vol. I, pp: 53-55, December 1998.
- Wawer MJ, et al, "Control of sexually transmitted diseases for AIDS prevention in Uganda: a randomised community trial", *Lancet*, February 13, 353 (9152), pp: 525-535, 1999.
- Wax Murray L, "The Paradoxes of "consent" to the practice of fieldwork", *Social Problem*, 27 (3), 1980.
- Wax Murray L, Cassell Joan, "From regulation to reflection: Ethics in Social Research", *The American Sociologist* 16 (Nov.), 1981.
- Weatherall D, "Academia and industry: Increasingly uneasy bedfellows", *Lancet*, 355, pp: 574, 2000.
- Weed DL, Coughlin SS, "New ethics guidelines for epidemiology: Background and rationale" *Annals of Epidemiology*, 9, pp: 277-80, 1999.
- Weiss E, Gupta GR, *Bridging the Gap - Addressing Gender and Sexuality in HIV Prevention*, New Delhi: International Centre for Research in Women, 1999.
- Werner D, "Turning Health into an Investment: Assault on Third World Health Care", *Economic and Political Weekly*, Vol. 30, pp: 147-252, 1995.
- White C, Williamson A (Ed.), Committee on Publication Ethics (COPE), "Guidelines on Good Publication Practice", *The COPE Report 2001*, London: BMJ Books, 2001.
- Women and health cell of the Medico Friend Circle, "Submission to the National Human Rights Commission on AFV immuno-contraceptives", *MFC Bulletin*, March-April: 10, 1996.
- World Medical Association, "*Declaration of Helsinki: Recommendations guiding physicians in biomedical research involving human subjects*", Adopted by the 18th World Medical Assembly, June 1964, amended in October 1975, October 1983, September 1989 and October 1996 and the 52nd WMA General Assembly, Edinburgh, Scotland, October 2000. Note of Clarification on Paragraph 29 added by the WMA General Assembly, Washington 2002.