Short Intensive Course on Ethics in Social Science and Public Health Research

Organiser
DLR Prerna, Darjeeling (+any other?)
Collaborator
St. Joseph's College North Point Darjeeling
Supported by:
Mariwala Health Initiative, Mumbai

Dates:
09 to 13 November 2019
Venue:
Darjeeling

About the course
The core faculty of the short course in research ethics is involved in training researchers, programmers and others since 2003-4. The curriculum for the course is developed over time to sensitise and equip participants in identifying and integrating ethical concerns in the methodologies in the different fields of health research.

The course is meant not only to provide information and knowledge of research ethics but also impart skills in ethics analysis using research case studies, videos and by organizing mock ethics review of research proposal and protocols by the participants.

Goal: To enable participants to appreciate the salience of research ethics in upholding research integrity; and identify and apply ethical reasoning to social science and public health research.

Specific objectives:
1. To learn about history and origins of research ethics discourse and principles in human research ethics in social sciences and public/mental health research and their relevance to contemporary research in social sciences and public health.

2. To introduce to participants the key theories and principles of research ethics, and the relevant national and international research ethics guidelines. To learn about the research governance, particularly about the structure and functioning of research ethics committees in India and the laws related to research ethics in India.

3. To strengthen the understanding of specific concepts in research ethics such as privacy, confidentiality, standard of care, informed consent process, collaborative research, publication ethics, research integrity, etc.

4. To appreciate research ethics challenges specific to quantitative and qualitative research methods, various designs of research (observational and experimental, including interventional research with complex public and mental programs).

5. To learn about the research situation and the personal and the social contexts making participants of research vulnerable and the methods to provide additional protection without restricting their participation.

6. To develop skills by discussion using adult learning methods and the study of real examples of cases and research protocols from Indian and the LMIC (Low and Middle Income Countries).

Course Faculty:
1. Dr Amar Jesani, MBBS, Independent Researchers and Consultant, Pubic Health and Bioethics, Mumbai; and Editor, Indian Journal of Medical Ethics (IJME)

2. Prof Mala Ramanathan, PhD (IIPS, Mumbai), Masters in Medical Anthropology (Amsterdam), Bioethics (Harvard), AMCHSS, SCTIMST, Trivandrum; Working Editor, IJME; Member Secretary, IEC

3. Dr Sunita Sheel Bandewar, PhD (Anthropology) and Masters in Bioethics (Toronto, Canada), Independent Researcher, Pune; Working Editor, IJME; and Director, HEaL (Health, Ethics and Law) Institute of Training, Research and Advocacy, Mumbai-Pune

4. Jasmine Kalha, MA in Social Work (Tata Institute of Social Sciences, Mumbai), MPhil in Sociology (Delhi School of Economics, Delhi University). Centre for Mental Health Law and Policy, Indian Law Society, Pune. Implementing evidence-informed research on mental health and human rights: With public mental health systems through WHO's QualityRights intervention at-scale in Gujarat; the scale-up of Atmiyata, community based mental health intervention in Mehsana District of Gujarat; intervention on implementing peer support within public mental health systems as part of a European Union consortium.

Learning methods:
Interactive Adult Learning methods will be used to enable participants to learn not only from the resource persons but also from each other. The interactive learning will be facilitated by shorter presentation with discussion, use of case studies and videos followed by discussion on them in every session and also constitution of participants in ethics committees to discuss and take decision in a mock ethics review session on the proposals/protocols used for research.

For whom it is meant?
1. The language of workshop will be English (Indian), so working knowledge of language is essential.

2. It would be helpful if the participants have qualification at least of Masters degree in social and basic sciences and/or graduation in a professional course.

3. Some knowledge of quantitative and qualitative research would be needed to understand ethics in research. Some experience in conducting research would help more but it is not an absolute must.

4. Readiness to read some of the background reading material that will be provided in advance.

5. The participants will be required to spare time for all five days – the course is organised such as to expose participants, gradually and stepwise, to various aspects of research and the ethical issues.

