

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

## Organisers

FMES' [Health, Ethics, and Law Institute for Training, Research and Advocacy \(HEaL Institute\)](#)

in collaboration with

**Indira Gandhi Institute for Development Research, Mumbai, MH and  
Vidhayak Trust, Pune, MH**

**Dates:** Tuesdays, Sept 6, 13, 20, 27, 2022;  
Tuesdays, Oct 4, 11, 18, 25; Tuesdays, Nov 1 and 8, 2022 |

**Time:** 1600 – 1930 hrs

**Venue:** Virtual

## 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. Prof Abhijit Nadkarni, Global Mental Health at the London School of Hygiene and Tropical Medicine (LSHTM), UK; Director of the Addictions Research Group, Sangath, Goa, India
2. Dr Amar Jesani, MBBS, Independent Researchers and Consultant, Public Health and Bioethics, Mumbai; and Editor, Indian Journal of Medical Ethics (IJME)
3. Dr Anant Bhan, Adjunct Professor, Yenepoya (deemed to be University), Mangalore, India and Adjunct Faculty, Kasturba Medical College, Manipal, India.
4. Prof Calvin Ho, Health Law, Policy & Bioethics - Associate Professor of Law, The University of Hong Kong; Co-Director, HKU Centre for Medical Ethics & Law, Hong Kong; Hong Kong SAR; Advocate & Solicitor of the Supreme Court of Singapore; and Solicitor of the Senior Courts of England and Wales
5. Prof Eunice Kamara, Moi University, Eldoret, Kenya
6. Prof Lakshmi Lingam, Dean & Professor, School of Media and Cultural Studies, TISS, Mumbai
7. Prof Lisa Schwartz, Faculty of Health Sciences, McMaster University; Professor, Health Research Methods, Evidence, and Impact, Faculty of Health Sciences; Member, Centre for Health Economics and Policy Analysis (CHEPA), Faculty of Health Sciences; Associate Member, Philosophy, Faculty of Humanities
8. Prof Mala Ramanathan, Achutha Menon Centre for Health Science Studies (AMCHSS), Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST), Thiruvananthapuram, Kerala, SCTIMST, Trivandrum, India; Working Editor, IJME
9. Sandhya Srinivasan, Consulting Editor, IJME; Editorial Board Member, Developing World Bioethics; Member, Network of Women in the Media-India, the Indian Association of Medical Journal Editors, and the World Association of Medical Editors.
10. Prof Srijit Mishra, Professor, IGIDR, Mumbai; Former Director, NCDS, ICSSR Institute, Bhubaneswar, Odisha, India. [Course Director]
11. Dr Sunita Sheel Bandewar, Working Editor, IJME; and Director, Health, Ethics and Law Institute of Training, Research and Advocacy, Mumbai-Pune; Founding Trustee, Vidhayak Trust, Pune, India [Course Director]
12. Tejal Barai, Independent Sr Research Professional, Mumbai
13. Prof Uma Kulkarni, Ophthalmology; Faculty at the Centre for Ethics, Yenepoya deemed to be University, Mangalore, KA, India
14. Prof Vina Vasvani, Forensic Medicine Dept; and Director Centre for Ethics Yenepoya (deemed to be University), Mangalore, KA, India

#### **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**  
Sept 6, 2022 to Oct 25, 2022

(Every Tuesday during this period between 1600 to 1930 hrs)

