Hutch IACUC

Researcher's Guide

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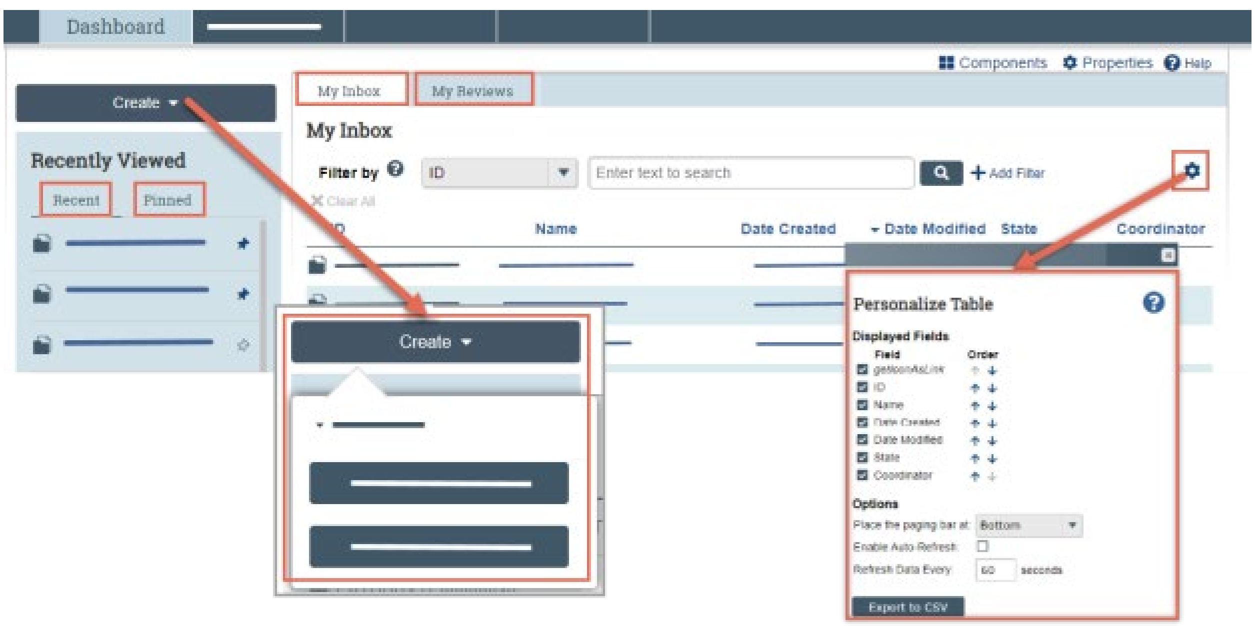
Navigation and Basic Tasks

When you first log in, you land on the Landing page Dashboard tab, which is the starting point for finding items and performing many basic tasks.

To find key items

From your Dashboard, you will see:

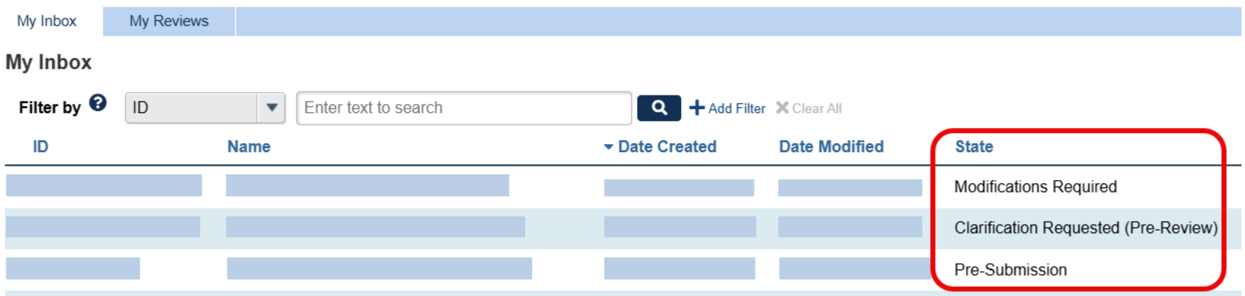
- **My Inbox:** Items that require you to take action.
- **My Reviews:** Items assigned to you to review, such as Concerns where you are identified as the responsible party. These are a subset of the items in My Inbox.
- **Create Menu:** The buttons to create a new Concern or a new Protocol.
- **Recently Viewed:**
  - **Recent:** The last several items you viewed. Scroll through this list to find an item you worked on recently.
  - **Pinned:** You can pin items in the 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 by using the Personalize Table gear icon.



