RESEARCH ADMINISTRATION PORTAL (WRAP)

Creating and Reviewing COE-CTA Agreements Quick Guide

Topics

Overview

This quick guide is designed specifically for this training session, with step-by-step instructions for managing a Clinical Trial Agreement (CTA) or COE review from creation to finalization. It covers essential processes such as creating and submitting an agreement, requesting and responding to clarifications, completing COE reviews, and reviewing and activating a CTA record. Additionally, it outlines procedures for creating and approving amendments. Designed for both PI and non-PI roles, this guide ensures users can navigate the system effectively, manage agreement workflows accurately, and maintain compliance through thorough documentation and efficient approval processes. The steps are intended for training purposes, and participants are encouraged to make their own adjustments during the session as needed.

The WRAP Agreements Module features include:

- **Automated routing** by **agreement type** to the appropriate offices
- **Customized submission** forms by agreement type
- Ability to **link agreements** to **other projects**
- Flexible **management of ancillary reviews** and approval

Note: Certain types of agreements will be initiated by the **WVU Research Community**, and other types of agreements will be initiated by the **agreement offices**.

Agreement Types

Agreement Type	Initiated by	Assigned to Offices
COE Review/Clinical Trial Agreement	Principal Investigator (PI) or Designee	Clinical Study Agreement Office
Data Use Agreement	Principal Investigator (PI) or Designee	Award Negotiation Office or Clinical Study Agreement Office
Facility Use Agreement	Principal Investigator (PI) or Designee	Office of Innovation and Commercialization (OIC) Agreement Office
Material Transfer Agreement	Principal Investigator (PI) or Designee or Office of Innovation and Commercialization (OIC)	Office of Innovation and Commercialization (OIC) Agreement Office
Non-Disclosure Agreement	Principal Investigator (PI) or Designee	Office of Innovation and Commercialization (OIC) Agreement Office or Clinical Study Agreement Office
Teaming Agreement	Office of Innovation and Commercialization (OIC) or PI/Designee/Support	Office of Innovation and Commercialization (OIC) Agreement Office

Memorandum of Understanding	Research Office OSP Award Negotiation	Award Negotiation Office
Master Agreement	Research Office OSP Award Negotiation	Award Negotiation Office or Clinical Study Agreement Office or Office of Innovation and Commercialization (OIC) Agreement Office
Research Agreement	Research Office OSP Award Negotiation	Award Negotiation Office
Outgoing Subaward	Research Office OSP Award Negotiation or Center of Excellence (COE) (not generated by general research community)	Award Negotiation Office, Clinical Study Office
Other Agreement	Research Office OSP Award Negotiation	Award Negotiation Office

Steps

Access

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

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.

1. Once logged into the site, click **Agreements** in the top navigator.
2. Click the **Create Agreement** button to start a new agreement record.
3. 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.

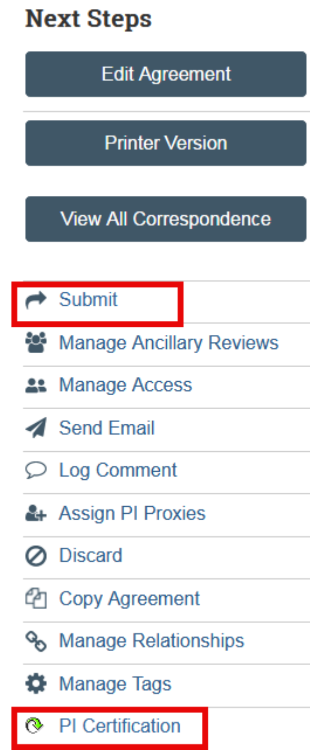
1. Click **Manage Relationships** and search for a funding proposal or award record. You can search by typing the title in the **Related Submissions** search box.
2. Select it and click **OK.**
3. Navigate to the **Related Projects** tab and ensure the award is present.

PI Certification

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

N**ote:** 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. 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 #3: Assign an Owner to an Agreement

1. Navigate to the **Agreements** tab and click the **Unassigned** tab to find the agreement.
2. Select and open the COE Review/Clinical Trial Agreement you created.
3. In the agreement workspace, click **Assign Owner** on the left panel.
4. Choose the appropriate owner from the dropdown list and click **OK** to assign ownership.
5. Confirm success by ensuring that the assigned owner appears in the agreement workspace and that the agreement status is now **Internal Review**.

