



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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STANDARD OPERATING PROCEDURES TO BE FOLLOWED BY THE COMMITTEE FOR VULNERABLE POPULATION

Vulnerable populations are individuals or groups who may have an increased likelihood of being wronged or of incurring additional harm in research due to diminished autonomy or social disadvantages. The Institutional Ethics Committee (IEC) of Maganbhai Adenwala Mahagujarat University is committed to ensuring additional safeguards to protect the rights, safety, and well-being of such participants.

i. Defining Vulnerable population & its Common Characteristics:

- Children and minors
- Pregnant women and fetuses
- Mentally or cognitively impaired individuals
- Elderly or terminally ill patients
- Prisoners or institutionalized individuals
- Economically or educationally disadvantaged individuals
- Refugees or displaced populations
- Gender or sexual minorities
- Individuals with serious health conditions
- Social, economic, or political disadvantage, making them susceptible to exploitation.
- Limited autonomy, either temporarily or permanently (e.g., unconscious individuals, differently abled persons).
- Compromised voluntariness due to situational factors.
- Influenced by expectations of benefits or fear of retaliation, affecting consent.

ii. Principles of Research Involving Vulnerable Populations

- They have equal rights to participate in research to ensure they benefit from scientific advancements.
- Research solely involving a vulnerable group must address their specific health needs.
- Participants should be empowered to make their own decisions regarding consent.
- When individuals lack the capacity to consent, a Legally Authorized Representative (LAR) must be involved.
- Privacy and confidentiality must be strictly protected to prevent further vulnerability.

- Additional safeguards must be in place to protect their dignity, rights, safety, and well-being.

Stakeholders	Obligations/Duties
Researchers	<ul style="list-style-type: none"> - Recognize vulnerability and implement additional safeguards. - Justify inclusion/exclusion of vulnerable groups. - Address conflicts of interest (COI). - Ensure a balanced benefit-risk ratio with well-defined SOPs. - Confirm competence for informed consent or obtain LAR consent when necessary. - Respect participant dissent and seek approval from relevant authorities. - Adhere to relevant guidelines and regulations.
Ethics Committees (ECs)	<ul style="list-style-type: none"> - Assess whether participants in a study are vulnerable. - Review justification for inclusion/exclusion of vulnerable populations. - Ensure COI does not increase harm or reduce benefits. - Evaluate risks/benefits and recommend risk minimization strategies. - Suggest additional safeguards, such as more frequent monitoring. - Full committee review required for vulnerable group research, with community representatives if possible. - Special care for research on mental illness/cognitive impairment. - Have SOPs for handling proposals involving vulnerable groups.
Sponsors	<ul style="list-style-type: none"> - Justify inclusion of vulnerable populations in research. - Provide for monitoring, quality assurance (QA), and quality control (QC). - Ensure participant and researcher protection, especially for sensitive research topics.

iii. Submission requirements for vulnerable population

Investigators must submit additional documentation, including -

- Justification for inclusion of vulnerable groups.
- Specific risk minimization strategies.

- Details of the consent process (including use of legally authorized representatives or assent forms for children).
- Procedures for enhanced monitoring of participant safety.
- Information on special protections or benefits provided to participants.

iv. Review procedure:

- All protocols involving vulnerable populations shall undergo full board review.
- The IEC shall ensure that the proposal includes sufficient justification for including vulnerable participants.
- A subject expert or community representative with experience in the specific vulnerable group should be involved in the review process.
- The risk–benefit ratio must be critically assessed to ensure that potential risks are minimized.

v. Informed consent, assent, monitoring and oversight:

- Informed consent must be obtained from participants or their legally authorized representatives (LARs).
- For children (ages 7–18), assent must be obtained in addition to parental or guardian consent.
- The consent process must be tailored to the participant’s level of comprehension and should be conducted in a language they understand.
- Extra care should be taken to avoid coercion or undue influence.
- Approved studies involving vulnerable populations will be subject to more frequent monitoring (e.g., quarterly progress reports).
- The IEC may conduct site visits to ensure adherence to ethical standards.
- Any adverse events or protocol deviations must be reported immediately and reviewed with priority.

vi. Others:

- All other principles i.e. confidentiality and privacy, compensation and care record keeping and reporting are same as mentioned in general SOP.