YASHODA ACADEMY OF MEDICAL EDUCATION AND RESEARCH (YAMER)

RESEARCH POLICY MANUAL

LOGO

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FOREWORD

Research is fundamental to advancing healthcare, improving patient outcomes, and strengthening evidence-based clinical practice. The **Yashoda Academy of Medical Education and Research (YAMER),** which is housed in the Yashoda Health Care Services Limited (YHS), is committed to fostering a culture of scientific excellence, ethical conduct, innovation, and collaboration.

These Research Policies Manual establishes the institutional framework for the governance of research across Yashoda Hospitals (YHS). It defines the principles, responsibilities, and standards that guide research activities and provides a common framework for investigators, departments, and administrators. Detailed operational procedures are contained in the YAMER Research Operations Manual (Volume II) and associated manuals.

INTRODUCTION

Vision: To generate high-quality, ethical, and impactful research that addresses India's major disease burden, improves patient outcomes, and advances affordable, evidence-based healthcare.

Aim: Yashoda Academy of Medical Education and Research (YAMER), housed in Yashoda Health Care Services Limited (YHCS-quaternary care hospital), aims to improve the health of patients and communities through multidisciplinary research in cardiometabolic diseases, pulmonary and lifestyle disorders, infectious diseases, cancer, neurosciences, transplantation, critical care, digital health, artificial intelligence (AI), precision medicine, public health, and other priority areas. The Academy recognizes research, innovation, and the generation of new knowledge as integral to its mission of advancing clinical excellence, education, and healthcare delivery.

YAMER is committed to ensuring that all research activities are conducted with the highest standards of scientific integrity, professional excellence, ethical responsibility, and regulatory compliance.

Purpose of these Policies:

The policies establish the institutional framework for the governance, ethical conduct, management, administration, and oversight of all research conducted under the auspices of **Yashoda Academy of Medical Education and Research (YAMER).**

The policies provide guidance to Principal Investigators (PIs), Co-Investigators (Co-Is), clinicians, faculty members, scientists, students, research staff, and administrative personnel involved in research.

they define the principles, responsibilities, governance mechanisms, and procedures governing the planning, ethical review, conduct, funding, administration, monitoring, reporting, publication, intellectual property management, and dissemination of research.

These policies apply to all categories of research undertaken through YAMER, including: Clinical research, Basic medical research, Medical device and diagnostic research, Government-funded research, Industry-sponsored research, Clinical trials, Academic and dissertation research, Translational and implementation research, Digital health, artificial intelligence, and precision medicine research, Collaborative national and international research

These policies ensure that research conducted through YAMER complies with applicable laws, national regulatory requirements, ethical guidelines, sponsor obligations, and institutional policies, while promoting scientific excellence, innovation, transparency, accountability, and responsible stewardship of research resources.

Scope of these Policies:

These policies apply to all academic and administrative departments, divisions, units, and personnel of YAMER involved in any form of research activity, including the administration of sponsored awards(Industry sponsored studies), investigator-initiated research, and academic research studies (Dissertation work).

Specifically, these policies are applicable to:
a. All staff, whether temporary or permanent, engaged in teaching, research, administration, or the provision of support to the core functions of the Academy.
b. All students participating in research activities conducted within YHCS.
c. All mentors, guides, external experts, collaborators, and sponsors associated with any research activities of the Academy.

Research Governance

YAMER serves as the central authority for research governance and establishes institutional policies, oversees research administration, promotes scientific excellence, ensures regulatory compliance, and strengthens research capacity. Governance is exercised through the Director, YAMER, the Research Office, the Scientific Review Committee, the Institutional Ethics Committee, and Departmental Research Committees.

Research governance ensures that every project undergoes appropriate scientific, ethical, financial, and administrative oversight from conception to completion, promoting transparency, accountability, and responsible stewardship of institutional resources.

Governance Responsibilities:

Function	Responsible Authority
Research strategy	Director, YAMER
Scientific review	Scientific Review Committee
Ethical review	Institutional Ethics Committee
Grant administration	Research Office
Research quality	Research Quality Unit

Function	Responsible Authority
Departmental oversight	Department Heads

General Research Guidelines

Administration of Research Grants

The YAMER Research Office provides centralized support for grant administration, budgeting, contracts, regulatory approvals, financial management, project monitoring, and study closure. Principal Investigators remain responsible for the scientific conduct of research, while the Research Office facilitates efficient project administration and compliance with institutional and sponsor requirements.