Exercise #4: Request Clarification

If a reviewer has questions or requires you to change your submission, you will receive an e-mail notification indicating this. Review the request details and then respond to the request.

1. In the agreement workspace, click the **Request Clarification** activity.
2. Type a message requesting clarification (e.g., Please provide more details on the purpose of the exchange on the Agreement Information page") and click **OK**.
3. Confirm success by ensuring the **History** tab shows the **Clarification Requested** activity and that the agreement is in the **Clarification Requested** state.

Exercise #5: Generate a Draft Agreement

Once the score is assigned, the COE reviewer will either:

a. Generate and attach the COE approval notification as a supporting document using the **Generate Agreement** activity, then reassign the owner to the CTA team to complete the CTA negotiation and signing.
b. Use the generate agreement activity to create an approval letter, which the system will automatically attach as the agreement document, then activate the agreement.

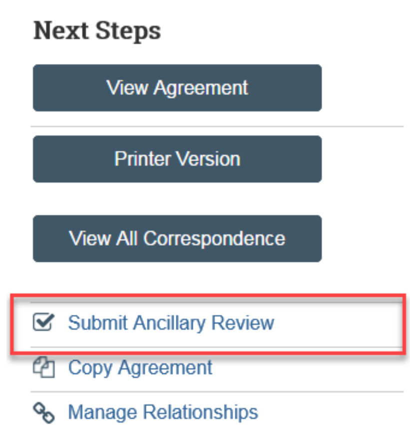
1. In the agreement workspace, click the **Generate Agreement** activity from the bottom of the list.
2. Select the appropriate template for the agreement and click **Generate**.
3. Confirm that the system has generated the agreement and that the draft version is available for review.

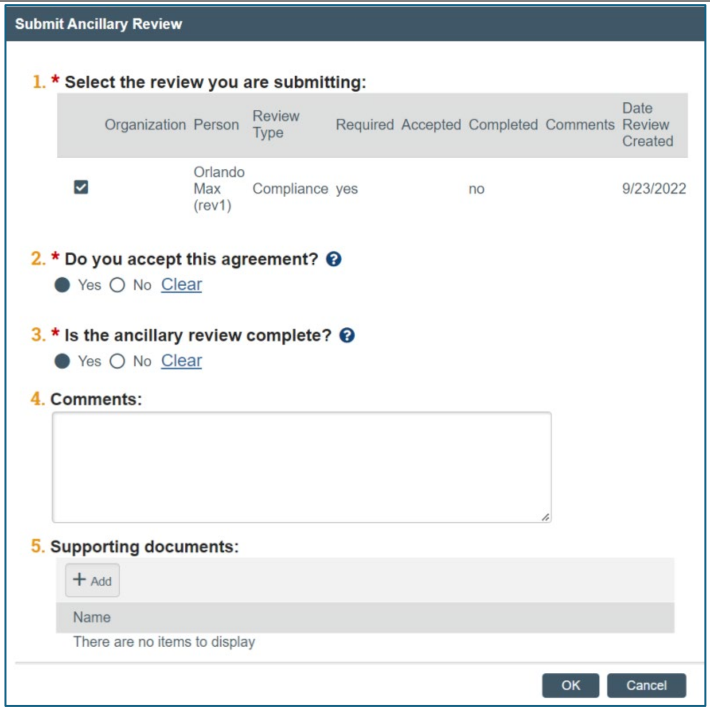
Exercise #6: Assign an Ancillary Reviewer

1. In the agreement workspace, click **Manage Ancillary Reviews**.
2. Click **Add**, and select the reviewer from the dropdown e.g., Ancillary Review Office - Innovation and Commercialization
3. Set the review type to **Research Data Management & Protection**.
4. Set **Is a response required** to **Yes** and click **OK**.
5. Confirm success by verifying that the **Ancillary Reviews** tab lists the reviewer and the **History** tab shows the **Managed Ancillary Reviews** activity.

If you are assigned as an ancillary reviewer, you get an e-mail notification, the related agreement appears in your inbox, and the Submit Ancillary Review activity becomes available in the Agreement workspace. This procedure assumes you have finished reviewing the agreement and are ready to submit your review.

