

# **REQUEST FOR PROPOSALS: Design, Development and Implementation of a Digital Research Ethics Review System for the Rwanda National Research Ethics Committee (RNEC)**

## **1. Background**

The Centre for Impact, Innovation and Capacity building for Health Information Systems and Nutrition (CIIC-HIN), coordinating the TRACE Project in Rwanda, on behalf of the Rwanda National Research Ethics Committee (RNEC), invites eligible firms to submit proposals for the design, development, and implementation of a Research Ethics Review System for RNEC and Institutional Review Boards (IRBs) in Rwanda.

The TRACE Project (Trial Regulation and Clinical Ethics Optimization), funded by the Gates Foundation, is supporting Rwanda in strengthening its ethics and regulatory systems through digital transformation and institutional capacity building. RNEC is mandated by the Ministry of Health to oversee the ethical conduct of health research in Rwanda. The current platform used for protocol submission and review has operational and compliance limitations, while most IRBs in Rwanda operate using manual or semi-digital processes. This has resulted in inefficiencies in submission, review timelines, communication, monitoring, and reporting.

Following a comprehensive needs assessment that was conducted, RNEC intends to procure a qualified firm to design, develop, and implement a Research Ethics Review System that will support RNEC and IRBs through a shared application portal and a multi-tenant review platform. The new system will improve efficiency, transparency, compliance, reporting, and overall management of research ethics review processes in Rwanda.

## **2. Objective of the Assignment**

The objective of this assignment is to design, develop, and implement a Research Ethics Review System that will support the submission, review and notification, approval, certification, and monitoring of research protocols for RNEC and IRBs in Rwanda.

The system will provide a single shared online application portal for applicants and a multi-tenant environment that allows RNEC and each IRB to manage their review processes independently.

The system will also support digital payments, digital ethical clearance certificates, reporting, communication, document management, and integration with other relevant national systems where applicable.

## **3. Scope of Work**

The selected vendor will be responsible for the design, development, implementation, and support of a Research Ethics Review System that will support the Rwanda National Research Ethics Committee (RNEC) and Institutional Review Boards (IRBs) from initial application, screening, review and monitoring of the study.

The system shall be developed as a single shared online application portal for applicants and a multi-tenant platform that allows RNEC and each IRB to manage their review processes independently within the same system.

The system shall include, but not be limited to, the following modules and functionalities:

### **3.1 Shared Applicant Portal**

A single online portal shall be developed for all applicants submitting research protocols in Rwanda. Applicants shall create and manage a single account, submit applications, select the institution to which the application is being submitted, track application status, respond to queries, upload additional documents, and receive decisions, certificates, and notifications through the portal.

### **3.2 Submission and Application Workflow Management**

The system shall support online submission of research protocols and related documents, including new applications, amendments, renewals, progress reports, adverse event (AE) and serious adverse event (SAE) reports, protocol deviations, and study closure reports. The system shall support document upload, completing the required forms, completeness checks, application tracking, resubmission, revision workflows and notifications. Each application shall be assigned a unique reference number.

### **3.3 Integrated Digital Payment**

The system shall support application fee management, invoice generation, online payment integration, receipt generation, and payment verification. The system shall be integrated with an approved payment aggregator to support multiple payment methods, including mobile money, debit/credit cards, and bank payments.

### **3.4 Review Management**

The system shall support administrative screening, reviewer assignment, protocol review, reviewer comments, query management, review tracking, and meeting preparation. The workflow shall be configurable to accommodate different review processes for RNEC and each IRB, including full review, expedited review, and exempt review where applicable.

The system shall incorporate AI-assisted screening capabilities to support administrative pre-screening of submitted protocols. This shall include, but not be limited to:

- OCR-based detection of missing mandatory sections and required attachments prior to administrative screening.
- Smart validation to flag logical inconsistencies within submission content before the application enters the formal screening queue.
- Auto-classification of amendments as minor or major based on content analysis to support efficient routing and review.

### **3.5 Decision and Digital Certification**

The system shall support the recording of committee decisions and the automatic generation of decision letters and digital ethical clearance certificates. The system shall support digital signatures and verifiable certificates, such as QR codes or verification numbers.

### **3.6 Monitoring and Compliance**

The system shall support post-approval monitoring, including submission of progress reports, amendments, adverse event (AE) and serious adverse event (SAE) reports, protocol deviations, renewals, and study closure reports. The system shall support tracking of protocol status and compliance monitoring.

For adverse event and serious adverse event management specifically, the system shall support:

- Online submission of AE and SAE / SUSARs reports by principal investigators and study teams.
- Automated notifications to RNEC administrators and designated reviewers upon AE/SAE submission.
- Workflow-based follow-up tracking, including assignment of review responsibility, query management, and resolution recording.
- Configurable escalation pathways for unresolved or high-severity SAEs, with automated alerts to RNEC leadership.
- Status tracking of each AE/SAE report through its full lifecycle (Submitted, Under Review, Resolved, Closed).
- A complete audit trail of all AE/SAE submissions, reviews, follow-up actions, and outcomes.

