RESEARCH ETHICS POLICY

2026 Edition

Policy No. : EOMS 21001: 2018/Pol/RE/2025-2026/01

Sathyabama Institute of Science and Technology

(Deemed to be University)

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TABLE OF CONTENTS

DOCUMENT CONTROL SHEET

Particulars	Details
Policy Title	Research Ethics Policy
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DOCUMENT CLASSIFICATION : This document constitutes an official policy of the Deemed to be University. The provisions of this policy shall be implemented and interpreted in accordance with the applicable statutory and regulatory requirements, and in conjunction with other relevant policies, regulations, ordinances, and guidelines of the Institution.

1. PREAMBLE

Sathyabama Institute of Science and Technology foresees research twinned academic curriculum and believes in fostering the same ethically with due diligence to the individual and the organization. This policy shall be used to understand the institution's ethical research standards and navigate the approval process. Before beginning to research, the individual is insisted to ensure subject-specific and professional codes of conduct, Institutional guidance on research ethics and all applicable legal and regulatory frameworks.

2. POLICY OVERVIEW

Scope of Policy

- Defines who and what the policy applies to.

Core Ethical Principles

- The fundamental ethical standards guiding all research activities.

Governance & Accountability

- Roles & Responsibilities
- Clear definitions of duties for individual staff members, researchers, and formal
- Ethical Review Bodies.

Ethical Review Pathways

- Graduate Students and Research Degree Students - Procedures tailored for undergraduate, postgraduate projects.
- Procedures for PhD, and other research-focused postgraduate programs - Staff & Associate Researchers
- Procedures for faculty, institutional staff, and external or visiting research associates.

Deviations Non-Compliances and Violations

- Deviations from Approved Research - Protocol for handling mid-project modifications or unexpected changes.
- Continuing Ethical Review - Monitoring, annual progress reports, and end-of-project sign-offs.
- Non-Compliance & Policy Violations - Consequences and procedures for failing to adhere to approved protocols.

Appeals & Dispute Resolution

- Review of Decision (Appeals) - The mechanism for researchers to challenge an adverse decision by a Review Body.
- Complaints Procedure - How to report issues regarding the conduct, behaviour, or administration of a Review Body.

3. SCOPE OF POLICY

- All research activity should be conducted according to good ethical practice and with the highest standards of integrity. This Policy, however, sets out the principles and procedures for research. Ethical issues arising from learning and teaching should be addressed by the programme or module leader seeking advice as appropriate from the Chair of the relevant Research Ethics Panel.
- For the purpose of this Policy the term research refers to:
  - ✓ original investigation leading to the creation of knowledge
  - ✓ replication of an investigation for the purposes of developing the researcher
- For the purpose of this Policy, the term researcher, refers to:
  - ✓ any member of staff at the institution engaging in research
  - ✓ any student at the institution engaging in research
  - ✓ any individual who is not a member of staff or student at the institution, undertaking research using Institution premises and facilities, and/or in the Institution's name (hereafter referred to as an associate researcher)
- It is important that all research is conducted to the highest standards of integrity. All researchers are expected to consider the ethical implications of their research and to submit their research for ethical review as appropriate.

- This Policy will be reviewed by the Institution's Research Integrity and Governance Committee on a bi-annual basis.

4. ETHICAL PRINCIPLES

4.1 The institution's research ethics is governed by the following key principles:

- ✓ Research must be justified
- ✓ Informed consent must be given by participating researchers
- ✓ Participation in research must be voluntary
- ✓ Confidentiality must be ensured
- ✓ Any risk of harm to participants, animal subjects or the researcher(s) should be appropriately mitigated

4.2 Researchers

They should be able to demonstrate that the research they undertake is unique and novel. In the case of students undertaking an undergraduate independent study or postgraduate dissertation it is, however, permissible for them to replicate existing research as part of their development as researchers.

4.3 Informed consent

Those involved in research whether as participants or researchers should be informed of the nature and purpose of the research, and any potential benefits, risks, obligations or inconvenience associated with the research before they choose to participate. It is therefore normal practice to provide an information sheet or similar to potential participants prepared by the researchers with expertise that sets out the details of the research in a form accessible to the non-expert and in a format appropriate to them.

Wherever possible, and proportional to the nature of the research, evidence of consent (either written consent, or oral consent witnessed by another) should be obtained and retained as appropriate. Participants should be informed that they are free to withdraw this consent and request that any data provided by them will be destroyed should they request it where this is practicable and within a reasonable timescale.

Particular care is needed in gaining consent from vulnerable groups, especially from persons whose first language is not English.

