# Accessing and Managing Migrated Protocols from KC to WRAP Quick Guide

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# 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**

### Access

### **Training Environment (WRAP Test & Training System):**

- Go to the WVU Research Operations website under the Electronic Research Administration Systems page. <a href="https://researchoperations.wvu.edu/administration-and-compliance-systems">https://researchoperations.wvu.edu/administration-and-compliance-systems</a>
- 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**

- 1. **Create Menu:** Create studies or report new info.
- 2. **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.
- 3. My Reviews: Subset of inbox for review items.
- 4. **State Column:** Indicates current workflow stage.

5. **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.

### Before you begin

- 1. Make sure you can sign in to WRAP using your WVU or HSC credentials.
- 2. All active expedited and full board studies will be imported from KC into WRAP. These migrated records include some data from KC, but not everything.
- 3. Have your study title, KC protocol number, and PI name ready.
- To update any part of a migrated record, you will need to submit a Modification &
   Continuing Review (Mod/CR). This is the only required way to add or update information in WRAP for migrated studies.

**Note:** WRAP allows the combination of a Modification and Continuing Review (Mod/CR) and also allows standalone Mod and CR submissions. For migrated studies, a Mod/CR is required to update the expiration date for migrated studies. Many minimal risk migrated studies will no longer have an expiration date after the Mod/CR is approved.

- 5. Open your migrated study in WRAP and review each section to confirm that all transferred information is accurate. Select **View Study** to read through your existing submission.
- 6. Required fields are marked with a red asterisk (\*). Any missing required information must be completed during your first touch.
- 7. Your first submission in WRAP will involve filling in any fields that did not transfer from KC, reviewing and updating any fields with imported information for accuracy, and uploading all currently approved study materials.

- 8. This includes attaching a completed protocol and other documents, which you can download from the HRPP Toolkit on the OHRP website.
- 9. Use a Mod/CR to finish populating your migrated study, upload required documents, or close the study.
- 10. If the study is complete, submit a study closure following the available guidance.

#### **Choosing the Submission Path for Migrated Protocols**

Migrated studies in WRAP follow one of two submission paths, and selecting the correct one keeps your record accurate and prevents delays.

### **Modification and Continuing Review**

Use this path when you need to add information that did not migrate, update study team members, research locations, funding, or study documents, or when you need to close a migrated study. This option keeps the WVU IRB study record complete and up to date.

**Note:** Some full board studies may choose to submit a Modification only if changes are needed more than 90 days before the expiration date.

#### **Site Modification**

Use this path for studies that rely on an External IRB, such as a Central IRB (CIRB) or a Single IRB (sIRB). Since the external IRB manages the overall study, the Site Modification only updates items specific to WVU's local site, including PI changes, local study documents, WVU study team updates, and local research locations.

**Tip:** Choosing the wrong path may require discarding the submission and starting again, so take a moment to confirm which option applies before you proceed.

#### Exercise #1: Find the migrated study

To get started, locate your migrated study in WRAP. Use key details, such as the study title, PI name, or legacy KC ID, to search for and open the correct record before reviewing its contents.

- 1. Click on the IRB tab.
- 2. Select Submissions tab
- 3. Select All Submissions tab
  - If you only see "In Review" with nothing listed, switch to Active (internal WVU-IRB studies) or External IRB (CIRB/sIRB studies). Migrated studies will not appear under "In Review."
- 4. Use the search and column filters (Title, PI, Legacy/KC ID) to locate the record. **Note:** Filter by allows you to sort through your studies by name, PI first and last name, and submission type.
  - You can also use the % wildcard to expand your search results:

- Type % before characters to find items containing those characters
- 5. Click the study title to open the **Study Workspace**.

#### Exercise #2: Reviewing Migrated Study Information in WRAP (Read-Only )

After locating your migrated study in the previous exercise, you will now complete an information check to review what was transferred from KC into WRAP. At this stage, the study is read-only, so the goal is to identify missing or inaccurate information that you will later update through a Modification & Continuing Review submission.

- 1. In the **Study Workspace**, confirm the following at the top of the page:
  - Study Title
  - o PI and PI Proxy (if used)
  - Legacy ID (KC protocol number in the study number)
  - Dates: Review all dates and make a note of anything that appears incorrect.
    - o Initial Approval: KC's initial approval date
    - o Approval Date: Most recent KC approval date
    - o Initial Effective: Initial KC effective date
    - Effective Date: Most recent KC approval's effective date
    - Approval end: The end date of the current approval period
    - Last updated: The last time the record was changed or updated after migration into WRAP
- 2. Click **Review Study** in the Study Workspace to view the submission.
- 3. **Review each section of the study**. You can scroll through the submission or use the Left Navigator to jump to specific sections of the study.
  - **Basic Study Information:** Basic study details were transferred, but the protocol itself was not attached. Review for accuracy.
  - **Study Funding Sources:** Funding information did not transfer. Add any applicable sources.
  - Local Study Team Members: Team member names and roles were transferred.
     Confirm they are current and note any missing or outdated entries.
  - Local Research Locations: Location details did not transfer from KC and must be added
  - **Drugs/Devices:** No drug or device information was transferred. Add these details if applicable.
  - **Local Site Documents:** Site documents were not transferred and will need to be uploaded.

