GSFC UNIVERSITY
EDUCATION RE-ENVISIONED
An ISO 9001:2015 Certified

Constitution of the Ethical Review and Clearance Board at GSFC University

GSFC University
Academic Division
Office Order No. Provost/092024/153
Date: 07.10.2024

1. Preamble

The Ethical Review and Clearance Board (ERCB) aims to uphold the highest ethical standards in research, projects, and institutional activities carried out under the aegis of GSFC University. The establishment of the ERCB reflects the University's commitment to maintaining the integrity, transparency, and accountability of all research involving human subjects (non-invasive) and sensitive data. By promoting rigorous ethical oversight, the ERCB ensures that all research and activities associated with GSFC University are conducted with methodological rigor and ethical responsibility.

The ERCB will foster a research environment rooted in respect, fairness, and public trust, while preventing any potential risks or abuses in research practices. Its composition includes diverse and experienced members from various disciplines, ensuring a comprehensive review process that aligns with the ethical and academic values of the University.

2. Decision

The ERCB is responsible for safeguarding the rights, dignity, and welfare of all participants, while ensuring compliance with applicable national regulations, ethical guidelines, and University standards. The ERCB is tasked with the following key responsibilities:

1. **Ethical Review:** Conducting thorough ethical evaluations of proposed research studies, projects, and institutional activities, ensuring they adhere to established ethical guidelines and principles.
2. **Risk-Benefit Analysis:** Assessing potential risks to participants and ensuring that the benefits of the research or project justify any risks involved.

3. **Informed Consent:** Reviewing the informed consent process to ensure participants are fully aware of the nature of the study, their rights, and any potential risks or benefits.

4. **Confidentiality**: Ensuring that all data collected during the research or project is securely stored and that participants' confidentiality is maintained.

5. **Ongoing Monitoring:** Overseeing the research or project throughout its duration to ensure continued compliance with ethical standards and approving any necessary amendments.

The **validity of the board** shall extend for a duration of **two years,** commencing from **October 8, 2024.** The ERCB includes the following members:

Sr. No.	Name & Designation	ERCB Designation
1	Dean, R&D Cell*	Chairperson
2	Prof. Prabal Sengupta, Professor of Practice	Member
3	Dr. Nilesh Bahadure, Professor	Member
	Dr. Jignesh Valand, Assistant Professor	Member
4	Dr. Jahanvi Bansal, Associate Dean, R&D Cell	Co-ordinator

*In the absence of the Dean of the R&D Cell, Prof. Prabal Sengupta shall serve as the Chairperson of the Committee.

Note: An External Reviewer or Legal Expert shall be engaged to review research or project approvals, as deemed necessary.

The Ethical Review and Clearance Policy for Research Involving Human Subjects (non-invasive) and Sensitive Data at GSFC University has been duly prepared and approved by the President, and is enclosed herewith as ***Annexure-I.***

Provost
GSFC University

To,

All the Concerned

CC,

President Office, GSFC University - For kind information, Please
Provost's Office, GSFC University
Director (Adm) & Registrar Office, GSFC University
Dept. Dir. (Adm) & Director Campus, GSFC University
Dean / HoDs, GSFC University
DOST - AI Cell, GSFC University
Finance Division, GSFC University
HR Division, GSFC University
Lab Assistants of Various Computer Labs
Department of Information Technology Enabled Services
Department of Computer Science & Engineering
Department of Chemical Engineering
Department of F & EHS
Department of Chemical Sciences
Department of Life Sciences
Department of Computer Applications
Department of Data Science
Department of Management Studies & Liberal Arts
Department of Account & Finance
Department of Internship & Placement
Department of Examination & Assessment
Department of Administration
Department of Admission
Teaching Staff & Non-Teaching Staff, GSFC University
All Visiting Faculty, GSFC University
Select File- Dy. Registrar (I/C), GSFC University

Policy
on
Ethical Review and Clearance for Research Involving Human Subjects (non-invasive) and Sensitive Data
at
GSFC University

Doc.No.: GSFCU/Ethical Review/ Policy

GSFC University

Details

Sr. No	Document	Date	Details	Approval By	Remarks
1.	New Policy	19.09.2024	—	The President	Approved

Table of Contents

1. Preamble

The Ethical Review and Clearance Policy for Research Involving Human Subjects (non-invasive) and Sensitive Data at GSFC University ensures that all research, projects, and institutional activities maintain ethical and methodological integrity. This policy is designed to protect the rights, dignity, and welfare of participants, ensure compliance with regulations and standards, and uphold the highest ethical standards across all university-associated activities. By adhering to this policy, GSFC University commits to fostering a research environment that values transparency, accountability, and respect for all individuals involved. The policy also aims to promote public trust in the research conducted under the university's auspices by ensuring rigorous ethical oversight and safeguarding against potential risks and abuses.

