Short-Duration Intensive Training in Research Ethics for Social Science and Public Health Research Organisers

Forum for Medical Ethics Society (FMES), Mumbai;
FMES' Health, Ethics, and Law Institute for Training, Research and Advocacy

in collaboration with

Nabakrushna Choudhury Centre for Development Studies (NCDS), Bhubaneshwar, Odisha

Dates: Wednesday, June 26 to Sunday, June 30, 2019| 0930 - 1730
Venue: Conference Hall, Nabakrushna Choudhury Centre for Development Studies, Bhubaneshwar

About the course

The course curriculum has a legacy of 15 years to which a number of scholars including those trained in bioethics have contributed. Over time they developed research ethics case studies from the Indian context. These serve as one of the key resources for the course.

The course aims to equip course participants with knowledge and skills in research ethics. They would serve as significant human resource to take the learnings to their own ecosystems and facilitate knowledge transfer in research ethics.

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

Specific objectives:
1. To learn about history and origins of research ethics discourse and principles in research ethics in social sciences and public health research and their relevance to contemporary research in social sciences and public health.
2. To strengthen the awareness of participants of ethical issues in research involving human participants, and their appreciation of the need for research integrity
3. To draw upon the key resources in international ethics guidance such as the Tri-Council Policy Statement, Canada; the Helsinki Declaration, and other ethics guidelines issued by both national and international organizations, pertaining to the social sciences and public health fields; and help locate them in local contexts.
4. To strengthen the understanding of specific concepts in research ethics (privacy, confidentiality, standard of care, informed consent process, collaborative research, publication ethics, research integrity,); and appreciate research ethics challenges specific to research design, special groups with enhanced vulnerabilities; situational vulnerabilities in the context of research in social sciences (in health) & public health sciences.
5. To learn the application of ethical reasoning to respond to the aforesaid challenges posed by social science (in health) and public health research; and enhancing skills in operationalizing research ethics principles in practice.

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 Dr Srijit Mishra, PhD, Development Economist; Director, Nabakrushna Centre for Development Studies (ICSSR Research Centre), Bhubaneshwar [Course Director]
3. Dr Sunita Sheel Bandewar, PhD (Anthropology) and Masters in Bioethics (Toronto, Canada), Independent Researcher, Pune; Working Editor, IJME; and Director, Health, Ethics and Law Institute of Training, Research and Advocacy, Mumbai-Pune [Course Director]
4. Prof Mala Ramanathan, PhD, Masters in Medical Anthropology, Bioethics (Harvard), AMCHSS, SCTIMST, Trivandrum; Working Editor, IJME; Member Secretary, IEC

Learning methods:
1. Interactive methods involving small batches case studies, short videos; role play; and mock ethics review board meetings.
2. Case studies sourced and developed from within India to be complemented by those involved in international collaborative research.
3. Mock ethics review boards consisting of the training program participants conducting a mock ERB meeting to evaluate 2-3 anonymised research ethics protocols.

Short-Duration Intensive Training Program in

Research Ethics for Social Science and Public Health Research
Wednesday, June 26 to Sunday, June 30, 2019

Programme Schedule

DAY 1| Wed, June 26, 2019			
Unit 1|Social Sciences and Public Health Research ethics: History, Theoretical Approaches, and Ethics Principles			
Hours & Session no	**Topic**	**Faculty**	**Learning Objectives**
0945-1000	Registration and Refreshments		
1000-1015	Welcome & Inauguration	Directors, NCDS and HEaL Institute	
1015 -1030	Course overview and introduction to course objectives; and Round of Introduction;,	HEaL Institute Colleagues	
Session 1 1030 – 1200	Importance of Ethics in Human Health Research	Amar Jesani	**Film Screening** ➢ What is research? ➢ What are social sciences and their histories? ➢ History of ethics violations/challenges & Learnings
Session 2 1200-1330	Morality, ethics, human rights and law: Challenges posed in research across disciplines	Sunita Sheel OR Srijit Mishra	➢ To learn about the concept of ethics, facts, value, duties, morality, ➢ To recognize the relationship between ethics and law; ➢ Ethics and various disciplines - Basic Sciences, Medical or clinical Sciences, Social Sciences, Public health
1330-1415	LUNCH		
Session 3 1415-1545	Bioethics: Theoretical approaches and	Srijit Mishra & Sunita Sheel	➢ Theories: Deontology/Kant; Utilitarianism /Consequentialism, Virtue, Principlism

