RESEARCH ADMINISTRATION PORTAL (WRAP)

IRB Initial Submission Quick Guide

Topics

Overview

This quick guide is designed specifically for the IRB training session. It provides step-by-step instructions for completing key IRB tasks in the WRAP system. The steps are intended for training purposes, and participants are encouraged to make their own adjustments during the session as needed

Steps

Accessing WRAP IRB

Training Environment (WRAP Test & Training System):

1. Go to the WVU Research Operations website under the Electronic Research Administration Systems page. https://researchoperations.wvu.edu/administration-and-compliance-systems
2. Click the middle blue button labeled **WRAP Test**.
3. This version is used for training and practice.
4. Sign in using your WVU Single Sign-On (SSO) credentials.

Production Environment (Live System):

1. On the same page, click the left gold button labeled **WRAP**.
2. This version is used for real, live submissions.
3. Log in with your WVU Single Sign-On (SSO) credentials.

Tip: Always confirm which environment you are in before starting your work.

IRB Navigation and Basic Tasks

Navigate the Dashboard Video (opens in a new tab)
Navigate the IRB Page Video (opens in a new tab)
Navigate the Study Workspace Video (opens in a new tab)

WRAP Dashboard Terms & Definitions

- **Create Menu:** Create studies or report new info.
- **My Inbox:** Shows all records you are associated with, including drafts and pre-submission items. You can reopen anything still in progress or needing review, approval, or clarification. The inbox includes items from all WRAP modules, including funding proposals, agreements, COIs, and IRBs. The **State** column indicates where each item is in the workflow and helps you understand what comes next.
- **My Reviews:** Subset of inbox for review items.
- **State Column:** Indicates current workflow stage.
- **Breadcrumb Trail:** Navigation links at the top of each page.

IRB Tab

The IRB tab includes several categories that organize submissions based on their status in the workflow.

- **In-Review:** Submissions undergoing IRB review.
- **Active:** All approved submissions as well as external IRB, non-human research, human research not engaged, lapsed, and suspended submissions.
- **New Information Reports:** All Reportable New Information (RNI) submissions, in any state.
- **External IRB:** All studies managed by an external IRB.
- **Relying Sites:** All participating sites relying on the local IRB as the single IRB of record
- **All Submissions:** All submissions, in any state.
- **Archived:** All closed, disapproved, discarded, and terminated submissions.

From this same page, users can also create new studies and report new information.

Study Workspace Terms & Definitions

- **State:** Displays the workflow status of the submission.
- **Activities:** Left-panel actions available based on role and submission state.
- **History:** Activity log with newest actions at the top.
- **Funding:** Displays funding sources and linked grants.
- **Contacts:** Lists the PI, study team, and guests.
- **COI:** Shows conflict of interest certifications tied to the study team.
- **Documents:** All study documents and version history.
- **Reviews:** Researchers see ancillary reviews; IRB staff see full review details.
- **Snapshots:** Auto-generated HTML records of key study actions (PI submissions, IRB letters).
- **Training:** CITI Human Subjects Protection Training records for the study team.

Before Getting Started

1. **Review the Investigator Manual**
    - Before using WRAP, investigators are expected to review the HRP-103 Investigator Manual. This manual outlines WVU IRB policies, investigator responsibilities, and requirements for conducting research under WVU oversight. Reviewing it before submission ensures that your study complies with both institutional and regulatory standards.

2. **Complete Your Study Protocol**
   - You must have a finalized study protocol before beginning your IRB submission.
     - **This is a new requirement moving forward when using WRAP.** Under the previous system (KC), a study protocol was not required.
     - Protocol templates are available on the [OHRP website].
     - Attach your **Word protocol document** (Appropriate HRP-503 – TEMPLATE -PROTOCOL) to the first page of your WRAP IRB application.
     - A sponsor's protocol or other protocol document will be accepted, but should include HRP-508-TEMPLATE-SITE SUPPLEMENT

3. **Gather All Required Study Documents**
   - You will need to upload **all supporting documents** at the time of initial submission.

4. **Identify Your Study Team**
   - Make sure you know who will serve as study team members and confirm their roles with them before submission.

5. **Submission Permissions**
   - Only the Principal Investigator (PI) or an assigned PI Proxy can submit the study for review.