For research involving children and young people (i.e. those under the age of 18), researchers should seek to gain the consent or for younger children the assent of the child in keeping with India's, National Commission for Protection of Child Rights

(NCPCR).The consent of the child's parent/legal guardian should normally also be obtained when children related research pursued.

When access to participants is controlled by a 'gatekeeper'1/security official, researchers should adhere to the principle of gaining informed consent/assent from the participants themselves, whilst respecting the legitimate interests of the gatekeeper.

4.4 Voluntary Participation

As well as being informed, consent should also be freely given. Researchers should ensure that participants are taking part in the research voluntarily, that they do not feel pressured or obliged to participate, and are not subject to coercion.

Researchers should be aware that where there is a power relationship between the researcher (or representative of the researcher, e.g. a gatekeeper) and the participant - such as between a lecturer and their students or a doctor and their patients – a person may feel compelled to participate. In these circumstances, a researcher should endeavour to find ways of ensuring voluntary participation, e.g. by using a neutral intermediary to gain consent.

4.5 Confidentiality

Except where explicit written consent is obtained to the contrary, researchers should protect the confidentiality and anonymity of the experimental data or any other data relevant to the personnel involved in the research.

Researchers should be aware of the risks to anonymity, confidentiality, privacy and security posed by the data they collect and store, and take measures to prevent accidental breaches of confidentiality.

4.6 Risk of harm

Researchers should seek to minimize the risk of harm to any individual (the participants, the researcher him/herself, other researchers) or organisations arising from the research.

Harm is broadly conceived to include physical injury and psychological distress (beyond that encountered in daily life), but also negative impacts on economic or social standing.

Researchers should assess potential risks prior to the commencement of a project and alter the project design accordingly and make provisions to provide help and support for any individual who suffers harm.

Most fundamentally, researchers must always ensure that participants and other researchers are fully aware of any potential risk of harm. This will enable the individual

to make their own risk assessment before choosing to participate and, if fully informed, the individual is best placed to make this judgment.

For research with animals, organisms the use of animals in the research needs to be fully justified and high standards should be set for their care and welfare, and any experimental techniques should be designed to minimise distress to the animals.Guidelines for Institutional Bio safety Committee is to be followed.

5. ETHICAL REVIEW PATHWAYS : ROLES AND RESPONSIBILITIES OF STAFF AND OF ETHICAL REVIEW BODIES

5.1 Staff & Associate Researchers:

Many staff both from the academic and research divisions are engaged in the supervision of student research (hereafter referred to as "supervisors") whether in the context of Doctoral or Masters supervision, as mentor for an undergraduate independent study or project or as a module leader where research is a significant element of the module content and/or assessment. It is the responsibility of these staff:

- To support their students towards a greater understanding and engagement with ethical issues in research
- To ensure their students are fully aware of this policy
- To approve Applications for Ethical Approval for students as set out in this policy
- To attend appropriate staff development events on ethics to ensure their knowledge is up-to-date and relevant. An exclusive planning shall be ensured in devising research ethics related workshops/developmental programmes

5.2 Ethical committee and Ethical Panels

More broadly it is the expectation that staff with experience of research and/or of ethics to advise and support less experienced staff in developing Applications for Ethical Approval and in engaging in ethical research. This shall be facilitated by smaller ethical panels under a larger Ethical committee functionalized based on the research domain as the requirement may be. These smaller panels may be expanded in numbers as demand arises. Smaller panels as formulated during review meetings for research scholars as per the faculty they fall shall be ensured for other research executed in the institution. The objectives of which will be

- To promulgate good conduct in research across the particular domain (eg life science, circuit branch, chemical sciences etc.,)
- To review all Applications for Ethical Approval from staff and research degree students

• To review all Applications for Ethical Approval from taught degree students referred by the Supervisor and to hear appeals against decisions of Supervisors

• To facilitate training and development for staff and students in the concerned faculty of the institution on Ethics, Research Integrity and Research Data Management

• To report to each meeting of the Institution's Research Ethics Committee

• To provide an annual report to the Institution's Research Ethics Committee on its activities

• To audit a proportion at least 10% of Applications for Ethical Approval signed off by Supervisors within the Faculty affiliated with the institution

• To act in an advisory capacity to researchers applying for external ethical approval within the institution.

6. DEVIATIONS NON-COMPLIANCES AND VIOLATIONS

6.1 Deviations from Approved Research Protocol

This section outlines the procedures for handling any modifications, mid-project adjustments, or unexpected changes to a research protocol after it has received initial Institutional Review Board (IRB) or Research Ethics Committee (REC) approval. No changes may be implemented without prior review and approval, except when necessary to eliminate immediate hazards to participants.

