VOLUME V

RESEARCH QUALITY MANAGEMENT SYSTEM (RQMS)

Yashoda Academy of Medical Education and Research (YAMER)

Version 1.0

FOREWORD

Research quality is fundamental to scientific credibility, participant safety, regulatory compliance, and institutional reputation. High-quality research requires more than compliance with regulations; it requires a systematic approach to planning, monitoring, evaluation, risk management, and continuous improvement.

The YAMER Research Quality Management System (RQMS) establishes an institution-wide framework for assuring the quality of research conducted across Yashoda Hospitals. The system integrates governance, quality assurance, quality control, monitoring, audits, performance metrics, corrective and preventive actions (CAPA), investigator development, and organizational learning into a single continuous improvement framework.

Introduction

The Research Quality Management System (RQMS) provides a structured approach for maintaining and continuously improving the quality of all research conducted under YAMER. It applies to investigator-initiated studies, sponsored research, clinical trials, registries, digital health projects, artificial intelligence research, and academic research.

The objectives of the RQMS are to:

- Ensure scientific quality and participant safety.
- Promote regulatory and ethical compliance.
- Strengthen data integrity.
- Standardize research processes.
- Detect and mitigate risks.
- Promote continuous improvement.
- Enhance institutional research performance.

Research Quality Framework

Research quality is integrated throughout the entire research lifecycle.

Research Planning
|
Protocol Development
|
Scientific Review
|
Ethics & Regulatory Review
|

Study Initiation
|
Study Conduct
|
Monitoring
|
Data Verification
|
Analysis
|
Publication
|
Project Closure
|
Lessons Learned
|
Continuous Improvement

Research Quality Governance

Research quality is overseen through a multidisciplinary governance structure.

Function	Responsibility
Governing Board	Strategic oversight
Director, YAMER	Overall accountability
Research Quality Committee	Quality oversight
Research Office	Operational coordination
Scientific Review Committee	Scientific quality
Institutional Ethics Committee	Ethical compliance
Principal Investigator	Project quality
Research Team	Daily implementation

Risk-Based Quality Management

Research projects shall be classified according to their potential risk to participants, data integrity, and institutional reputation.

Low Risk

- Student projects
- Anonymous surveys
- Retrospective chart reviews

Moderate Risk

- Prospective observational studies
- Registries
- Digital health evaluations

High Risk

- Clinical trials
- AI-assisted clinical decision support
- Medical device studies
- First-in-human research
- International collaborative studies

The level of monitoring, documentation, and oversight shall be proportionate to the level of risk.

Quality Assurance

Quality Assurance (QA) focuses on preventing problems before they occur.

QA activities include:

- SOP development
- Staff training
- Scientific review
- Ethics review
- Investigator qualification
- Protocol standardization
- Regulatory compliance
- Quality planning

Quality shall be built into research processes rather than inspected at the end of the project.

Quality Control

Quality Control (QC) verifies that research is being conducted according to approved protocols.

QC activities include:

- Source data verification
- Database review
- Consent verification
- Eligibility verification
- Data accuracy checks
- Laboratory quality checks
- Equipment calibration
- Documentation review

Quality Control is performed throughout the conduct of the study.

Monitoring and Audits

Monitoring ensures ongoing compliance and early identification of issues.

Monitoring activities include:

- Study initiation visits
- Routine monitoring
- Remote monitoring
- Risk-based monitoring
- Close-out monitoring

Internal audits may evaluate:

- Ethics compliance
- Regulatory compliance
- Financial compliance
- Data integrity
- Investigator responsibilities
- Documentation
- Participant safety

Audit findings shall be documented and followed by corrective actions where necessary.

Corrective and Preventive Actions (CAPA)

When quality issues are identified, CAPA shall be implemented using a structured process.

CAPA Process

Problem Identification

Immediate Containment

Root Cause Analysis

Corrective Action

Preventive Action

Verification of Effectiveness

Closure

Performance Indicators (KPIs)

YAMER shall monitor institutional research performance using measurable indicators.

Scientific Performance

- Number of active studies- improve patient care/ diagnostics/ preventive medicine
- Study completion rate
- Publications
- Citation impact/ translation / policy relevance
- Grant success rate

Regulatory Performance

- Ethics approval timelines
- Protocol deviations
- SAE reporting compliance
- CTRI registration compliance

Quality Performance

- Monitoring findings
- Audit observations
- CAPA completion rate
- Data query rate
- Consent documentation accuracy

Operational Performance

- Recruitment performance
- Budget utilization
- Project completion timelines
- Contract turnaround time

Capacity Building

- Investigators trained
- Workshops conducted
- Student research projects
- Multidisciplinary collaborations

KPIs shall be reviewed quarterly by the Research Quality Committee.

Quality Dashboards

The Research Office shall maintain institutional dashboards summarizing:

- Active studies
- Recruitment
- Ethics approvals

- Publications
- Grants
- Monitoring status
- CAPA status
- Audits
- KPIs

Dashboards shall support evidence-based management decisions.

Continuous Improvement

Quality improvement shall be driven through:

- Internal audits
- Lessons learned
- Investigator feedback
- Participant feedback
- Monitoring findings
- Regulatory inspections
- Performance metrics

Improvement initiatives may include:

- SOP revision
- Additional training
- Digital automation
- Process redesign
- Resource optimization

Continuous improvement shall be reviewed annually.

Research Excellence Framework

YAMER shall assess departmental performance annually using six domains.

Domain	Examples
Scientific Quality	Publications, citations
Compliance	Ethics, regulatory performance
Innovation	Patents, AI tools, devices
Translation	Clinical implementation
Capacity Building	Mentorship, training
Societal Impact	Policy, public health, community benefit

RESEARCH QUALITY SCORECARD

Each project may be assessed using a standardized scorecard across key domains:

Domain	Indicator
Scientific Quality	Protocol quality, methodology
Ethics	Timely approvals, consent compliance
Data Quality	Accuracy, completeness, query resolution
Safety	SAE reporting, participant protection
Operations	Recruitment, milestones, budget adherence
Outputs	Publications, dissemination, implementation

INSTITUTIONAL COMMITMENT

YAMER is committed to embedding quality into every stage of the research lifecycle. Through standardized processes, competent investigators, risk-based monitoring, meaningful performance measurement, and continuous organizational learning, the Academy seeks to build a sustainable culture of research excellence.

The Research Quality Management System is not intended solely to ensure compliance; its primary purpose is to improve the quality, efficiency, reproducibility, and impact of research while safeguarding participants and strengthening public confidence in research conducted under YAMER.