Programme Schedule

DAY ONE: 09 NOV 2019

Time	Topic	Resource	Learning Objectives
0830-0845	Registration		
0845-0915	Inauguration, Objective of workshop, and Introductions of participants & their expectations	To be moderated by Roshan Rai	
0915-1030	What is research and how it is different from healthcare professional practice, programs and evaluation (case study, followed by discussion & presentation)	Amar Jesani	• Defining research, practice, program, evaluation and surveillance in healthcare • Understanding their differences and the differential standards of ethics in each
	1030-1100: Break – tea/coffee		
1100-1230	Morality, ethics, human rights and law: Challenges posed in research across disciplines (Viewing of video, followed by discussion and presentation)	Amar Jesani	• Defining morality, ethics in relations to healthcare and research, relationship of ethics with human rights and law • History of evolution of research ethics, international and Indian controversies that resulted in codification of ethics standards • Various stakeholders in the research – their roles and responsibilities posing ethical challenges of power-relationship in research
	1230-1330: Lunch break		
1330-1500	Bioethics theories and guidelines	Mala Ramanathan	• Bioethics Theories & Perspectives: Deontology/Kant; Utiliarianism /Consequentialism, Virtue, Communitarianism, Care/Feminist • Principles of ethics (Principalism) and Benchmarks of ethical research
	1500-1530: Break – Tea/coffee		
1530-1700	Conceptual approaches/paradigms of various research methodologies and designs	Mala Ramanathan	• Natural science and positivist paradigm: "reality independent of subjects" – conceptual basis of unbiased quantitative research • Non-positivist paradigm: Iterative framework, voice for subjects, interaction, and interpretation • Cultural vs moral relativism in research • Meaning and explanation of various research designs
	Evaluation of sessions & closure of the day		

DAY TWO: 10 NOV 2019

Time	Topic	Resource	Learning Objectives
0845-0900	Recap of previous day and queries from participants		
0900-1030	Voluntary Informed Consent (video/case study, followed by discussion and presentation)	Amar Jesani	• Principle of autonomy and consent: respect for autonomy and respect for person & Components of Informed consent • Informed consent process • Withholding full disclosure (deception) in research • Consent and vulnerability of participants
	1030-1100: Break – tea/coffee		
1100-1230	Privacy and confidentiality (P&C) (video/case study, followed by discussion and presentation)	Mala Ramanathan	• Understanding privacy as a right, and confidentiality as professional ethical obligation • Why are P&C important in research? Its importance in various stages and of contexts of research? What are the consequences of their violations? • Various methods to protect P&C • In what kind of research privacy is not an issue, and what are the limitation of the promise of confidentiality
	1230-1330: Lunch break		
1330-1500	Research using medical records of hospitals/clinics, individual and community data on health and mental health in public health projects/programs (case studies, discussion and presentation)	Mala Ramanathan	• Who have right to use the existing data of hospital/clinics/public health programs/NGO projects? • The condition in which they could be used and how? • Is there an ethical obligation to make research data available in public domain? If so, how to do it? • How to ensure confidentiality of biological material/specimen? Ethical governance of biio-banking.
	1500-1530: Break – Tea/coffee		
1530-1630	Research governance: composition and functioning of research ethics committees, and their legal status (presentation only)	Amar Jesani	• Deconstructing ethics governance: various components • Research ethics committees: Composition as per Indian law, and their registration • Standard operating procedures of the EC, including process of reviewing protocols and decision making
1630-1700	Formation of Research Ethics Committees (REC)	Amar Jesani	• RECs from among the participants, role of members • Distribution of protocols for review by RECs on 5th day
	Evaluation of sessions & closure of the day		