1. Open the COE Review/Clinical Trial Agreement.
2. From the Agreements workspace, click **Submit Ancillary Review**.
3. In the Submit Ancillary Review form, select the ancillary review to submit.





4. Select **Yes** if you agree with the agreement terms, and **No** if the agreement terms are not accepted in the **Do you accept this agreement?** field.
5. Select **Yes** if the ancillary review is complete, and **No** if the ancillary review is not complete and requires corrections or clarifications in the **Is the ancillary review complete?** field.
6. Add any comments and supporting documents you think necessary, then click **OK**.
7. When you accept and indicate that the ancillary review is complete:
8. It does not change the state of the agreement.
9. The agreement no longer displays in your inbox.
10. The details of the ancillary review show on the **Ancillary Reviews** tab of the agreements workspace.

Note:

All the required ancillary reviews needs to be completed before the **Approve Language** activity is executed. For the ancillary reviews that are not required, the submit option will display till the agreement is sent for signatures.

Exercise #7: Review the Generated Agreement

Certain agreement types have agreement templates that you can use to generate the draft agreement.

Note: You can create and manage any number of (non-FDP) templates for each agreement type in coordination with RIT.

1. Generate an agreement using a template by using the **Generate Agreement** activity and selecting the **Template** option.

2. At the top of the workspace, click the document link in the **Agreement** section to review the generated agreement.

Exercise #8: Move an Agreement to External Review

1. Ensure the internal review process is complete, and all necessary changes have been made to the agreement.
2. Confirm that there are no outstanding ancillary reviews. If any are required and pending, the system will not allow you to move the agreement to external review.
3. In WRAP, locate the agreement you wish to send for external review and open it.
4. On the agreement workspace, click **Move to External Review** on the left.
5. Type some notes regarding the external review. For example, "Sending this to the main external party contact who will oversee the reviews at that organization."
6. Leave the external organization and contact information fields unchanged. These were auto populated from the agreement SmartForm pages. Click OK.After moving the agreement to external review in the system, send the agreement to external parties using your usual method (e.g., mail, email).
7. The agreement is now in the **External Review** state. The system tracks the time spent in this state for reporting purposes.
8. Move the agreement between internal and external review as needed until all parties agree on the language. This reflects the current review status and ensures accurate tracking.

Note: This activity only updates the status for tracking and does not send the agreement externally.

If the agreement must move back to internal review, use the **Move to Internal Review** activity. You can move the agreement back and forth between internal and external reviews until the agreement language is agreed upon by all parties.

Exercise #9: Approve Agreement Language

After all, parties have reviewed the agreement and it has been updated accordingly, the next step is to approve the agreement language and select the signing method that will be used digital or wet ink.

1. On the agreement workspace, click the **Approve Language** activity (halfway down the list of activities).

   Note: If any are required and pending, the system will not allow you to approve the language.

2. Complete the page by entering the following information:
   - **Signature type:** Select Wet Ink for signature.
   - **Should the agreement be routed for internal signature first:** Select Yes or No
   - **Does the agreement contain evergreen clauses**: Select Yes or No (Note that Evergreen clause is not commonplace at WVU.)

- **Effective date:** Set the effective date to today.
- **Expiration date: S**et the end date to one year in the future.

