VOLUME II

YAMER RESEARCH OPERATIONS MANUAL

(Standard Operating Procedures)

This manual describes the operational procedures for planning, conducting, monitoring, documenting, and completing research conducted under the auspices of the **Yashoda Academy of Medical Education and Research (YAMER)**. It complements the **YAMER Research Policy Manual (Volume I)** by translating institutional policies into standardized operational practices. The procedures apply to all investigator-initiated, sponsored, collaborative, and academic research undertaken across Yashoda Hospitals.

RESEARCH PROJECT LIFECYCLE

All research projects undertaken at YAMER shall follow a standardized lifecycle to ensure consistency, quality, and regulatory compliance.

Workflow

Research Idea

Concept Note

Scientific Review

Protocol Development

Budget Preparation

Ethics & Regulatory Approval

Grant/Contract Execution

Study Initiation

Participant Recruitment

Study Conduct

Monitoring & Quality Assurance

Data Analysis

Publication

Project Closure

Archiving

Operational Requirements

- Every project shall have a Principal Investigator.
- Institutional Ethical committee (IEC) and Scientific Review Board (SRB) approvals are mandatory before study initiation.
- Progress shall be monitored throughout the project lifecycle.
- Study records shall be archived after completion.

PROTOCOL DEVELOPMENT

Every research project shall begin with a scientifically robust protocol. Investigators shall develop protocols using institutional templates and obtain statistical consultation where appropriate.

Protocols shall include:

- Background and rationale
- Objectives
- Study design
- Sample size
- Study procedures
- Outcome measures
- Statistical analysis
- Ethical considerations
- Timeline
- Budget

Protocols shall undergo departmental review before submission to the Scientific Review Board.

SCIENTIFIC REVIEW AND ETHICS SUBMISSION

All investigator-initiated research shall undergo scientific review before ethics submission.

The Scientific Review Committee evaluates scientific merit, feasibility, methodology, statistical validity, and institutional relevance.

Following scientific approval, investigators shall submit the protocol and supporting documents to the Institutional Ethics Committee. Where applicable, additional approvals (CDSCO, CTRI, HMSC, Biosafety Committee) shall be obtained before commencing the study.

Workflow

Department Review → Scientific Review → Ethics Review → Regulatory Approval → Study Approval

GRANTS, CONTRACTS AND FINANCIAL MANAGEMENT

YAMER -Research Office shall coordinate grant applications, institutional approvals, budget review, contract execution, and financial administration.

Principal Investigators are responsible for scientific conduct and appropriate utilization of research funds.

Institutional overheads shall be applied in accordance with YAMER policy. Procurement, financial reporting, utilization certificates, and grant closure shall follow institutional financial procedures.

Operational Requirements

- Budget approval before submission.
- Legal review of all agreements.
- Dedicated project accounts where applicable.
- Periodic financial review.

STUDY IMPLEMENTATION

After obtaining all approvals, investigators may initiate the study.

Study initiation includes:

- Investigator meeting
- Team training
- Site preparation
- Study documentation
- Database preparation
- Participant recruitment
- Informed consent
- Data collection

The Principal Investigator shall ensure that all study personnel understand the approved protocol and their respective responsibilities.

DATA MANAGEMENT

Research data shall be collected using standardized procedures to ensure completeness, accuracy, confidentiality, and traceability.

Data management includes:

- Source documentation
- Case Report Forms (CRFs)
- Electronic databases
- Data validation
- Quality checks
- Data locking

- Statistical analysis
- Secure archiving

Electronic systems should maintain audit trails and controlled user access.

SAFETY REPORTING AND REGULATORY COMPLIANCE

Investigators shall comply with all applicable ethical and regulatory requirements throughout the conduct of the study.

The following shall be reported promptly:

- Serious Adverse Events (SAEs)
- Unexpected Adverse Events
- Protocol Deviations
- Protocol Violations
- Amendments
- Annual Progress Reports
- Study Completion Reports

The YAMER -Research Office shall maintain regulatory documentation for all active studies.

QUALITY MANAGEMENT

Research quality shall be maintained through continuous monitoring rather than retrospective inspection.

Quality activities include:

- Study monitoring
- Internal audits
- Data verification
- CAPA implementation
- Compliance review
- Inspection readiness

Monitoring shall be proportionate to the complexity and risk of the study.

Departments shall cooperate fully during internal quality reviews.

PUBLICATIONS AND DISSEMINATION

Investigators are expected to publish research findings in a timely and responsible manner.

Prior to publication:

- Verify data accuracy.
- Confirm authorship.
- Complete conflict-of-interest declarations.
- Obtain sponsor review where contractually required.

- Seek approval from Director- Medical Services (for-authorship, acknowledgement and intellectual property rights/ patenting if any)

Research findings should be disseminated through peer-reviewed journals, scientific conferences, policy briefs, institutional reports, and educational activities.

PROJECT CLOSURE

A research project shall be considered complete only after:

- Data analysis is finalized.
- Final report is submitted.
- Financial reconciliation is completed.
- Publications are initiated.
- Ethics Committee is notified of study completion.
- Sponsor reports are submitted where applicable.
- Research records are archived.
- Institutional assets are accounted for.

The YAMER-Research Office shall issue a formal project closure confirmation after verifying that all scientific, regulatory, financial, and administrative requirements have been fulfilled.

OPERATIONAL RESPONSIBILITY MATRIX

Activity	PI	Department	Research Office	Ethics Committee	Finance	Legal
Concept development	✓	✓				
Scientific review	✓	✓	✓			
Ethics submission	✓		✓	✓		
Budget	✓		✓		✓	
Contracts/agreements/MOU			✓			✓
Study conduct	✓	✓				
Monitoring	✓		✓	✓		
Publication	✓	✓				
Study closure	✓		✓		✓	

STANDARD PROJECT TIMELINE

Stage	Indicative Timeline
Concept note	Within one month of submission-approval by the Department and internal scientific committee
Protocol development	2–4 weeks
Scientific review	Annual meetings (external committee)
Ethics review (independent committee)	Quarterly meeting
Regulatory approvals (if applicable)	Variable
Study initiation	Within 2 weeks of approvals
Monitoring	Throughout the study
Final report	Within 90 days of study completion
Archiving	Following project closure