DAY THREE: 11 NOV 2019

Time	Topic	Resource Person	Learning Objectives
0845-0900	Recap of previous day and queries from participants		
0900-1030	Assessing risk and benefit of research (Case Studies, discussion and presentation)	Sunita Bandewar	• Explaining various types of risks and benefits of research • Learning about methods of assessing risk and benefits • Monitoring of research, management of adverse events in research, the research-stoppage rules and monitoring mechanisms, including Data Safety Monitoring Boards • Participant vulnerabilities and special efforts for protection
	1030-1100: Break – tea/coffee		
1100-1230	Ethical challenges in quantitative research (case studies, discussion and presentation)	Mala Ramanathan	• Recap of positivist paradigm of quantitative research and methods of minimizing bias • Various methods of quantitative data collection and ethical challenges • Ethical aspects of quantitative data analysis
	1230-1330: Lunch break		
1330-1500	Ethical Challenges in Qualitative Research (case studies, discussion and presentation)	Sunita Bandewar	• Various qualitative research methods • Various approaches (theories) of qualitative research • Application of ethics principles • Ethical challenges specific to qualitative research
	1500-1530: Break – Tea/coffee		
1530-1700	Ethical challenges in action and participatory action research	Amar Jesani	• Learning about action and participatory research designs. • Ethical challenges posed by the research design and methods of data collection • Political dimensions of research and problems of security • Ethical dimensions of evaluation and review of health programs
	Evaluation of sessions & closure of the day		

DAY FOUR: 12 NOV 2019

Time	Topic	Resource Person	Learning Objectives
0845-0900	Recap of previous day and queries from participants		
0900-1030	Standard of Care (SoC) in Observational and experimental Research	Sunita Bandewar	• Understanding the concept of SoC: Its origin and history of its application to research • What SoC is required in observational research? Explanation and discussion. • SoC in experimental research: for intervention arm and the control arm • Understand how and when placebo and no-intervention arm is permitted • Challenges in the non-inferiority design in clinical and public health research
	1030-1100: Break – tea/coffee		
1100-1230	General ethical issues in mental health research	Jasmine Kalha	• Learning about different types of mental health research being conducted (clinical drug trials to research in community mental health) and the variety of methods and designs used • Explain the vulnerability of participants suffering from various degree of mental health problems • Discuss different ways in which the ethical issues are mitigated in mental health research
	1230-1330: Lunch break		
1330-1500	Research integrity and publication ethics (video, discussion and presentation)	Amar Jesani	• Why integrity is important in research? • Various types of research misconduct and how to avoid them • Obligation to publish results, ethical aspects of publication and authorship • Data sharing
	1500-1530: Break – Tea/coffee		
1530-1700	Ethics of research collaboration – international and domestic	Sunita Bandewar	• Power relationship in collaboration • ethical issues to be attended to while entering into collaboration agreements • How to use (and limitation of) COHRED's Fairness in Research Collaboration tool kit
	Evaluation of sessions & closure of the day		

DAY FIVE: 13 NOV 2019

Time	Topic	Resource	Learning Objectives
0845-0900	Recap of previous day and queries from participants		
0900-1030	Ethical challenges in the complex public mental health intervention using research design of Cluster Randomised Controlled Trial (CRCT): Atmiyata experiences	Jasmine Kalha	• Explain what constitutes complex public mental health intervention, and what care needs to be taken to discover what works • Learning about the meaning of Communities and Clusters, who represent them, and the engagement process with the communities and clusters • Ethical issues: Cluster/community consent/permission, who constitute the participants (village persons trained and/or the people with mental health, how to identify and record adverse events, stoppage rules used, and the monitoring of such trials
	1030-1100: Break – tea/coffee		
1100-1200	Conflict of Interest (COI) in research	Sunita Bandewar	• Understanding the concept: How COI is different from other conflictual positions, how is it different from corruption • Different types of COI • Management and avoidance of COI: When is the disclosure not sufficient?
1200-1445	**Meeting of Ethics Committees to review protocols provided on Day Two**		• Ethics committees will meet at 12 noon and will continue their deliberation through the lunch and thereafter
1445-1545	Reporting of the Ethics Committee Deliberations and decision taken on each protocol	All faculty present	• Discussion on learning from reviewing of research protocols
1545-1600	**Evaluation of day's sessions**		
1600	Distribution of certificates and feedback		
	Closure with Tea/Coffee		