Research funds shall be managed responsibly, procurement shall follow institutional policies, and project records shall be maintained in accordance with regulatory and institutional requirements.

Institutional Overheads

YAMER will deduct 15 % of the total grant as overhead charges for all the government funded (extramural) research projects and 20% for Industry sponsored Research except Government Grants/ Specific Federal Funded Grants (where the overhead will be the maximum permissible by the funding agencies). The management reserves the right to revise the Institutional overheads from time to time based on Institutional requirements.

Where the overheads do not meet the Institutional norms, the grant budget should incorporate direct costs in each grant budget to support the administrative activities of Research within YAMER.

Research Budget and Approval

Investigators are requested to submit their budgets for approval to the Budget and Accounts section for review prior to grant application and submission. For all receipts a budget document with line items for all potential expenses should be submitted along with the Agreement. If the funding agency provides money on a per-patient basis (i.e., payment is linked to the number of patients enrolled or treated), then the Head of the Project / Principal Investigator (PI) is required to prepare a separate internal budget. This internal budget should detail how the per-patient funds will be allocated across various expense heads (such as investigations, consumables, staff time, participant compensation, etc.) and submit it to the institution for approval and record-keeping, even if the external agreement does not provide a detailed budget breakdown.

Purchases Guideline

All purchases for research projects will comply with the Purchase policy of YHCS. The main objective of the purchase guideline is to safeguard assets, prevent and detect error and fraud and optimize the uses of resources.

Assets Management Guideline

The Assets Management guideline covers all fixed and intangible Assets owned by the Hospital and Project. All assets procured through research projects will be maintained in an asset management electronic register at YAMER.

Regulatory Approval Requirements (Volume III):

YAMER is committed to meeting all regulatory approvals prior to the conduct of any research. This includes

1. Approval of the Institutional ethics committee (IEC)
2. Approval of Drug Controller General of India in case of Clinical Trials with new/novel compound or new Medical Devices (DCGI,CDSCO) or when a well-known marketed drug/compound is tested for a new indication.
3. Approval of Health Ministry Screening Committee (HMSC) for all studies involving Indo –Foreign Collaboration.
4. Approval of the Hospitals Bio-Safety Committee (HBSC) YHCS for any genetic and molecular studies.
5. Appropriate Material Transfer Agreement (MTA-ICMR) for the transfer of any biological Material outside the country
6. Registration prior to enrollment of all clinical trials in the national Clinical Trial Registry-India (CTRI).
7. Any other regulatory procedures as required by the sponsor or regulatory authorities

Research Integrity Policy

YAMER is committed to the conduct of research in an ethical manner fulfilling all ethical responsibilities related to

1. Procedures and processes as laid down by the Institutional Ethics Committee.
2. Compliance with Indian Council of Medical Research (ICMR) ethical policies for bio medical research on human participants
3. Ethical practices of investigators with regard to

- Ethical oversight of the studies for which they are responsible
- Fair and ethical publication procedure

All research studies have to be approved by the Scientific Review Committee and Institutional Ethics Committee (YAMER). In case of animal studies, review and approval by the Animal Ethics Committee is required.

The respective committees have guidelines that are updated periodically and are available on YAMER website.

Policy Statement and Commitments:

YASHODA ACADEMY OF MEDICAL EDUCATION and RESEARCH (YAMER) is committed to maintaining the highest standards of rigor and integrity in all aspects of research according to appropriate ethical, legal and professional frameworks, obligations and standards. YAMER is committed to working together to strengthen the integrity of research and to reviewing progress regularly and is committed to supporting a research environment that is underpinned by a culture of integrity and based on good governance, best practice, and support for the development of researchers. Allegations of research misconduct should they arise will be dealt with in a transparent manner.