3. Click **OK**.

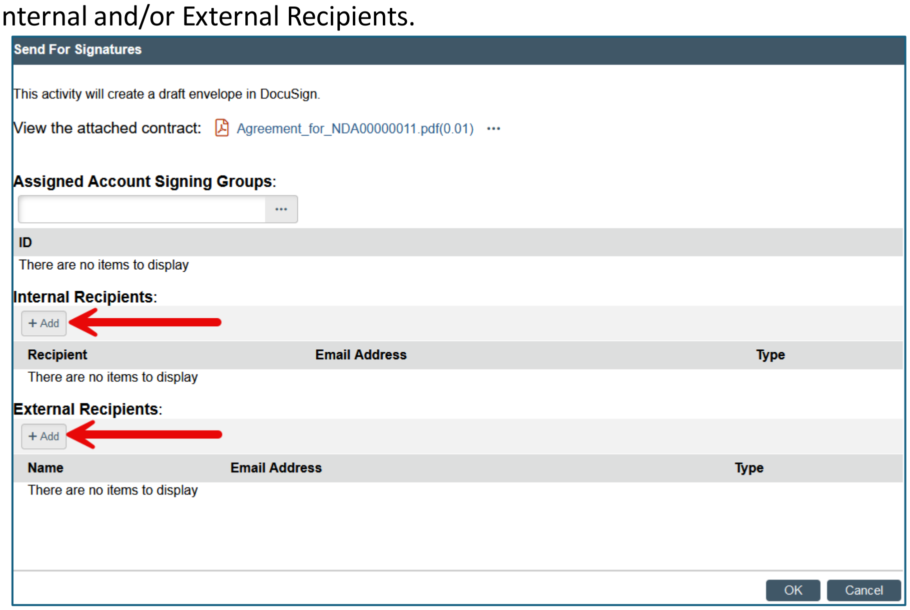
Exercise #10: Convert Agreement to PDF

You will create a PDF of the final agreement that will be signed by both internal and external parties. In the previous exercise, you indicated that the agreement would be signed by internal parties first, therefore, after you create the PDF, you will route it internally for signature.

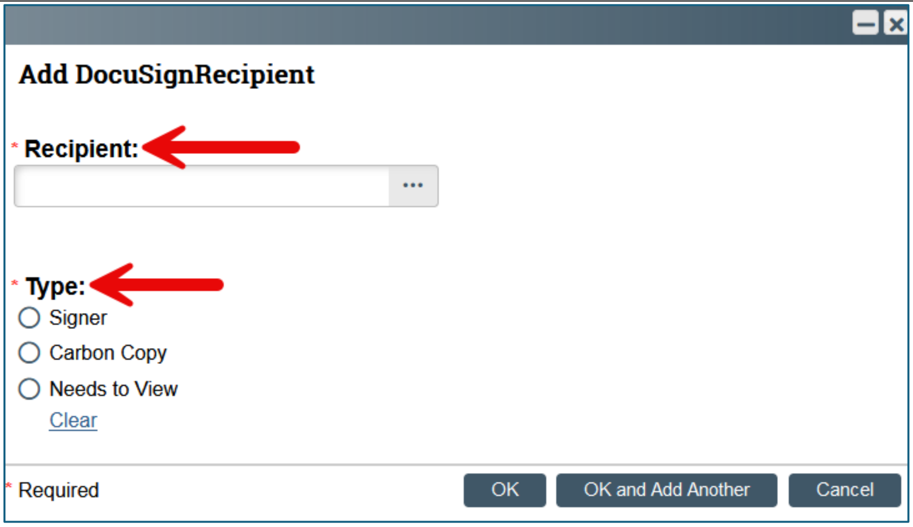
1. Once the agreement state changes to **Language Finalized** on the agreement workspace, click the **Convert to PDF** activity (halfway in the list of activities) and finalize your agreement.
2. Select the watermark.
3. Click **OK** to create the PDF. This action will attach the PDF to the **Final Agreement** section in the Workspace.
4. From the workspace, click the **Final Agreement** link at the top to open the PDF. You will see the **Active Until** text watermark at the top of the page.
5. Close the document and return to the agreement workspace.

