

**SHORT TERM
TRAINING
PROGRAMME**

BIOETHICS

21 – 23 June 2023

**INSTITUTIONAL ETHICS COMMITTEE
INDIAN INSTITUTE OF TECHNOLOGY
MADRAS**

Sardar Patel Road, Chennai – 600 036.

Short-term Training Programme on Bioethics

Date: 21 – 23 June 2023

Venue: Seminar Hall, Block-1, Department of Biotechnology

Description:

'Bioethics' is an interdisciplinary study involving biological, medical, legal, philosophical and social aspects in biomedical and health research. It addresses the ethical values and autonomy of the individual and ultimately improving the quality of life and well-being. The aim of this training is to introduce the participants to the concept of bioethics and its significance in academic research in accordance with the *"National ethical guidelines for biomedical and health research involving human participants (2017)"*. It enables the participants to understand and to apply the ethical principles in their innovative research and development activities.

Programme Organizers:

IIT Madras has a long standing history of being at the forefront of manpower training and teaching. The Institutional ethics committee at IIT Madras is one of the few ethics committees in the country and the first among 'Technological Institutions of National Importance' that is registered under the *"National Ethics Committee Registry for Biomedical and Health Research"* as mandated by the Department of Health Research (DHR Reg. No. EC/NEW/INST/2022/TN/0168). *Institutional Ethics Committee* with the technical support of the *Centre for Outreach and Digital Education (CODE)*, organizes the necessary manpower training on 'bioethics' in the unmet area of biomedical and health research as a skill development activity for faculty members, biomedical scientist, technocrats, start-up entrepreneurs, policy makers and students of the institution and for other institutions.

Scope of the programme:

To develop significant pool of ethically trained research cadre with knowledge and skills in *bioethics* and regulations. To promote professional establishments to have an ethics infrastructure to make ethical decisions and to affirm rights, safety and dignity of the human participants and contribute in building responsible citizens of the nation.

Modules covered:

The training programme covers the following modules and will be delivered as a class-room based teaching-learning activity with detailed discussions by the subject experts. The modules to be covered are; (i) Ethical principles and guidelines for biomedical research, (ii) Ethics Committee operations and registration, (iii) General ethical and legal Issues, (iv) Informed consent process and (v) Regulations on New Drugs and Clinical Trials Rules 2019 & Medical Devices Rules 2017 in accordance with the goals of the Department of Health Research.

Outcomes:

Participants are expected to learn the different concept and philosophies of health and will be able to identify some important ethical issues in biomedicine and healthcare. This course will familiarize the participants with some prominent ethical frameworks that they can employ in resolving ethical dilemmas and arrive at rational decisions.

Expert Resource Persons:

The eminent resource persons from Government sector, higher academic institutes, hospitals, legal experts, statistician and from pharma industry will be handling the training. Short profile of the resource persons, their area of expertise related to bioethics are given below;

I. Clinicians:

- **Dr. Vijayaprasad Gopichandran** Professor, Department of Community Medicine, ESIC Medical College & PGISMR, Chennai.
His areas of interest include non-communicable diseases epidemiology, health communication, doctor-patient relationships, medical and public health ethics. He serves as working editor for the prestigious Indian Journal of Medical Ethics since 2014. He consults for WHO for developing ethical guidelines for public health surveillance and developing curriculum for training in ethics of implementation research. He has been actively involved in community based epidemiological and bioethics research, more than 70 of which have been published in national and international journals.
- **Dr. P Paul Kumaran** Scientist F, Deputy Director (Medical), ICMR – National Institute for Research in Tuberculosis, Madurai Unit, Madurai.
His broad areas of interest include tuberculosis epidemiology, public health and bioethics. He has extensive experience in conducting clinical and epidemiological trials in the areas of Tuberculosis, HIV, HIV-TB, and Filariasis. Has undergone training in 'Bioethics and Ethics Committee Administration' at Western Institutional Review Board, USA. He served as the Member Secretary of NIRT- IEC till 2012, and as member till 2014. To his credit, he has surveyed 17 ECs (12 national and 5 foreign), as a surveyor for 11 ECs, lead surveyor for 4 ECs, and a survey coordinator for 2 ECs.
- **Dr. Nagarjuna Gandham** Consultant, Rakshith Hospitals & Member, IITM – IEC, Chennai.
His research interest is in the areas of medical devices development and validation. To his credit, he validated newly designed verbal autopsy instrument and obtained his PhD in Medicine & Epidemiology (2017). He has undergone training in Ethics Review of Health Research conducted by NIE-ICMR-WHO.