Research Misconduct:

YAMER recognizes that academic freedom is fundamental to the production of excellent research. Individual researchers are primarily responsible for ensuring that no misconduct occurs; However, both YAMER and funders of research have an active role to play in sustaining research integrity.

Examples of research misconduct: Making up results or other outputs (eg, artefacts) and presenting them as if they were real. Manipulating research processes or changing or omitting data without following the regulatory clause. Using other people's material without giving proper credit (plagiarism). Failure to meet ethical, legal and professional obligations, such as failure to declare competing interests, misrepresentation of involvement or authorship, misrepresentation of interests, breach of confidentiality, lack of informed consent, misuse of personal data, and abuse of research subjects or materials. Failing to address possible infringements such as attempts to cover up misconduct and reprisals against whistle blowers are also included. It is imperative that when an allegation of research misconduct arises suitable procedures are in place to deal with it effectively and fairly. There must be accountability when things go wrong and, where concerns are upheld, appropriate action must be taken. Researchers, mentors or guides act in good faith, whether in making allegations or in being required to participate in an investigation. They must report misconduct to employers, funders and professional, statutory and regulatory bodies as circumstances require.

Honest errors and differences in, for example, research methodology and interpretations are not examples of research misconduct.

YAMER will keep the funders of research and professional and/or statutory bodies informed as required by their conditions of grant and other legal, professional and statutory obligations. All researchers must be aware of the relevant contacts and procedures for making allegations.

Human Research Protection (Ethics) Policy

Purpose and Scope

This policy will cover all types of research activities involving Human subjects, both funded and non- funded and will also include undergraduate student projects, post graduate dissertations and postdoctoral thesis works.
Study population or participants or Subjects may include healthy volunteers or patients and other individuals who may be considered vulnerable due to medical, cognitive, emotional, economical, educational, age, or other factors.

Definition of human subjects:

ICMR defines human subjects as living individual(s) about whom an investigator conducting research obtains: (a) Data through intervention or interaction with the individual; or (b) Identifiable private information.
Since the definition of a human subject is a living individual, research involving autopsy materials or cadavers is not considered human subjects research and is not reviewed by the HRPP although it may come under the purview of Yashoda Academy of Medical Education and Research (YAMER) Ethics Committee.

Interventional studies:
Intervention studies are research studies in which the investigator actively introduces a specific action (intervention) to a group of participants or subjects and then measures its effect on predefined outcomes. Intervention includes a drug (compound), a device, diet, exercise program, education intervention or policy change etc. In intervention studies the researcher controls the intervention, and participants are followed over time to observe changes. Outcomes are compared before and after, or between intervention and control groups

Definition of an investigational product:
A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.

Interaction means any communication or interpersonal contact between the investigator and the participant. **Private information** refers to information about behavior occurring in circumstances where an individual has a reasonable expectation of privacy, as well as information provided for specific purposes with an expectation of confidentiality (e.g., medical records), which will not be accessed or used for research without prior informed consent, except as permitted by applicable ethical guidelines.

Responsibilities of the Yashoda Academy of Medical Education and Research (YAMER) Ethics Committee (Independent body)

- To oversee the implementation, supervision, and periodic evaluation of the institutional Human Research Protection Policy.
- To review existing ethics-related policies and procedures and recommend modifications, as required, to ensure compliance with applicable national and international guidelines.
- To engage with relevant institutional and external stakeholders to promote the protection of human participants and to facilitate dissemination of ethical principles and education for researchers and research participants.
- To receive, review, and address complaints, protocol deviations, non-compliance, allegations of undue influence, or ethical misconduct, and to conduct enquiries, audits, or investigations as necessary, with appropriate communication to investigators.
- To review and manage Conflicts of Interest disclosed in submissions and to exercise authority to suspend or terminate research in cases of serious ethical violations, including censuring investigators or restricting research privileges, in accordance with YGH policy.
- To periodically review research involving human participants that is exempt from prior ethics committee approval such as case reports or case studies, in order to ensure ongoing protection of participant rights and welfare.
- To monitor implementation of ethics committee recommendations and directives through ongoing communication to ensure compliance.
- To serve as an accessible forum for addressing concerns, questions, or complaints from researchers and research participants through written communication (e-mail or formal correspondence).
- In accordance with human research regulations, research is defined as a *systematic investigation designed to develop or contribute to generalizable knowledge*; therefore,

case reports or case studies involving a single patient do not meet this definition and do not require review by the YAMER Ethics Committee.

