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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CONDITIONS OF APPOINTMENT AND THE QUORUM REQUIRED

1. **Conditions of Appointment**

A member should be willing to disclose their full name, profession, and affiliation. All reimbursement for work and expenses, if any, related to the Committee will be made available to the appropriate authority upon request. A member must sign a confidentiality agreement regarding meeting deliberations, applications, information on research participants, and related matters. Additionally, all Committee administrative staff must sign a similar confidentiality agreement. Members are expected to:

- Show full commitment and responsibility.
- Respect divergent opinions.
- Maintain confidentiality.
- Review proposals without bias or external influence.
- New members will be appointed under the following circumstances:
- When a regular member completes their tenure.
- If a regular member resigns or leaves before completing their tenure.
- If the volume of proposals and frequency of reviews require additional members.
- When appointing a new member, it is advisable to induct a replacement from the same category to maintain committee norms.

2. **Tenure of Membership –**

- The tenure of Committee membership will be a continuous period of three (3) years.
- Extension of membership will be decided by the Head of the Institute (HOI).
- Membership extensions will be limited to one or two terms to prevent conflicts of interest and introduce fresh perspectives in the review process.

3. **Quorum requirement of the Committee –**

A minimum of five members must be present in the meeting. The quorum should include both medical, non-medical or technical and non- technical members.

Minimum one non-affiliated member should be part of the quorum.

Preferably the layperson should be part of the quorum.

The quorum for reviewing regulatory clinical trials should be in accordance with current New Drugs and Clinical Trials Rules 2019 requirements.

No decision is valid without fulfilment of the quorum.