**Short-Duration Intensive Training Program in Biomedical Research Ethics**

**Organised by**

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

**in collaboration with**

Calcutta School of Tropical Medicine, Kolkata (CSTM), Kolkata (http://www.stmkolkata.org/); and

Nabakrushna Choudhury Centre for Development Studies (NCDS), Bhubaneshwar, Odisha (http://ncds.nic.in/)

**Day & Dates:** Thursday, June 20 to Saturday, June 22, 2019

**Venue:** Calcutta School of Tropical Medicine, Kolkata

**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 in their organization and peer networks.

**Goal:** To enable course participants to identify ethical issues in biomedical research and apply ethical reasoning to resolve them towards safeguarding research participants' respect, dignity and rights; upholding research integrity.

**Specific objectives:**

1. To learn about history and origins of research ethics discourse and principles in biomedical research, and their relevance to contemporary biomedical research enterprise.,
2. To strengthen the awareness of participants of ethical issues in biomedical research involving human participants.,
3. To strengthen the understanding of select key concepts in biomedical research ethics, such as, informed consent, privacy, confidentiality, standard of care, ancillary care, compensation, risk & benefits, data sharing, conflict of interest, and publication ethics.
4. To learn the application of ethical reasoning to respond to ethical issues in biomedical research; and enhancing skills in operationalizing research ethics principles in practice.

**Short-Duration Intensive Training Program in**
**Biomedical Research Ethics**
Thursday – Saturday, June 20-22, 2019
**Programme Schedule**

| **DAY 1\| Thursday, June 20, 2019** | | | |
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| **Unit 1\|Biomedical Research ethics: History, Theoretical Approaches, and Ethics Principles** | | | |
| **Time & Session no** | **Topic** | **Faculty** | **Session Objectives** |
| 0900-0910 | Registration | | |
| 0910-0920 | Welcome & Inauguration | Director, CSTM | |
| **Session 1** 0920-0935 | Workshop Overview, Ice Breakers – Round of Introduction | HEaL Institute Colleagues | |
| **Session 2** 0935-1045 | Importance of Ethics in Human Health Research | Amar Jesani | ➢ **Film Screening**<br>➢ To appreciate historical controversies in biomedical sciences, public health and social science research<br>➢ To recognize its contribution to shaping biomedical research ethics guidance and discourse |
| **Session 3** 1045-1130 | Methods of Moral Reasoning | Sunita Sheel | ➢ To learn select key concepts: facts, value, duties, morality, ethics, law and human rights<br>➢ To recognize the distinction between morality, ethics and law |
| 1130-1145 | TEA | | |
| **Session 4** 1145-1215 | Theoretical Approaches in Bioethics and Perspectives in Human Research | Anant Bhan | ➢ To know briefly the theoretical approaches in bioethics<br>➢ To learn about their relevance to the practice of biomedical research ethics |
| **Session 5** 1215-1300 | Research Ethics Principles, Benchmarks and Ethics Guidelines | Anant Bhan | ➢ To learn about the key research ethics principles, benchmarks of ethical biomedical/clinical research<br>➢ To get introduced to the relevant international and national ethical guidelines |
| **1300-1445** | **LUNCH** | | |
| **Unit 2\| Overview of Research Designs and Research Methods in Biomedical Research** | | | |
| **Time &** | **Topic** | **Faculty** | **Session Objectives** |

| Session no | | | |
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| **Session 6**<br>1345-1445 | Overview of Biomedical Research Designs (incl. RCTs) | Santanu Tripathi | ➢ To learn about the select research designs in biomedical research<br>➢ To recognize the research ethics issues specific to particular research designs |
| **Unit 3\| Translating Research Ethics Principles into Practice** | | | |
| **Session 7**<br>1445-1600 | Informed consent in biomedical research | Sunita Sheel | ➢ To learn the foundation of the principle of autonomy and IC<br>➢ To learn various components of IC process – voluntariness, information, comprehension, documentation<br>➢ To recognize process of consent taking and its salience<br>➢ To learn IC in various situations, and permissibility of IC waivers<br>➢ To know guidelines and laws; and specific challenges<br>**Case studies will be discussed** |
| **1600-1615** | **TEA** | | |
| **Session 8**<br>1615-1730 | Privacy and confidentiality | Anant Bhan | ➢ **Film screening**<br>➢ To learn about the concepts of privacy and confidentiality<br>➢ To learn about mechanisms to ensure privacy and confidentiality<br>➢ To appreciate the limits to ensuring privacy and confidentiality and challenges to privacy and confidentiality<br>➢ To suggest some examples of good practices to meet such challenges to privacy and confidentiality in research<br>**Case studies will be discussed** |
| **17:30-1800** | **Faculty Meeting** | | |
| **DAY 2\| Friday, June 21, 2019** | | | |
| **(… Contd) Unit 3\| Translating Research Ethics Principles into practice** | | | |
| **Time & Session no** | **Topic** | **Faculty** | **Session Objectives** |
| 0900-0915 | RECAP and Resolving Queries | Participants / Sunita Sheel | ➢ To encourage course participants to reflect on the proceedings of the previous day<br>➢ To respond to course participants' questions on themes covered on the previous day |