To identify what action is needed

1. Review the **State** column of the items in My Inbox.

   The state gives a clue as to what to do next. For example, the Pre-Submission state means you have not submitted. You can open the submission to finish it and then submit to the IACUC.



To open an item awaiting your action

1. Click the submission name to open the submission workspace.

To view the submission history

1. From the submission workspace, click the **History** tab.
   You can view the list of actions performed on the submission to date, including comments, and an audit of who has completed each action.

To find a submission

1. In the Top Navigator, click **IACUC**.
2. On the Submissions tab, click the subtab matching the state of the submission you wish to find (e.g., In Review, Active, Archived).

   Tip: If you do not know the state, click the **All Submissions** tab.

3. Click the name of the submission in the list to open the submission workspace.

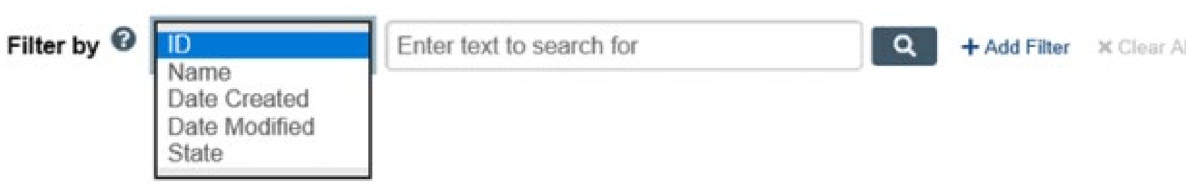
Filter and Sort Data

Many pages contain tables you can filter and sort to help you find the data you want.

- Filtering reduces the list to only the data that meets the criteria. The advanced filter lets you combine multiple filter criteria together.
- Sorting displays the data in ascending or descending order by a particular column.

To filter data

1. Select the column to Filter by from the drop-down menu. The menu lists only the columns you can filter by.
   Note: To combine multiple filter criteria, such as, ID, Name, and Date Created, use the advanced filters, as described below.



2. In the text box, type a % symbol as a wildcard before the characters you wish to search for.
   Examples:

- %71 shows all items containing 71 in any position

> **Tip:** For examples and a list of operators you can use, click the Help icon.
>
> 
>

3. Click the magnifying glass to apply the filter.

The table displays only those rows that are an exact match.

> **Tip:** If you do not see the expected items in the list, click **Clear All** in the Filter By area to remove the filter.

To use advanced filters

1. In the Filter by area, click **Add Filter**.

2. Enter filter criteria as explained in the previous section.
3. To add more criteria, click **Add Filter** once more.
4. Click the magnifying glass to apply the filter.
   The table shows only those rows that match all the filter criteria.

To sort data

1. Click the column header you want to sort by.
2. Click it a second time to reverse the sort order.
   The arrow indicates the column by which the data is sorted and the sort order, either ascending (up arrow) or descending (down arrow).

Note: If the column header is not a link, you cannot sort by that column.

Before You Create a Protocol

Plan out your protocol

- Determine the experiments and the number of animals required.
- Determine the procedures you will perform and the substances required for your experiments.

