RESEARCH ADMINISTRATION PORTAL (WRAP)

IRB Post-Approval Tasks 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 (Staging) Access

1. Navigate to WRAP Electronic Research Administration Systems: https://researchoperations.wvu.edu/resources/administration-and-compliance-systems
2. Click the **WRAP Test** button.
3. Click the Client Login button.
4. Sign in with your SSO credentials

Production Access

1. Navigate to WVU Research Operations Website: https://researchoperations.wvu.edu/home
2. Click the **WRAP** button.
3. If prompted sign in with your SSO credentials

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.

Exercise #1: Create and Submit a Continuing Review

You can submit a Continuing Review (CR), a modification, or both combined:

- To change an approved study or the study team members, submit a modification. Modification is used to update study team membership, protocol, documents, or other study details.
- Combined CR/Modification allows both to be reviewed at the same time.

---

1. From top navigation: Go to **IRB > Submissions**
2. On **IRB page > Active tab**, open the approved study.
3. Click **Create Modification / CR**.
4. Select **Continuing Review**.
5. Complete the CR form:
    - Enrollment totals: Enter numbers
    - Research milestones: Select all that apply. **Note:** If the first four milestones are complete, the study will be closed and IRB oversight ends. Also, if the first four milestones are selected, a new field will display stating that you acknowledge that this study will be closed.
    - Since Last IRB Approval: Check all that are true.
    - Attach supporting documents: (include an explanation of each item left unchecked above)
6. Click **Finish**.
7. To send the submission for review, click **Submit** on the next page and attest.
8. Click the breadcrumb to return to the study, then check the **Follow-on Submissions** tab.
9. Confirm:

- CR is in **Pre-Review** state
- CR is listed in **Follow-on Submissions** tab

Exercise #2: Create and Submit a Modification

You can submit a Continuing Review (CR), a modification, or both combined:

- To change an approved study or the study team's members, submit a modification. Modification is used to update study team membership, protocol, documents, or other study details.
- Combined CR/Modification allows both to be reviewed at the same time.

---

1. Open the original study from **IRB > Submissions > Active**.
2. Click **Create Modification / CR**.
3. Select **Modification/Update**
4. Select the Modification Scope (if applicable):
   - Study team member information
   - Other parts of the study (choose this option to change the PI)
5. For this training, select both the study team and other parts.
6. On the Modification Summary section:
   - Select the Study Enrollment Status
   - Notification of subjects: (check all that apply). Attach files: If notifying subjects, add notification materials and a description of the process to the "Other attachments" section of the Local Site Documents page.
7. Make required edits directly in the SmartForm.
8. Complete edits, attach a revised protocol, and click **Continue** through all pages.
9. Click **Save and Exit**.
10. Click **Submit**, re-authenticate and confirm.
11. Confirm:
    - Modification is in **Pre-Review** state
    - Listed in **Follow-on Submissions** tab

Exercise #3: Submitting an IRB Study Closure

How to Submit a Study Closure

- Click on the **IRB tab** in the top menu.
  - Select the **Active tab**
  - Click the **study name** of the study you wish to close
- From the **study workspace**, click **Create Modification/CR** in the left-hand menu.
  - In the prompt, select **Continuing Review**
    1. Specify enrollment totals at this investigator's sites

2. Specify enrollment totals at this investigator's sites since the last approval
3. Specify enrollment totals study-wide
4. Research Milestones (check the boxes for the first four research milestones confirming that):
    - Study is permanently closed to enrollment OR was never open for enrollment.
    - All subjects have completed all study-related interventions OR not applicable (e.g., study did not include interventions, no subjects were enrolled)
    - Collection of private identifiable information is complete OR not applicable (no subjects were enrolled)
    - Analysis of private identifiable information is complete OR not applicable (no subjects were enrolled)

- **Note:** If the first four research milestones above are complete, the study will be closed to discontinue IRB oversight.
    5. Additionally, if the first four milestones are selected, a new field will appear, stating that you acknowledge the study will be closed.
    6. Check the items that are true since the last IRB approval for all sites involved in the study: (initial review or last continuing review)
    7. Attach supporting documents: (include an explanation of each item left unchecked above)
- Click **Continue** to begin the form
- Click **Finish**.
- To send the submission for review, click **Submit** on the next page and attest.
- Click the breadcrumb to return to the study, then check the **Follow-on Submissions** tab.
- Confirm:
    - CR is in **Pre-Review** state
    - CR is listed in **Follow-on Submissions** tab

Notes:

- There is no separate **closeout** form outside of WRAP IRB
- To close a study, you must submit a Continuing Review and indicate in the submission that the study is ready for closure, even for studies that do not require a Continuing Review
- Study closure is triggered within the Continuing Review SmartForm by selecting all four research milestones
- Only the **Principal Investigator (PI)** or an **assigned PI Proxy** can submit the closure
- Once the first four boxes for research milestones in Question 4 will the message appear are checked, the acknowledgement message will appear:
    - "I acknowledge that this study will be closed"
    - Check this acknowledgement box to proceed
- Answer the **remaining questions** in the Continuing Review form.
- Click **Submit for IRB review**.

Exercise #4: Submit Reportable New Information (RNI)

Reportable New Information (RNI) is any new information or adverse event that could impact participant safety, study integrity, or regulatory compliance.

When to report:

- Review HRP-103- Investigator Manual for specific reporting requirements.

Expectation: Must be reported within 5 days of becoming aware of it, not delayed until continuing review

1. From **IRB > Submissions > Active**, open the study.
2. Click **Report New Information**.
    - Alternative: Open the active study workspace and select **Report New Information** from there.
3. Complete the **Reportable New Information page**:
    - Title: e.g., SAE: Emergency Room Visit
    - Date: e.g., Yesterday
    - Categories (check all that apply): Risk
    - Description: Briefly describe the new information
    - Risk/Revision questions:
        - Does this indicate a new or increased risk or safety issue? e.g., Yes
        - Does the study need revision? e.g., No
        - Does the consent need revision? e.g., No
        - If revisions are required, describe them and submit a study modification for review
    - **Related Studies/Modifications:**
        - Select the studies or modifications this RNI applies to.
        - Must add the **parent study first** before linking to a modification.
        - Cannot relate: sites, external studies (unless part of a WVU multi-site study), or other follow-ons.

    Automatic notifications: PI, proxies, and primary contact for each related submission will be notified throughout the RNI workflow. They can also edit or respond to clarifications
    - Attach supporting information
4. Click **Continue**.
5. Click **Finish** to exit the form.
6. To send the new information for review, click **Submit RNI** and confirm on the next page.
7. Confirm:
    - RNI is in **Pre-Review** state
    - Listed under **New Information Reports** tab