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| **Session 9**<br>0915-1000 | Risks, Risk-Benefit Analysis and Ethics Correlates in Human Research | Santanu Tripathi | ➢ To learn the ethics principles of risk/benefits<br>➢ To recognize various types of risks – frequency of their occurrence and magnitude<br>➢ Risk benefit analysis |
| **Session 10**<br>1000-1100 | Compensation as a research ethics obligation | Anant Bhan | ➢ To learn the concept of compensation in biomedical research as part of research ethics obligation<br>➢ To learn differences between reimbursement, incentives and compensation in biomedical research;<br>➢ To recognize ethical issues with providing monetary or non-monetary incentives and compensation;<br>➢ To know current operative approaches to these in our context<br>**Case examples embedded in presentation** |
| **1100-1115** | **TEA** | | |
| **Session 11**<br>1115-1300 | Rights of Research Participants – Care, Standard of Care | Sunita Sheel | ➢ To learn the concept of standard of care in biomedical research<br>➢ To learn about different approaches for evaluating standard of care (SOC) in biomedical research<br>➢ To recognize the special ethical dilemmas involving use of placebos in clinical trials.<br>➢ To learn about the existence guidance on SOC from national and international research ethics guidelines.<br>**Case examples embedded in presentation** |
| **1300-1345** | **LUNCH** | | |
| **Session 12**<br>1345-1430 | Rights of the Research Participants: Ancillary Care (AC) | Amar Jesani | ➢ To understand ethical obligations of AC care in setting where participants do not have universal access to healthcare.<br>➢ The AC obligations in the guidelines and laws; and the modalities for providing the AC benefits. |
| **Session 13**<br>1430-1600 | Rights of the Research Participants: Post Trial Access (PTA) | Amar Jesani | ➢ To appreciate increasing importance of the PTA in the clinical research – the PTA as the benefit sharing, |

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| | | | reduce or avoid exploitation.<br>➢ To examine the need for legal or regulatory framework for operationalising the PTA.<br>➢ To critically analyse the provision of PTA in the new clinical trial rules<br><br>**Case studies will be discussed** |
| **1600-1615** | **TEA** | | |
| **Unit 4\|Research integrity, reporting of research and publication ethics** | | | |
| **Session 14**<br>1615-1730 | Integrity in research: Research misconduct, authorship credits | Subrata Chattopadhyay | ➢ **Film screening**<br>➢ To learn the concept of research integrity<br>➢ To learn the relationship between research and society's trust<br>➢ To recognize various types of research misconduct: Plagiarism, fabrication, falsification, violations of participants' rights<br>➢ To learn about publication ethics : Rights and obligations to publish, authorship credit and authorship sequence, and ghost authorship |
| **1715-1800** | **Faculty Meeting** | | |
| **DAY 3\| Saturday, June 22, 2019** | | | |
| **Time & Session no** | **Topic** | **Faculty** | **Session Objectives** |
| 0900-0915 | RECAP and Resolving Queries | Participants/ Santanu Tripathi | ➢ To encourage course participants to reflect on the proceedings of the previous day<br>➢ To respond to course participants questions on themes covered on the previous day |
| **(…Contd)**<br>**Unit 4\|Research integrity, reporting of research and publication ethics** | | | |
| **Session 15**<br>0915-1000 | Reporting Guidelines and Data Sharing Obligations | Sunita Sheel | |
| **Unit 5\|Research Ethics Governance; and Legal and Regulatory Frameworks** | | | |
| **Session 16**<br>1000-1045 | Good Clinical Practice (GCP) | Santanu Tripathi | ➢ To learn about the good clinical practice, its evolution, and its salience to biomedical research<br>➢ To learn about the relationship between research ethics obligations and GCP<br>➢ To recognize challenges that may arise due to discord between |

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| | | | compliance with GCP and research ethics obligations |
| **Session 17**<br>1045-1130 | Regulatory Framework in Human Research in India | Santanu Tripathi | ➢ To learn about the regulatory frameworks applicable to biomedical research<br>➢ To recognize the relationship between regulatory framework and research ethics discourse in biomedical research |
| **1130-1145** | **TEA** | | |
| **Session 18**<br>1145-1300 | Research Ethics Committees (REC) | Amar Jesani | ➢ To recognize ethics guidelines and need for governance of research<br>➢ To recognize REC as a form of governance mechanism<br>➢ To learn about composition and structure of ethics review committees;<br>➢ To learn about their mandates, roles and responsibilities<br>➢ To know ethics review processes<br>➢ To Standard Operating Procedures of the REC and functions<br>➢ To recognize challenges faced by the REC |
| **1300-1345** | **LUNCH** | | |
| **Session 19**<br>1345-1500 | Conflict of Interest in Research | Amar Jesani | ➢ To understand what constitutes competing interest in research, in institutes, in ethics committee<br>➢ To identify various types of CoI and the threat they produce on the integrity of science<br>➢ To understand the mechanism of avoidance and management of the CoI |
| **Course Evaluation by participants, valedictory and certificate distribution** | | | |
| 1500-1530 | Open evaluation and feedback from the course participants | Sunita Sheel and Santanu Tripathi | |
| 1530-1600 | Valedictory and Certificate Distribution | Guest of Honour (TBC) | |
| **1600-1630** | **Closing TEA** | | |
| **1630-1730** | **Faculty meeting (closed)** | | |