

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

User Guide - Researcher

April 2024 - V1

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Navigation and Basic Tasks

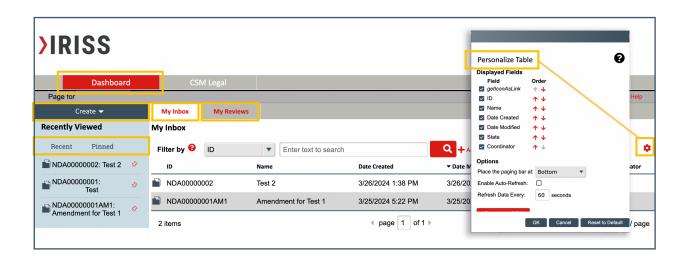
Learn where to go to perform basic actions on an agreement.

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

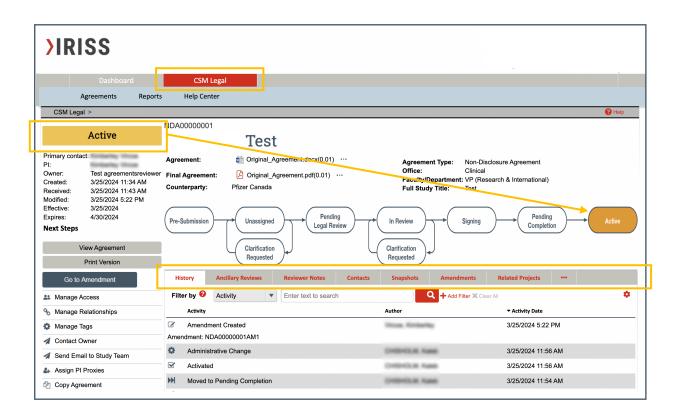
The agreement workflow map gives you an overview of the where the agreement's current state is with respect to the overall workflow of the review process.

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.



Activity menu

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

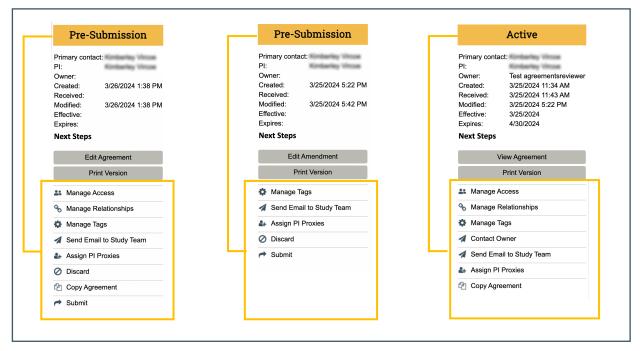
The available links in the menu are dependent on which activities can be executed in the **current state** of the agreement. Different activities will be available in different states.

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.
 - Pls, Primary Contacts and Pl 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.



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**.

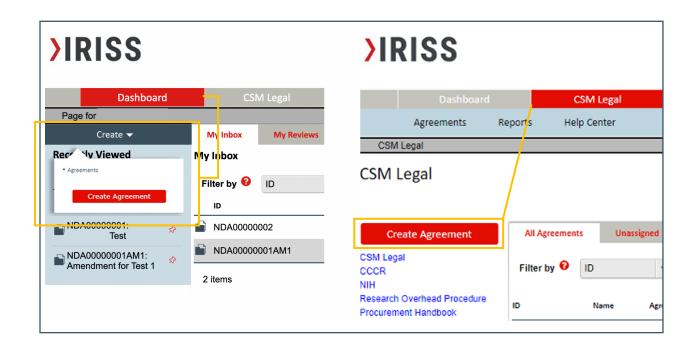
The workspace of the created agreement displays.

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*.



Agreement Upload Page

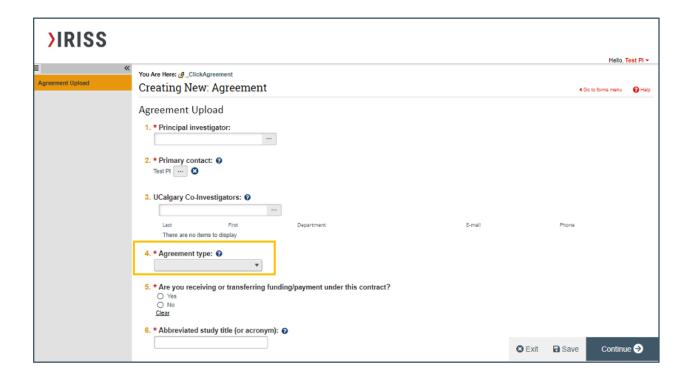
The **Agreement Upload** page is visible for all agreement types.

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 <u>Agreement Types</u> in the Reference Table Section for descriptions of each agreement type.



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.

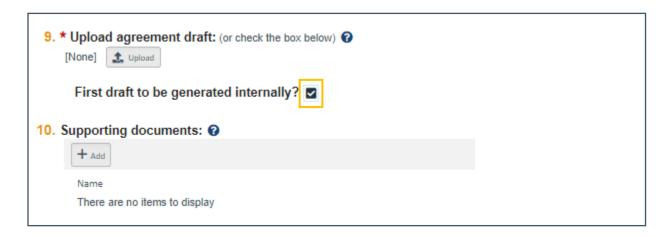
Be sure to also identify any Co-Investigators that would like access to the agreement in IRISS.

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.



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.