**Programme Schedule**

<b>DAY 1  Tuesday, Sept 6, 2022</b>			
<b>Unit 1 Social Sciences and Public Health Research ethics: History, Theoretical Approaches, and Ethics Principles</b>			
<b>Hours &amp; Session no</b>	<b>Topic</b>	<b>Faculty</b>	<b>Learning Objectives</b>
1530-1545	Welcome & Inauguration	IGIDR, HEaL Institute and Vidhayak Trust Director, IGIDR to inaugurate	
1545 -1600	Course overview and introduction to course objectives; and Round of Introduction	HEaL Institute Colleagues	
<b>Session 1</b> 1600 -1730	Importance of Ethics in Human Health Research	Amar Jesani	<b>Film Screening</b> ➤ What is research? ➤ What are social sciences and their histories? ➤ History of ethics violations/challenges & Learnings
<b>1730 - 1745</b>	<b>Break</b>		
<b>Session 2</b> 1745 - 1915	Morality, ethics, human rights and law: Challenges posed in research across disciplines	Sunita Sheel and 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
<b>End of the Day 1, Sept 6</b>			
<b>DAY 2  Tuesday, Sept 13, 2022</b>			
<b>Unit 1 Social Sciences and Public Health Research ethics: History, Theoretical Approaches, and Ethics Principles</b>			
<b>Session 3</b> 1600-1730	Bioethics: Theoretical approaches and perspectives	Srijit Mishra & Sunita Sheel	➤ <u>Theories:</u> Deontology/Kant; Utilitarianism /Consequentialism, Virtue, Principlism ➤ <u>Perspectives:</u> Gender, marginalisation/vulnerability, care, culture/religion <b>Case examples embedded in the presentation</b>
<b>1730 - 1745</b>	<b>Break</b>		
<b>Session 4</b> 1745 - 1915	Social sciences: Positivist and non-positivist	Mala Ramanathan	➤ To identify the potential ethical challenges in positivist and non-positivist approaches to research in social sciences

	approaches; cultural and moral relativism vs universalism		<ul style="list-style-type: none"> <li>➤ To describe relativist approaches vs universalist approaches to resolving ethical dilemmas in research</li> </ul> <p><b>Case examples embedded in the presentation</b></p>
<b>END OF THE DAY 2   Tuesday, Sept 13, 2022</b>			
<b>DAY 3   Tuesday, Sept 20, 2022</b>			
<b>Unit 2   Translating Research Ethics Principles into practice</b>			
Hours & Session no	Topic	Faculty	Learning Objectives
1530-1600	RECAP of Day 1 & 2 Resolving Queries	Participants and course directors and any other available faculty to respond to questions	
<b>Session 5</b> 1600-1730	Informed consent (IC)	Anant Bhan	<p><b>Film Screening</b></p> <ul style="list-style-type: none"> <li>➤ To learn the foundation of the principle of autonomy and IC</li> <li>➤ To learn various components of IC process – voluntariness, information, comprehension, documentation</li> <li>➤ To recognize process of consent taking and its salience</li> <li>➤ To learn IC in various situations, and permissibility of IC waivers</li> <li>➤ To know guidelines and laws; and specific challenges</li> </ul> <p><b>Group work for case studies or case study based discussions in plenary</b></p>
1730 - 1745	<b>Break</b>		
<b>Session 6</b> 1745 - 1915	Privacy and confidentiality	Uma Kulkarni	<p><b>Film screening</b></p> <ul style="list-style-type: none"> <li>➤ To recognise the need for privacy and confidentiality in a research process</li> <li>➤ To identify the challenges to privacy and confidentiality in both qualitative and quantitative research and</li> <li>➤ To suggest some examples of good practices to meet such challenges to privacy and confidentiality in research</li> </ul> <p><b>Group work for case studies or case study based discussions in plenary</b></p>
<b>END OF THE DAY 3   Tuesday, Sept 20, 2022</b>			
<b>DAY 4   Tuesday, Sept 27, 2022</b>			
<b>Unit 2   Translating Research Ethics Principles into practice</b>			
<b>Session 7</b> 1600-1730	Justice and Equity in Research	Srijit Mishra,	<ul style="list-style-type: none"> <li>➤ To learn and exploring ethics principle of justice; its importance in conceptualising research and in its conduct</li> <li>➤ Research participant selection</li> <li>➤ Vulnerability and fairness</li> <li>➤ Right to post-research benefit</li> </ul> <p><b>Case examples embedded in the presentation</b></p>