Hours & Session no	Topic	Faculty	Learning Objectives
	perspectives		➢ Perspectives: Gender, marginalisation/vulnerability, care, culture/religion **Case examples embedded in the presentation**
1545-1600	TEA		
Session 4 1600-1730	Social sciences: Positivist and non-positivist approaches; cultural and moral relativism vs universalism	Mala Ramanathan & Srijit Mishra	➢ To identify the potential ethical challenges in positivist and non-positivist approaches to research in social sciences ➢ To describe relativist approaches vs universalist approaches to resolving ethical dilemmas in research **Case examples embedded in the presentation**
1730	END OF THE DAY 1		

DAY 2| Thursday, June 27, 2019			
Unit 2| Translating Research Ethics Principles into practice			
Hours & Session no	**Topic**	**Faculty**	**Learning Objectives**
0930-1000	RECAP of Day 1 Resolving Queries	Participants and All faculty to respond to questions	
Session 5 1000-1130	Informed consent (IC)	Sunita Sheel	**Film Screening** ➢ To learn the foundation of the principle of autonomy and IC ➢ To learn various components of IC process – voluntariness, information, comprehension, documentation ➢ To recognize process of consent taking and its salience ➢ To learn IC in various situations, and permissibility of IC waivers ➢ To know guidelines and laws; and specific challenges **Group work for case studies or case study based discussions in plenary**
1130-1200	TEA		
Session 6 1200-1330	Privacy and confidentiality	Mala Ramanathan	**Film screening** ➢ To recognise the need for privacy and confidentiality in a research process ➢ To identify the challenges to privacy and confidentiality in both qualitative and quantitative research and ➢ To suggest some examples of good practices to meet such challenges to privacy and confidentiality in research **Group work for case studies or case study based discussions in plenary**
1330-1415	LUNCH		
Session 7 1415-1545	Risks and Benefits assessment of research	Amar Jesani	➢ Ethics principles and risk/benefits ➢ Various types of risks – frequency of their occurrence and magnitude ➢ Risk benefit analysis **Case examples embedded in the presentation**

1545-1600	TEA		
Session 8 1600-1730	Justice and Equity in Research	Srijit Mishra	➢ To learn and exploring ethics principle of justice; its importance in conceptualising research and in its conduct ➢ Research participant selection ➢ Vulnerability and fairness ➢ Right to post-research benefit **Case examples embedded in the presentation**
1730-1800	**FACULTY MEETING**		
1800	**END OF THE DAY 1**		

DAY 3| Friday, June 28, 2019

Unit 3|Research ethics obligations and issues in relation to research designs and research

Hours & Session no	Topic	Faculty	Learning Objectives
0930-1000	RECAP of Day 2 Resolving Queries	Participants and All faculty to respond to questions	
Session 9 1000-1130	Ethical challenges in quantitative research methods	Srijit Mishra Mala Ramanathan	➢ To recognise the ethical challenges posed by the application of methodological requirements of quantitative research in social science ➢ To suggest some possible ways to mitigate against the ethical challenges **Case examples embedded in the presentation**
1130-1200	TEA		
Session 10 1200-1330	Ethical challenges in qualitative research methods	Mala Ramanathan	➢ To recognise the ethical challenges posed by the nature of qualitative research in social science ➢ To suggest some possible ways to mitigate against the ethical challenges **Case examples embedded in the presentation**
1330-1415	LUNCH		
Session 11 1415-1545	Ethical challenges in Action and Participatory social science action research designs	Sunita Sheel	➢ To learn about action and participatory action research; and Monitoring and evaluation ➢ To identify and discuss specific ethical challenges in each design ➢ To suggest some possible ways to mitigate against the ethical challenges **Group work for case studies or case study based discussions in plenary**
1545-1600	TEA		
Session 12 1600-1730	Ethical challenges in complex intervention – experimental research designs (Cluster randomised trials)	Mala Ramanathan And Srijit Misra /Sunita Sheel	➢ To learn about experimental and quasi experimental social science and public health research designs and longitudinal studies ➢ To learn about population-based Cluster Randomised Trials ➢ To recognize and discuss ethical challenges in each