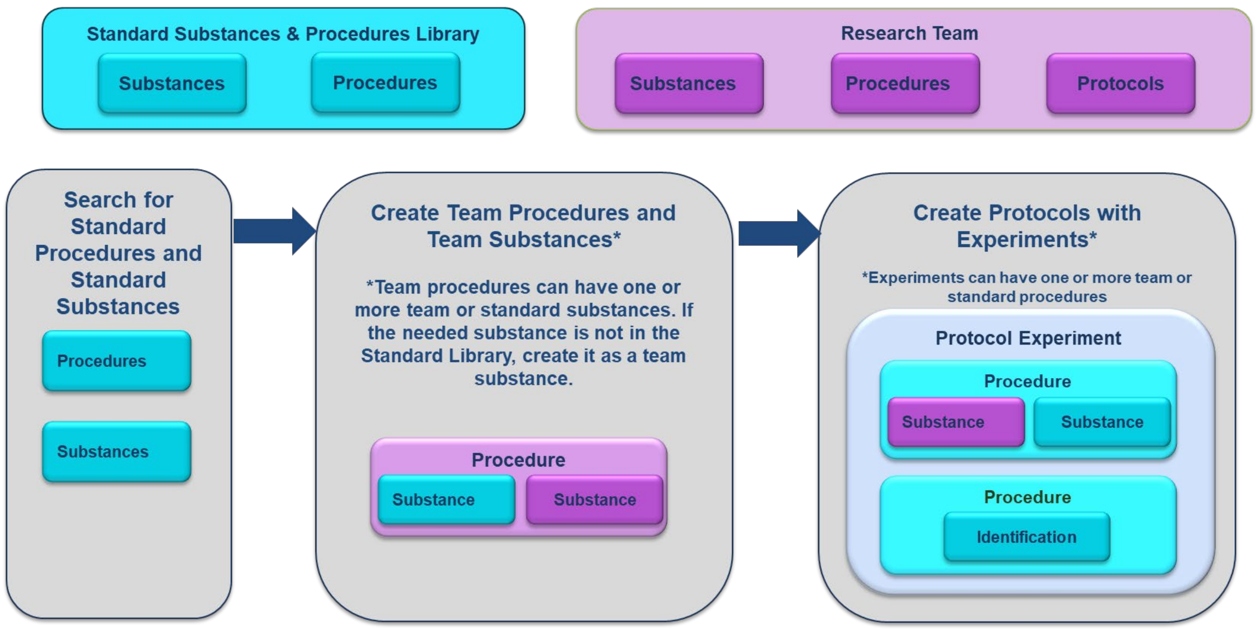
Set up building blocks

Building blocks are the substances and procedures that form the foundation for a protocol. Once they are set up, you can create your protocol. The diagram below shows the concept of building blocks.

- Check the Standard Library for the procedures and substances required for your protocol experiments.

  If the necessary procedures and substances are not in the library:

  - Create the missing substances
  - Create the missing procedures

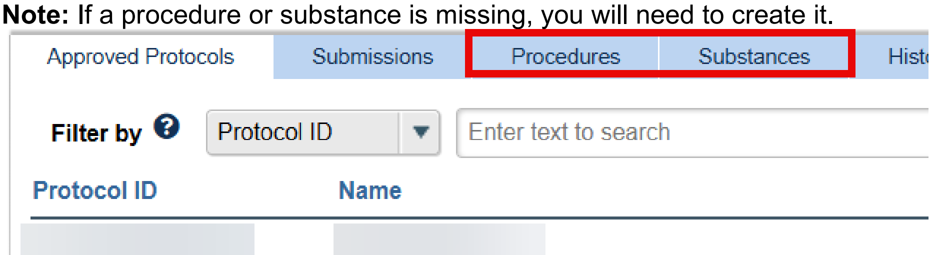


Check for Existing Building Blocks

Check the system to see if there are standard building blocks that you can use in your protocols.

To check for building blocks

1. In the Top Navigator, click **IACUC**.
2. On the Research Teams subtab, click the name of your research team (if you do not have a research team, contact iacuc@fredhutch.org).
3. On the research team workspace, click the **Procedures** subtab and check for the procedures you need. Do the same for substances (on the Substances subtab).
   Note: If a procedure or substance is missing, you will need to create it.



