VOLUME IV

AI, DIGITAL HEALTH AND REAL-WORLD EVIDENCE (RWE) RESEARCH GOVERNANCE MANUAL

Yashoda Academy of Medical Education and Research (YAMER)

Version 1.0

FOREWORD

Artificial Intelligence (AI), digital health technologies, and real-world evidence (RWE) are transforming healthcare delivery, clinical research, and decision-making. These technologies create new opportunities for improving patient outcomes, increasing healthcare efficiency, accelerating clinical discovery, and supporting evidence-based practice. They also introduce new ethical, legal, scientific, and operational challenges.

This manual establishes the governance framework for research involving AI, digital health, and real-world data conducted under the auspices of the Yashoda Academy of Medical Education and Research (YAMER). It provides guiding principles, institutional responsibilities, and operational expectations to ensure that emerging technologies are developed, evaluated, and implemented safely, ethically, transparently, and responsibly.

Introduction

YAMER recognizes Artificial Intelligence, Digital Health, and Real-World Evidence as strategic research priorities that complement traditional clinical research. Research in these domains shall be scientifically robust, ethically sound, clinically relevant, and aligned with applicable regulatory and institutional requirements.

This manual applies to all research involving AI algorithms, clinical decision support systems, machine learning models, digital therapeutics, mobile health applications, wearable technologies, electronic health records, health information exchanges, registries, real-world data, and other digital innovations.

Guiding Principles

- Patient benefit
- Scientific validity
- Ethical AI
- Transparency
- Fairness
- Accountability
- Human oversight
- Data security

Governance of AI and Digital Health Research

AI and digital health research shall be governed through a multidisciplinary oversight framework involving clinicians, data scientists, statisticians, ethicists, information technology specialists, legal experts, and patient representatives where appropriate.

Projects shall undergo scientific review, ethical review, technical evaluation, and data governance review before implementation.

Governance Structure

Function	Responsible Authority
Strategic oversight	Director, YAMER
Scientific review	Scientific Review Committee
Ethics review	Institutional Ethics Committee
AI governance	AI & Digital Health Committee
Data governance	Data Governance Committee
Cybersecurity	Information Technology Department

Artificial Intelligence Research

YAMER supports research involving machine learning, deep learning, computer vision, natural language processing, predictive analytics, clinical decision support, and generative AI where these technologies have the potential to improve healthcare.

AI research shall demonstrate:

- Clinical relevance
- Scientific validity
- Algorithm transparency
- Appropriate validation
- Human oversight
- Patient safety
- Continuous monitoring

AI systems shall assist, not replace, professional clinical judgement unless specifically approved for autonomous use under applicable regulations.

Digital Health Research

Digital health research includes studies involving telemedicine, remote monitoring, wearable devices, mobile applications, electronic health records, patient portals, digital therapeutics, and connected healthcare systems.

Digital interventions shall be evaluated for:

- Clinical effectiveness
- Safety
- Usability
- Accessibility
- Equity
- Cybersecurity
- Interoperability
- Cost-effectiveness

Digital solutions should improve healthcare delivery without increasing disparities in access to care.

Real-World Data and Real-World Evidence

YAMER recognizes the importance of Real-World Data (RWD) and Real-World Evidence (RWE) in complementing traditional clinical trials and informing healthcare decisions.

Sources of RWD may include:

- Electronic Health Records
- Disease Registries
- Administrative databases
- Insurance claims
- Laboratory information systems
- Pharmacy records
- Wearable devices
- Patient-reported outcomes

RWE studies shall employ scientifically appropriate methodologies to minimize bias and ensure reliable interpretation.

Data Governance and Privacy

Digital health and AI research require strong data governance.

Research data shall be:

- Accurate
- Secure
- Confidential
- Traceable
- Auditable
- Legally compliant

Researchers shall implement appropriate safeguards for data collection, storage, processing, sharing, and retention.

Secondary use of clinical data shall require appropriate institutional approvals and ethical oversight.

