RESEARCH ADMINISTRATION PORTAL (WRAP)

Creating and Submitting COE-CTA Agreements Quick Guide

Topics

Overview

This quick guide provides step-by-step instructions for creating and submitting a COE/CTA agreement and responding to clarifications.

Steps

Access

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

RESEARCH ADMINISTRATION PORTAL (WRAP)

Agreements Navigation and Basic Tasks

Navigate the General Dashboard Video (opens in a new tab)

Navigate the Agreements Page Video (opens in a new tab)

Navigate the Agreement Workspace Video (opens in a new tab)

WRAP Dashboard Terms & Definitions

- **Create Menu:** Create drop-down menu buttons that allow you to create various items in the system, such as proposals or agreements
- **Recent: L**ists the last several items a user has accessed, with the most recent at the top. Items can be pinned for quick access using the pin icon.
- **Pinned:** Pinned items are stored for easy access, regardless of when they were last viewed. Pinned items remain until manually unpinned.
- **My Inbox:** Displays all items requiring user action to move forward in the workflow e.g. proposals, agreements, and awards.
- **My Reviews:** Shows a subset of items **from My Inbox**, specifically those awaiting the user's review. Useful for users who may have multiple roles, like researchers who also serve as ancillary reviewers.
- **State Column:** Shows item workflow status and helps guide the next steps.
- **Personalize Table:** Users can adjust table settings using the gear icon, enabling them to configure the columns and data that appear. They can also export data to CSV files.
- **Top Navigator:** The main navigation tool at the top of the dashboard allows users to move to different parts of WRAP.
- **Breadcrumb Trail:** Located under the top navigator, this trail indicates the current page and allows users to navigate back to previous pages.
- **Filter by Text:** Type the first part of the text you want to find. Use % as a wild card. Users must prepend the '%' wildcard before entering search terms (e.g., '%defense') when using the search function. Add a prompt or help text instructing users to use a wildcard before typing search terms.

Exercise #1: Creating and Submitting a COE/CTA Review

Note:

COE reviews will be completed as an agreement and will be completed along with the clinical trial agreement (if applicable) with which it is associated all in one record. The COE/CTA process will be unique to the other agreement types because they will always be initially created by a PI or their designee as opposed to the Clinical Research Agreement Office.

- To start, the PI or department administrator will create an agreement record and select **COE Review/Clinical Trial Agreement** as the agreement type. The PI/dept admin will fill out all of the fields on the SmartForm pages, with the exception of the application score on the **COE Review Additional Information** page, and then submit it for review.
  - If the submission is for an investigator-initiated clinical trial, the PI department name and email should be added as the contracting party, and the **draft to be generated internally** should be selected on the agreement upload field.
  - If not, PI initiated, there should be an agreement draft, which should be attached to the agreement upload page. The contracting party and contact should be from the CTA funding source.

When you create an agreement, you are required to complete a series of pages. The number of pages depends on the type of review required.

1. From the Dashboard, click the **Create** menu and then select **Create Agreement**.
2. On the **Agreement Upload** page, fill out the following information:

Agreement Upload

1. **Principal investigator:** Enter yourself as the **PI**.
2. **Primary contact:** This field is automatically populated with the person who created the agreement but can be changed if necessary.
3. **Upload agreement draft:** Attach the draft agreement file or, if applicable, select the check this box First Draft to Be Generated Internally.

Note: If the agreement document has already been drafted, you can attach it to the Agreements SmartForm by clicking the Upload button. However, if Agreements office staff are going to create the first draft of the agreement, check the First draft to be generated internally? box instead. Agreements office staff will generate or upload a draft by running the Generate Agreement activity.

4. **Title or internal reference number:** Enter the title or internal reference number
5. **Agreement type:** Select COE Review/Clinical Trial Agreement
6. **Description:** If applicable provide a description
7. **Supporting documents:** If applicable provide attach any documents
8. **Sponsor Deadline Date:** Enter any further date.

When you click **Continue**, a number of new pages will appear in the list. Fill the following pages out one at a time, providing a value for each field:

General Information

1. **Contracting Party**: Select the external organization involved in the agreement.
2. **Contracting Party Contact Name**: Enter the name of the representative from the contracting party.

3. **Contracting Party Contact Email**: Provide the email address of the contracting party contact.
4. **Contracting Party Contact Phone**: Enter the phone number of the contracting party contact.
5. **Additional Contracting Parties?**: Select Yes or No to indicate if there are additional contracting parties involved.
6. **Responsible Department/Division/Institute**: Specify the internal department responsible for this agreement. By default, this field displays the department of the PI entered on the Agreement Upload page. If no value is displayed, then you must select a value.
7. **Agreements Collaborators**: List any collaborators who will have read/edit access to the agreement, or indicate none if not applicable.
8. **Bilateral or Unilateral**: Specify if the agreement is bilateral (Both parties sign the agreement) or unilateral (one party), or unknown.
9. **Is a Proposal Associated with This Agreement?**: Select Yes or No to indicate if a related proposal exists.
10. **Does this project require an agreement?** Select Yes or No to indicate if this project requires an agreement. Selecting **Yes** will prompt the system to add the SmartForm for CTA Agreement Information. Clinical research that is unfunded, an investigator-initiated study, or funded by a grant may NOT require an agreement.

COE Basic Information

1. WVU IRB Number: Enter a WVU IRB Number
2. WVU IRB Title: Enter the WVU IRB Title

COE Review Additional Information

- On the **COE Review Additional Information** page, enter values in **Q1-Q10**. Leave **Q11** blank.