### **3.7 Communication and Notification**

The system shall support communication between applicants, reviewers, and administrators, including queries, responses, alerts, reminders, and automated notifications at different stages of the review process.

### **3.8 Reporting and Dashboards**

The system shall provide dashboards and reports for monitoring submissions, review timelines including clinical trials, approvals, workload, revenue from fees, and other key performance indicators for RNEC and IRBs. The system shall support data export in standard formats such as Excel, CSV, and PDF.

### **3.9 Public Registry and Transparency**

The system shall include a public-facing component to publish approved studies and selected non-confidential information in line with transparency requirements and institutional policies.

### **3.10 Multi-Tenant IRB Management**

The system shall be designed as a multi-tenant platform where each IRB operates independently with its own users, workflows, and access to its own applications and data, while RNEC maintains national-level oversight and reporting capabilities.

### **3.11 User Management and Role-Based Access Control**

The system shall support different user roles, including applicants, reviewers, IRB administrators, RNEC administrators, finance users, chairpersons, and system administrators, with appropriate role-based access controls.

### **3.12 Integration and Interoperability**

The system shall support integration and data exchange with other relevant national systems where applicable through secure APIs.

### **3.13 Audit Trail and System Logs**

The system shall maintain a complete audit trail of all system activities, including submissions, reviews, decisions, payments, review timelines per type of studies and user activities, for compliance and accountability purposes.

### **3.14 Hosting, Security, and Data Protection**

The system shall be designed for secure hosting in Rwanda in compliance with National Data Protection and Privacy Laws. The vendor shall propose system architecture, hosting requirements, backup mechanisms, disaster recovery, and security measures. The developer shall handover clean source codes to RNEC for its own management after the period of handover as it will be stipulated in the contract.

### **3.15 Search and Cross-Application Intelligence**

The system shall provide a robust search and cross-application intelligence capability accessible only to institutional users, including RNEC administrators and secretariat staff, IRB coordinators and chairs within their own institution scope, and reviewers within protocols assigned to them.

This capability shall include:

- Full-text search across all application records, decisions, reviewer comments, and protocol documents within a user's authorized scope.
- Filtering by institution, date range, study type, status, principal investigator, timelines from submission to final decision and research area.
- Automatic surfacing of related applications when a new submission is opened, including same principal investigator, same institution, similar study area, and prior amendments or renewals.
- Cross-application intelligence to help reviewers identify precedent decisions, recurring issues, and research alignment across the portfolio.
- Enables identification of trends, recurring issues, and performance metrics across applications, supporting informed decisions.
- Provides recommendations, anomaly detection, and automated linking of related submissions, boosting reviewer efficiency and consistency.
- Ensures that sensitive information is only visible to authorized users and maintains an audit trail for compliance and traceability.

### **3.16 Data Migration**

The vendor shall be responsible for the migration of validated historical data from the existing legacy ethics review platform to the new system. This shall include data mapping, extraction, cleaning, transformation, validation in a staging environment, and production migration with RNEC sign-off. Only validated non-sensitive data shall be migrated. Legacy archives shall be retained for audit purposes.

### **3.17 Artificial Intelligence (AI) Integration**

The system shall incorporate artificial intelligence capabilities to improve the efficiency, accuracy, and analytical depth of ethics review processes. AI integration shall be implemented in phases aligned with system maturity and data availability.

**Phase 1 AI capabilities:**

- OCR-based document pre-screening as referenced under Section 3.4.
- Smart form validation to detect logical inconsistencies within submission content.
- Auto-classification of amendments as minor or major based on content analysis.

**4. Deliverables and Payment Milestones**

Milestone	Deliverables	Payment
<b>Milestone 1:</b> Inception and Requirements Validation	Inception report, detailed work plan, stakeholder consultation workshops, validated and consolidated URS, System Requirements Specification (SRS), and updated implementation plan.	20%
<b>Milestone 2:</b> System Design	System architecture document, database design, UI/UX prototypes, workflow diagrams, and system design document.	15%
<b>Milestone 3:</b> System Development and UAT	Fully developed system, integrations, system testing, security testing, performance testing, and User Acceptance Testing (UAT) completed and approved.	35%
<b>Milestone 4:</b> Deployment, Training, and Support	System deployment (go-live), training, documentation, and knowledge transfer.	20%
<b>Milestone 5:</b> Maintenance Support	Six months of post-implementation support and maintenance.	10%

Payment shall be made upon submission and approval of deliverables by RNEC and CIIC-HIN in accordance with the agreed milestones.

**5. Implementation Timeline and Project Management**

The assignment is expected to be completed within Three (3) months for system design, development, testing, and deployment, followed by six (6) months of post-implementation support and maintenance.