## **Exercise #3: Create a Modification and Continuing Review**

Once your study is migrated from KC to the WRAP, additional information must be entered, and all study documents must be uploaded in order to make your study complete. The only way to upload documents and update information to a WRAP record is through a **Modification/CR** 

- 1. Click on the IRB tab.
- 2. Select Submissions tab
- 3. Select All Submissions tab
- 4. Open your study.
- 5. Select Create Modification/CR.
- 6. Select the two options under the modification scope
  - o **Study team member information** (if adding or removing personnel other than PI)
  - o Other parts of the study (for all other changes including changing the PI)
- 7. Click Save and then Continue

**Note:** Once saved, purpose/scope cannot be edited. If wrong, exit and discard.

# **Exercise #4: Complete the Modification Summary**

This part of the submission focuses on completing the Continuing Review and Modification Summary information. You will verify enrollment totals, identify applicable research milestones, note any changes since the last approval, attach supporting documents, and provide a summary of the modifications you plan to make. Once these sections are complete, you can move into the detailed modification pages to update the study.

- 1. Complete the Continuing Review/Study Closure Information page:
  - 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: 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 to discontinue IRB oversight.

- 5. Check the items that are true since the last IRB approval for all sites involved in the study: (initial review or last continuing review)
- 6. Attach supporting documents: (include an explanation of each item left unchecked above)
- 7. On the **Modification Summary** section:
  - 1. Select the Study Enrollment Status
  - 2. **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.

- Summarize the Modifications: Write only a brief overview of the study modifications. On subsequent forms, you can update the protocol document and change all applicable details of the existing study in the appropriate places.
- 8. Click **Continue** to begin the modification details.

#### **Exercise #5: Modification Details**

The **Modification Details** section allows you to make the actual updates to your migrated study. You will move through each SmartForm page to add or correct information, update study documents, add/remove/update the team members, add locations if applicable, and provide any new details required for drugs, devices, or funding. Complete all the required fields to ensure all changes are fully captured before submitting the Mod/CR.

- Go through each page in order using Save and Continue.
- Fill in all missing fields (marked with \*), verify migrated info, attach missing documents.

#### **Basic Study Information Page**

- Fields marked with a red asterisk (\*) must be completed. Key study details were migrated from KC into WRAP, including:
  - Title of study
  - Short title
  - Brief description
  - What kind of study is this
  - o Will an external IRB act as the IRB of record for this study (No by default)
  - Local principal investigator
- Action Items:
  - o Confirm that all migrated information is accurate.
  - o Update any fields that are incomplete or incorrect.
  - Upload your protocol on the Basic Study Information Page.
    - Include any previously included protocol documents as well as protocol questionnaire from WVU+kc.

#### **Study Funding Sources Page**

Funding ties studies to grants and impacts reporting.

- Identify all external and internal funding linked to the study. This ensures proper tracking.
  - Funding Organization: Select the sponsor, agency, or department. Contact WVU ITS
    if your funding source is missing from the list. If funded by the department, add the
    department under funding. If personally funded, list "Personal Funding." If
    unfunded, leave blank.
  - o **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**

Study team information was migrated from KC into WRAP.

- Action Items:
  - o Confirm that all listed study personnel are current.
  - o Add or remove personnel as needed.
    - Add study team members:
    - Click Add
  - o Update study team member's role
    - Click the **Update** button next to the listed person to open the "Edit Study Team Member" window
    - Select their Role in Research
    - Indicate if they are involved in the consent process
- Do not add anyone under External team member information without prior approval from WVU OHRP.

**Note:** Each person listed on this page must have active Human Subjects Research CITI training linked to their WVU account. Review the Training Tab in the submission to confirm linkage and completion.

#### **Study Scope**

- For all migrated legacy studies, the default response to Questions 1–3 is No:
  - Use of approved or unapproved drugs or biologics, or supplements
  - o Evaluation of a device or use of a HUD
  - Use of radioactive materials or ionizing radiation solely for research
- For the PI risk assessment question, the default response is No (Minimal risk).
- For "Please select all that apply," the default response is None of the above.
- Action Items:
  - Update fields, if applicable.
    - If your study involves drugs or devices, change the response from No to Yes.
      - When you select **Yes**, additional page(s) will appear in the left navigation.
      - Complete all new pages before continuing.

#### **Local Research Locations**

- No location information was transferred from KC into WRAP.
- Action Items:
  - Provide all locations where your research will take place.
    - o To add the location(s) where your research will take place:
    - In the Local Research Locations page, select Add

- WVU and WVU Health System locations are listed in the system for selection.
- Off-site locations can be added manually.

