

Submitting Cumming School of Medicine (CSM) Legal Agreements in IRISS

User Guide - Researcher

April 2024 – V2

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Navigation and Basic Tasks

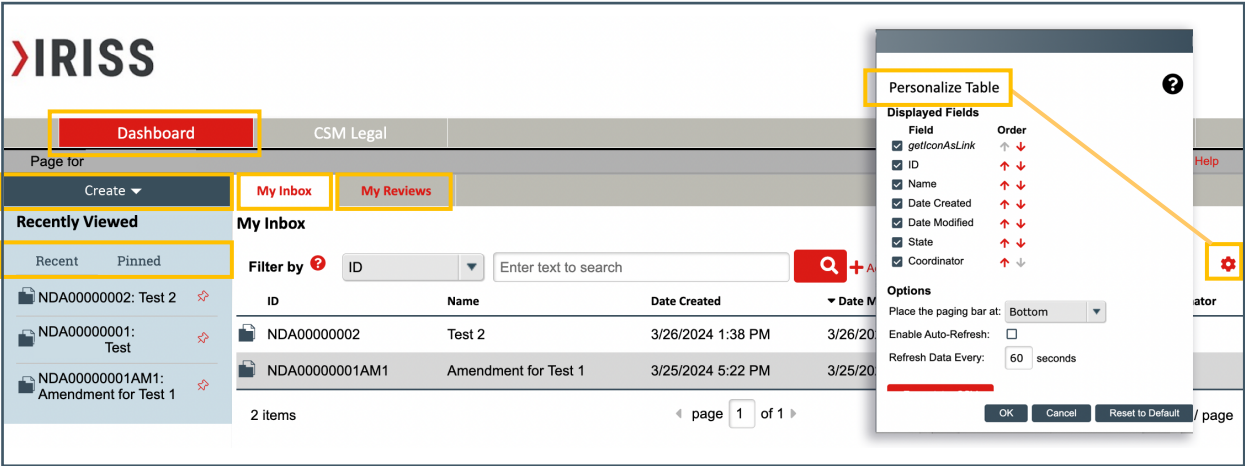
Learn where to go to perform basic actions on an agreement.

The CSM Legal Dashboard

The dashboard contains high-level information about the agreements associated with your profile.

The dashboard includes:

- **My Inbox:** Items requiring action.
- **My Reviews:** All agreements you are listed on regardless of state.
- **Create:** Create an agreement.
- **Recently Viewed:**
 - **Recent:** The last several items you viewed. Scroll through this list to find an item you worked on recently.
 - **Pinned:** You can pin the items in Recently Viewed section for quick and easy access. This is where those pinned items are listed.
- **Personalize Table:** You can alter the tables displayed on the Dashboard in **My Inbox** or **My Reviews** by using the Personalize Table gear icon in the top-right corner.



CSM Legal Agreement Workspace – locating key areas

Current State

The yellow box indicates the state or relevant sub-state in the top left-hand side of the agreement workspace next to the agreement CSM ID.

See [Agreement States](#) in the Reference Table Section for descriptions of each state.

Agreement Workflow Map

The agreement workflow map gives you an overview of where the agreement's current state is with respect to the overall workflow of the review process.

See [Agreement States](#) in the Reference Table Section for descriptions of each state.

Detail Tabs

Below the Agreement Workflow Map reside a series of tabs for quick access to more details for the agreement.

See [Agreement Tabs](#) in the Reference Table Section for descriptions of each tab.

The screenshot displays the IRISS CSM Legal Agreement Workspace for agreement ID NDA00000001. The 'Active' state is highlighted in a yellow box in the top left. The workflow map shows the progression from Pre-Submission to Active, with the 'Active' state highlighted in a yellow box. The activity history table below the workflow map is also highlighted in a yellow box.

Active NDA00000001

Test

Primary contact: [Redacted]
PI: [Redacted]
Owner: Test agreementsreviewer
Created: 3/25/2024 11:34 AM
Received: 3/25/2024 11:43 AM
Modified: 3/25/2024 5:22 PM
Effective: 3/25/2024
Expires: 4/30/2024

Agreement: Original_Agreement.docx(0.01) ...
Final Agreement: Original_Agreement.pdf(0.01) ...
Counterparty: Pfizer Canada

Agreement Type: Non-Disclosure Agreement
Office: Clinical
Faculty/Department: VP (Research & International)
Full Study Title: Test

Next Steps

- View Agreement
- Print Version
- Go to Amendment

History Ancillary Reviews Reviewer Notes Contacts Snapshots Amendments Related Projects ...