6. **Finish vs. Submit**
   Clicking Finish completes the SmartForm but does not send the study to the IRB. You must click Submit to send it forward officially.

Exercise #1: Create a Study

Start a New Study

1. Log into WRAP
2. From your dashboard, click **Create > Create New Study**.

Note

- Use the "**Continue**" button to move through each section.
- Required fields are marked with a red asterisk (*).
- Use wildcard searches (e.g., %smith) in fields like team members or locations to improve search results.
- Only the Principal Investigator (PI) or an assigned PI Proxy can submit the study for review.

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3. Complete the following SmartForm pages:

Basic Study Information

1. **Title**: Enter the full descriptive study title. (e.g., "Evaluation of Opioid Prescribing Patterns."). Should match sponsor protocol if applicable.
2. **Short Title**: Keep under 50 characters (e.g., "Youth Screen Study"), appears in inboxes.
3. **Brief Description**: Describe the central question, objective, and method.
4. **Type of Study**: Choose:
    - **Single-site**: All research occurs at one institution.
    - **Multi-site:** Multiple institutions are involved. WVU may act as IRB of record or cede to another IRB
5. **External IRB?**: Select "No" unless WVU IRB has agreed to cede review to another IRB. This determines if WVU IRB reviews or relies on another. Review HRP-103 Investigator Manual for institutional requirements for relying on an external IRB.
6. **Principal Investigator**: Auto-populates, but can be changed.
7. **Attach Protocol**: Upload the complete study protocol. Attach the appropriate **HRP-503 – TEMPLATE -PROTOCOL** document here. A sponsor's protocol or other protocol document will be accepted, but should include HRP-508-TEMPLATE-SITE SUPPLEMENT.

Study Funding Sources

Funding ties studies to grants and impacts reporting.

1. Identify all external and internal funding linked to the study. This ensures proper tracking.
    - **Funding Organization**: Select the sponsor, agency, or department. Contact the IRB if your funding source is missing from the list. If personally funded, list "Personal Funding." If unfunded, leave blank.
    - **Sponsor's Funding ID**: Number assigned by the sponsor (if applicable).
    - **Grants Office ID**: Leave blank.
    - **Attachments**: Upload grant applications or sponsor award letters.

Local Study Team Members

1. Click **Add Study Team Member**.
2. Search and select each individual's name. Review HRP-103-Investigator Manual to determine who qualifies as study personnel.
3. Assign the person's **role** (Co-Investigator, Research Assistant, Statistician, etc.).
4. Indicate if the individual is involved in the **consent process**.
5. Remove team members by clicking the **X** next to their name.
6. Do not re-add the PI.

Note

- Only individuals who are searchable in WRAP should be added.

- The person who creates the study is automatically assigned as **Primary Contact**, but this can be changed after submission.

Study Scope

1. Indicate if the study involves an approved/unapproved drug, biologic, or dietary supplement to diagnose, cure, treat, or mitigate a condition.
2. Indicate if the study evaluates a device's safety/effectiveness or uses a humanitarian use device (HUD).
3. Indicate if radioactive materials or ionizing radiation will be used solely for research.
4. Principal investigator must assess participant risk: Minimal / Greater than minimal
5. Select all applicable study features (e.g., clinical trial, biospecimen collection, secondary analysis, recordings, surveys, behavioral interventions, etc). Choose "None of the above" if no categories apply.

Local Research Locations

1. Select research sites affiliated with WVU or other applicable locations.
    - If a location is missing or research will take place at a non-WVU site, add the location using the Add Research Location Information.
    - **Do not** list other multi-site participating institutions here.

Drugs (If Applicable)

1. List all drugs, biologics, and supplements used in the study.
2. Indicate if study is conducted under an IND number.
3. Attach supporting documents: FDA letter, sponsor protocol, or IND confirmation.

Devices (If Applicable)

1. Identify any HUDs or investigational devices.
2. Specify device exemption, if applicable:
    - IDE number *(must identify number if selected)*
    - HDE number *(must identify number if selected)*
    - Claim of abbreviated IDE (nonsignificant risk device)
    - Exempt from IDE requirements

Local Site Documents

1. **Consent Forms**: Include written forms or oral scripts, plus translations. Ensure consistency across protocol, consent, and contracts.
2. **Recruitment Materials**: Upload all ads, flyers, video/audio scripts, and surveys.
3. **Other Attachments**: Include any additional study-related documents.