2. Policy for Ethical Review and Clearance Process

Under this policy, the review and clearance process is for:

- **Ethical Review:** Conducting thorough evaluations of research studies, projects, and institutional activities, ensuring adherence to established ethical guidelines and principles.
- **Risk-Benefit Analysis:** Assessing potential risks to participants and ensuring that the benefits justify any risks involved.
- **Informed Consent:** Reviewing the consent process to ensure participants fully understand the study’s purpose, risks, benefits, and their rights.
- **Confidentiality:** Ensuring secure data management and the protection of participants’ confidentiality.
- **Ongoing Monitoring:** Ensuring continued compliance with ethical standards throughout the duration of research or projects and approving necessary amendments.

3. Implementation Mechanism

- **Communication of the Policy:** The policy, along with all required templates for applying for ethical review and clearance, will be circulated via email to all teaching staff. Additionally, these resources will be made available on the GSFC University website to ensure easy access and adherence to the new guidelines.

- **Formation and Composition of the ERCB:** The Ethical Review and Clearance Board (ERCB), as detailed in the policy, will be chaired by the Dean (R&D) or a senior faculty member with extensive research experience. The Board will include a multidisciplinary team of faculty members and external reviewers to ensure comprehensive evaluations. The Associate Dean (R&D) will coordinate the review process and oversee a pool of reviewers for application assessments

- **Research Project Proposal Submission Template:** Researchers will submit their projects using the detailed Research Project Submission Template **(Annexure 1).** This template ensures that all necessary documentation, including research proposals is provided for thorough evaluation .

4. Role of the Ethical Review and Clearance Board (ERCB)

The Ethical Review and Clearance Board (ERCB) for the ethical review process and clearance is composed of:

- **Chairperson:** Dean (R&D) or any senior faculty with extensive research experience.
- **Board Members:** A multidisciplinary team, including faculty members and external reviewers when necessary, to ensure diverse perspectives. This will include one faculty from each school.
- **Coordinator:** Associate Dean (R&D): In addition to the ERCB, a pool of reviewers will be involved for reviewing the applications of ethical clearance.

5. Guiding Principles

The ERCB is guided by the following core ethical principles:

- Voluntary and informed consent
- Respect for individual autonomy
- Right to withdraw participation at any stage
- Protection against harm and safeguarding personal integrity
- Right to access research information
- ·Ensuring privacy and the overall well-being of participants

6. Submission and Review Process

- **Application Submission:** Researchers must submit comprehensive documentation, including a research proposal **(Annexure 1)**, consent forms **(Annexure 2)**, and data management plans. This will include an undertaking by the Principal Investigator (PI), ensuring their commitment to fulfilling the necessary compliance requirements **(Annexure 3)**.
- **Initial Screening:** An administrative review ensures all necessary documents are submitted.
- **Evaluation:** A detailed ethical review is conducted, focusing on participant safety, risk/benefit analysis, research design, and confidentiality **(Annexure 4)**.
- **Decision Making:** The review process results in one of the following decisions:

  a. *Approval:* The project meets ethical standards and can proceed.

  b. *Conditional Approval:* Minor revisions are needed.

  c. *Revise and Resubmit***:** Significant revisions are required for reconsideration.

  d. *Rejection:* The project does not meet the necessary ethical standards and cannot proceed.

- **Notification:** The Principal Investigator (PI) or Project Coordinator will be informed of the decision, along with any required modifications.

7. Informed Consent Process

The ERCB requires that the informed consent process includes:

- **Clear and Concise Information:** Participants must be provided with clear documentation outlining the study's purpose, risks, benefits, and their rights.
- **Voluntary Participation:** Participants must be made aware that participation is entirely voluntary and that they can withdraw at any time without consequences.
- **Documentation:** Signed consent forms must be retained securely for future reference.

8. Confidentiality and Data Management

- **Data Protection:** All data must be securely stored with restricted access.
- **Anonymization:** Where feasible, data should be anonymized to protect participants' identities.
- **Data Retention:** Data must be stored for a minimum period, as per institutional guidelines, and securely disposed of afterward.

9. Appeals Process

Principal Investigators (PIs) may appeal the review decision by submitting a written request for reconsideration, including any additional information or clarification. The ERCB will review the appeal and issue a final decision.

10. Compliance Mechanisms:

- **Review and Approval Process:** The ERCB will conduct initial screenings and detailed ethical reviews as outlined in the policy. The review process will result in decisions including approval, conditional approval, revise and resubmit, or rejection.
- **Ongoing Monitoring and Reporting:** The ERCB will oversee ongoing compliance with ethical standards throughout the research duration. Regular reports will be provided to the President by the Research & Development Cell, detailing activities, decisions, and significant ethical issues encountered.

