RESEARCH ADMINISTRATION PORTAL (WRAP)

# External IRB 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.

# RESEARCH ADMINISTRATION PORTAL (WRAP)

## 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.

## 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. Specifically, review Single IRB reliance for guidance on when an external IRB can be used and how to request to rely on an external IRB.

2. **Protocol**
    - While the system does not require a protocol document to be submitted when relying on an external IRB, WVU OHRP requires a protocol to be attached. A sponsor's protocol or other protocol document will be accepted, but should include HRP-508-TEMPLATE-SITE SUPPLEMENT if clarifications are needed between the sponsor protocol and WVU's specific role.

3. **External IRB Selection (Required)**
    - When submitting to an external IRB, you must identify the external reviewing IRB. Please confirm which IRB will serve as the IRB of record for this study. Once you start completing the WRAP SmartForm, you will be able to select the IRB of record from a list of external IRBs. If the IRB you need is not listed, contact WVU ITS for assistance. Please review the HRP-103 Investigator Manual for institutional requirements when relying on an external IRB. WVU must

confirm that it will cede review to the external IRB **before** the submission is entered in WRAP.

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

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

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

7. **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 and Submit a New IRB Single-Site External Study

**Create an External Single-Site Study**

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

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**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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- Complete the following SmartForm pages:

**Basic Study Information**

- **Title**: Enter the full descriptive study title. (e.g., "Evaluation of Opioid Prescribing Patterns."). Should match sponsor protocol if applicable.
- **Short Title**: Keep under 50 characters (e.g., "Youth Screen Study"), appears in inboxes.
- **Brief Description**: Describe the central question, objective, and method.

- **What kind of study is this?**: Choose: **Multi-site / Collaborative Study** will apply in most reliance scenarios, even if WVU is only one of many sites. Single-site may be used in rare cases, but reliance agreements are typically part of multi-site studies.
- **External IRB?**: Select "**Yes"** This triggers additional fields where you must enter the name of the reviewing External IRB and later upload the appropriate reliance documentation. This selection also updates the system workflow to reflect an external IRB submission pathway. **Note:** This field remains editable until reliance on the external IRB is confirmed. Review **HRP-103 Investigator Manual** for institutional requirements for relying on an external IRB.
- **Principal Investigator**: Auto-populates to the individual currently completing the SmartForm. You may change if appropriate.
- **Attach the protocol:** Attach the **sponsor protocol** (or equivalent protocol document for the external study). The WRAP system may mark the protocol as **optional** for external submissions however WVU **expects a protocol to be attached** for external IRB submissions and it should include HRP-508-TEMPLATE-SITE SUPPLEMENT if clarifications are needed between the sponsor protocol and WVU's specific role.

**External IRB**

- **External IRB**: Select the IRB outside WVU that will act as the IRB of record for this study. If you cannot find the external IRB in the list, contact WVU ITS for assistance. Review HRP-103-Investigator Manual for institutional requirements for relying on an external IRB. Confirmation that WVU will cede review to an external IRB is required prior to submission.
- **External Study ID**: Enter if available.
- **Specify the reason the study should be reviewed by an external IRB:** Optional, but recommended for clarity. Review HRP-103-Investigator Manual for requirements to rely on an external IRB. Prior permission is required before submitting in WRAP.

**Study Funding Sources**

- **Identify each organization supplying funding for the study:** Identify every source of funding for the study, whether external (such as industry or government), internal (such as university or departmental support), or personal funds. This ensures the IRB can accurately link the study to its associated funding.

**Additional Local Funding Sources**

- If additional local funding sources are available identify each organization supplying funding for the local site.

**Local Study Team Members**

  - **Identify each additional person involved in the design, conduct, or reporting of the research:** List only WVU-affiliated individuals who will be engaged in the research. Co-Investigators share research responsibilities with the PI; select **Student Co-Investigator** for students and **Co-Investigator** for faculty or staff. Include other study team members such as research assistants or coordinators who

help design the study, enroll or consent participants, determine eligibility, conduct procedures, or analyze/report data.

**Tips:**

Do not add the study's primary contact person for IRB communications unless the person is also engaged in the research. The person who creates the study in the IRB system is assigned as the primary contact by default, and can be changed using the Assign Primary Contact activity.