Final Page

- Click **Finish** to exit the SmartForm.
- In the Study Workspace, the PI or PI Proxy must click **Submit** to send the study to the IRB.

Note:
Clicking "Finish" only saves and closes the form; it does not submit the study. The study remains in **Pre-Submission** until the PI or proxy clicks the **Submit** button in the workspace.

Post-Submission Options

Once the study is in Pre-Review:

- **Assign Primary Contact**: Designate a person for ongoing IRB communication.
- **Assign PI Proxy**: Allow another individual to submit or manage the study on behalf of the PI.
- **Manage Ancillary Review**: Invite additional reviewers outside the IRB. See HRP-309-Worksheet- Ancillary Review Matrix for guidance.
- **Manage Guest List**: Provide view-only access to others.
- **Add Comment**: Share notes or attach supporting documents for the IRB.
- **Copy Submission**: Create a duplicate for a new project.
- **Withdraw:** Moves submission back to pre-submission state from a pre-review or IRB review state. Use this option if you have submitted a study, but need to make a change prior to IRB review.
- **Discard**: Permanently deletes submission. There is no undo for this action.

Exercise #2: Submit a Study

1. As a PI open the study from the PI's inbox.
2. Click **Submit** under Next Steps.
3. Click **OK** to confirm intent.
4. Re-authenticate and click **Submit**.
5. Confirm the following:
    - Study has moved to **Pre-Review** state
    - **History** tab shows the **Submitted** activity
    - **Submit** button is no longer available; **Edit Study** changes to **View Study**
    - Study appears on the **IRB Submissions > In-Review** tab

Note:
Studies are not visible to IRB staff until the PI/Proxy clicks **Submit**.

Exercise #3: Respond to the Request for Clarification

Note:
WVU OHRP staff screeners and IRB Reviewers may require additional information or corrections before proceeding with the review. The request does not mean rejection; it means more detail or edits are required

- You will receive an email notification when a clarification is requested.
- The study will show a new activity in the History tab labeled Clarification Requested.

If a WVU OHRP staff screener or IRB reviewer has questions or requests changes to your submission, you will receive an email notifying you of this.

1. Click the submission ID link in the email to open it. Alternatively, you can open the study submission in WRAP
2. Go to the **History** tab.
3. Locate the **Clarification Requested** entry to see reviewer comments.
4. If a reviewer attached a file, a link will appear.
5. If the response requires changes to documents, upload them in the Supporting Documents area.
6. Attach Word docs with tracked changes to make edits clearer for the reviewer.
7. For this training, click **Edit Study**:
    - Update Brief Description on Basic Study Information page
    - Add a funding source on the Study Funding Sources page
    - Save and Exit
8. Click **Submit Response**, include a summary in the **Notes box** to explain how you addressed the reviewer's requests and submit.
9. Confirm:
    - Study returns to **Pre-Review** state
      Appears under **IRB > Submissions > In-Review**

Exercise #4: Assign a PI Proxy

A PI Proxy is a study team member designated by the Principal Investigator (PI) to submit materials to the IRB on the PI's behalf. Only the PI and assigned PI Proxies can submit to the IRB.

- The PI must assign the first proxy.
- Assigned PI Proxies can submit studies, submit continuing reviews, and modify the study on behalf of the PI.
- A PI Proxy can receive all system notifications related to the study.
- If the PI has left WVU, an assigned PI Proxy must submit a Modification (MOD) to update the new PI.

Note:

- Assigned PI Proxies cannot assign additional PI Proxies.
- You can assign multiple PI Proxies.
- Only study team members already listed on the study are eligible to be assigned as PI Proxies.
- If the PI has left WVU, ensure a **Modification** is submitted to update the PI.

Assign a PI Proxy

1. Navigate to the **workspace of the study** where you want to assign a PI Proxy.
2. From the study workspace, click **Assign PI Proxy**.
3. Under **Question 1**, click the **ellipses (...)** to open the list of eligible study team members.
4. Select one or more team members to assign as PI Proxies and confirm.
5. Click **OK**.