Filter by Activity [v] Enter text to search [q] + Add Filter [x] Clear All [g]

| Activity | Author | Activity Date |
|-----------------------------|------------|--------------------|
| Amendment Created | [Redacted] | 3/25/2024 5:22 PM |
| Amendment: NDA00000001AM1 | | |
| Administrative Change | [Redacted] | 3/25/2024 11:56 AM |
| Activated | [Redacted] | 3/25/2024 11:56 AM |
| Moved to Pending Completion | [Redacted] | 3/25/2024 11:54 AM |

Activity menu

To take action on an agreement, click an **activity link in the left side menu** of the Agreement Workspace.

The available links in the menu are dependent on which activities can be executed in the **current state** of the agreement. Different activities will be available in different states.

Notable activities for the CSM Legal module include:

- **Assign PI Proxies** – Allows study team members to function on behalf of the PI or Primary Contact to action the agreement. Executing this activity does not require approval from CSM Legal – proxy roles are effective as soon as the activity is submitted.
- **Withdraw** – Moves the agreement back into **Pre-Submission** state so it can be submitted at a later date or discarded. The Withdraw activity **retains the agreement's unique ID**.
 - PIs, Primary Contacts and PI Proxies can withdraw an agreement in any state **prior to submission** or when the agreement is in the **Clarification Requested** state.
 - ONLY CSM Legal can withdraw an agreement **after it has been submitted** upon request.
- **Discard** – Moves the agreement into the discarded state. Discarding should happen when there is no intent to submit. The Discard activity **retires the unique ID**.

Once discarded, the agreement can be copied to create a new version that can then later be submitted under a new ID.

- ONLY PIs, Primary Contacts and PI Proxies can discard an agreement.
- Discarding can be done in any state **prior to submission**.
- **Manage Relationships** – Allows the PI, Primary Contact or PI Proxy to link agreements that are related to each other.

The diagram illustrates the available activities for three different states of an agreement: Pre-Submission, Pre-Submission, and Active. Each state is represented by a card with a title bar, metadata, and a list of activities.

- Pre-Submission (Left Card):**
 - Metadata: Primary contact: Kimberly Weiss, PI: Kimberly Weiss, Owner: Kimberly Weiss, Created: 3/26/2024 1:38 PM, Received: 3/26/2024 1:38 PM, Modified: 3/26/2024 1:38 PM, Effective: 3/26/2024 1:38 PM, Expires: 3/26/2024 1:38 PM.
 - Next Steps: Edit Agreement, Print Version.
 - Activities: Manage Access, Manage Relationships, Manage Tags, Send Email to Study Team, Assign PI Proxies, Discard, Copy Agreement, Submit.
- Pre-Submission (Middle Card):**
 - Metadata: Primary contact: Kimberly Weiss, PI: Kimberly Weiss, Owner: Kimberly Weiss, Created: 3/25/2024 5:22 PM, Received: 3/25/2024 5:22 PM, Modified: 3/25/2024 5:42 PM, Effective: 3/25/2024 5:42 PM, Expires: 3/25/2024 5:42 PM.
 - Next Steps: Edit Amendment, Print Version.
 - Activities: Manage Tags, Send Email to Study Team, Assign PI Proxies, Discard, Submit.
- Active (Right Card):**
 - Metadata: Primary contact: Kimberly Weiss, PI: Kimberly Weiss, Owner: Test agreementsreviewer, Created: 3/25/2024 11:34 AM, Received: 3/25/2024 11:43 AM, Modified: 3/25/2024 5:22 PM, Effective: 3/25/2024 5:22 PM, Expires: 4/30/2024.
 - Next Steps: View Agreement, Print Version.
 - Activities: Manage Access, Manage Relationships, Manage Tags, Contact Owner, Send Email to Study Team, Assign PI Proxies, Copy Agreement.

Create and Submit an Agreement

When you create an agreement, you are required to complete a series of information fields. The number and content of the pages depend on the type of agreement selected.

Create an Agreement

1. From the **Dashboard**, click the **Create** menu and then select **Create Agreement**. From the **CSM Legal workspace**, click the **Create Agreement** button.
2. Complete the pages. To move to the next page, click **Continue**.
3. On the last page, click **Finish**.