- **Conflict of Interest and Appeals:** Board members must disclose any potential conflicts of interest and recuse themselves from relevant reviews. Principal Investigators (PIs) may appeal decisions by submitting additional information for reconsideration, ensuring fairness and transparency in the review process.
- **Enforcement and Documentation:** Investigators will be required to affirm their commitment to ethical standards and comply with all guidelines. Any deviations from approved protocols may lead to project suspension or termination, with disciplinary actions enforced as necessary

11. Reporting

The ERCB will provide an annual report to the President of GSFC University through the office of the Provost that includes activities, decisions, and any significant ethical issues encountered throughout the year.

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Annexure 1

Research Project Proposal Submission Template

1. Project Information

   i. Title of the Project:

   ii. Principal Investigator (PI):

   iii. Institutional Affiliation:

   iv. Contact Information:

   v. Email:

   vi. Phone Number:

   vii. Co-Investigators (if any):

2. Research Proposal

   i. Abstract: Provide a brief summary of the research, including objectives, methodology, and expected outcomes.

   ii. Research Objectives: Outline the main goals and specific objectives of the study.

   iii. Research Methodology: Describe the research design, including sampling methods, data collection procedures, and analytical techniques.

   iv. Participant Selection Process: Explain how participants will be selected, including any criteria for selection and recruitment methods.

3. Ethical Considerations

   i. Informed Consent: Describe the process for obtaining consent from participants.

   ii. Risk-Benefit Analysis: Detail the potential risks to participants and how they will be mitigated, as well as the benefits of the research.

   iii. Confidentiality Measures: Describe how participant data will be kept confidential, including data storage and access controls.

4. Data Management Plan

i. **Data Collection:** Outline the types of data to be collected and the methods for data collection.

ii. **Data Storage:** Describe how data will be securely stored and who will have access to it.

iii. **Data Retention:** Specify the duration for which data will be retained and the process for data disposal.

5. Compliance and Approval

i. **Regulatory Compliance:** Confirm adherence to applicable regulations and standards.

ii. **Institutional Approval:** Include any required institutional approvals or permits for the research.

6. Additional Documents

i. **Research Instruments:** Provide copies of any questionnaires, surveys, or other research instruments used.

ii. **Budget and Funding:** Include a budget outline and information on funding sources, if applicable.

iii. **Ethical Review History:** Provide information on any previous ethical reviews or approvals received for similar studies, if applicable.

Submitted By:_____

Signature:_____

Date:_____

Annexure 2

Consent Form Template

1. **Title:** Participant Consent Form for [Project/Study Name]

2. **Purpose of the Study:** Provide a brief explanation of the purpose and objectives of the study.

3. **Methods/Procedures:** Describe the procedures involved in the study.

4. **Risks and Benefits:** Outline any potential risks and benefits.

5. **Confidentiality:** Explain how participant information will be kept confidential.

6. **Voluntary Participation:** State that participation is voluntary and that participants can withdraw at any time.

7. **Contact Information:** Provide contact details for further inquiries.

8. **Consent Statement:** I, the undersigned, confirm that I have read and understood the information provided above, and I consent to participate in this study.

Signature: _____

Date: _____

Annexure III

Principal Investigators' Undertaking

1. We certify that, to the best of our knowledge, the proposal herein is not unnecessarily a duplication of previously reported research.
2. We certify that we possess the necessary qualifications, education, training, and experience required to conduct this study.
3. We certify that the study will be initiated only upon review and approval of the scientific intent by the GSFC University Ethical Review and Clearance Board (ERCB) and receipt of the appropriate certification from the ERCB.
4. We agree to make necessary changes to the study protocol as per the suggestions provided by the ERCB members during the review meeting before obtaining the final approval letter. We will submit any significant changes to the ERCB for approval prior to implementation.
5. We will conduct the study in accordance with GSFC University's ethical guidelines and best practices, and maintain all study-related records. We agree to produce these records to the ERCB upon request.
6. We will promptly report any adverse events or unexpected outcomes encountered during the research to the ERCB as soon as they arise.
7. We certify that we will adhere to the recommendations of the ERCB and comply with all relevant regulations and guidelines issued by GSFC University.
8. We certify that we will maintain a record of any premature termination of the study, including a summary of the reasons, and submit a final report upon completion of the study. This will include any relevant documentation such as microfilms, CDs, and video recordings, which will be provided to the ERCB.

Signature:_____

Date: _____

Annexure 4

Evaluation Sheet Template

1. Project/Study Name:

2. Principal Investigator:

3. Date of Submission:

4. Evaluation Criteria:

5. Ethical Considerations: [Score/Comments]

6. Methodological Soundness: [Score/Comments]

7. Confidentiality Measures: [Score/Comments]

8. Risk/Benefit Analysis: [Score/Comments]

9. Informed Consent Process: [Score/Comments]

10. Final Decision: [Approved/Not Approved/Revise and Resubmit]

Signature of Board Chair: _____

Date: _____