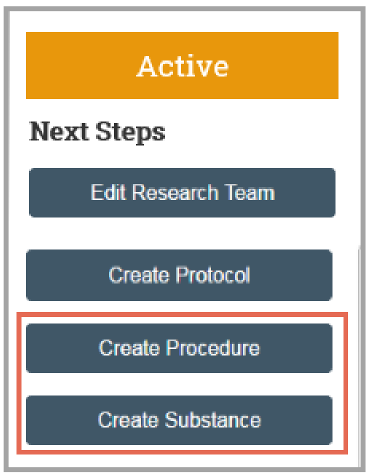
4. If the building block exists, review its details:
    a. On the Procedures or Substances subtab, click the item name.
    b. In the item’s workspace, click **View Procedure** or **View Substance**.

Create Building Blocks

After you have checked the system for standard building blocks, create any Substances and Procedures that are required for your protocol and that are not available as standards.

To Create a Substance or Procedure

1. From the research team workspace, click **Create Substance** or **Create Procedure**.
   Note: Create the Substances you will use in your Procedures before creating the procedures.



2. Complete all pages, clicking **Continue** to move through the pages.
3. On the final page, click **Finish**.
   The respective **Substance** or **Procedure** appears on the corresponding research team workspace subtabs.

Create and Submit a Protocol

Once all the building blocks are set up, you are ready to create your protocol.

To Create a Protocol

1. From your Dashboard or the research team workspace, click **Create Protocol**.

2. Complete all pages, clicking **Continue or using the left navigator** to move through the pages.
3. Pay attention to the following pages:
   a. **Protocol Team Members**: Add each person who will work on the protocol (all animal handlers, administrative staff, and co-investigators). Do not add the PI here.
   b. **Experiments**: When you add an experiment, select the procedures that apply. If the selected procedure contains a nested procedure, it will be automatically added in the experiment. A team procedure referenced by at least one other approved protocol is prefixed with a check mark.
4. On the final page, click **Finish**.
   The protocol workspace appears.

Note: You can continue to edit the protocol until you submit it for review.

To submit a protocol for review

1. From the protocol workspace, click **Submit**.
2. Click **OK** to agree to the statement and submit the protocol for review.

Request Pre-Submission Assistance

The PI or a protocol team member can request assistance from IACUC staff or veterinarians before submitting a protocol for the formal IACUC review process. The **Request Pre-Submission Assistance** activity allows you to request feedback and comments on specific aspects of a submission. The activity is available when a submission is in the Pre-Submission state.

After you submit the request, IACUC staff will assign a vet or an IACUC coordinator to provide assistance, based on the type of assistance requested.

To request pre-submission assistance

1. From the submission page, click the submission you need assistance for.
2. Click **Request Pre-Submission Assistance**.
3. Select assistance type you require (either IACUC Staff or Veterinarian).
4. Complete the form, indicating the SmartForm pages, questions, and/or procedures for which input is requested, and the specific input needed.
5. Click **OK**.
   The submission moves to the Pre-Submission Assistance state and the Submit activity no longer displays in the submission workspace.

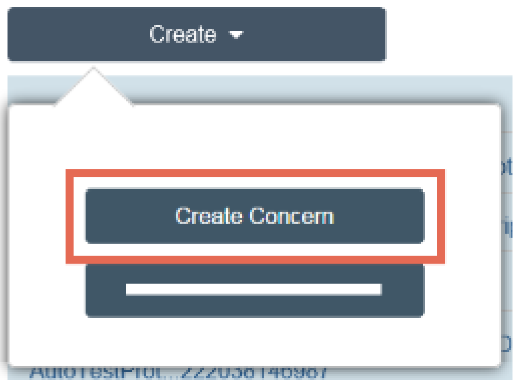
6. The assigned IACUC Staff or Veterinarian will submit a reply to the Pre-Submission Assistance request in the system.
7. The submission returns to the Pre-Submission state and the PI and all protocol team members are notified via email that the pre-submission assistant has provided input on their submission.

Create a Concern

Anyone with Hutch IACUC access can enter a concern or reportable event.