The workspace of the created agreement displays.

You can continue to edit the agreement until you submit it for processing.



Tip: You can click the **History** tab from the agreement workspace to view who **created** the agreement.

The image displays two screenshots of the IRISS CSM Legal workspace. The left screenshot shows the 'Dashboard' tab with a 'Create' dropdown menu open, highlighting the 'Create Agreement' button. The right screenshot shows the 'CSM Legal' workspace with a 'Create Agreement' button highlighted in the top navigation bar. Both screenshots show a list of agreements in the 'My Inbox' section, including items like 'NDA00000001: Test' and 'NDA00000001AM1: Amendment for Test 1'.

Agreement Upload Page

The **Agreement Upload** page is visible for all agreement types.

A unique CSM ID number is automatically created based on the agreement type selected.

➔ **Note:** If you start an agreement, then change the agreement type, the **number will update** to reflect the new agreement type. Remember to update the most current ID number in any documentation where the CSM ID appears.

See [Agreement Types](#) in the Reference Table Section for descriptions of each agreement type.

The screenshot shows the IRISS web interface for creating a new agreement. The page title is 'Creating New: Agreement' and the breadcrumb is 'You Are Here: > ClickAgreement'. The form is titled 'Agreement Upload' and contains the following fields:

- 1. * Principal investigator:** A text input field with a dropdown arrow.
- 2. * Primary contact:** A text input field with a dropdown arrow and a plus icon. Below it, 'Test PI' is displayed.
- 3. UCalgary Co-Investigators:** A table with columns for Last, First, Department, E-mail, and Phone. Below the table, it says 'There are no items to display'.
- 4. * Agreement type:** A dropdown menu, highlighted with a yellow box.
- 5. * Are you receiving or transferring funding/payment under this contract?** Radio buttons for 'Yes' and 'No', and a 'Clear' link.
- 6. * Abbreviated study title (or acronym):** A text input field.

At the bottom right of the form are three buttons: 'Exit', 'Save', and 'Continue'.

UCalgary Co-Investigators

Select any Co-investigators at the University of Calgary that are **listed on any applicable REB or ACC certifications** for this study/project.

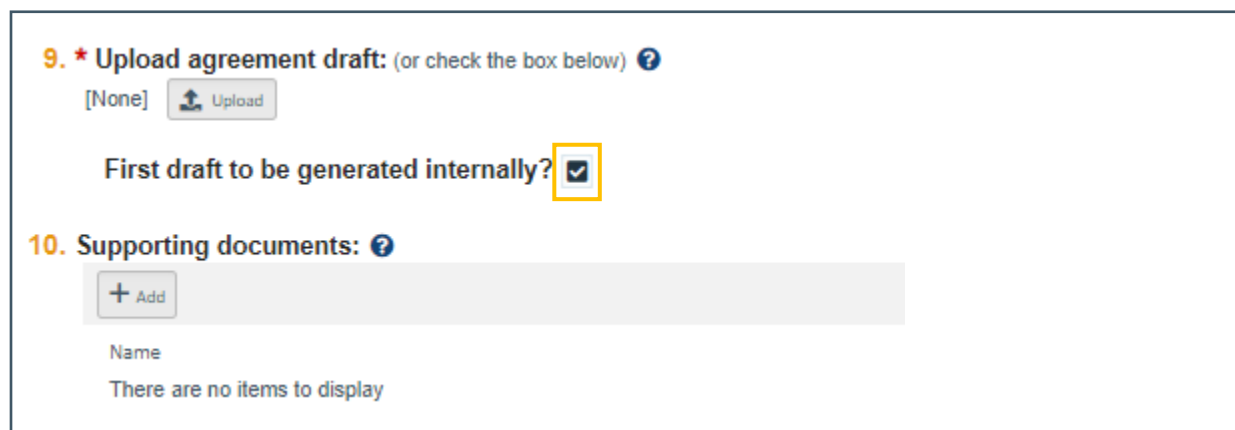
Be sure to also identify any Co-Investigators that would like access to the agreement in IRISS.

Co-Investigators can edit the agreement submission **but will not receive any system notifications and cannot submit the agreement.**

Upload Draft Agreement

If the agreement document has already been drafted by the counterparty, attach it in Word format to the agreement submission by clicking the Upload button.

