



Value Added Course (VAC), Presidency University, Session 2026

Course Title: Ethical and Regulatory Norms in Human Health Research

Teaching mode: Online

Credit level: 2

Duration: 2 weeks (30 hours)

Course Coordinators: Hadida Yasmin, Paulomi Ghosh, Somsubhra Nath

SYLLABUS

Objectives

The course is designed for people interested or involved in ethics of biomedical research with human subjects. The course describes the various principles involved in the ethical and regulatory aspects for conducting research on human subjects, including the role of research investigators as well as the role of Institutional Ethics Committee. The course has been designed keeping in mind the National Ethical Guidelines for Biomedical Research Involving Human Participants as per ICMR, Govt. of India.

Course

Module I: Introduction to the Course

- Historical Basis of guiding ethical conduct of clinical research
- General Ethical Issues
- Importance of ethics in translational biomedical research

Module II: Functioning of Institutional Ethics Committee (IEC)

- Composition and Selection of IEC members
- Roles and responsibilities
- Standard Operating Procedure (SOP)

- Review Process
- Registration & Accreditation of IECs
- Expedited review process
- Evaluation of technology driven biomedical research
- Risk categorization and adverse event reporting during clinical investigations

Module III: Informed Consent process

- Quality of Informed Consent
- Approaches to Informed consent
- Capacity to Consent
- Responsibility of researchers & Documentation of the process
- Waiver and Re-consent
- Special situations

Module IV: Biological materials and Bio-banking

- Storage of Bio-specimen and data
- Ethics related to donors and researchers
- Bio-bank/bio-repository
- Secondary use of stored samples
- Special issues