			Group work for case studies or case study based discussions in plenary
17:30	END OF THE DAY 3		

DAY 4| Saturday, June 29, 2019
Unit 4| Research Ethics Governance

Hours & Session no	Topic	Faculty	Learning Objectives
0930-1000	RECAP of Day 3 Resolving Queries	Participants and All faculty to respond to questions	
Session 13 1000-1130	Research Ethics Committees (REC)	Amar Jesani	➢ To recognize ethics guidelines and need for governance of research ➢ To recognize REC as a form of governance mechanism ➢ To learn about composition and structure of ethics review committees; ➢ To learn about their mandates, roles and responsibilities ➢ To know ethics review processes ➢ To Standard Operating Procedures of the REC and functions ➢ To recognize challenges faced by the REC
1130-1200	TEA		
Session 14 1200-1330	Ethics of collaborative research	Sunita Sheel	➢ To learn the salience of collaborative research in the contemporary context of global health research ➢ To recognize research ethics principles which inform collaborative research ethics discourse ➢ To learn about approaches to conceptualize and implement collaborative research in alignment with research ethics principles and obligations
1330-1415	LUNCH		
Session 15 1415-1545	Data sharing	Sunita Sheel	➢ To learn about the concept of data sharing and underlying ethics principles ➢ To learn about data transparency, including the public archiving of data for reanalysis by others from the peer community ➢ To learn about the risks involved in data sharing
1545-1600	TEA		
**Unit 5|Research integrity, reporting of research and publication ethics**			
Session 16 1600-1700	Conflict of interest (CoI)	Amar Jesani	➢ What is Conflict of Interest? ➢ What are the types of conflict of interest? ➢ CoI of researchers, gatekeepers, institutions, RECs, etc ➢ Management of conflict of interest: disclosure requirements, recusing from position of decision making ➢ CoI and corruption

1700-1730	Preliminary discussion on protocols for review, including queries	Amar Jesani Mala Ramanathan	Formation of ERB committees comprising of course participants (three to four groups) ➢ For the faculty to form the ethics committees comprising of the course participants ➢ To know the process of reviewing the study protocols assigned to the groups ➢ To know the process of documenting deliberations and arriving at the decision on the research protocol
17:30	**END OF THE DAY 4**		

Day 5| Sunday, June 30, 2019

(… Contd)Unit 5|Research integrity, reporting of research and publication ethics

Hours & Session no	Topic	Faculty	Learning Objectives
0930-1000	RECAP of Day 3 Resolving Queries	Participants and All faculty to respond to questions	
Session 13 1000-1130	Integrity in research: Research misconduct, authorship credits	Amar Jesani and Srijit Mishra	**Film screening** ➢ To learn the concept of research integrity ➢ To learn the relationship between research and society's trust ➢ To recognize various types of research misconduct: Plagiarism, fabrication, falsification, violations of participants' rights ➢ To learn about publication ethics : Rights and obligations to publish, authorship credit and authorship sequence, and ghost authorship
1130-1145	**TEA**		
Session 14 1145-1215	Reporting guidelines	Sunita Sheel	➢ To learn various standards for reporting of the research findings ➢ To recognize the significance of and critique of reporting guidelines
Session 15 **1215-1330**	Mock ERB meetings		➢ To learn the processes involved in serving on ERBs, responsibilities, and briefs of ERB via mock ERB ➢ To learn to deliberate research ethics issues in ERB meetings, to offer substantive justifications either in support of an argument/point of view, or offer a counter argument supported by substantive argument ➢ To learn the process of certifications and notification to applicant research team /researchers ➢ To recognize needs for on-going monitoring of projects
1330-1415	**LUNCH**		

Session 15 1415-1545	ERB Meetings Review Outcomes Presentation	Course participants Moderated by Amar Jesani	➤ To learn to present the outcome of ERB review outcome and defend it. ➤ To recognize the roles and responsibilities of ERB of educating applicant in research ethics and serving as sounding board for the peer community to discuss research ethics issues going beyond ethics review in compliance with regulations
1545-1600	**TEA**		
Session 16 1600-1730	➤ Open and Written Evaluation ➤ Valedictory ➤ Course certificate distribution		➤ For course organizers to know the areas of improvement in the course content, learning methods, allocation of time and related matters.
17:30	**END OF THE DAY 5 AND COURSE CLOSURE**		