Algorithm Development and Validation

Algorithms developed under YAMER shall undergo systematic evaluation before clinical implementation.

Evaluation should include:

- Internal validation
- External validation
- Clinical validation
- Performance benchmarking
- Bias assessment
- Explainability
- Robustness testing
- Prospective evaluation where appropriate

Algorithm performance shall be monitored throughout deployment.

Ethical AI

AI research shall respect the principles of:

- Human autonomy
- Beneficence
- Non-maleficence
- Justice
- Explainability
- Transparency
- Accountability

Researchers shall actively evaluate:

- Algorithmic bias
- Fairness
- Population representativeness
- Clinical safety
- Potential unintended consequences

AI shall support equitable healthcare rather than reinforce existing inequalities.

Clinical Implementation

Research demonstrating satisfactory safety and effectiveness may proceed to phased clinical implementation.

Implementation shall include:

- Pilot evaluation
- User training
- Clinical monitoring

- Performance evaluation
- Feedback mechanisms
- Incident reporting
- Periodic review

Clinical implementation shall remain under appropriate clinical governance.

Cybersecurity and Digital Risk

Digital research platforms shall comply with institutional cybersecurity requirements.

Risk management shall address:

- Unauthorized access
- Data breaches
- Malware
- System failure
- Business continuity
- Disaster recovery
- Audit trails

Security assessments shall be proportionate to the level of risk.

Capacity Building

YAMER shall strengthen institutional expertise through:

- AI education
- Digital health training
- Biostatistics
- Data science
- Clinical informatics
- Health economics
- Regulatory science
- Responsible AI

Multidisciplinary collaboration between clinicians and technical experts shall be encouraged.

Strategic Vision

YAMER aims to become a national leader in responsible AI-enabled healthcare research by integrating clinical expertise, digital technologies, and real-world evidence to improve patient care.

Priority initiatives include:

- AI-enabled Clinical Decision Support
- Predictive Analytics
- Precision Medicine
- Hospital Digital Twins

- Learning Health Systems
- Real-Time Clinical Registries
- Federated Learning
- Digital Biomarkers
- Remote Patient Monitoring
- Implementation Science
- Health System AI Evaluation

Research shall focus on translating innovation into measurable improvements in patient outcomes, healthcare quality, efficiency, and equity.

AI GOVERNANCE PRINCIPLES

Every AI project undertaken at YAMER should satisfy the following principles:

- **Clinical Need:** Address a clearly defined healthcare problem.
- **Scientific Validity:** Use appropriate study design and validation methods.
- **Human Oversight:** Clinicians retain responsibility for patient care decisions.
- **Transparency:** Document data sources, model development, assumptions, and limitations.
- **Fairness:** Evaluate and mitigate bias across patient populations.
- **Privacy:** Protect patient confidentiality and comply with data governance requirements.
- **Security:** Ensure secure storage, processing, and transmission of data.
- **Accountability:** Assign clear responsibility for development, validation, deployment, and monitoring.
- **Continuous Evaluation:** Monitor model performance after implementation and recalibrate when necessary.

DIGITAL HEALTH GOVERNANCE FRAMEWORK

Clinical Need
|
Scientific Review
|
Ethics Review
|
Data Governance Review
|
Technical Validation
|
Clinical Validation
|
Pilot Implementation
|
Performance Monitoring
|
Continuous Improvement

INSTITUTIONAL COMMITMENT

YAMER is committed to advancing responsible innovation through the ethical development, evaluation, and implementation of Artificial Intelligence, Digital Health, and Real-World Evidence. The Academy will foster multidisciplinary collaboration, strengthen digital research capacity, protect patient rights and data, and ensure that emerging technologies are used to improve healthcare safely, transparently, and equitably. Through robust governance and continuous evaluation, YAMER aims to establish itself as a leader in technology-enabled healthcare research in India and contribute to the responsible adoption of digital innovations for the benefit of patients and society.