The vendor shall propose a detailed implementation plan and timeline as part of their technical proposal.

**Project Management**

The vendor shall:

- Assign a dedicated project manager
- Conduct stakeholder consultation workshops
- Provide monthly progress reports
- Support User Acceptance Testing
- Support system deployment and training
- Provide post-implementation support

## Reporting

The vendor shall submit:

- Inception Report
- SRS Document
- System Design Documents
- Development Progress Reports
- Testing and UAT Report
- Deployment/ Go-Live Report
- Training Reports
- Final Project Reports
- Support Reports

## 6. Non-Functional and Technical Requirements

The system shall meet the following requirements:

- Secure hosting environment
- Role-based access control
- Full audit trail
- Data encryption
- Backup and disaster recovery
- High availability
- Web-based system accessible via browsers
- Mobile-friendly interface
- API support for integration
- Data export (Excel, CSV, PDF)
- Technical documentation and knowledge transfer
- User Authentication mechanism (One Time Password (OTP), 2-Factors Based Authentication etc)

All source code and system documentation developed under this assignment shall become the property of RNEC.

## 7. Vendor Qualifications and Experience

Proposals will only be considered from vendors who meet all of the following eligibility requirements:

- Legally registered company in Rwanda or in the region or with a demonstrable capacity to operate in Rwanda.
- Qualification of the team: At least 2 software developers with Bachelor's degree and above in Software engineering, computer Science, IT, or other related fields with proven experience in similar assignment.

- For companies registered within the last five (5) years, the vendor shall submit CVs demonstrating that the proposed key team members individually possess at least five (5) years of relevant professional experience.
- Relevant experience shall include proven experience in software development, health information systems, regulatory systems, or similar digital platforms.
- Demonstrated experience in requirements gathering, gap analysis, system design, and full software development lifecycle delivery.
- Demonstrated experience with system integrations and interoperability, including API-based data exchange within government or health sector institution.
- Demonstrated capacity to incorporate AI or machine learning capabilities within digital platforms.
- Experience in user training, and building internal digital capacity within government or health sector institutions.

## **8. Submission Proposal Requirements**

All proposals must be submitted electronically in two separate files in PDF format

- File1: Technical Proposal
- File2: Financial Proposal

Combined submissions will be disqualified.

### **8.1 Technical Proposal Contents**

- Cover letter confirming interest and eligibility.
- Company profile and registration documents.
- Understanding of the assignment: interpretation of the TOR and proposed approach.
- Technical solution description covering system architecture, technology stack, security design, and hosting plan.
- Methodology and implementation plan including phased work plan with milestones and timelines.
- Team composition: CVs and roles of all key personnel.
- Proof of at least two comparable completed/active projects with reference contacts.
- A prototype design is encouraged in the submission.

### **8.2 Financial Proposal Contents**

- Detailed cost breakdown.
- Payment schedule aligned to project milestones.
- Annual maintenance and support cost for Years 2 to 5.
- Any assumptions or exclusions clearly stated.

All financial proposals must be submitted in RWF. Prices must be fixed and inclusive of all applicable taxes and fees.

Applicants whose financial proposal contains arithmetic errors will be automatically disqualified.

## 9. Evaluation Criteria

Stage	Weight	Description
Stage 1: Qualification and Experience	45%	Evaluation of vendor's technical capability, experience, and past performance: <ul style="list-style-type: none"> <li>• Company qualification:10%</li> <li>• Team qualification and experience:35%</li> </ul>
Stage 2: Technical Proposal and Implementation Plan	35%	Evaluation of the proposed solution, methodology, team, and implementation approach: <ul style="list-style-type: none"> <li>• Understanding of the assignment: 5%</li> <li>• Technical solution description: 5%</li> <li>• Methodology: 10%</li> <li>• Work plan: 10%</li> <li>• Prototype design: 5%</li> </ul>
Stage 3: Financial Proposal	20%	Evaluation of cost competitiveness, value for money, and payment structure.

**Note: Pass mark to financial evaluation is 80%**

## 10. Contract Duration

The contract duration shall be eight (8) months:

- 3 months of development
- 5 months of maintenance and support

## 11. Submission Instructions

- All proposals must be submitted electronically to: [administration@ciichin.org](mailto:administration@ciichin.org) copying [info@ciichin.org](mailto:info@ciichin.org) for reference.
- The application deadline is Friday, 24th April 2026.
- Subject line must read: RFP CIIC-HIN/TRACE/2025/001 – [Vendor Name].
- Technical and financial proposals must be submitted as separate PDF or Word documents clearly labelled.
- Proposals submitted after the deadline will not be considered under any circumstances.

CIIC-HIN reserves the right to cancel this RFP, reject any or all proposals, and is not obliged to award a contract. CIIC-HIN will not be responsible for any costs incurred in preparing proposals.

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