II. Legal Experts:

- **Mr. Ashok Venkateshmurthy** Advocate, High Court of Karnataka & Partner, Factum Law, Bengaluru.
He advises clients in the health, pharmaceutical, data analytics and medical electronics industry in setting up joint ventures, negotiating clinical trial agreements and risk

management. He has served as a member of the Ethics Committee of a multi-national super speciality hospital, in Bengaluru and routinely participates in the review of clinical trials involving interventional and observational studies. His expertise includes healthcare regulations in addressing emerging issues of confidentiality of health information.

- **Mr. Bimalendhu Sahu** Chief Manager (Advocate), IC & SR, IIT Madras & Member, IITM – IEC, Chennai.

He has rich experience in litigation and corporate houses. He has undergone training in Bioethics at IIT Madras and actively involved in IEC activities. He reviews proposals and prepares legal documents i.e Memorandum of Understanding (MoUs).

III. Social Scientist:

- **Dr. Hema Swaminathan** Professor, Centre for Public policy, Indian Institute of Management (IIM), Bangalore & Member, IITM – IEC, Chennai.

Her broad interests are in the areas of poverty and inequality using a gender perspective. Her research focuses on inequality in income and wealth distributions between men and women, female labour participation in India, and survey methodology to collect improved data on several domains. She is currently serving on the Standing Committee of Economic Statistics, Govt. of India.

IV. Statistician:

- **Dr. R. Ramakrishnan** Scientist G (Rtd), ICMR – NIE & Member, IITM – IEC, Chennai.

His field of interest are Medical Statistics, Epidemiology and Bioethics. He has undergone training in Applied Epidemiology at Australian National University. He has extensive experience in conducting clinical investigations and surveillance studies. He has been associated with Ethics and ethics review committees for more than 20 years, which includes a role as Co-ordinator, PG diploma course on bioethics. Have mentored more than 50 scholars on their Master's degree and Ph. D in the field of Public Health.

V. Basic Scientists:

- **Dr. Priya Kannian** Scientist & Head, Department of Clinical Research, VHS Hospital & Research Institute, Chennai.

Her area of interests is in the field of Clinical research, immunology and infection. She has extensively trained in bioethics and involved in clinical research; dealing patients and physicians at Voluntary Health Services Hospital. She is the Member Secretary of VHS-IEC. She has been the resource persons for many of the bioethics events and published in the related areas.

- **Dr. Abel Arul Nathan** Project Scientist, IITM – IEC, Chennai.

His expertise is in the areas of vascular biology and metabolic syndrome. His research involves preparing consent forms, participant information sheets, collecting blood samples and computing statistics. He has published his research works in reputed journals, recipient of Gandhian Young Technological Innovation Award and many travel awards. He has been guiding research scholars in designing experiments, sample collections and in statistical analysis. He currently takes care of the operations of IITM-IEC and its registration with Department of Health Research.

VI. Data Scientist:

- **Dr. P. Thiyagarajan** Associate Professor & Head, Department of Computer Science (Cyber Security), Rajiv Gandhi National Institute of Youth Development (RGNIYD), Chennai.

His areas of research interest are Information security, Big Data Analytics and Cryptography. He has extensive experience in conducting data analytical studies related to prediction of mild cognitive impairments in Alzheimer's using machine learning algorithms. He has published his research works in reputed journals, received Young Scientist Fellowship by Tamilnadu State Council for Science and Technology and Post-Doctoral Fellowship by Department of Atomic Energy, Govt. of India.

VII. R&D Scientist - Industry:

- **Dr. Srikar Raman** Vice-President & Head of R&D, Levim Biotech, Chennai.

He has 15+ years of experience in biotechnology product development. To his credit, he has developed several biosimilars, technology platforms and patents. He has working knowledge in the dossier preparation for clinical regulatory submissions and also has hands-on in transferring the products for scale-up optimization and GMP manufacturing.

References:

1. National ethical guidelines for biomedical and health research involving human participants (2017).
2. National ethical guidelines for biomedical research involving children (2017).