If the **counterparty does not have a draft** to provide and/or you require CSM Legal to create the first draft of the agreement, check the “**First draft to be generated internally**” box.



9. * Upload agreement draft: (or check the box below) ?

[None]

First draft to be generated internally?

10. Supporting documents: ?

Name

There are no items to display

Add any and all supporting documents that are relevant to the agreement. Note that the more information CSM Legal has, the easier the review.



Tip: Kinds of supporting documents you should include:

Budget

Submit a budget document in Word or Excel format that clearly identifies relevant budget line items for any outgoing or incoming funding related to this agreement. If the budget is included in the body of the agreement, please upload it as a separate document. *Note that for Clinical Research Contracts (CRCs)/Clinical Trial Agreements (CTAs), the Calgary Centre for Clinical Research (CCCR) finance team will review, make recommendations, and negotiate (if required), and approve the budget.*

Protocol

Submit the final research protocol in Word or PDF format. The protocol will be reviewed by CSM Legal to ensure that the terms and conditions of the agreement align with the protocol. In most instances, the protocol will also be attached to the agreement.

Other

Other relevant documents include: (i) a Statement of Work setting out the services or research to be conducted by the research team at UCalgary or the counterparty pursuant to the agreement, (ii) any relevant correspondence, (iii) any relevant contracts or agreements such as the prime agreement, (iv) and any other documentation that you think would assist CSM Legal in understanding the agreement, Study or research project in order to conduct a thorough and efficient legal review.

General Information Fields

Counterparty Information

Select the name of the counterparty on the agreement from the dropdown list provided. If the counterparty cannot be found, select **Not Available** and enter the name of the counterparty in the provided field.

The screenshot shows the 'General Information' section for editing agreement CTA00000019. The 'Counterparty Information' field is highlighted with a yellow box. Below it, a dropdown menu for 'Select Organization' is also highlighted with a yellow box, showing a list of organizations with columns for 'Name', 'Org ID', and 'Category'. The 'Not available' option is selected in the dropdown.

Selecting Certifications

IRISS will display all available ACC or REB studies where the Principal Investigator listed on the agreement is found within the ACC/REB studies.



What studies show under the REB/ACC section?

All studies where the PI on the agreement is found in an ACC or REB application will be listed.

They do not have to be the PI on the REB or ACC application (i.e., they can be a Co-Investigator on the REB/ACC application but the PI on the agreement).

The screenshot shows the '5. * Select any required certifications/permits associated with this agreement:' section. The 'ACC/REB Studies:' dropdown is highlighted with a yellow box. Below it, a table is shown with columns for ID, Short Title, Study PI, Study Co-Is, State, Submit Date, Original Effective Date, Current Effective Date, and Current Expiry Date. The table is empty, and the text 'There are no items to display' is shown below the table.



I have an REB or ACC study that is not showing in the agreement application, why?

It could be one of two reasons:

1. Someone listed on the REB or ACC application has an **inactive IRISS account** and is causing the import to fail.
Solution: Reactivate the inactive account OR Remove the inactive study team member from your REB or ACC application and re-save.
2. The account for the PI is different in the CSM module than it is in the REB / ACC application.
Solution: Update the REB/ACC application with the account used in the agreement application.
Contact [IRISS helpdesk](#) if you require further support to resolve this.

Budget

Insert the estimated total amount of funding being provided pursuant to the agreement, **including the applicable overhead**.

For studies with a per patient budget, the estimated total amount of funding should be **the maximum amount of funding** that could be provided.

I.e., the amount of funding per patient x the anticipated number of patients + any additional study funding costs (e.g., start-up fees, REB fee, etc.) + the overhead fee (please refer to the [Research Overhead Procedure](#)).

Submit an Agreement

1. Check if all the information is accurate and complete.
2. Click **Finish or Exit** to go to agreement workspace.
3. At the left of the workspace, click **Submit**.
4. Click **OK** to accept the statement and submit the agreement.



Note: By default, the **person who creates** an agreement is assigned as the **Primary Contact** in the system. The Primary Contact can be changed however in that case, the person who creates the agreement will no longer have read and write permissions, or the ability create amendments.



Tip: You can click the **History** tab from the agreement workspace to view who **submitted** the agreement.

Clarification Requests

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.