CTA Agreement Information

- On the **CTA Agreement Information** page, enter values in **Q1-Q6**.

CTA Additional Information

- On the **CTA Additional Information** page, enter values in **Q1-Q8**.

Use the **Validate** button in the top left corner to ensure that no field values were missed, then save and exit to return to the **Agreement Workspace**.

Manage Relationships

If the COE/CTA record is related to another agreement (such as a DUA) or a proposal/award, the agreement reviewer or PI/dept admin can use the **Manage Relationships** activity to relate it to the COE/CTA record. This will create a bi-directional, navigable link between the records.

1. Click **Manage Relationships** and search for a funding proposal or award record. You can search by typing the title in the **Related Submissions** search box.
2. Select it and click **OK.**

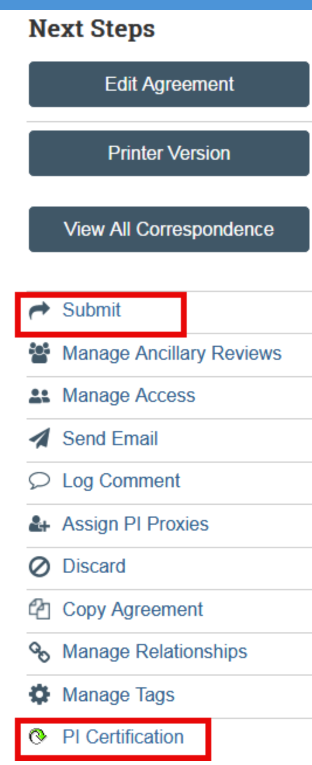
3. Navigate to the **Related Projects** tab and ensure the award is present.

PI Certification

1. Use the **PI Certification** activity to certify the agreement information is correct: I certify

Note: When the record is submitted for review initially, or anytime clarifications are requested, the PI will need to use the **PI Certification** approval activity to certify the information in the record, after which they (or their designee) can submit the record for review. Only the PI can certify the agreement, and if the COE&CTA was created by a PI designee, the designee should use the send email activity to let the PI know to log in to the system and certify. There is no automated notification or routing step for PI certification (which is different from KC).

Exercise #2: Submit an Agreement for Review



1. On the COE Review/Clinical Trial Agreement you just created.
2. In the agreement workspace, click the **Submit** activity on the left side.
3. Read and agree to the submission statement, then click **OK** to submit the agreement for review.
4. Return to the **Dashboard** to confirm that the agreement is no longer in your inbox and has been sent for review.

Once the COE/CTA record is submitted for review, all the staff in the Clinical Studies Agreement office will get a notification and the agreement record will appear in their inboxes in the **Unassigned** state. COE staff will navigate to the record and assign it to a COE reviewer, who will review the information in the SmartForm and assign a score. Optionally, the reviewer can send back for clarifications to the PI/project team as well.

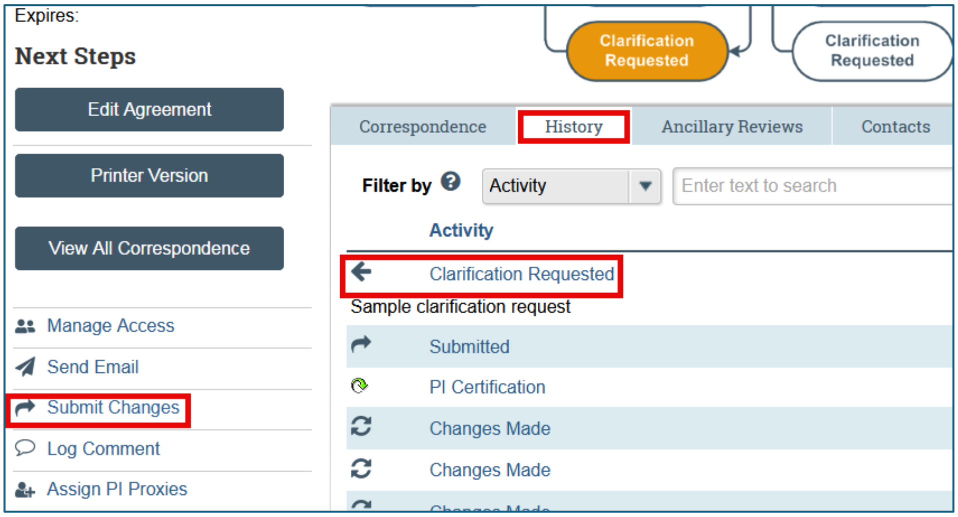
Note: When the record is submitted for review initially, or anytime clarifications are requested, the PI will need to use the **PI Certification** approval activity to certify the information in the record, after which they (or their designee) can submit the record for review.

Exercise #3: Respond to a Clarification Request

1. From My Inbox, click the agreement name to open it.
2. Click the **History** tab.
3. Look for the **Clarification Requested** activity and review any reviewer comments.
4. If required, click **Edit Agreement** on the left and make the changes.

Note: You can enter a response for the reviewer before submitting the agreement.

5. Click **Submit Changes**.



Note: In case you have changed the agreement type, make sure to complete the related pages of the agreement type in the SmartForm. In case you miss filling out the pages or mandatory entries then the system will validate and throw an error message. Only when the validation is approved, you can go ahead and submit the change.

6. In the Notes box, type a response to the reviewer's comments or questions.
7. Click **OK**.