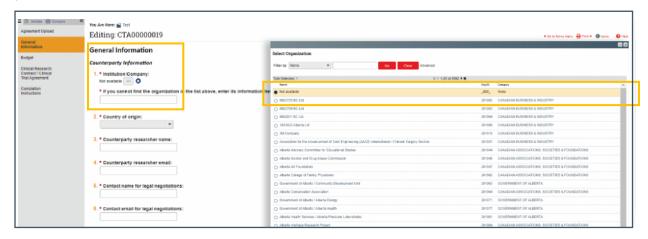
Other

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.



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).



?

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.

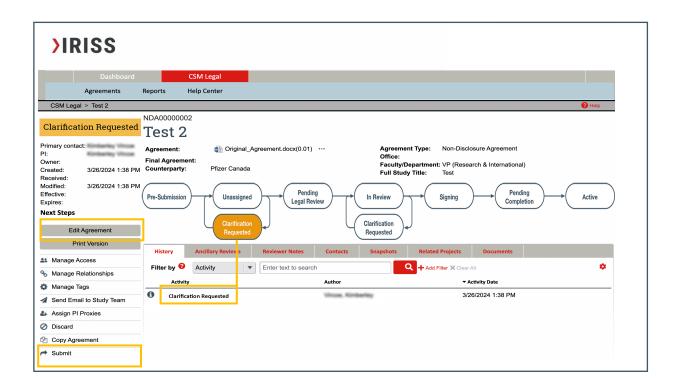


Note: You can enter a response for the reviewer **before** submitting the agreement.



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.



Create and Submit an Amendment

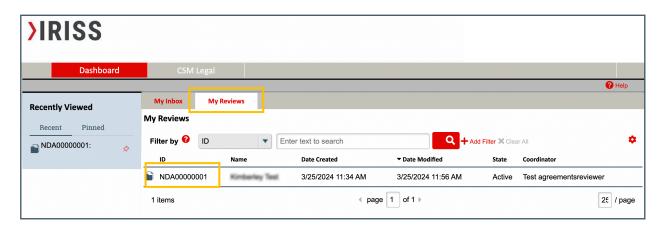
You can create amendments for agreement in the **Active or Expired** state. Only one amendment can be in progress at a time.



Note: 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.

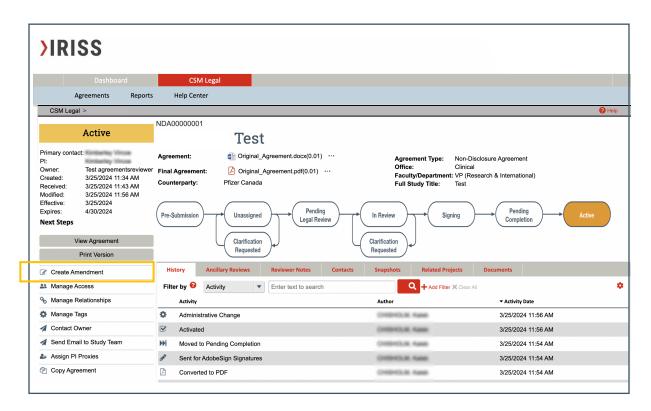
I.e., If you start 3 amendments but only the second version is processed, the number will be XXXXXXXX-AM3.

Create an Amendment



- 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.



Amendments to Agreements Submitted through SharePoint

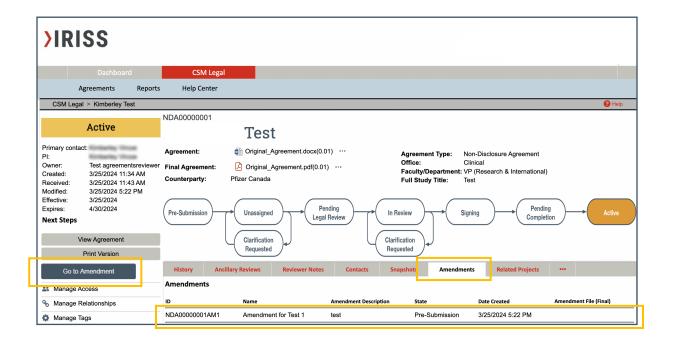
For amendments needed for agreements previously processed through the SharePoint process, you will need to **upload the prime agreement into IRISS** before you initiate the amendment process.

- 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.



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

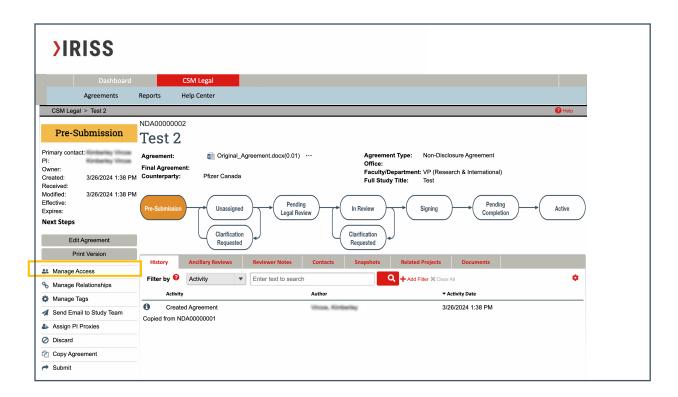
You can add or replace study staff (collaborators) or a Primary Contact in an agreement in any state without going through the amendment process.

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.



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 oneway 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 should be made before any submissions for the subsequent sub-site agreements.
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 UCalgary investigator initiated clinical study or trial in their geographic location.

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.