To Respond to a Clarification Request

1. From **My Inbox**, click the agreement name to open it.
2. Look for the **Clarification Requested** activity link and review any reviewer comments.
3. If required, click **Edit Agreement** on the left and make the changes.
4. Click **Submit** to execute the activity.
5. In the **Notes** box, type a response to the reviewer's comments or questions.
6. Click **OK**.

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

➔ **Note:** In case you have changed the agreement type, make sure to **complete the related pages** of the agreement type in the SmartForm.

The system will validate and present an error message if any pages or mandatory entries are blank. Only when the validation is approved with no error messages can the change(s) be submitted.

The screenshot displays the IRISS system interface for a 'Clarification Requested' activity. The top navigation bar includes 'Dashboard', 'CSM Legal', 'Agreements', 'Reports', and 'Help Center'. The main content area shows the agreement details for 'Test 2' (NDA00000002), including the primary contact, owner, created date, and agreement type. A workflow diagram illustrates the process from 'Pre-Submission' to 'Active', with a 'Clarification Requested' step highlighted. The 'Next Steps' section on the left lists actions like 'Edit Agreement', 'Print Version', and 'Submit'. The 'History' table at the bottom shows the 'Clarification Requested' activity with its author and date.

| Activity | Author | Activity Date |
|-------------------------|------------------|-------------------|
| Clarification Requested | Vivian, Winifred | 3/26/2024 1:38 PM |

Create and Submit an Amendment

You can create amendments for agreement in the **Active or Expired** state. Only one amendment can be in progress at a time.

➔ **Note:** You can **add or replace Primary Contact** and collaborators for an agreement without creating an amendment. This can be done through **Manage Access** activity from the parent agreement workspace. Primary Contact has the same edit rights to the amendment as the Principal Investigator (PI).

➔ **Note:** Unique CSM ID numbers are assigned to amendments based on the number of amendments that have been **initiated in IRISS** – not the final number processed.

I.e., If you start 3 amendments but only the second version is processed, the number will be XXXXXXXX-AM3.

Create an Amendment

The screenshot shows the IRISS dashboard with the 'My Reviews' section active. The 'My Reviews' tab is highlighted in yellow. Below the tab, there is a search bar and a table of reviews. The table has columns for ID, Name, Date Created, Date Modified, State, and Coordinator. One review is listed with ID NDA00000001, Name Kimberley Test, Date Created 3/25/2024 11:34 AM, Date Modified 3/25/2024 11:56 AM, State Active, and Coordinator Test agreementsreviewer. The 'My Reviews' tab and the first row of the table are highlighted with yellow boxes.

1. From the Dashboard, find and click the **name of the agreement** under My Reviews.
2. Click **Create Amendment** activity in the left side menu.
3. Make necessary changes and **add a draft amendment document** or request CSM Legal to draft an amendment. Add any other supporting documents.
4. Click **Continue** to move to the next page or use the left menu to jump to a specific page. If the amendment includes additional funding, ensure you update the **Budget** page with the total amount of funding that include the original amount plus the additional funding.
5. When satisfied with your changes, click **Save**, and then **Exit**.
6. At the left of the workspace, click **Submit** to submit the amendment for review.
7. Click **OK** to confirm the amendment is complete and correct.

Note: When you initiate an amendment, the documents previously uploaded as an agreement or supporting document in the parent agreement or previous amendment **will not be present/accessible** in the amendment application. You are **required to submit any draft amendment or supporting documents** for the amendment.

The screenshot displays the IRISS CSM Legal interface for an agreement titled "Test" (ID: NDA00000001). The agreement is currently in the "Active" state. The workflow diagram shows the following stages: Pre-Submission, Unassigned (with a sub-stage for Clarification Requested), Pending Legal Review, In Review (with a sub-stage for Clarification Requested), Signing, Pending Completion, and finally Active. The interface includes a sidebar with options like "Create Amendment" (highlighted in a yellow box), "Manage Access", and "Manage Relationships". The main content area shows agreement details such as "Original_Agreement.docx(0.01)", "Original_Agreement.pdf(0.01)", and "Counterparty: Pfizer Canada". Below the workflow, there is a "History" section with a table of activities.

| Activity | Author | Activity Date |
|-------------------------------|--------------------|--------------------|
| Administrative Change | CHRISTINA.M. PAASE | 3/25/2024 11:56 AM |
| Activated | CHRISTINA.M. PAASE | 3/25/2024 11:56 AM |
| Moved to Pending Completion | CHRISTINA.M. PAASE | 3/25/2024 11:54 AM |
| Sent for AdobeSign Signatures | CHRISTINA.M. PAASE | 3/25/2024 11:54 AM |
| Converted to PDF | CHRISTINA.M. PAASE | 3/25/2024 11:54 AM |

Amendments to Agreements Submitted through SharePoint

For amendments needed for agreements previously processed through the SharePoint process, you will need to **upload the prime agreement into IRISS** before you initiate the amendment process.