Exercise #11: DocuSign

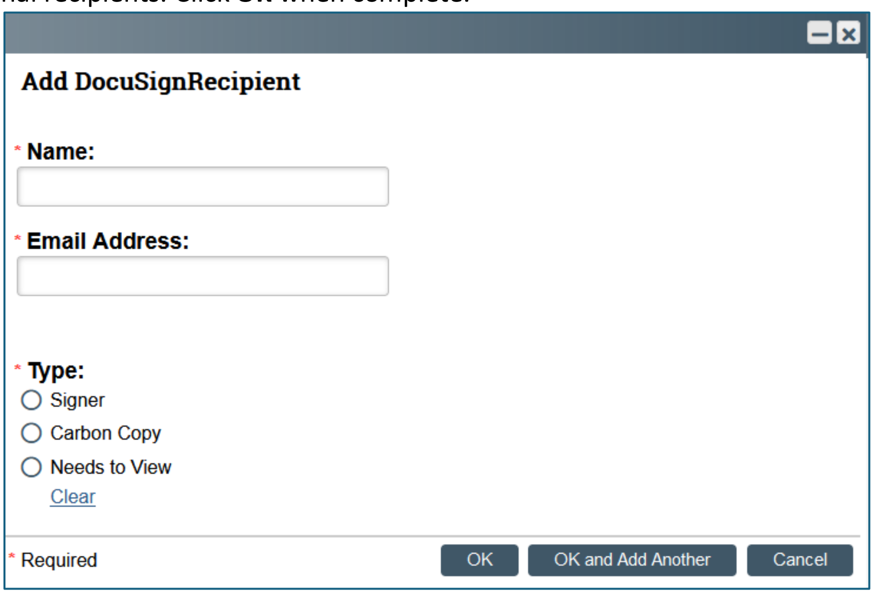
1. From your Agreement Workspace, execute the **Send For Signatures** activity.
2. The **Send For Signatures** pop-up window will appear.
3. Add Internal and/or External Recipients.



4. **Internal Recipients:** A pop-up will open for internal recipients. Click the ellipses to select a Recipient. Add only yourself as an internal signer. Click **OK**. Select a Type. Select **OK and Add Another** for additional recipients. Click **OK** when complete.



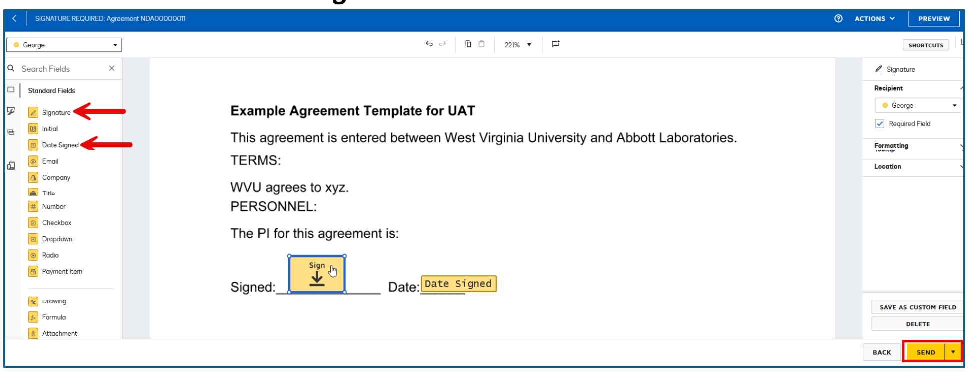
5. External Recipients: A pop-up window will open for external recipients. Enter the **Name** and **Email Address** of the recipient. Select Type.Select **OK and Add Another** for additional recipients. Click **OK** when complete.



6. The DocuSign tab will appear in the Workspace

7. Click **Send Envelope** to route the document for signatures

8. Clicking **Send Envelope** opens the DocuSign web interface, where you can add standard fields such as signatures, and dates. Drag a **Signature** and **Date** signed to the appropriate locations on the agreement, then **click send**. After the signing process is complete, the signed document will be available in both the **DocuSign** and **Attachments** tabs.



9. Check your email until you see an email from DocuSign, which will contain a button to navigate you back to the site to complete the signatures. If a pop-up blocker appears, disable it to proceed.
10. Once finished, navigate back to your test record and go to the **DocuSign tab**. Click the button to **Update Envelope** status, tick the box to indicate you wish to force a status update, and then click **OK.**

Exercise #12: Send Agreement for External Signature

1. On the agreement workspace, click the **Send for External Signature** activity.
2. Assume all the information is correct in the Send for External Signature window and then click **OK**.

Note: Executing this activity changes the state so you know where the agreement is in the signing process. Your next step is to send the agreement to the external organization so the appropriate people can sign it. You could also create a correspondence item to follow up with the external parties by a certain date.

3. Confirm you met the success criteria below:
   - The History tab shows the Sent Out for Signature activity.
   - The agreement is in the **External Signature** state.
   - The workflow map shows the agreement is still in the **Signing** phase of the review process.

Note: You either send for DocuSign signatures (See exercise 11) or manually via email. You should not do both.