#### **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.
- To add study drug(s):
  - o In the **Drugs** page, select **Add** in Q1.
  - Ensure all questions in the Add Drug Information SmartForm are completed before selecting OK.

### **Devices (If Applicable)**

- Identify any HUDs or investigational devices.
- Specify device exemption, if applicable:
  - o IDE number (must identify number if selected)
  - o HDE number (must identify number if selected)
  - Claim of abbreviated IDE (nonsignificant risk device)
  - o Exempt from IDE requirements
- To add study device(s):
  - o In the Devices page, select Add in Q1
  - Specify the device exemptions applicable to this study in Q2

#### **Local Site Documents**

- No study documents were migrated from KC into WRAP.
- Action Items:
  - Upload all current site documents needed for your study.
    - Consent Forms: Include written forms or oral scripts (consent documents or cover letters). Ensure consistency across protocol, consent, and contracts.
    - Recruitment Materials: Upload all ads, flyers, video/audio scripts, and surveys. All participant facing material should be included.
    - Other Attachments: Include any additional study-related documents.

### **Optional: Validating Study Responses**

- You may validate your submission before sending it to the IRB by clicking Validate.
- The system will display a list of any incomplete items that need attention.

#### **Final Page**

- Click Finish to exit the SmartForm.
- In the Study Workspace, the PI or PI Proxy (if PI Proxy was added) 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 #6: Submit a Study**

Once all updates are complete and you have reviewed the SmartForm for accuracy, you'll submit the Mod/CR for IRB review. Submitting routes the study to the IRB, where coordinators and reviewers will assess your changes, request clarifications if needed, and issue the final determination. Make sure all required documents are attached and all pages are marked complete before clicking Submit.

- 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 available for review until the PI/Proxy clicks **Submit**.

### Exercise #7: 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 #8: 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
  - o 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 #9: Create Site Modification (External IRB Studies)**

This process is used when a Central IRB (CIRB) or Single IRB (sIRB) study requires updates to information specific to the WVU local site. These updates may include a PI change, revised local documents, or changes to the local study team, funding, or research locations. A Site Modification allows you to update only WVU-related details while keeping the Reviewing IRB's approved study intact.

- Open the IRB module, select the External IRB tab, and click the name of the study to open the applicable pSite.
- From the study workspace, click Create Site Modification.
- What is the purpose of this submission? Select **Modification/Update**.
- Under Modification Scope, choose all checkboxes that apply:
  - Study team member and research location information: Select if adding, removing, or updating study team members, and updating the local research locations.
  - Other parts of the study: If Other parts of the site is selected, you may edit:
    - Additional Local Funding Sources
    - Local Site Documents
- Click Continue to move to the next page.
- Subject enrollment status: Indicate the subject enrollment status at the WVU Site.
- **Notification of subjects:** (check all that apply)
  - Indicate whether current and/or former subjects will be notified of the changes.
  - Leave unchecked if notification is not required.
- **Summarize the modification:** Write only a brief overview of the study modifications.
- Click Continue to proceed.
- Continue through the remaining SmartForm pages and update applicable sections
  - Basic Local Site Information: Local principal investigator and brief description of activities this site will perform.
  - Additional Local Funding Sources: Identify each organization supplying funding for the local site, if applicable
  - Study team information was migrated from KC into WRAP.
    - Action Items:
    - Confirm that all listed study personnel are current.
    - Add or remove personnel as needed.

- Add study team members:
- Click Add
- Update study team members
  - Click the **Update** button next to the listed person to open the "Edit Study Team Member" window

**Note:** Each person listed on this page must have active Human Subjects Research CITI training linked to their WVU account. Review the Training tab in the submission to confirm linkage and completion

- Local Research Locations: Provide all locations where your research will take place.
  - To add the WVU/local location(s) where your research will take place:
    - In the Local Research Locations page, select Add
    - WVU and WVU Healthsystem sites are available for selection.
    - Off site locations can be added manually.
- Local Site Documents: Upload all current site documents needed for your study.
  - Consent Forms: Include written forms or oral scripts, plus translations. Ensure consistency across protocol, consent, and contracts.
  - o **Recruitment Materials**: Upload all ads, flyers, video/audio scripts, and surveys.
  - o Other Attachments: Include any additional study-related documents.
- On the final page, click Finish to exit the form. (This does not submit the modification.)
- If needed, click Edit Modification from the workspace to make additional changes.
- When ready, click **Submit** from the submission workspace.
  - Only the PI or PI Proxy can submit pSite modifications.
- Review the terms and click **OK**. The modification is now submitted.
- Ensure the PI or PI Proxy clicks Submit so the modification can proceed to the IRB for review.

### **Exercise #10: 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.
- PI or PI Proxy and assigned coordinators may 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.
- 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 #11: 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!

- 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 #12: 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