1. **Create** a new agreement.
2. Select the **agreement type** based on the prime agreement.
3. Upload the fully executed **original agreement**.
4. Upload **supporting documents** – include all relevant documents for the original agreement and any previous amendments processed in SharePoint.
5. Upload the **budget** for the prime agreement.
6. Include a **comment noting this is an agreement previously processed in SharePoint** and can be expedited in order for an amendment to be processed in IRISS.

Once the primary agreement has been processed and is in the system, you will **receive a notification** the primary agreement is now **Active**. You can then begin the amendment process outlined above.

View the Amendment Workspace From the Parent Agreement

1. From your CSM Legal workspace, open your **Active Agreements** tab.
2. Locate the **agreement title** and click to open the Agreement Workspace.
3. Click the **Go to Amendment** button OR open the **Amendments** tab.

The screenshot displays the IRISS CSM Legal workspace for an agreement titled "Test" (ID: NDA00000001). The interface includes a navigation bar with "Dashboard", "CSM Legal", "Agreements", "Reports", and "Help Center". The main content area shows agreement details such as "Primary contact", "Owner", "Created", "Received", "Modified", "Effective", and "Expires". It also lists "Agreement Type", "Office", "Faculty/Department", and "Full Study Title". A workflow diagram illustrates the process from "Pre-Submission" to "Active", with intermediate steps like "Unassigned", "Pending Legal Review", "In Review", "Signing", and "Pending Completion". A "Next Steps" section contains buttons for "View Agreement", "Print Version", and "Go to Amendment". Below this, a table titled "Amendments" lists the following entry:

| ID | Name | Amendment Description | State | Date Created | Amendment File (Final) |
|----------------|----------------------|-----------------------|----------------|-------------------|------------------------|
| NDA00000001AM1 | Amendment for Test 1 | test | Pre-Submission | 3/25/2024 5:22 PM | |

From the parent agreement workspace, you can find information about related amendments under:

- **Amendments tab:** Displays list of amendments initiated for the agreement along with its ID, description, state, and final amendment document link (if any).
- **Documents tab:** Displays name and IDs of the agreement project along with the list of final agreement and amendment files and any supporting documents (in ascending alphabetical order) uploaded in the parent agreement and amendments.



Tip: You can click the **History tab** from the amendment workspace to view who created and submitted the amendment along with activity date and time.


Manage Access

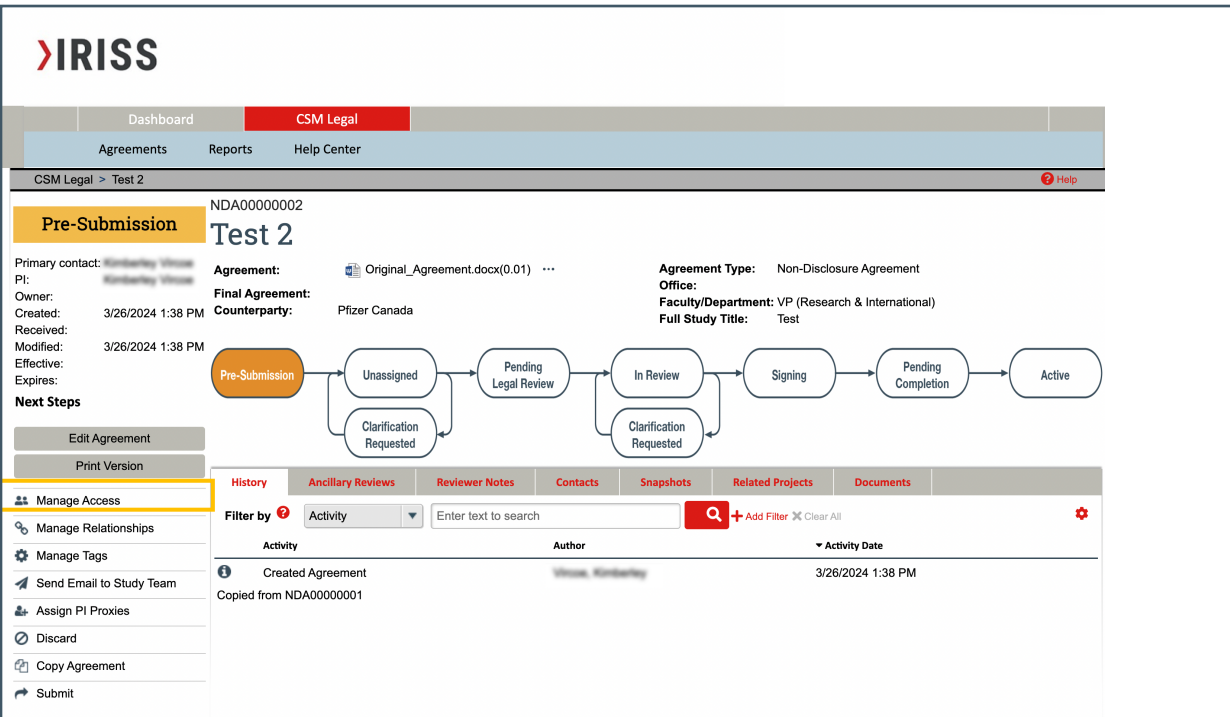
You can add or replace study staff (collaborators) or a Primary Contact in an agreement in any state without going through the amendment process.

