



Huron Safety Researcher's Guide

October 2022

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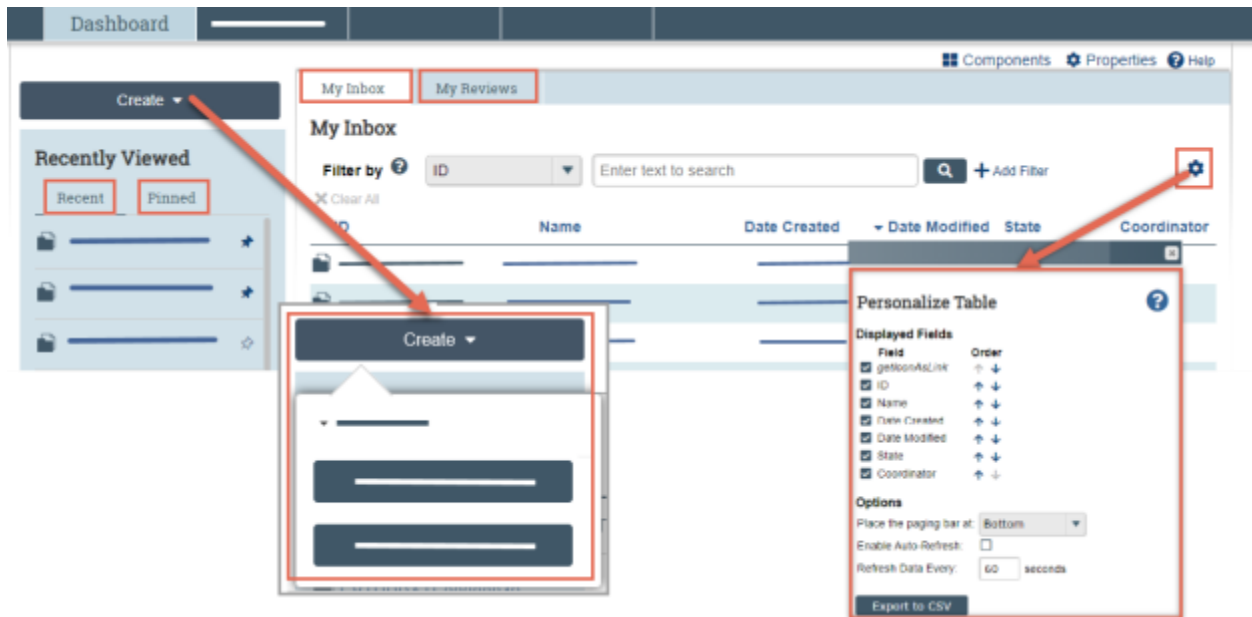
Navigation and Basic Tasks

When you first log in, you will be on the Dashboard. This topic lists where to find Safety protocols and the basic tasks you will perform.

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. These are a subset of the items in My Inbox.
- **Create menu and buttons:** Actions you can perform. The menu will not show if you do not have access to any buttons.
- **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 by using the Personalize Table gear icon.



To identify what action is needed

1. Review the state of submissions in My Inbox.
The state gives a clue as to what to do next. For example, Pre-Submission state means you haven't submitted the Safety protocol.

My Inbox

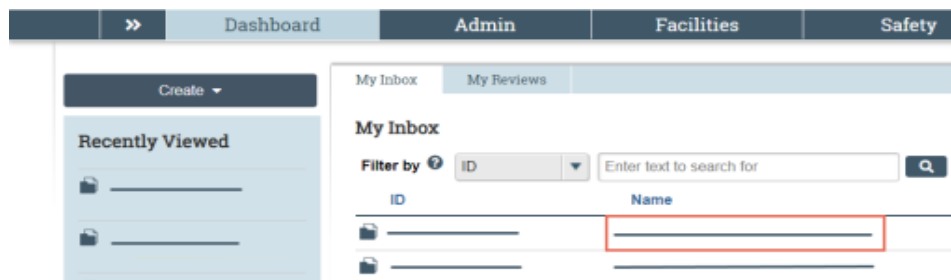
Filter by ? ID ▼

ID	Name	Date Created	▼ Date Modified	State
	_____	_____	_____	Pre-Submission
	_____	_____	_____	Modifications Required

2. You can finish and submit the Safety protocol for review.

To open a submission

1. From My Inbox, click the submission name.
The submission workspace opens.

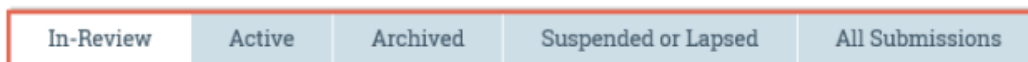


To view submission history

1. From the submission workspace, click the **History** tab.
The history lists the activity taken on a submission, including any comments, attachments, or correspondence added.