<b>1730-1745</b>		<b>Break</b>	
<b>Session 8</b> 1745-1915	Risks and Benefits assessment of research	Lisa Schwartz	<ul style="list-style-type: none"> <li>➤ Ethics principles and risk/benefits</li> <li>➤ Various types of risks – frequency of their occurrence and magnitude</li> <li>➤ Risk benefit analysis</li> </ul> <b>Case examples embedded in the presentation</b>
<b>END OF THE DAY 4   Tuesday, Sept 27, 2022</b>			
<b>DAY 5  Tuesday, Oct 4, 2022</b>			
<b>Unit 3 Research ethics obligations and issues in relation to research designs and research</b>			
<b>Hours &amp; Session no</b>	<b>Topic</b>	<b>Faculty</b>	<b>Learning Objectives</b>
1530-1600	RECAP of Day 3 & 4 Resolving Queries	Participants and course directors and any other available faculty to respond to questions	
<b>Session 9</b> 1600-1745	Ethical challenges in quantitative research methods	Mala Ramanathan	<ul style="list-style-type: none"> <li>➤ To recognise the ethical challenges posed by the application of methodological requirements of quantitative research in social science</li> <li>➤ To suggest some possible ways to mitigate against the ethical challenges</li> </ul> <b>Case examples embedded in the presentation</b>
<b>1730-1745</b>		<b>Break</b>	
<b>Session 10</b> 1745-1915	Ethical challenges in qualitative research methods	Lakshmi Lingam	<ul style="list-style-type: none"> <li>➤ To recognise the ethical challenges posed by the nature of qualitative research in social science</li> <li>➤ To suggest some possible ways to mitigate against the ethical challenges</li> </ul> <b>Case examples embedded in the presentation</b>
<b>END OF THE DAY 5   Tuesday, Oct 4, 2022</b>			
<b>DAY 6  Tuesday, Oct 11, 2022</b>			
<b>Unit 3 Research ethics obligations and issues in relation to research designs and research</b>			
<b>Session 11</b> 1600-1730	Ethical challenges in Action and Participatory social science action research designs	Sunita Sheel	<ul style="list-style-type: none"> <li>➤ To learn about action and participatory action research; and Monitoring and evaluation</li> <li>➤ To identify and discuss specific ethical challenges in each design</li> <li>➤ To suggest some possible ways to mitigate against the ethical challenges</li> </ul> <b>Group work for case studies or case study based discussions in plenary</b>
<b>1730-1745</b>		<b>break</b>	
<b>Session 12</b> 1745-1915	Ethical challenges in complex intervention – experimental research designs	Abhijit Nadkarni	<ul style="list-style-type: none"> <li>➤ To learn about experimental and quasi experimental social science and public health research designs and longitudinal studies</li> </ul>

	(Cluster randomised trials)		<ul style="list-style-type: none"><li>➤ To learn about population-based Cluster Randomised Trials</li><li>➤ To recognize and discuss ethical challenges in each</li></ul> <b>Group work for case studies or case study based discussions in plenary</b>
END OF THE DAY 6   Oct 11, 2022			
DAY 7  Tuesday, Oct 18, 2022			
Unit 4  Research Ethics Governance			
Hours & Session no	Topic	Faculty	Learning Objectives
1530-1600	RECAP of Day 5 & 6 Resolving Queries	Participants and course directors and any other available faculty to respond to questions	
<b>Session 13</b> 1600-1730	Research Ethics Committees (REC)	Vina Vaswani	<ul style="list-style-type: none"><li>➤ To recognize ethics guidelines and need for governance of research</li><li>➤ To recognize REC as a form of governance mechanism</li><li>➤ To learn about composition and structure of ethics review committees;</li><li>➤ To learn about their mandates, roles and responsibilities</li><li>➤ To know ethics review processes</li><li>➤ To Standard Operating Procedures of the REC and functions</li><li>➤ To recognize challenges faced by the REC</li></ul>
<b>1730-1745</b>	Break		
<b>Session 14</b> 1745-1915	Ethics of collaborative research in social sciences and public health research spaces	Eunice Kamara	<ul style="list-style-type: none"><li>➤ To learn the salience of collaborative research in the contemporary context of global health research</li><li>➤ To recognize research ethics principles which inform collaborative research ethics discourse</li><li>➤ To learn about approaches to conceptualize and implement collaborative research in alignment with research ethics principles and obligations</li></ul>
END OF THE DAY 7   Oct 18, 2022			
DAY 8  Tuesday, Oct 25, 2022			
Unit 4  Research Ethics Governance			
<b>Session 15</b> 1600-1730	Data sharing in Social Sciences and Public Health Research: Ethics, Law and Regulatory Frameworks	Calvin Ho	<ul style="list-style-type: none"><li>➤ To learn about the concept of data sharing and underlying ethics principles</li><li>➤ To learn about data transparency, including the public archiving of data for reanalysis by others from the peer community</li><li>➤ To learn about the risks involved in data sharing</li></ul>
<b>1730-1745</b>	Break		
Unit 5 Research integrity, reporting of research and publication ethics			