To submit a concern

1. From the Dashboard, click **Create** menu and then click **Create Concern**.



2. Complete all the questions on pages one and two, the remaining pages are for IACUC staff only.
3. When done, click **OK** to return to the Concern workspace**.**
4. Form the Concern workspace click **Submit**. The concern will move to the pre-review state and will no longer be visible to the creator.

Respond to a Clarification Request

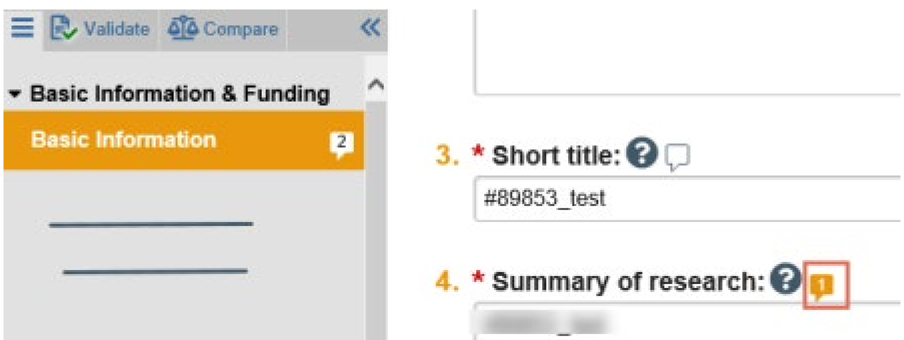
If a reviewer has questions or requires you to change your submission, the PI, PI proxy and the primary contact will receive an email notification indicating this. Review the request details and then respond to the request.

To review the request details

1. Click the email link to open the submission or, open the submission from My Inbox.
2. On the History tab, find either the “Clarification Requested…” activity or the “Modifications Required” letter and read the comments. Generally, the comments will refer you to the reviewer notes.
3. If there are reviewer notes, they will be available in read-only mode on the **Reviewer Notes** subtab.

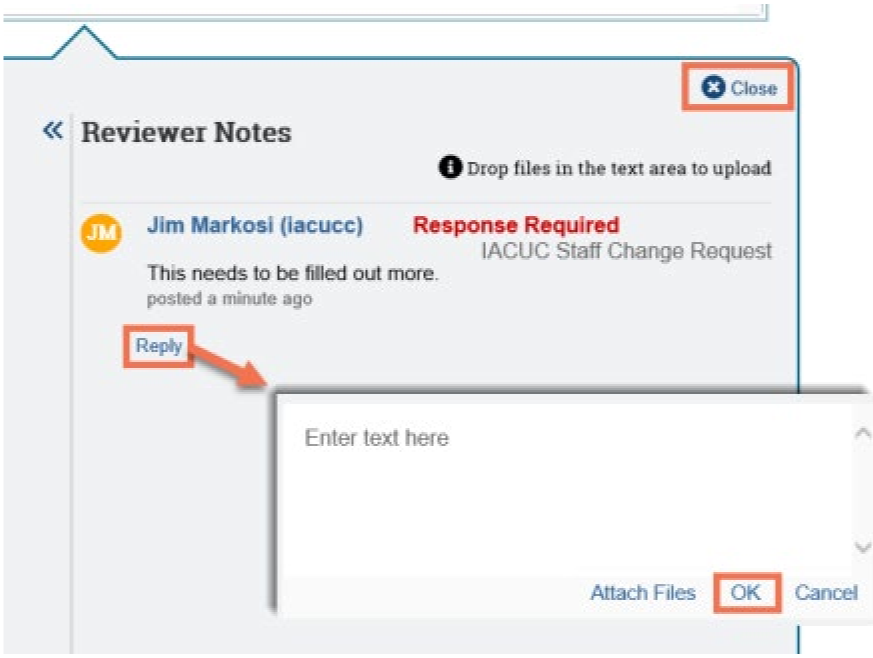
To respond to a reviewer note

1. From the **Reviewer Notes** subtab on the submission workspace, click the page or question link to go to that submission page.
2. On the page, click the orange note icon to open the reviewer note dialog box.