- **External team member information:** Do not list anyone in this section without prior confirmation from WVU OHRP. WVU Healthsystem affiliates not listed in the search in the previous question should not be added here. Collaborating individuals from other institutions should not be listed here.

**Study Scope**

Identify factors involved in the study that may require review of additional details. Your answers determine whether you must provide additional information after answering these questions and clicking Continue.

- Indicate if the study involves an approved/unapproved drug, biologic, or dietary supplement to diagnose, cure, treat, or mitigate a condition.
- Indicate if the study evaluates a device's safety/effectiveness or uses a humanitarian use device (HUD).
- Indicate if radioactive materials or ionizing radiation will be used solely for research.
- Principal investigator must assess participant risk: Minimal / Greater than minimal
- 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**

- 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)**

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

**Devices (If Applicable)**

- Select each device the study will use as an HUD or evaluate for safety or effectiveness.
- 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

The SmartForm separates **overall study documents** from **local site documents (WVU)**.

**Study-Related Documents**

- **Only include documents here related to the overall study. Not documents that are specific to WVU. Consent Forms Templates**: Provided by the external IRB or sponsor. Include written forms or oral scripts, plus translations. Typically include template forms; not WVU specific forms (those will be included on the next screen).
- **Recruitment Materials**: Upload all ads, flyers, video/audio scripts, and surveys.
- **Other Attachments**: Include any overarching study documents used across sites.

**Local Site Documents**

Upload **WVU-specific items**

- **WVU-specific Consent Forms**: Include written forms or oral scripts, plus translations. Ensure consistency across protocol, consent, and contracts. See HRP-103-Investigator Manual for more information.
- **WVU-specific Recruitment Materials**: Upload all ads, flyers, video/audio scripts, and surveys.
- **Other Attachments**: Include any additional local study-related documents

In some reliance situations (for example, when a specific office is negotiating reliance), the reliance documentation may be uploaded later by the IRB office.

**Final Page**

- Click **Finish** to exit the SmartForm.
  - This saves the study and exits the SmartForm.
  - You will be taken to the study workspace.
  - The study remains in **Pre-Submission** status until it is submitted.
  - You can continue editing the study (using **Edit Study**) until it is submitted.
- In the Study Workspace, the PI or PI Proxy must click **Submit** to send the study to the IRB.

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**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.

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**Submit the External Study for Review**

- From the **study workspace**, click **Submit**.
- Click **OK** to agree to the terms.
- Click **Submit**

- Once submitted, the study moves into the **Pre-Review** state.

**Locate External IRB Submissions**

All studies submitted to an external IRB can be accessed under the External IRB tab in WRAP.

**Notes**

- External IRB field is required and must be completed.
- Finish & Submit: Clicking Finish saves your work, but you must click Submit to send the study for IRB review.
- The IRB Coordinator must confirm external IRB reliance before the submission is finalized.

## 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 #2: Create Site Modification

**Site Modifications** will be the primary method WVU uses to track **local changes** for external IRB studies. Create Site Modification is used to updated changes at the WVU site. See HRP-103-Investigator Manual for guidance on when a Site Modification is required.

**Site Modifications** are intended to:

- Capture changes in **local personnel or principal investigator**.
- Capture changes related to **HIPAA** and other local institutional oversight items.

- Communicate the **local WVU updates** required by OHRP and institutional policy.

**To create a site modification for an external study**

- In the Top Navigator, click **IRB** and then **Submissions**.
- Click the **External IRB** tab and open the study.

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**Note:** Active multi-site external IRB studies are in the Active state.

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- Click **Create Site Modification**.
- After selecting Modification, the **Modification Scope** question appears. Select Study team and research location information to update them, or select Other parts of the study to update Basic Local Information (like the PI), Additional Funding Sources, or Local Site Documents, or you can select both options. Click **Continue**.
- On the **Modification Information** page, summarize the updates.
- Complete the rest of the Smartform.
- From the study workspace, click **Submit**.
- Click **OK** to agree to the terms.
- Type your login credentials and click **Submit**.

Both selections, whether study team and research location information or other parts of the site, go to WVU local IRB for review. Other parts of the site will also be reviewed by the external IRB.

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**Please note:** Update Study Details may be used to update changes to the sponsor protocol, investigator brochure, sponsor consent forms, and other items that affect the study across the board. These updates are generally not required by the WVU OHRP for ceded studies. See HRP-103- Investigator Manual for additional information.

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