<b>Session 16</b> 1745-1845	Conflict of interest (CoI)	Amar Jesani	<ul style="list-style-type: none"> <li>➤ What is Conflict of Interest?</li> <li>➤ What are the types of conflict of interest?</li> <li>➤ CoI of researchers, gatekeepers, institutions, RECs, etc</li> <li>➤ Management of conflict of interest: disclosure requirements, recusing from position of decision making</li> <li>➤ CoI and corruption</li> </ul>
1845-1915	Preliminary discussion on protocols for review, including queries	Sunita Sheel, Tejal Barai, Srijit Mishra	Formation of ERB committees comprising of course participants (three to four groups) <ul style="list-style-type: none"> <li>➤ For the faculty to form the ethics committees comprising of the course participants</li> <li>➤ To know the process of reviewing the study protocols assigned to the groups</li> <li>➤ To know the process of documenting deliberations and arriving at the decision on the research protocol</li> </ul>

**END OF THE DAY 8 | Tuesday, Oct 25, 2022**

**Day 9 | Tuesday, Nov 1, 2022**

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

Hours & Session no	Topic	Faculty	Learning Objectives
1530-1600	RECAP of Day 7 & 8 Resolving Queries	Participants and course directors and any other available faculty to respond to questions	
<b>Session 17</b> 1600-1730	Integrity in research: Research misconduct, authorship credits	Sandhya Srinivasan	<b>Film screening</b> <ul style="list-style-type: none"> <li>➤ To learn the concept of research integrity</li> <li>➤ To learn the relationship between research and society's trust</li> <li>➤ To recognize various types of research misconduct: Plagiarism, fabrication, falsification, violations of participants' rights</li> <li>➤ To learn about publication ethics : Rights and obligations to publish, authorship credit and authorship sequence, and ghost authorship</li> </ul>
<b>1730-1745</b>	<b>Break</b>		
<b>Session 18</b> 1745-1815	Reporting guidelines	Sunita Sheel	<ul style="list-style-type: none"> <li>➤ To learn various standards for reporting of the research findings</li> <li>➤ To recognize the significance of and critique of reporting guidelines</li> </ul>
<b>Session 19</b> 1815-1915	Mock ERB meetings	Tejal Bara, Srijit Mishra, and Sunita Sheel	<ul style="list-style-type: none"> <li>➤ To learn the processes involved in serving on ERBs, responsibilities, and briefs of ERB via mock ERB</li> <li>➤ 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</li> </ul>

			<ul style="list-style-type: none"> <li>➤ To learn the process of certifications and notification to applicant research team /researchers</li> <li>➤ To recognize needs for on-going monitoring of projects</li> </ul>
<b>END OF THE DAY 9   Tuesday, Nov 1, 2022</b>			
<b>Day 10  Tuesday, Nov 8, 2022</b>			
<b>Unit 4  Research Ethics Governance</b>			
<b>Session 20</b> 1600-1730	ERB Meetings Review Outcomes Presentation	Course participants Moderated by Tejal Barai Sunita Sheel, and Srijit Mishra	<ul style="list-style-type: none"> <li>➤ To learn to present the outcome of ERB review outcome and defend it.</li> <li>➤ 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</li> </ul>
<b>1730-1745</b>	<b>Break</b>		
<b>Session 21</b> 1745-1915	<ul style="list-style-type: none"> <li>➤ Open and Written Evaluation</li> <li>➤ Valedictory</li> <li>➤ Course certificate distribution</li> </ul>		<ul style="list-style-type: none"> <li>➤ For course organizers to know the areas of improvement in the course content, learning methods, allocation of time and related matters.</li> </ul>
<b>END OF THE DAY 10 AND COURSE CLOSURE</b>			