

**Short-Duration Intensive Training Institute for ARMMAN**  
**in**  
**Research Ethics for Social Science and Public Health Research with focus on**  
**Evaluation Programs in Health Arena, and**  
**Digital Health Technologies as Programmatic Interventions**

**By**  
**Health, Ethics and Law Institute ([HEaL Institute](#)) of**  
**Forum for Medical Ethics Society FMES**

**Day and Date** | Wed, Thu, Fri, Nov 10, 11, 12, 2021 |

**Time:** 10.00 am to 4.00 pm

**Venue:** Virtual

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**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 scientific integrity of research enterprise in general; and identify and apply the methods of ethical reasoning to health research with special focus on mHealth, Digital Technologies in Health, and program evaluations.

**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 with focus on evaluation research and program interventions involving digital health technologies.
2. To strengthen awareness of participants of ethical issues in research involving human participants, and their appreciation of the need for research integrity
3. To strengthen the understanding of specific concepts in research ethics (social value, scientific validity, privacy, confidentiality, informed consent process, risks and benefits in research context, collaborative research, publication ethics, research integrity, post-trial access, ancillary care); 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.
4. To learn Indian laws and regulations relevant to mHealth, and digital health technologies and its interfacing with research ethics obligations such as data sharing.

- To learn the application of ethical reasoning to respond to the aforesaid challenges posed by social science and public health research; and enhancing skills in operationalizing research ethics principles in practice.

#### Course Director and core Faculty:

- [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](#)];
- [Dr Amar Jesani](#), MBBS, Independent Researchers and Consultant, Public Health and Bioethics, Mumbai; and Editor, Indian Journal of Medical Ethics ([IJME](#))
- [Mala Ramanathan](#), PhD, Masters in Medical Anthropology, Bioethics (Harvard), AMCHSS, SCTIMST, Trivandrum; Working Editor, IJME; Member Secretary, IEC
- [Dr Anant Bhan](#), MBBS, MPH MHS, Sr Health Researcher in Global Health and Bioethics; Adjunct Professor, Yenepoya (deemed to be University), Mangalore, India and Adjunct Faculty, Kasturba Medical College, Manipal, India.
- [Ms Gracy Andrew](#), Clinical psychologists, Country Director, [CorStone](#), India.
- [Adv Apar Gupta](#), Exe Director, [Internet Freedom Foundation](#), New Delhi.

#### Learning methods:

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

DAY 1   Wed, Nov 10, 2021		
Hours & Session no	Topic & Faculty	Learning Objectives
1000-1015	Welcome & Inauguration; and Round of Introduction	<b>Dr Bhuvaneshwari Sunil</b> , Lead, Research Program, ARMMAN to provide an overview of ARMMAN's research program <b>Dr Sunita Sheel</b> , FMES-HEaL Institute
1015-1030	Course overview and introduction to course objectives	
<b>Session 1</b> 1030-1200	Importance of Ethics in Human Health Research and Morality, ethics, human rights and law: Challenges posed in research across disciplines  <b>Dr Amar Jesani</b>	<b>Film Screening</b> <ul style="list-style-type: none"> <li>➤ History of ethics violations/challenges &amp; Learnings</li> <li>➤ To learn about the concept of ethics, facts, value, duties, morality,</li> <li>➤ To recognize the relationship between ethics and law;</li> <li>➤ Ethics and various disciplines - Basic Sciences, Medical or clinical Sciences, Social Sciences, Public health</li> </ul>
12.00-12.15	<b>Break</b>	
<b>Session 2</b> 1215-1330	Research ethics principles and Benchmarks  Informed consent (IC)	<b>Film Screening</b> <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> </ul>

	<b>Dr Anant Bhan</b>	<ul style="list-style-type: none"> <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>
1330-1400	<b>Lunch break</b>	
<b>Session 3</b> 1400-1500	Privacy and confidentiality  <b>Dr Sunita Sheel</b>	<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>Session 4</b> 1500-16:00	Implementation research and Ethical challenges in Implementation research  <b>Dr Anant Bhan</b>	<ul style="list-style-type: none"> <li>➤ To learn about the emerging field of implementation science-research (IS/R), and its historical context</li> <li>➤ To know the distinct features of IS/R compared to traditional research</li> <li>➤ Specific issues, challenges, and ethical concerns in IS/R</li> </ul>
<b>End of Day 1   Wed, Nov 10, 2021</b>		
<b>DAY 2   Thursday, Nov 11, 2021</b>		
<b>Session 5</b> 1000-1130	Risks and Benefits assessment of research  <b>Dr Mala Ramanathan</b>	<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> <li>➤ <b>Case examples embedded in the presentation</b></li> </ul>
11.30-11.45	<b>Break</b>	
<b>Session 6</b> 1145-1300	Evaluation research and Ethical challenges in Evaluation research  <b>Gracy Andrews</b>	<ul style="list-style-type: none"> <li>➤ To learn program monitoring and evaluation research</li> <li>➤ To identify and discuss specific ethical challenges in monitoring and evaluation research</li> <li>➤ To suggest some possible ways to mitigate against the ethical challenges</li> </ul>
1300-1330	<b>Lunch break</b>	
<b>Session 7</b> 1330- 1430	IT Rules, Laws and regulatory frameworks  <b>Adv Apar Gupta</b>	<ul style="list-style-type: none"> <li>➤ To know the broad legal and regulatory frameworks in India relating to digital technology</li> <li>➤ To understand strengths and limitations of these frameworks in relation to digital technology-based health interventions-programs</li> <li>➤ To know about interfacing legal and ethics issues in digital technology based health interventions-programs</li> </ul>
1430-1445	<b>Break</b>	
<b>Session 8</b> 1545-1600	Ethics of collaborative research  <b>Dr Sunita Sheel</b>	<ul style="list-style-type: none"> <li>➤ To learn the salience of collaborative research in the contemporary context of global health research</li> </ul>

		<ul style="list-style-type: none"> <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>
<b>END OF DAY 2   Thursday, Nov 11, 2021</b>		
<b>DAY 3   Friday, Nov 12, 2021</b>		
<b>Session 9</b> 1000-1130	Data sharing, Surveillance in the context of Digital Health Technologies  <b>Dr Sunita Bandewar</b>	<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>
1130-1145	<b>Break</b>	
<b>Session 10</b> 1145-1330	Conflict of interest (CoI)  <b>Dr Sunita Bandewar</b>	<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> </ul> <p>CoI and corruption</p>
1330-1400	<b>Lunch break</b>	
<b>Session 11</b> 1400-1530	Integrity in research: Research misconduct, authorship credits  <b>Dr Amar Jesani</b>	<p><b>Film screening</b></p> <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>Session 12</b> 1530-1600	Reporting guidelines  <b>Dr Sunita Bandewar</b>	<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>
1600-1630	Valedictory	ARMMAN and FMES
<b>END OF DAY 3 and the Training Institute   Friday, Nov 12, 2021</b>		