6.1.1Categorization of Changes

Modifications are classified into two categories, each requiring a different review pathway:

Major Amendments (Full/Expedited Review Required): Significant changes that alter the study's risk-benefit ratio, scope, or design.

Examples :

1. increasing participant risk or introducing invasive procedures.
2. altering inclusion/exclusion criteria
3. changing the primary target population
4. modifying informed consent documents to reflect new risks.

Minor Amendments (Administrative Review Required): Changes that do not increase risk to participants or alter the central scientific focus.

Examples :

1. updating contact information or correcting typographical errors in documents

2. adding or replacing key research personnel (provided they have completed required ethics training)
3. slight adjustments to recruiting materials (e.g., flyers, social media text)
4. handling unexpected deviations & adverse events

Unexpected Deviations include:

Emergency Deviations: If a researcher must deviate from the protocol to protect a participant from immediate physical or psychological harm, the deviation may be implemented immediately. This must be reported to the ethics committee within 24 to 48 hours.

Minor Protocol Deviations: Accidental or logistically forced deviations that do not impact participant safety or data integrity (e.g., a participant missing a scheduled follow-up window by one day) must be logged internally and reported during the annual review.

6.2 Continuing Ethical Review

Ethical oversight does not end with initial approval. Continuing ethical review ensures that the conduct of the research remains ethically sound, that the risk-benefit ratio has not shifted unfavourably, and that the project concludes with proper data management and transparency.

Monitoring & Annual Progress Reports

Mandatory Interval Reporting: All approved active research projects are subject to continuing review at intervals appropriate to the degree of risk, but not less than once per year.

Annual Progress Report Requirements: Principal Investigators (PIs) /Supervisors must submit a progress report at least 30 days prior to the expiration of their current approval. This report must include:

- The total number of participants recruited to date for the approved research receiving external/internal funding.
- A summary of any multi-site findings, recent literature, or new information that might alter the ethical evaluation of the study.
- A log of all minor protocol deviations and any reported adverse events.

Lapse in Approval: If an annual report is not submitted and approved by the expiration date, all research activities including recruitment, data collection, and data analysis must cease immediately until formal re-approval is granted.

Completion reports

Upon completion of the study, the PI/Supervisor is required to submit a Final Project Close-Out Report. This formal sign-off addresses:

- Confirmation of project termination and final participant metrics.
- A summary of data dissemination plans (e.g., publications, sharing of anonymized datasets).
- Assurances regarding secure long-term data storage, de-identification, or destruction protocols in alignment with data privacy laws.

6.3 Non-Compliance & Policy Violations

This section defines what constitutes non-compliance and establishes the investigation procedures and disciplinary pathways for researchers who fail to adhere to approved protocols, institutional policies, or relevant legal regulations. Definitions of Non-Compliance : Any action or omission by a researcher that violates institutional ethics policy, IRB/REC requirements, or federal/state regulations.

7. APPEALS & DISPUTE RESOLUTION

While Institutional Review Boards (IRBs) and Research Ethics Committees (RECs) operate with independent authority to protect human and animal subjects, researchers must be afforded a transparent, fair, and objective mechanism to challenge adverse decisions. Furthermore, this section establishes clear pathways for stakeholders to lodge complaints regarding the administrative behaviour, conduct, or conflicts of interest within the Review Body itself.

7.1 Review of Decision (Appeals)

7.1.1 Purpose

To establish a formal framework for researchers to appeal a final adverse decision (such as a formal disapproval of a protocol, a forced suspension of active research, or a mandated destruction of data) when a resolution cannot be reached through standard dialogue and amendment cycles.

7.1.2 Reasons for Appeal

An appeal cannot be filed simply because a researcher disagrees with the ethical judgment of the Review Body. A formal appeal will only be entertained if it is substantiated by one or more of the following grounds:

- Procedural Irregularity: Evidence that the Review Body failed to follow its own written policies, bylaws, or standard operating procedures, and that this failure materially affected the outcome.
- Conflict of Interest: Evidence that a member of the reviewing panel had an undisclosed personal, financial, or professional conflict of interest that biased the decision.
- New Evidence or Context: Substantive new scientific information, regulatory updates, or contextual data that was impossible to provide during the original review, which fundamentally alters the risk-benefit equation of the research.
- Manifest Unfairness: Evidence that the conditions, restrictions, or sanctions imposed by the Review Body are grossly disproportionate to the actual risks or infractions identified.

