

**FMES' legacy in bioethics trainings:** It is since over about 15 years that FMES has been engaged with conceptualizing and organizing customized short duration training programs in various sub-fields of bioethics. The idea has been to respond to specific needs of researchers, interventionists, programmers, service providers in health and allied themes working in specific contexts. It requires wide ranging expertise from across disciplines with grounding in bioethics and the evolving scholarship in respective fields. FMES and now since 2018 through its programmatic platform namely Health, Ethics, and Training Institute (HEaL Institute) has been able to design such training programs as it draws upon its multidisciplinary network, bioethicists and scholars from allied thematics.

Collectively, over time, we have a created a pool of resources, especially ethics case studies from the Indian context drawing upon actual research studies and scenarios of ethical dilemmas researcher were confronted with. These serve as one of the key resources for the course. This continues to expand as we get opportunity to engage with diverse constituencies working in wide ranging context. As such, every training program we organize, provides us a peer learning opportunity.

This training program is steered towards facilitating participants to learn and equip themselves with foundations of research ethics and its operational or applied facets. The focus on the context and nature of their own work. The course participants would serve as significant human resource to take the learnings to their own ecosystems and facilitate knowledge transfer in research ethics.

**Thematic modules:** The course organized around two main thematic modules and sub-themes therein as below:

I. **Foundations of research ethics:** This module comprises of five sessions to cover the foundational principles of research ethics, such as, respect to personhood, researchers' commitment to maintain







privacy and confidentiality of the research participants and information collected from them; concept of risks and benefits; publication ethics and research integrity; and a sneak peek at the history and origins of ethical concerns to help appreciate the salience of research ethics discourse in the cotemporary context of research and programs in the space of gender-based violence.

Vignettes and case scenarios for these sessions on foundational research ethics principles are drawn from VAW-GBV research and intervention spaces.

- II. Ethics of intervention research towards evidence-based advocacy and program: This module consists of two sessions to cover the themes, namely, ethics of interventions research and prospective research studies which involves re-contacting individuals; developing evidence base using intervention/programmatic data on aspects of violence against women; and ethical considerations in using secondary data.
- **III. Navigating through conflicting interfaces of law and ethics:** This module will comprise of one session in the form of a space for discussing diverse case scenarios on conflicting ethics and legal measures. Many a times ethics norms, principles, and values stand to be in conflict with legal frameworks. These pose challenges to researchers and interventionists/program teams/organisations. In such situations what takes precedence law or ethics is a key question, and ways to ensure survivors safety and dignity is upheld becomes central to a resolution.

**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 intervention research in the spaces of gender-based violence/violence against women, use of intervention/program data for generating evidence to inform ongoing interventions and advocacy.

## **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 and interventions in the space of violence against women.
- 2. 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); and appreciate research ethics challenges specific to research design, special groups with enhanced vulnerabilities; situational vulnerabilities in the context of research in the space of violence against women.
- 3. 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.
- 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.

## **Course Director and core Faculty:**

- 1. <u>Sunita Sheel Bandewar</u>, PhD (Anthropology) and Masters in Bioethics (Toronto, Canada), Independent Researcher, Pune; Working Editor, <u>IJME</u>; and Director, Health, Ethics and Law Institute of Training, Research and Advocacy, Mumbai-Pune [Course Director];
- 2. <u>Anant Bhan</u>, MBBS, PGDMLE, MHSc, 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.







- 3. <u>Amar Jesani</u>, MBBS, Independent Researchers and Consultant, Pubic Health and Bioethics, Mumbai; and Editor, Indian Journal of Medical Ethics (<u>IJME</u>)
- 4. <u>Lakshmi Lingam</u>, M.A. (Andhra University); Ph.D. (IIT, Bombay), Professor, Tata Institute of Social Sciences, Mumbai campus; Dean, School of Media and Cultural Studies
- 5. <u>Mala Ramanathan</u>, PhD, Masters in Medical Anthropology, Bioethics (Harvard), AMCHSS, SCTIMST, Trivandrum; Working Editor, IJME; Member Secretary, IEC

**Learning methods:** Interactive methods involving small group case studies, short videos, and ample discussion space. Case studies sourced and developed from within India to be complemented by those involved in international collaborative research.

