



MAGANBHAI ADENWALA MAHAGUJARAT UNIVERSITY COLLEGE ROAD, NADIAD - 387001

Standard Operating Procedure (SOP) For Institutional Ethics Committee (IEC)

(VERSION 1, Effect from 1st FEBRUARY 2024)

This SOP has been prepared based on National Ethical Guidelines for Biomedical Research Involving Human Participants, ICMR 2017 the guidelines of ICMR for research involving human participants, Good Clinical Practice ICH-GCP and GCP-ASU guidelines and New Drugs and Clinical Trial rules, 2019.

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POLICY TO MONITOR OR PREVENT THE CONFLICT OF INTEREST ALONG WITH STANDARD OPERATING PROCEDURES

COI occurs when secondary interests (financial, personal, academic, or political) override primary interests such as participant welfare or research integrity. It can arise at the institutional, researcher, or IEC level.

Purpose:

The purpose of this policy is to define conflict of interest (COI) in the context of human research ethics review and outline the procedures to identify, manage, and prevent COIs among IEC members, investigators, and institutional staff, thereby ensuring the independence, objectivity, and integrity of the IEC's decisions.

Scope:

This policy applies to:

- All IEC members (permanent and temporary)
- Investigators and co-investigators submitting protocols for review
- Any external experts/consultants involved in IEC review process

Definition of Conflict of Interest (CoI):

A CoI arises when the primary interests of an individual (i.e., protecting the rights and welfare of research participants) are unduly influenced by secondary interests such as financial gain, personal relationships, academic competition, or institutional affiliations.

Institution Policy / SOP to monitor or prevent CoI:

1. The IEC shall ensure that –

- All members declare their potential conflicts prior to appointment and before each meeting.
- Members with a conflict shall recuse themselves from the review and decision-making for the relevant proposal.
- The IEC functions independently and avoids bias in decision-making.

2. Researchers Must:

- Disclose any conflicts of interest in documents and submit to IEC before the meeting starts. Format of CoI declaration form is also prepared by IEC and will be available from member secretary whenever require.
- Avoid reviewing grants, publications, or proposals from close colleagues, relatives, or students.

3. IEC Must:

- Evaluate all submitted studies.
- Suggest appropriate actions if COI is detected.
- IEC members must disclose their COI (Confidentiality Agreement & COI Form) and recuse themselves from reviewing affected proposals.
- Follow SOPs for COI management.

4. Meeting Conduct & Decision-Making

- Members must declare COI before discussions and leave the room during deliberations. This must be recorded in minutes.
- Quorum is required for decision-making.
- Investigators & study team members cannot participate in IEC decisions related to their project.