3. Read the request. Edit the submission as appropriate.
4. Reopen the reviewer note dialog box and click **Reply**, type a response, and click **OK**.

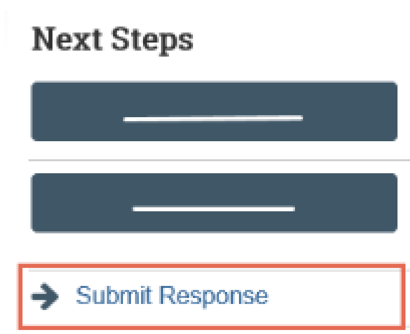
   Note: A reviewer note that is labeled Response Required means the submission can’t move forward in the workflow until you respond to the reviewer note.



5. Close the reviewer note.
6. On the Left Navigator look for any other pages that contain orange note icons and respond to all remaining reviewer notes.
7. Once all reviewer notes are responded to and you are done making edits, exit the protocol SmartForm and submit the response.

To submit a response

1. Only the PI or the PI proxy will see the Submit Response activity on the protocol workspace. Click **Submit Response**.



2. In the Comments box, type your response if desired.
3. Click **OK**.

Create and Submit a Follow-On Submission

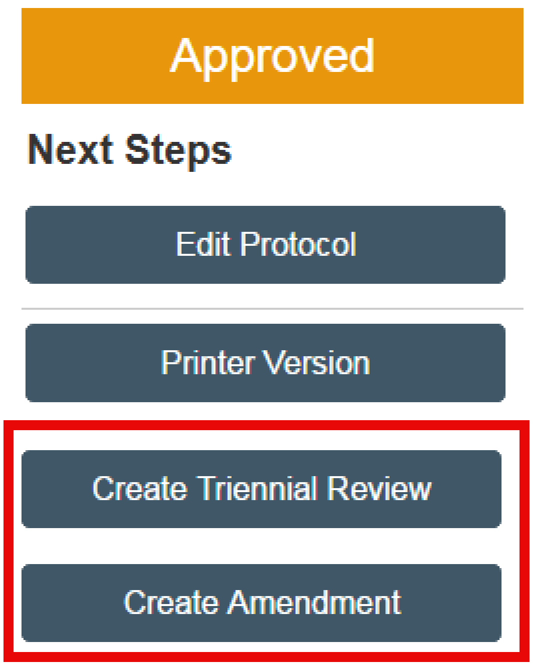
If you need to make changes to an approved protocol or submit a triennial review, you can create the following follow-on submissions:

- **Triennial Review:** A review of an approved protocol that is conducted every three years.
- **Amendment:** Created to submit a change to an approved protocol.

Note: Only one submission can be working thru the system at a time. If an amendment or triennial is already in review, another submission cannot be created.

To create a follow-on submission

1. In the Top Navigator, click **IACUC**.
2. From the Research Teams tab, click the name of your research team.
3. Select the name of the approved protocol.
4. Click the appropriate **Create** button (Triennial Review or Amendment).

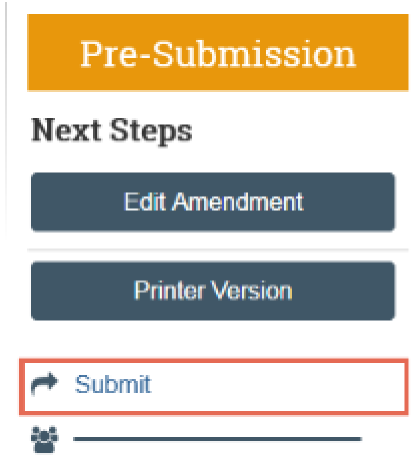


5. Complete the pages. Click **Continue** to move to the next page.
6. When done, click **Exit** or click **Finish** on the final page.
   The submission workspace appears.

Note: You can continue to edit the submission until you submit it for review.

To submit a follow-on submission for review

1. From the follow-on submission's workspace, click **Submit**. (This activity will only be visible to the PI and the PI proxy.)



2. Click **OK** to agree to the statement and submit it for review.