Exercise #13: Send Agreement for Internal Signature

1. On the agreement workspace, click the **Send for Internal Signature** activity.
2. Assume all the information is correct in the Send for Internal Signature window and then click **OK**.
3. Confirm you met the success criteria below:
    - The History tab shows the Sent Out for Signature activity.
    - The agreement is in the **Internal Signature** state.

Note: You either send for DocuSign signatures (See exercise 11) or manually via email. You should not do both.

Exercise #14: Activate an Agreement

1. On the agreement workspace, click the **Activate** activity.
2. Complete the page by entering the following information:
    - **People who have signed:** Will automatically default
    - **Internal signing date:** Select the date
    - **External signing date:** Select the date
    - **Effective date:** Select the date
    - **Expiration date**: Select the date
3. Click OK.
4. Confirm you met the success criteria below:
    - The effective and expiration dates you entered appear in the top left of the agreement workspace (under the state).
    - The agreement is in the **Active** state.
    - The workflow map shows the agreement is in the **Active** phase of the review process. In other words, the review process has been completed.

Exercise #15: Create an Amendment

2. Click **Agreements** in the Top Navigator.
3. On Agreements page, click the **Active** tab.
4. Find and open the **COE Review/Clinical Trial Agreement you** created.
5. On the agreement workspace, click the **Create Amendment** activity.
6. **Upload draft amendment file**
7. **Supporting documents**
8. **Amendment Description:** In the **Amendment Description** box, type “This amendment extends the agreement expiration date by one year”.
9. **Is this a no cost extension or continuation without a change in scope or additional terms?** Select **Yes**
10. Click **Save** and then **Exit** on the navigation bar without updating other information.
11. Confirm you met the success criteria below:

- The amendment title starts with "Amendment for…"
- The amendment is in the **Pre-Submission** state.

Exercise #16: Submit an Amendment for Review

1. From the amendment workspace, click the **Submit** activity.
2. Read the statement and click **OK** to submit the amendment for review.
3. Return to the Dashboard. The amendment now appears in your inbox. This is because the amendment appears in the inboxes for all people assigned the Agreements Reviewer and Agreements Manager roles for the agreement office.
4. Confirm you met the success criteria below:

   - The amendment appears in My Inbox.
   - The amendment is in the **Unassigned** state.

Note: If the amendment includes uploading an amendment file or generating one through the institution, then that amendment will follow the same workflow as an agreement in which it is routed for signature. If it does not, then you can expedite the amendment's approval.

Exercise #17: Take Ownership of an Amendment

1. Click **Agreements** in the Top Navigator.
2. On the Agreements page, click the **Unassigned** tab.
3. Find and open the amendment you created.
4. On the amendment workspace, click the **Assign Owner** activity on the left to assign yourself as the owner.
5. Click **OK**.
6. Confirm you met the success criteria below:

   - The amendment is in the **Internal Review** state.
   - The workflow map shows the amendment is in the **In Review** phase of the review process.

Exercise #18: Expedite Approval of an Amendment

When the amendment is in the Internal Review or External Review state, you can expedite or fast-track the amendment approval process by using the Expedite Approval activity. You can use this activity if the amendment does not include a file that requires signing and you did not indicate that a draft will be generated internally.

Note: Expedited approval is only available when an agreement file is not uploaded, and the **Generate Internally** option is not selected.

Note: The amendment will not appear in your inbox. Click Agreements on the Top Navigator and find the amendment on the All Agreements or the In Progress tab.

1. From the amendment workspace, click the **Expedite Approval** activity.

Note: This activity will not show if the amendment does not qualify for expedited approval.

2. Complete the page by entering the following information:
   - **1. Effective date:** Select today's date
   - **2. Expiration date:** Type a date that is two years minus a day from the effective date
   - **3. Comments:** Add comments if applicable.

3. Click **OK**.

Note: Amendments follow the same workflow as agreements. You can expedite approval or complete all steps if signatures or negotiation are required.

4. Confirm you met the success criteria below:
   - The amendment is in the **Approved** state.
   - The effective and expiration dates display in the top left of the amendment workspace.
   - The History tab shows the Expedited Approval activity along with your comments.

The date change is reflected not only in the amendment workspace but also in the parent agreement workspace. (Find the parent agreement using the breadcrumb navigator or on the Agreements page.)