Title: Scope of Authority for Institutional Ethics Committee (IEC-III), ACTREC, Tata Memorial Centre

Issuing Authority: Dr Surekha Zingde, Chairperson of IEC-III, ACTREC,

Effective date: 15th May 2025

Purpose and Objectives: **The Institutional Ethics Committee (IEC) is established to safeguard the rights, safety, dignity, and well-being of individuals involved in research**. The IEC operates within the framework of ethical guidelines, regulatory standards, and institutional policies to ensure compliance and promote ethical practices.

The Institutional Ethics Committee (IEC-III) of Tata Memorial Centre has been constituted by the Director, Tata Memorial Centre (TMC), under the authority vested by the Governing Council of TMC. The head of the Institute, who serves as appellate, has the power to dissolve the IEC or re-appoint the IEC-III, ACTREC.

Authority and Responsibilities: The IEC has the authority to:

1. **Review and Approve or Disapprove research projects:** Evaluate research proposals, clinical trials, and other research-related institutional activities such as live workshops,clinical registries, biorepository etc to ensure adherence to ethical principles and applicable regulations.
2. **Monitor Compliance:** Conduct periodic reviews and monitoring to ensure ongoing compliance with approved protocols, ethical guidelines, and legal requirements.
3. **Overseeing post-approval activities:**
    a. **Post-approval amendments: The IEC is responsible for the review and approval of all post-approval documents such as protocol amendments, IB, ICF, Budget, CRF, updation of the study team, CTA/MOU, etc.**
    b. **Protocol Deviations or Changes**: Ensuring investigators promptly report any deviations or changes to eliminate immediate hazards to trial subjects.
    c. **Increased Risks or Impact**: Evaluating changes that increase risks to participants or significantly affect the trial's conduct.
    d. **New Safety or Efficacy (or any other new) Information**: Assessing new information that may impact the safety or outcome of participants or the trial's execution, including off-site SAE, DSMB/IDMC report, SUSAR, PSUR DSUR, etc.

4. **Suspend or Terminate research studies:**IEC has the authority to suspend or terminate the research or activities that deviate from approved protocols or violate ethical standards.The IEC also should recommend termination of the research if the study no longer meets the criteria that justified its initial approval.
5. **Conflict of Interest (COI) Management:** The Ethics Committee (EC) is responsible for ensuring transparent and effective management of conflicts of interest (COI) among its members, which includes:

    a. **Declaration of Conflicts**: Requiring all EC members to disclose any actual, potential, or perceived conflicts of interest (Financial and non-financial) related to the studies under review.
    b. **Prohibition on Participation**: Prohibiting EC members with a declared conflict of interest from participating in the review, discussion, or decision-making process for any study in which they have a conflicting interest.
    c. **Oversight and Documentation**: Maintaining oversight to ensure adherence to COI practices and documenting all disclosures and subsequent actions taken to mitigate conflicts.

6. **Advisory Role:** Provide ethical guidance to researchers, faculty, and institutional staff on complex or emerging ethical issues and provide recommendations for updating institutional policies.
7. **Develop and Update IEC SOPs:** Formulate, review, and update IEC SOPs.
8. **Ensure Training:** Organize and promote training programs on research ethics, compliance, and best practices for stakeholders.
9. **Address Complaints:** Investigate and address complaints or concerns related to research.
10. **Maintain Confidentiality:** Ensure confidentiality of sensitive information and protect the privacy of stakeholders involved in research.
11. **IEC's decision not to approve a study cannot be overruled, except in cases of abuse of authority as determined by a regulatory agency or court.**

The TMC IEC-III, ACTREC, will work according to its effective Standard Operating Procedures (SOPs) formulated in accordance with the prevailing national regulations and /or guidelines to define its function and purpose.

Signature and Date:

S. Zingde 15/5/25

Dr Surekha Zingde,
Chairperson
IEC III, ACTREC