To find previous submissions

1. From the Top Navigator, click **Safety**.
2. Click the appropriate tab to see all of your submissions:
 - **In-Review**: All submissions undergoing Safety committee review.
 - **Active**: All approved submissions.
 - **Archived**: All discarded and closed submissions.
 - **Suspended or Lapsed**: All submissions that have been suspended or have surpassed the continuing review due date.
 - **All Submissions**: All submissions, in any state.

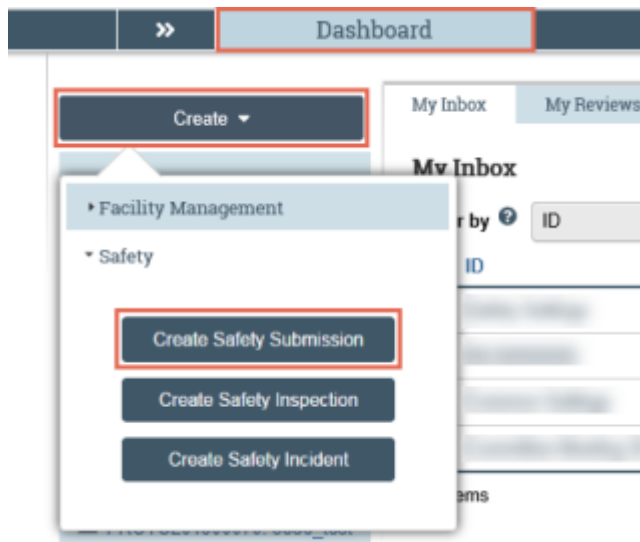


Create and Submit a Protocol

When you create a Safety protocol, you will complete a series of pages. The number of pages depends on the type of review required like biosafety, chemical safety etc.

To create a protocol

1. From the Dashboard, click the **Create** menu and then select **Create Safety Submission**.

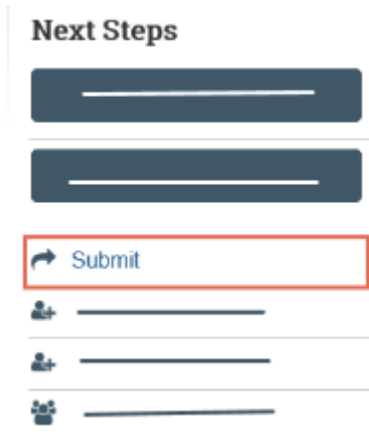


2. Complete the pages. To move to the next page, click **Continue**.
3. On the last page, click **Finish**.

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

To submit a protocol for review

1. From the submission workspace, click **Submit**.



2. Read the statement and select the check box if you agree with the statement.
3. Click **OK** to submit the protocol for review.

Copy a Protocol

Copying a protocol is helpful if the protocols are similar but uses different agents, different funding sources, or have different PIs such as when a PI starting a new but similar research.

When a protocol is copied, all details, including the biosafety summary, agents, toxins, and microorganisms are copied along with it. Once the protocol is copied, the new protocol and other details like biosafety summary, Risk management details can be edited before the new protocol is submitted for review and approval since it is in the Pre-Submission state.

To copy a protocol

1. In the Top Navigator, click **Safety**.
2. Click the **All Submissions** tab.
3. Click the protocol name you want to copy.
4. On the protocol's workspace, click **Copy Submission**.



5. Type a name for the new protocol in the New submission name box.
6. Click **OK**.
You are taken back to the protocol workspace.

7. On the **History** tab, click the new protocol ID link.

The new protocol workspace appears.

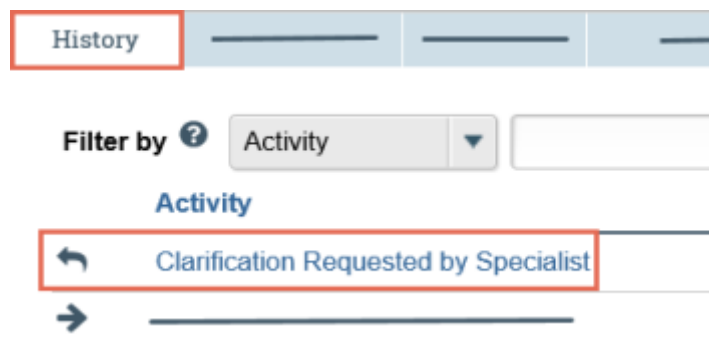
Note: You need to refresh the page until the new protocol link appears in the **History** tab.

Respond to a Clarification Request

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

To review the request details

1. Click the e-mail link to open the submission. If you no longer have the e-mail, click the name of the submission from My Inbox. See [Open a Submission](#) and then [View Submission History](#) to see reviewer comments.
2. From submission workspace, click **History** tab to view the reviewer comments.
3. On the History tab, click the **Clarification Requested...** activity and read the comments.