This action is done through **Manage Access** activity which can be executed only in the parent agreement by the PI, Primary Contact, or Agreement study staff.

Add or Replace Primary Contact or Collaborators in an Agreement

1. From the **My Reviews** tab, click the agreement name to open it.
2. On the left, click **Manage Access** activity.
3. To add or replace the Primary Contact, next to the Primary Contact field, **click the ellipsis** and select a primary contact, and then click **OK**.
4. To add one or more collaborators, next to the Agreements Collaborators field, click the **ellipsis** and select the collaborator(s) and then click **OK**.
5. When done, click **OK**.

 **Note:** The changes made through this activity will immediately **reflect in the parent agreement** and as well as in the related amendments.



The screenshot displays the IRISS CSM Legal interface for an agreement named 'Test 2' (ID: NDA00000002). The agreement is currently in the 'Pre-Submission' state. The interface includes a navigation menu on the left with 'Manage Access' highlighted. The main content area shows agreement details such as 'Primary contact', 'PI', 'Owner', 'Created', 'Received', 'Modified', 'Effective', and 'Expires'. It also displays the 'Final Agreement' as 'Pfizer Canada' and the 'Agreement Type' as 'Non-Disclosure Agreement'. A workflow diagram shows the progression from 'Pre-Submission' through 'Unassigned', 'Pending Legal Review', 'In Review', 'Signing', 'Pending Completion', and finally 'Active'. The 'History' table at the bottom shows a record for 'Created Agreement' on 3/26/2024 at 1:38 PM.

Reference Tables

Agreement States

| State | Summary |
|-------------------------------|---|
| Pre-submission | The agreement has been created and has not yet been submitted to CSM Legal for processing. Once the agreement submission is complete, go to the agreement dashboard and execute Submit activity to submit agreement to CSM Legal for processing. |
| Unassigned | The agreement has been submitted to CSM Legal for initial review. From this state the agreement will be picked up for initial review and moved to the Internal Review state. Once the initial review is complete, the agreement will be moved to Clarifications Requested whereby the agreement will be sent back to the PI and Primary Contact, or it will be moved to Pending Legal Review . |
| Internal Review | Applies to agreements being reviewed by CSM Legal during initial review. |
| Clarifications Requested | The agreement has been sent back to the PI and Primary Contact from the Unassigned state or the Internal Review state with questions and comments. |
| Pending Legal Review | The agreement submission is complete and is awaiting legal review by a contract specialist or legal counsel. Agreements will not be moved to this state until the agreement submission is complete and will be reviewed by a contract specialist or legal counsel based on the date the agreement is moved into this state. |
| Internal Review | Applies to agreements being reviewed by CSM Legal during legal review by a contract specialist or legal counsel. |
| External Review | CSM Legal has completed its internal legal review and sent the agreement to the counterparty . |
| Language Finalized | The agreement has been finalized between CSM Legal and the counterparty. |
| Sent for AdobeSign Signatures | The agreement has been sent for signatures . |

| | |
|---------------------------|---|
| Pending Completion | The agreement has been fully executed and is in final review . Agreements pending active REB or ACC will be in this state until the certificate is issued. |
| Active | The agreement is fully executed , final review is complete and if required, the file has been sent to RSO or Project Maintenance for set up. |