7.1.3 The Appeals Process

1. Notice of Intent to Appeal: The Principal Investigator (PI) must submit a written Notice of Appeal to the designated Institutional Official within 30 calendar days of receiving the final adverse decision.
2. The Institutional Official conducts a preliminary review strictly to determine if valid grounds for appeal exist. If the appeal is based purely on a difference of philosophical opinion, it is dismissed.
3. Formation of an Ad Hoc Appeals Committee: If the grounds are valid, the Institutional Official convenes an independent *Ad Hoc Research Ethics Appeals Committee*. To ensure absolute objectivity, this committee must consist of:
    - Members who were completely un-involved in the original review.
    - At least one external ethicist or peer reviewer from a separate institution.
    - A non-voting legal/regulatory advisor.
4. The Hearing and Review: The Appeals Committee reviews all original documentation, the minutes of the initial review meeting, and the PI's written appeal. The PI and the Chair of the original Review Body may be invited to make brief oral presentations and answer questions.

5. Final Adjudication: The Appeals Committee possesses the authority to uphold, modify, or completely overturn the original Review Body's decision. The written decision of the Appeals Committee is final and binding on both the researcher and the original Review Body.

7.2 Complaints Procedure

To provide a secure, confidential mechanism for researchers, study staff, participants, or the public to report allegations of misconduct, bias, administrative negligence, or unprofessional behavior specifically committed by the Review Body, its individual members, or its administrative staff.

7.2.1 Scope of Eligible Complaints

This procedure applies to administrative and behavioral grievances, distinct from disputing an ethical verdict (which is covered under 5.1). Valid complaints include:

- Unreasonable Administrative Delay: Documented patterns of the Review Body missing its statutory review windows without justifiable cause, resulting in severe disruption to research timelines.
- Breach of Confidentiality: A committee member sharing proprietary research designs, intellectual property, or sensitive data obtained during the closed-door review process.
- Unprofessional or Hostile Conduct: Aggressive, discriminatory, or harassing behavior directed at researchers during meetings or written correspondence.
- Failure to Manage Conflicts: A committee member actively participating in the debate or voting on a protocol submitted by a direct competitor or collaborator, despite a known conflict.

7.2.2 Filing and Investigation Workflow

- Lodging a Complaint: Complaints must be submitted in writing to the Office of Research Compliance or via the institution's secure, anonymous whistleblower portal. The identity of the complainant will be protected to prevent retaliation.
- Independent Inquiry: Because the Review Body itself is the subject of the complaint, the investigation is handled entirely outside of its jurisdiction. The

institutional Office of Legal Counsel or an independent integrity officer is assigned to investigate.

- Fact-Finding: The investigator will review meeting logs, email communications, audio recordings of panel sessions, and interview relevant parties. The inquiry must be completed within 45 business days.

7.2.3 Corrective Measures & Remedies

If the complaint is substantiated, the Institutional Official will issue a formal resolution report. Depending on the infraction, remedies targeting complaint may include:

Individual Panel Member: Mandatory removal from the specific protocol; temporary suspension from the committee; permanent termination of their Review Body membership; referral to Human Resources for disciplinary action.

Administrative Staff : Retraining on service-level agreements ; personnel re-assignment; standard institutional disciplinary pathways for staff.

Review Body : Voiding a compromised vote and forcing a re-review of the protocol by a newly constituted panel ; structural restructuring of the office; implementing automated tracking to prevent timeline delays.

Serious Non-Compliance: Violations that materially compromise the rights, safety, or well-being of research participants, or significantly damage the integrity of the scientific data.

Continuing Non-Compliance: A persistent pattern of non-compliance across one or multiple projects, or a failure to respond to corrective action plans mandated by the committee.

7.3 Procedures for Handling Violations

Reporting: Suspected non-compliance can be reported by any research team member, participant, or institutional official. The institution will provide confidential or anonymous whistle blowing channels.

Inquiry and Investigation: Upon receiving a report, the ethics committee chair will initiate a preliminary inquiry. If evidence suggests substantive non-compliance, a formal investigation subcommittee will be formed to review documents, interview witnesses, and issue a finding.

7.4 Consequences and Corrective Actions

Depending on the severity and intent of the violation, the institution may enforce a range of consequences:

Severity Level Actions & Consequences

Minor / Administrative Actions: Required remedial training for staff; minor modifications to the protocol; increased frequency of progress reporting. Serious / Continuing Formal reprimand: mandatory suspension of participant recruitment or data collection; withholding of institutional research funds.

Severe Ethical Breach: Permanent termination of protocol approval; destruction of illegally obtained data; suspension of the PI's privilege to conduct research at the institution; reporting of the breach to federal regulatory bodies and funding agencies.

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