MAGANBHAI ADENWALA MAHAGUJARAT UNIVERSITY

COLLEGE ROAD, NADIAD - 387001

Standard Operating Procedure (SOP)

For

Institutional Ethics Committee (IEC)

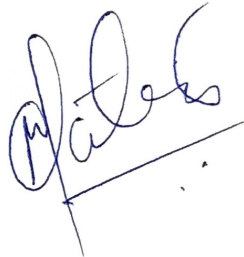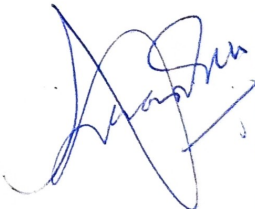## (VERSION 1, Effect from 1st FEBRUARY 2024)

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 REGARDING TRAINING FOR NEW AND EXISTING MEMBERS ALONG WITH STANDARD OPERATING PROCEDURES

Purpose:

To ensure that all members of the Institutional Ethics Committee (IEC) are adequately trained and familiarized with guidelines related to research and ethics, to maintain the highest standards of ethical review and oversight.

Scope:

This policy applies to all members of the IEC, including the Chairman, Member Secretary, and members.

Responsibilities:

All IEC members must familiarize themselves with relevant guidelines, including:

- GCP Guidelines for ASU medicine (2013)
- ICMR National Ethical Guidelines (2017)
- New Drugs and Clinical Trials Rules (2019)

- Member-secretary or an IEC member will provide an introductory training to the new member.

- All IEC members must undergo a refresher course in Good Clinical Practice (GCP) in online or offline mode.

- The appointing authority will provide support and encouragement for members to attend such training programs.

- The SOPs will be updated periodically based on changing requirements, and members will be informed of any changes.

Training mode

- The Chairman, Member Secretary, and members are encouraged to attend training programs, conferences, workshops, seminars, and courses in research ethics to improve the quality of review and related activities.

- Training can be taken in both Online and offline mode from authentic and approved source/institutions

Training Requirements:

- IEC members must complete the required training within 6 months of appointment and every 1 years thereafter.

- Training programs must be approved by the appointing authority.

- Members must provide proof of completion of training to the Member Secretary.

Record Keeping of trainings:

- The Member Secretary/secretariate will maintain records of member training, including dates, topics, and proof of completion.

- Records will be updated regularly and made available to the appointing authority upon request.