جامعة الخليج الطبية
GULF MEDICAL UNIVERSITY
ACADEMIC HEALTH CENTER

GMU-POL-S04-002 - Ethical Research

Standard 04: Research and Scholarly Activities

Process Owner Vice Chancellor Research

Prepared by College Research Coordinators

Reviewed by Task Force appointed for review of GMU Policies and Procedures Manual

BOT Approval Approved

First Issue Date 28/09/2020

Last Review Date 14/03/2024

Modification History

MODIFICATION HISTORY		
Policy / Version Number	**Date**	**Revision summary**
1.1	14.03.2024	The role of College Research Committee has been added to the procedures. Documents required for IRB submission have been added.

Relevant to All Faculty Members and students involved in conducting research and Research Scholars.

Used with Research Support, Student Involvement in Research, Commercialization of Research Output.

Purpose and Scope

The purpose of the Ethical Research Policy is to establish the principles and responsibilities for ethical conduct in research conducted by all members of Gulf Medical University. Research ethics govern the standards of conduct for scientific researchers. It is important to adhere to ethical principles to protect the dignity, rights, and welfare of research participants. It applies to all researchers, clinicians, employees, and students involved in research at GMU.

Abbreviations and Definitions

- **IRB:** Institutional Review Board
- **CRC:** College Research Coordinator
- **PI:** Principal Investigator
- **SME:** Subject Matter Experts

Policy

1. In accordance with its mission, Gulf Medical University shall aim to uphold the highest standards of ethics in its research activities conducted by all members of the GMU community.
2. Gulf Medical University shall adhere to the principles and responsibilities for ethical conduct in research. The research undertaken shall be in accordance with recognized research ethical principles and obeying to principles of integrity and personal responsibility.
3. The Institutional Review Board (IRB) shall oversee the adherence of GMU community to Ethical guidelines of research.
4. The IRB through the college research committee shall invite SMEs for reviewing the

research.

5. In case of researches involving a human subjects (including research on identifiable human material and data), the IRB shall apply the principles and regulations of ethical principles defined by the World Medical Association (WMA), namely “the Declaration of Helsinki” as a statement of ethical principles for medical research involving human subjects https://www.wma.net/policy/hb-e-version-2019/.
6. In case of research involving animal subjects, the IRB shall apply the principles and regulations defined by the USDA Animal Welfare Act and Animal Welfare Regulations (https://www.aphis.usda.gov/animal_welfare/downloads/bluebook-ac-awa.pdf).
7. For all research proposals involving or not human or animal subjects, the proposal shall be submitted to the IRB for approval.
8. Research cannot be conducted until the IRB approval letter is received.
9. The IRB could use additional guidelines and / or procedures governing ethical principles of human or animal research. These guidelines shall be provided by appropriate professional and international known bodies relevant to the specific areas of research.
10. The IRB shall ensure that GMU researchers do not receive or apply for research funding from inappropriate sources. In case of private funding, the researcher shall disclose clearly the funding agent in all further publications or presentations.
11. The IRB shall delegate responsibilities to the respective College Research Committee, especially when the nature of research within a specific area requires a separate committee.

Procedures

1. **Submission and Initial Screening:** Researchers submit their research proposals to the respective College Research Coordinator, who conducts an initial screening for completeness and adherence to college-specific requirements. This initial review is facilitated by the College Research Committee, which assesses the proposal's alignment with college research priorities and ethical standards.
2. **College Research Committee Review:** The College Research Committee reviews the proposal for its scientific merit, ethical considerations, and relevance to the field. This committee may provide feedback or request amendments to ensure the proposal meets the necessary standards and guidelines.
3. **Review by Designated Reviewer(s):** Once the College Research Committee approves the proposal, it is forwarded to one or more designated reviewers with expertise in the relevant field. These reviewers provide detailed comments and suggestions to enhance the research proposal's quality and ethical considerations.
4. **Principal Investigator (PI) Revisions:** The Principal Investigator (PI) receives feedback from the designated reviewers and is responsible for addressing all comments and concerns. The College Research Coordinator revises the proposal, accordingly, ensuring that all reviewer feedback is adequately incorporated.
5. **Submission to the Institutional Review Board (IRB):** After the PI addresses the reviewers' comments, the College Research Coordinator submits the revised proposal to the Institutional Review Board (IRB) for final review and approval.
6. **Qualifications Review:** The IRB evaluates the qualifications and experience of investigators in the study area, ensuring they are adequately prepared to conduct the research ethically and effectively.
7. **Information Adequacy Review:** The IRB reviews the proposal to ensure that subjects are provided with sufficient information to protect their rights and well-being. This includes a thorough examination of the informed consent process and materials.
8. **Studies Requiring Consent From:** For studies requiring consent from, a representative, the IRB ensures that the proposal and consent process adhere to ethical and regulatory requirements, safeguarding the interests of subjects who cannot consent for themselves.
9. **Other Studies with no Consent Form:** In cases where prior consent is not required, the IRB assesses the proposal to confirm that it addresses ethical concerns and meets regulatory requirements for such type of research.
10. **IRB Response:** Following the review, the IRB documents its decisions in writing,

clearly indicating whether the proposal is approved, requires modifications, is disapproved, or if any previous approvals are reversed. This documentation provides clear guidance for the PI on the next steps or necessary revisions.

Appendices

Documents Required for IRB Submission

Researchers must submit the following documents for IRB review:

1. Research Proposal/protocol
2. Any protocol amendment
3. Written informed consent form.
4. Information provided to subjects.
5. Investigator’s qualifications (CV or other documentation).
6. Information on payments and compensation for investigators and subjects.
7. College Research Committee approval letter.
8. Investigator's Brochure (if applicable).
9. Other documents as required by the IRB.