**IRB module of IRIS (Intelligent Research Information management System)**

# Introduction

**The IRB module** is designed to streamline the submission, review, and management of Institutional Review Board (IRB) protocols and related regulatory documents. It is used by researchers, IRB administrators, reviewers, and institutional officials to manage compliance documentation and workflow efficiently.

This document provides a systems-level design of how IRBNet works, focusing on architecture, key components, data flows, and functional modules to guide the development team.

# Key Functional Modules

## User Management

* **Roles**: Users can be Scientific staff, IRB Staff, IRB Members, Institutional Officials. (an IRB member can also be scientific staff)
* **Permissions**: Role-based access control (RBAC); granular access defined per project.
* **Authentication**: defined elsewhere.
* **Audit Trail**: Every user action is timestamped and logged.

## Project Workspace

Each research study exists within a **Project Workspace** that encapsulates all related submissions, documents, correspondence, and reviews.

* **Version Control**: Each submission (initial, amendment, continuing review, etc.) is versioned.
* **Document Binder**: A document-centric view allowing stakeholders to browse the full project history.

## Form Builder / Smart Forms

* Drag-and-drop configurable forms for protocol submissions.
* Dynamic fields (logic branching based on prior answers).
* XML/JSON-based form schema definitions.

## **Submission & Review Workflow**

* **Submission Lifecycle**:
  1. PI initiates project and uploads documents.
  2. Submission is routed to the IRB office.
  3. Review is assigned based on criteria (e.g., expedited, full board).
  4. Reviewer(s) provide comments, which are compiled and sent to PI.
  5. PI responds to comments and resubmits.
  6. Final decision (approved, modifications required, disapproved).
* **Workflow Engine**: Configurable workflows using a finite state machine (FSM) pattern.
* **Event Hooks**: Trigger emails, actions, or form updates on status transitions.

## Collaboration Tools

* Internal discussion threads and comment system.
* Notification system (email + in-platform).
* Access delegation for research teams or IRB staff.

## Institutional Configuration

* Institution-specific templates, workflows, and notification rules.
* IRB staff configuration

# **Data Model Overview**

## Entities

* **User**
* **Project**
* **Submission**
* **Form**
* **Document**
* **Review**
* **EventLog**
* **WorkflowStatus**

## Sample Relationships

* One **Project** has many **Submissions**.
* One **Submission** has many **Documents** and one or more **Reviews**.
* Each **Form** is linked to a Submission and stores responses as structured data.
* **WorkflowStatus** is linked to a Submission and drives visibility/actionability.

# Document Handling

* **Upload**: Supports Word, PDF, Excel, images.
* **Storage**: Documents stored in encrypted format; access control enforced via signed URLs or tokens.
* **Binder System**: Files are logically grouped by type (e.g., protocols, consent forms, continuing review).
* **Versioning**: All document updates are version-controlled.

# Compliance and Audit Features

* **Audit Trail**: Immutable, timestamped logs of all system actions.
* **Electronic Signatures**: Compliant with FDA 21 CFR Part 11; tied to user credentials.
* **Export Capabilities**: Structured exports for regulatory audits (XML/CSV/PDF).

# Notifications and Messaging

* **Email Templates**: Configurable per institution and event type.
* **In-System Messaging**: Project-specific comments or IRB communication.
* **Reminders**: Automatic reminders for expiring protocols, incomplete submissions, etc.

# Security Considerations

* **Data Encryption**: At-rest and in-transit (TLS 1.2+).
* **Access Controls**: Role-based, time-bound, and context-sensitive.
* **Regular Security Audits**: SOC2 compliance or equivalent recommended.
* **Session Management**: Idle timeout, forced logouts, 2FA support.

# Reporting and Analytics

* Predefined compliance reports (e.g., protocol status, review turnaround).
* Custom report builder with filters and export functions.
* Dashboard widgets for institutional metrics (e.g., submission trends, reviewer load).

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