

Study Coordinator User Manual

This guide covers the core features available to Study Coordinators and study team members.

Your Role

- Support the PI in preparing submissions and managing study documents
- Respond to IRB requests and upload revisions
- Track submission status and communicate with the IRB

Access & Permissions

- Regular user account added to Study via StudyPersonnel
- Access limited to studies where you are a team member

Daily Tasks

1) Study Access

- Ensure you are listed on the Study Personnel to gain access
- Confirm your role (Coordinator/Staff) is correctly assigned

2) Submissions

- Create and edit drafts on behalf of the PI (if permitted)
- Create: provide Title and Type only; after saving, use "Manage attachments" to upload files
- Upload and manage required documents; files are validated and AV-scanned
- Coordinate responses to reviewer comments or modification requests

3) Tracking Decisions

- Monitor submission status changes
- View Determinations and Decision Letters for your studies

4) Documents

- Study Documents aggregates all files across the study; Submission Documents lists files per submission
- Click a PDF to open it in the in-app viewer (inline); non-PDFs show a fallback with Download

Tips

- Keep close coordination with the PI to ensure timely responses to IRB
- Use the submissions list to track deadlines and required actions