GDrive Resources   Sessionwise available: https://drive.google.com/drive/folders/1krzcXH48KxidXpUtZObB8tCXENOnj4NV?usp=sharing							
DAY 1   Thursday, Dec 9, 2021							
Hours & Session no	Topic & Faculty	Learning Objectives					
1000-1015	Opening of the training program <b>Dr Sanjida Arora</b> , CEHAT	<ul> <li>Welcome,</li> <li>Overview of CEHAT's collaborative project in GBV</li> </ul>					
1015-1030	Dr Sunita Sheel, FMES-HEaL Institute; and	<ul><li>Course overview</li><li>Round of Introduction</li></ul>					
	Module I: Foundations of research ethics						
Session 1 1030-1200	Importance of Ethics in Human Health Research and Morality, ethics, human rights and law: Challenges posed in research across disciplines	<ul> <li>Film Screening</li> <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	Tea Break						
Session 2 1215-1345	Research ethics principles and Benchmarks; and Respect to personhood and Informed consent (IC) <b>Dr Sunita Sheel</b>	<ul> <li>Film Screening</li> <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> <li>Group work for case studies or case study-based discussions in plenary</li> </ul>					
1345-1415	Lunch						







Session 3 1415-1545Privacy and confidentialityFilm screeningDr Anant Bhan➤ To recognise the need for privacy and confidential research process➤ To identify the challenges to privacy and confident both qualitative and quantitative research and	-					
Dr Anant Bhan       research process         ➤ To identify the challenges to privacy and confident	-					
To identify the challenges to privacy and confident						
both qualitative and quantitative research and	ality in					
To suggest some examples of good practices to me						
challenges to privacy and confidentiality in researc	h					
Group work for case studies or case study-based						
discussions in plenary						
Session 4Risks and Benefits> Ethics principles and risk/benefits						
1545-1700assessment of research➤Various types of risks – frequency of their occurrent	nce and					
magnitude						
Prof Mala Ramanathan ▷ Risk benefit analysis						
Case examples embedded in the presentation						
End of Day 1   Thursday, Dec 9, 2021						
DAY 2   Friday, Dec 10, 2021						
Module II: Ethics of intervention research towards evidence-based advocacy and progra	m					
Session 5Intervention research and $\succ$ To learn about the intervention research						
1000-1130 research ethics issues $\blacktriangleright$ To know about specific research ethics issues in						
intervention research						
Dr Sunita Sheel         ➤         Specific issues, challenges, and ethical concerns in	IS/R					
11.30- 11.45 Tea Break	Tea Break					
Session 6 Ethics of data sharing, re- ➤ To learn about what comprises of 'data'						
1145-1300 using program/intervention > To learn about the concept of data sharing and und	erlying					
data, secondary data, and re- ethics principles						
connecting with program $\triangleright$ To learn about the risks involved in data sharing, a	nd re-					
participants in prospective use of data						
research > To learn about data transparency, including the put	olic					
archiving of data for reanalysis by others from the	peer					
Dr Sunita Sheel community and/or using secondary data sources	-					
1300-1330 Lunch break						
Module III: Navigating through conflicting interfaces of law and ethics						
Session 7 Conflicting ethics and legal > To know the broad legal and regulatory framework	ts in					
1330-frameworksIndia relating GBV, POCSO, CLA-2013 with focu	s on					
1500 clauses conflicting with ethics principles						
Prof Lakshmi Lingam  ► To know about interfacing legal and ethics issues i	n using					
case scenarios						
<ul> <li>To learn to respond to these complex and conflicting</li> </ul>	ng					
scenarios						
1500-1515 Tea Break						
Module I: Foundations of research ethics						
Session 8         Integrity in research:         Film screening						
1515-1645Research misconduct, $\succ$ To learn the concept of research integrity						
authorship credits $\blacktriangleright$ To learn the relationship between research and soc	iety's					
trust						
Dr Amar Jesani  ► To recognize various types of research misconduct	:					
Plagiarism, fabrication, falsification, violations of						
participants' rights						







		A	To learn about publication ethics: Rights and obligations to publish, authorship credit and authorship sequence, and ghost authorship		
1645-1700	Valedictory	•	Closing remarks		
		•	Feedback from the course participants		
		•	Certificate of participation issuance (virtually)		
END OF DAY 2   Friday, Dec 10, 2021					
End of the Training Program					





