### 1. Login Page

- Login using NIMS Employee code and password
- Each user can have multiple roles, However the user will be allowed access to the documents as per the role selected while login.

### **User Roles**

Role	Capabilities
Principal/ Co- Investigator	Submit new projects, upload documents, track status, respond to reviewer comments, Ongoing Projects submissions
ISRC Committee Member	Review assigned projects, add comments, approve/reject
ISRC Committee Chair	Assign reviewers, finalize decisions
Project Budget committee(PBC) member and chair	Review submitted project budget, View ISRC report and approve/reject/add comment
NIMS IEC committee- member	Review assigned projects, View ISRC & PBC reports, SAE reports, add comments, approve/reject the Proposal/ Amendment
NIMS IEC Committee- Member-secretary	Review assigned projects, view ISRC & PBC reports, Assign reviewers, finalize decisions.
NIMS IEC Committee - Chairman	Review assigned projects, Assign reviewers, view ISRC & PBC reports, finalize decisions.
Admin	Manage users, committee membership, timelines, forms, backup data

### 2. Flow Overview

Dashboard  $\rightarrow$  Submit Project  $\rightarrow$  Upload Docs & Details  $\rightarrow$  Auto-Route to Committees in order- ISRC, PBC, NIEC  $\rightarrow$  Review & Feedback  $\rightarrow$  Final Decision  $\rightarrow$  Download Approval Letters

- 3. Principal Investigator login Home page Dashboard-
  - 1. Submit new research proposal
  - 2. Review / View ongoing submitted research proposal
  - 3. Review/View ongoing Approved research Proposal

- **Project Status Table** with filters:
  - | Project Title | Submission Date | Status | Comments | Decision Letter |
- Notifications/Reminders (e.g., "Submit revised protocol", "Budget Review Complete")

## **New Submission Page**

Under submit new research proposal

First choose type of study:

- a. Regulatory clinical trial /
- b. Drug/ Device intervention trial- Approved drug for New indication or New dose/route of administration
- c. Bio-availability and Bio-equivalence study
- d. Drug/ Device intervention trial- Already Approved Drug in the same indication/route and dose
- e. Case Control/Cohort studies
- f. Retrospective studies
- g. Cross-sectional studies
- h. Socio-Behavioural
- i. Epidemiological/Public health
- j. Biological sample / Clinical Documentation material (data/document/records):
- k. Biological sample (From Blood bank, tissue banks and left-over clinical sample) that are non-Identifiable
- 1. Retrospective study on Clinical Documentation material (data/document/records) that are non-Identifiable
- m. Any other Specify Text box to write

If option a-c is chosen- direct to NIEC-AP-02A form for Clinical trials

If option d-j is chosen- direct to NIEC-AP-02B form for biomedical and health research studies

If option k and l are chosen- direct to Form for expedited review, waiver of consent and NIEC- AP-02B( Skip Section C in form )

For option m- Discuss with SRC

### 1. **Declaration Checkbox**

- 2. After the Principal Investigator submits- Notification E-mail to be sent to Guide/ other Investigators
- 3. Final Submission only after all the listed Co-Investigators have clicked the submit button
- 4. The Principal Investigator will be notified via E-mail that all investigators have reviewed and approved the project.
- 5. Once submitted Project ID to be auto-Populated

### **Scientific Committee Dashboard**

• Filterable list of assigned projects

- View submitted documents inline
- **Review Form** (scientific validity, feasibility, references)
- Add comments, request clarification
- Recommendation: Approve / Revise / Reject

# **Budget Committee Dashboard**

- View ISRC reports
- View Forms ABCD
- Review Form:
  - Justification of costs
  - Source of funding
- Recommendation: Approve / Modify / Reject

### **Ethics Committee Dashboard**

- Access all relevant documents + prior approvals (scientific + budget)
- Ethics Review Form:
  - o Risk/Benefit Analysis
  - Informed Consent Adequacy
  - o Privacy/Safety Considerations
- Assign Reviewers, Schedule for next IEC meeting
- Record decision + upload scanned approval letter (optional auto-generated PDF)

### **Review & Comment Module**

- Inline annotations on PDFs (optional)
- Threads for back-and-forth queries (like GitHub pull requests)
- PI notified via email/portal inbox

# **Decision Page**

- Summary of reviews
- Final outcome
- Downloadable approval/rejection/modification letter
- Status updated across all dashboards

### **Admin Panel**

- Add/edit users, assign committee roles
- Track project flow & bottlenecks
- Generate reports (e.g., number of projects per department, average approval time)
- Manage backups, update forms/templates

# **Design Considerations**

- **Progress Bar** for multi-step submissions
- Auto-save Drafts

• Color-coded status indicators:

Pending, Under Review, Approved, Rejected