Agreement Types

| Agreement types | Summary |
|---|---|
| Non-Disclosure Agreement (NDA) | An agreement that binds parties to keep confidential information amongst themselves. These can be one-way or mutual. |
| Clinical Research Contract 9CRC) /Clinical Trial Agreement (CTA) | An agreement to perform a research project that is conducted on, or for the treatment of human subjects. Clinical research includes projects where living human subjects, or patient information (including de-identified databases) are used. This category includes clinical trials, observational studies, and clinical service agreements. |
| Non-Clinical Research Agreement | An agreement other than a research grant agreement or sub-contract/sub-grant regarding a research project that is not conducted on human subjects and that does not involve clinical intervention or health information. |
| Research Grant Agreement | An agreement where funding is provided for a research project to advance a scientific, cultural, or humanitarian purpose and the Funder does not dictate how the project should be conducted or request anything in return beyond basic reporting, such as intellectual property rights. |
| Sub-Contract/Sub-Grant | An agreement whereby an external researcher or institution has received funding directly from a Funder and is providing funds to UCalgary for UCalgary to perform part of the research (incoming). Similarly, an agreement whereby UCalgary has received funding directly from a Funder and is providing part or all of that funding to an external |

| | | |
|--|--|---|
| | | researcher or institution to perform part of the research (outgoing). |
| | Data Transfer Agreement (DTA) | An agreement whereby data is being received by UCalgary from an external party for no compensation (incoming), or whereby data is being sent to an external party by UCalgary without compensation for same (outgoing). An outgoing DTA may include the transfer of AHS data. |
| | Material Transfer Agreement (MTA) | An agreement whereby UCalgary is receiving material(s) needed for a UCalgary PI's research from an external party, or whereby UCalgary is sending out material(s) to a third party for that third party's research. |
| | Service Agreement | An agreement whereby UCalgary is either hiring a third party or is being hired by a third party to perform research-related analysis or technical services for consideration. |
| | Master Agreement | A research agreement with a specific third party that UCalgary anticipates collaborating with on multiple future projects. This agreement sets out the general terms and conditions for all future projects/agreements between the parties. |
| | SUB-00 Agreement | A template sub-site agreement drafted by CSM Legal and used for all sub-sites involved in the study. A submission for a SUB-00 agreement must be made in IRISS before any submissions for a Sub-Site Agreement(s) can be processed in order to link the relevant SUB-00 and Sub-Site Agreement(s). Please note that a SUB-00 submission is required in IRISS even if one was previously made in SharePoint. |
| | Sub-Site Agreement(s) | An agreement whereby UCalgary is the lead site and engages third party institutions and researchers who act as sites ("sub-sites") conducting a clinical study or trial in their geographic location. When making a submission for Sub-Site Agreement(s), you are required to link the Sub-Site Agreement(s) submissions to the relevant SUB-00 Agreement in IRISS. |

Agreement Tabs

| Tab | Summary |
|------------------|--|
| History | An overview of all activities executed under this agreement. |
| Ancillary Review | Any notes, comments, or decisions made by an ancillary review assigned to the agreement. |
| Reviewer Notes | A list of any and all Reviewer Notes added within the agreement submission that have to be addressed by the PI or Primary Contact. |
| Contacts | A summary of everyone associated with the agreement as identified in the agreement submission. |
| Snapshots | Set captures of the agreement submission at certain times. |
| Amendments | Will only be visible if amendments have been made to the agreement and will show any and all amendments initiated through IRISS for the agreement. |
| Related Projects | Identifies any agreements that are linked through the activity Manage Relationships . |
| Documents | Any documents submitted, including the draft agreement and any supporting documents. |

Agreement Roles

| Roles | Summary |
|--|--|
| PI (Principal Investigator) | Can create and submit an agreements, create amendments and respond to changes. |
| Primary Contact/PI Proxy | Has same functions as PI. |
| Co-Investigator /Agreement Study Staff | Can edit agreements in pre-submission and respond to a reviewer note when clarification is requested. These roles cannot submit agreements or amendments to CSM Legal. |