Investigator Responsibilities:

All faculty and staff who are conducting Research involving Human Subjects within the course and scope of their Academic duties, as well as students who are conducting Research involving Human Subjects within the course and scope of their academic course and studies, regardless of whether the Research is funded and regardless of the source of funding, must submit Human Subject Research protocols to the YAMER for approval or follow YAMER policies and/or procedures for obtaining an exempt determination prior to commencing Research. Investigators must maintain YAMER approval for the lifespan of the project, submit continuing review documents to the YAMER as necessary to maintain the approval, and follow all YAMER and Academy policies for the protection of human subjects in the conduct of the project.

Intellectual Property rights (IPR) Policy

Yashoda Academy of Medical Education and Research (YAMER) is committed to fostering innovation, research excellence, and ethical conduct in health care and biomedical research. YAMER IPR Policy provides a framework for the identification, ownership, protection, management, and utilization of intellectual property generated through clinical care, academic activities, and research conducted under the aegis of YAMER and YHCS.

Scope

This policy applies to all permanent and temporary employees of YAMER and YHCS, including clinicians, faculty, consultants, visiting faculty, scientists, nurses, students and technical staff. Collaborators, and any individual using YAMER and YHCS resources. All intellectual property created using institutional facilities, data, or patient-related resources.

Definitions

- **Intellectual Property (IP):** Includes but not limited to inventions, development of novel devises, discoveries, innovations, data, software, biological materials, protocols, and know-how, generated in the course of research conducted at or under the auspices of YHCS, whether investigator-initiated or sponsored, shall be governed by the Intellectual Property Policy of YHCS and applicable Indian laws.
- **Creator/Inventor:** An individual who has made an intellectual contribution to the creation of IP.
- **Institutional Resources:** Facilities, funds, equipment, patient data, clinical material, or administrative support provided by YHCS/YAMER.

Ethical and Regulatory Compliance

- All IP-related activities shall comply with ICMR National Ethical Guidelines, IEC approvals, informed consent requirements, and data protection norms.

- Patient care, safety, and access to health innovations shall take precedence over commercial interests.
- Methods of medical treatment shall not be patented in accordance with Section 3(i) of the Indian Patent Act.

Ownership of Intellectual Property

- Intellectual property created in the course of employment or using substantial institutional resources shall ordinarily be owned by YAMER/YHCS.
- In the case of sponsored, collaborative, or per-patient funded research, the rights and obligations of the sponsor, investigators, and Yashoda Hospitals with respect to intellectual property, data access, and commercialization shall be mutually agreed upon in writing and shall comply with national and ethical standards.
- IP created without use of institutional resources and outside the scope of employment may be owned by the individual, subject to disclosure and review.

Disclosure of Intellectual Property

- All potential IP must be promptly disclosed in writing to the designated Institutional IPR or Technology Transfer Office.
- Disclosure should occur prior to public presentation, publication, or external communication.
- Failure to disclose may result in loss of individual rights.
- All individuals involved in IP generation or commercialization must disclose actual or potential conflicts of interest.

Revenue Sharing

- Net revenues from commercialization shall be distributed among inventors, departments, and the institution according to institutional norms.
- Revenue-sharing percentages shall be defined separately in institutional SOPs.

Data Sharing Policy

Access to and use of healthcare and research data for other research analytics and statistical purposes will be conducted in accordance with the ICMR data sharing guidelines, with the aim of improving diagnostics, therapeutics, and advancing patient care.

Principles of the ICMR Data Sharing Policy

- **Data Ownership:** Participants own their biological samples and data.
- **Data Custodianship:** the Principal investigator and Co-Investigators of a research study, the Head of the respective department and the Head of the Organisation.
- **Informed Consent:** Researchers must obtain explicit, voluntary, written informed consent from participants for data collection, storage, and foreseeable secondary use. The consent form must clearly outline how the data will be used and shared.
- **Anonymization and De-identification:** To protect privacy, raw identifiable data cannot be freely shared with third parties, especially international collaborators.