4. If the reviewer added reviewer notes, click the **Reviewer Notes** tab and respond to each note. If not, you can submit the response.

Note: Response Required means the protocol cannot move forward in the workflow until you respond to the Reviewer Note.

To respond to reviewer notes

For each reviewer note:

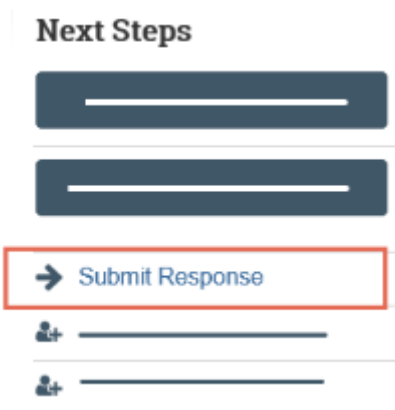
1. Click the name of the question to jump to that question in the SmartForm.



2. On the page, click the Note icon to view the Reviewer Note.
3. Click **Reply** and then type your response.
4. Attach files if needed and click **OK**.
5. Close the Reviewer Note.
6. Respond to all other Reviewer Notes and when done, submit the response.

To submit the response

1. On the protocol workspace, click **Submit Response**.



2. In the Comments box, type a response for the reviewer.
3. Click **OK**.

View the Change Log

If the protocol team made changes to the submission, you can view the changes on the Change Log tab. The Change Log shows changes only after the submission has entered the Pre-Review state. For approved protocols, the Change Log shows only the changes made on the initial submission. Changes from amendments are logged in the Change Log for the amendment.

To view the change log

1. From My Inbox, click the name of the submission to open it.
2. In the submission workspace, click the **Change Log** tab.
The tab lists the protocol page, the item on the page that changed, the original and new values, who made the change, and date of change.

History	Documents	Reviews	Contacts	Training	Related Projects	Change Log
Page	Location of Change	Original Value	New Value	User	Date of Chang	
Amendment Introduction	Safety Submission.Amendment.summaryOfChanges	test	Description changed	System Administrator	4/6/2020	
« 1-1 of 1 »						

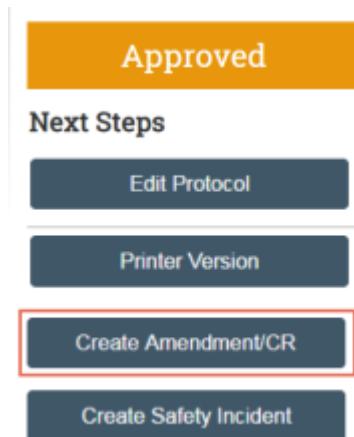
Create and Submit a Follow-On Submission

If you need to make changes to an approved protocol or review it, you can create following submissions:

- **Amendment:** Created to submit a change to an approved protocol. You can submit multiple amendments for review at any given time, including protocol team member changes, providing there is no existing open amendment of the same type.
- **Continuing Review (CR):** Created to request an extension of the approval period for your protocol.
- **Amendment/CR:** Created to request changes to an approved protocol and extension of the approval period in a single submission. Amendment/CR can only be submitted if there is no existing open CR and / or an existing amendment of the same type. The submission follows the same review process as the original protocol submission.
- **De Novo Submission:** Created as a copy of the parent protocol. It is a part of the de novo review process which is a three year approval period. After the approval period, the protocol is started over again. Depending on your institution's settings, you can create and submit de novo review providing there are no active follow-on submissions. Once the de novo submission is approved, the parent protocol moves to closed and the de novo submission becomes an active protocol.

To create an amendment/continuing review submission

1. From the Top Navigator, click **Safety**.
2. On the **Active** tab, select the name of the approved protocol.
3. On the left of the workspace, click the **Create Amendment/CR** button.



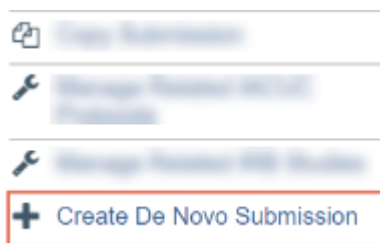
4. Select whether the submission is an Amendment, CR or a combination of both.
5. If your submission is an Amendment or Amendment /CR, select an appropriate amendment type.
6. Complete the SmartForm. Click **Continue** to move to the next page.
7. When done, save changes and click **Exit** or click **Finish** on the final page. The submission workspace appears.

Tips:

- You can continue to edit the submission until you submit it for review.
- You can convert a follow-on submission to another submission type before it is approved. See [Convert an Amendment or CR](#).