Exercise #5: Assign Ancillary Reviewers

- **PIs** and **IRB staff** can invite additional people or organizations to review a submission.
- Ancillary reviewers can be assigned in almost any state, starting at **Pre-Submission.**
- At Pre-Submission, only the **PI or PI Proxy** may assign reviewers.
- After Pre-Submission, the **assigned coordinator** can also assign reviewers.
- Ancillary reviewers receive notifications and see submissions in their **Inbox** once the review is required.
- Ancillary notifications and inbox assignments are triggered during the Pre-Submission and Pre-Review stages of the process.
- Ancillary reviewers **do not have approval authority**; they only supplement the process.
- Ancillary reviews are **not** designed for back-and-forth messaging with the PI. If a reviewer needs clarification or to suggest changes (e.g., consent language), use: A **comment** in the ancillary review for central

staff visibility, and **Direct email or a meeting** with the study team for discussion.

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1. From **My Inbox** or an **IRB page tab**, click the name of the submission.
2. In the **study workspace**, click **Manage Ancillary Reviews**.
3. In the Manage Ancillary Reviews form, click **Add**.
4. On the **Add Ancillary Review form**:
    - Select an **organization** or **person** to perform the review.
    - Select the **Review Type**.
    - Indicate whether the review is **Required** (choose Yes if completion is mandatory).
5. Click **OK** to add the ancillary review.
    - Or click **OK and Add Another** to add multiple reviews.
6. Return to the study workspace.
    - Assigned reviewers will receive an **email notification** (except at Pre-Submission)

Note:
WRAP will automatically create and route ancillary reviews when the study team answers "Yes" to the following specific scope questions:

- Q1: Uses an approved/unapproved drug or biologic, or uses food/dietary supplements to diagnose, cure, treat, or mitigate disease. Answering Yes to Q1 only triggers IDS ancillary review.
- Q3: Involves radioactive material. Answering Yes to Q3 only triggers Radiation Safety ancillary review.

Exercise #6: Withdraw or Discard an IRB Study

When to Use Withdraw or Discard

1. **Withdraw:** Use if the submission is already under review but you no longer want to proceed. The record is kept, but review stops, and it returns to Pre-Submission for possible edits and resubmission.
2. **Discard:** Use if the submission is still in Pre-Submission and you no longer plan to submit it. This permanently removes the submission.

Note

1. Use Withdraw (not Discard) to preserve records.

2. Only the PI or PI Proxy listed on the study can withdraw or discard a submission.

Withdraw a Study Submission

1. From top navigation: Go to **IRB > Submissions**
2. On **the IRB page > In-Review tab,** locate and click on the study you wish to withdraw.
3. Confirm the study is in a reviewable state (e.g., Pre-Review, IRB Review). If the study is in Pre-Submission, already approved, or closed, withdrawal is not available.
4. On the left-hand side of the study workspace, click **Withdraw** in the Activities menu.
5. In the pop-up window, enter a reason for withdrawing the submission. This reason will be recorded in the history log.
6. Click **OK** to complete the withdrawal.

Note: The submission will be returned to the Pre-Submission state where you can choose to change and resubmit it.

Discard a Study Submission

Warning: Discarding a submission cannot be undone!

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1. From **My Inbox** or an **IRB page tab**, locate and click on the study you wish to discard. The study must still be in Pre-Submission status.
2. Ensure the study is in Pre-Submission. If the study has been submitted for review, it cannot be discarded and must be withdrawn instead.
3. On the left-hand side of the study workspace, click **Discard** in the Activities menu.
4. Click **OK** to complete the discard. The study will no longer appear in your active submissions.

Note:

- The study will be in **Discarded** state
- The Discarded study is listed in **IRB page** tab>**Submissions**>**All Submissions**

Exercise #7: Copying a Submission

- Only the PI and assigned PI Proxies can copy an existing study into a new study submission for IRB review.
- Copying is helpful when submitting a **new study** that is very similar to a prior submission (e.g., same protocol, team members, locations).
- Saves time because most study information is **pre-populated**

Copy a Submission

1. Navigate to the **workspace** of the study you want to copy.
2. In the study workspace, click **Copy Submission**.
3. When prompted, **enter a name** for the new submission that clearly identifies it as a separate study.
4. Click **OK** to begin the copying process.
5. Open the **copied submission** and make all necessary updates, including:
    - Revising study-specific details
    - Uploading updated or new study documents
6. Once all updates are complete, **submit the new study for IRB review**