Only de-identified or anonymized data can typically be shared for secondary research purposes, and this requires further ethics committee approval.

- **Ethics Committee Review:** The YHCS Ethics Committee (YAMER) must review and approve all data sharing proposals, ensuring that adequate safeguards for confidentiality are in place. For data sharing with third parties not specified in the original consent, approval from the relevant ECs is mandatory.
- **Collaboration Agreements:** For collaborative research, especially involving external or foreign institutions, appropriate Memorandums of Understanding (MoUs) and Material Transfer Agreements (MTAs- ICMR) must be in place to define terms of ownership, publication, and data transfer.
- **Data Preservation:** Research records and data must be preserved securely for a minimum period (3-5 years for biomedical research and 5 years for clinical trials) to allow for confirmation of findings or re-analysis by other authorized researchers or regulators.
- **Compliance with National Laws:** Data sharing must comply with all applicable Indian laws and guidelines, including the **Digital Personal Data Protection Act, 2023**.

For detailed information, refer to the ICMR Policy on Research Integrity and Publication Ethics and the National Ethical Guidelines for Biomedical and Health Research involving Human Participants.

Research Publication Policy

Purpose and Scope

Yashoda Academy of Medical Education and Research (YAMER) conducts research across multiple disciplines and is committed to ensuring that research outputs are appropriately disseminated and, wherever feasible, made freely accessible. In accordance with its Data Sharing Policy**,** YAMER promotes responsible data sharing to maximize the economic, social, and cultural impact of its research, while safeguarding participant confidentiality and complying with ethical, legal, and regulatory requirements.

Publication Policy Statement:

1. Research Publications must acknowledge the funding source and grant number
2. All publications arising out of research work carried out in YAMER and YHCS facility must acknowledge the YASHODA ACADEMY OF MEDICAL EDUCATION AND RESEARCH and YASHODA HEALTH CARE SERVICES ltd.
3. Authors must record bibliographic details of all research outputs in YAMER publications database, within three months after the date of acceptance for publication.
4. Authors must deposit full text copies of research outputs, i.e. final accepted peer-reviewed journal articles and conference papers (and where appropriate, monographs) in the institutional repository within three months after the date of acceptance for publication.

5. Where publisher's copyright permissions allow and there are no confidentiality or commercial constraints, the research outputs in the institutional repository must be made 'open access', i.e. freely accessible over the internet.
6. Where outputs are not embargoed for any period they must be made open access within one month of deposit. After an embargo period, outputs must be made open access immediately after the last day of the embargo period.
7. Authors must comply with the funders' policies relating to open access and research data management.
8. Authors must use a standardized institutional affiliation YASHODA ACADEMY OF MEDICAL EDUCATION AND RESEARCH (YAMER) and "YASHODA HEALTH CARE SERVICES" along with their respective Institutional affiliation, in all research outputs to ensure clear affiliation with the YAMER /YHCS.
9. Authors must acknowledge the source of grant funding associated with a research output in the publication itself. Information about the grant should also be linked, by the author, to the record of the publication in the YAMER Publications Database.
10. Authors should register for an individual ORCiD2 identifier and should include it on a personal webpage, when submitting publications, when applying for grants, and in any research workflow to ensure that the individual is credited for their work and that the correct institutional affiliation is achieved.
11. The policy applies to all research outputs. Where copyright permits, monographs may also be deposited. Other forms of published outputs, e.g. articles or letters published in the press, may also be added to the institutional repository. These often contribute to the impact of the researchers' work and provide valuable permanent accounts of our research activities.
12. Yashoda Academy of Medical Education and Research (YAMER) will comply with the Indian Council of Medical Research (ICMR) guidelines for publishing research manuscripts, International Committee of Medical Journal Editors (ICMJE) and the Committee on Publication Ethics (COPE).

Policy on Plagiarism

Plagiarism is defined as presenting someone else's words, ideas, or work as your own without proper acknowledgment, covering everything from small phrases to entire texts, whether published or not, and even extending to unintentional errors in citation. It's a serious ethical breach, encompassing direct copying (verbatim plagiarism or paraphrasing ideas) without citation, and can occur accidentally or intentionally, leading to severe academic/professional consequences.