To create a de novo review

1. On the left of the workspace, click **Create De Novo Submission**.

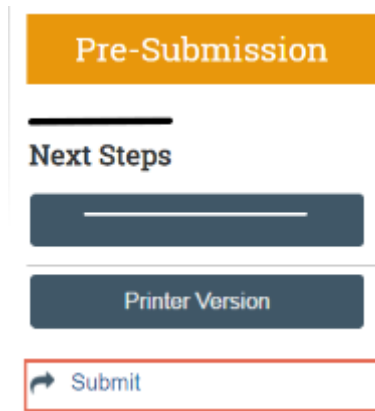


2. Read the statement and select **Yes** to indicate that you are ready to create this De Novo submission.
3. Click **OK**.
4. On the History tab, click the De Novo submission ID you just created to navigate to the submission workspace.

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

To submit the follow-on submission for review

1. From the follow-on submission's workspace, click **Submit**.



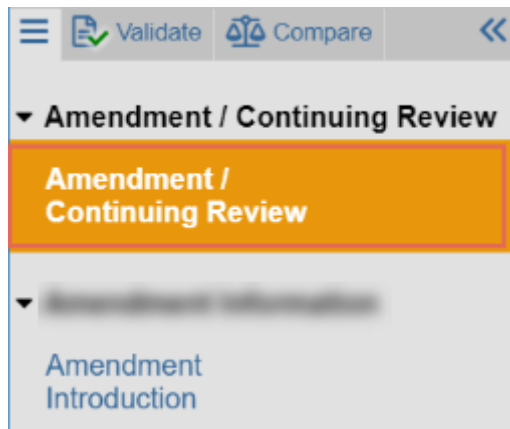
2. Read the statement and select the check box at the bottom in agreement.
3. Click **OK** to submit the protocol.

Convert an Amendment or CR

As a protocol team member, you can convert a follow-on submission to another submission type before it is approved. Once the follow-on submission is submitted, you are only able to convert the submission when it is in an editable state such as Clarification Requested. You can convert a follow-on submission to any other type provided there are no open submissions of the same type. For example, an Amendment can only be converted to an Amendment/CR if there are no open CRs for the protocol.

To convert an amendment or CR

1. From My Inbox, open the follow-on submission.
2. On the left of the workspace, click the **Edit...** button.
3. Click **Amendment/Continuing Review** on the Left Navigator.



4. Change the submission type and click **Save**.
You will notice that SmartForm changes according to your submission.

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

Search Your Solution


To help you work more efficiently, you can use search to locate a wide range of information in your solution. You can search for project data, documents, or content from specific pages on your site. The search results appear in a secondary window and display only those items you have permission to view. Results are ranked to show items where the search term is most prevalent at the top.

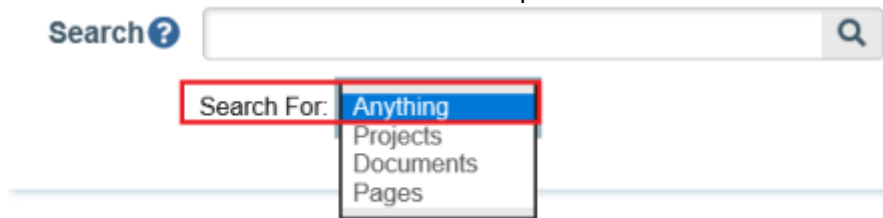
After your initial search, you can further refine results using the following filter options:

- **Projects**— Projects are the day-to-day items you use to manage your research in a Huron solution. They include items such as funding proposals, studies, protocols, agreements, and disclosures. You can search for any project in your solution using properties on the project, including its name, ID, and description. Depending on the solution, other properties are also available to search. When you select the Projects filter, the system will only display results that match search criteria in your project data.
- **Documents**— Documents are third-party files uploaded to your solution outside the context of a project. When you select the Documents filter, the system will only display results that match search criteria from documents. The search includes metadata on a document, such as its name and description. It also includes the contents of a document. From the results, you can click directly on the provided link to open a document.
- **Pages**— Pages organize information on your site into a hierarchy that you can use to view and manage your work. The Pages filter provides a way for you to search one type of page within your solution - content pages. Content pages are presented outside the context of a project. They supply supporting information for your solution, such as the Help Center, Reports, and Meetings. Dashboards and project workspaces are not included with this filter.

Note: Content on the site is updated periodically. If you are searching for something you just added, results might not be available immediately. Try your search again at another time.

To search your solution

1. In the Top Navigator, click **Safety**.
2. In the **Search** box, type your search criteria. You can use the following operators:
 - **And**: Finds all the specified words.
 - **Or**: Finds at least one of the specified words.
 - **Not**: Excludes the specified word. You cannot start a search with the Not operator.
 - **Quotation marks**: Finds the exact phrase.
3. Press Enter or click the search icon  to perform the search.



Please enter search terms

The search results appear.

4. Click the **Search For** arrow to apply filter of your choice.

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