Policy Statement and Commitments

Evaluation of academic and research work of scholars and students and also faculty members leading to the partial fulfilment for the award of degrees at Master's and research level in the form of thesis, dissertation and publication of research papers, chapters in books, full-fledged books and any other similar work, reflects the extent to which elements of academic integrity and originality are observed in various relevant processes adopted by YAMER.

It is mandatory for all faculty, researchers and students to adhere to the policy of academic malpractice and plagiarism and strives to use best tools and practices to identify and detect academic malpractice and plagiarism.

Responsibility of the Researcher

1. The Medical researcher or the DNB student should be aware of responsible conduct of research, thesis, dissertation, promotion of academic integrity and prevention of misconduct including plagiarism in academic writing.

2. The Medical researcher or the DNB student should know thoroughly about the impact of plagiarism and the penalties of the act.

3. It is an utmost important duty not to attempt any misconduct during the research work either during experimental data collection or data analysis or report writing or publication of research articles, research journals or presentation of scientific findings in conferences.

4. It is very essential to submit the manuscripts to plagiarism detection mechanisms available in the institution and detect the percentage of plagiarized matter and revise the script to minimize it.

Institutional Guidelines for the Prevention of Plagiarism

Plagiarism may take several forms, including the use of invalid or nonexistent sources; citing secondary sources as primary references; self-plagiarism through reuse of one's own previously published work without disclosure; and paraphrasing that misrepresents another's ideas as original. It also includes repetitive research with reused data or text, duplicate or multiple submissions of the same manuscript, inaccurate authorship attribution, unethical use of collaborative work without acknowledgment, verbatim copying without citation, and complete plagiarism involving submission of another person's work as one's own.

The medical researcher, the postgraduate, and the post-doctoral students / scholars are required to submit a signed statement that they are aware of the plagiarism policy of the Hospitals and no part of their work, be it a project report or thesis or dissertation or images is copied in any form and it is their own creation.

Research Quality and Capacity Building

YAMER is committed to continuous improvement in research quality through systematic monitoring, internal audits, education, mentorship, and performance evaluation. Research quality shall be integrated throughout the research lifecycle, from protocol development to publication and translation into clinical practice.

The Academy will strengthen research capacity by investing in infrastructure, investigator development, multidisciplinary collaboration, and institutional quality systems while recognizing excellence in research and innovation.

Key Policy Requirements

- Risk-based monitoring of research projects.
- Periodic quality audits.
- Continuing education and mentorship.
- Annual review of research performance.
- Recognition of research excellence.

STRATEGIC RESEARCH PRIORITIES

YAMER will focus its research efforts on areas of major disease burden and emerging scientific opportunities. Priority areas include cardiometabolic diseases, cancer, neurosciences, pulmonary medicine, infectious diseases, maternal and child health, nutrition, devices and diagnostics, organ transplantation, and preventive healthcare.

The Academy will also strengthen research in artificial intelligence, digital health, precision medicine, real-world evidence, implementation science, clinical registries, translational research, and healthcare innovation. Through strategic partnerships, investment in infrastructure, and development of clinician-scientists, YAMER aims to become a nationally recognized centre of excellence in healthcare research.

Strategic Priorities

- Address national health priorities.
- Promote multidisciplinary and translational research.
- Advance AI, digital health, and precision medicine.
- Generate high-quality real-world evidence.
- Strengthen national and international collaborations.
- Build sustainable research capacity and innovation.

INSTITUTIONAL COMMITMENT TO RESEARCH EXCELLENCE

Yashoda Academy of Medical Education and Research is committed to fostering a research environment that integrates scientific excellence, ethical conduct, innovation, education, and patient-centred care. Every member of the YAMER research community shares responsibility for maintaining the highest standards of integrity, protecting research participants, generating high-quality evidence, and translating research into improved clinical practice and public health.

Through effective governance, responsible stewardship of resources, continuous learning, and strategic collaboration, YAMER will strive to become a leading academic healthcare research institution, contributing to national and global scientific advancement while improving the health and well-being of the communities it serves.