Creating and submitting a modification

Human Research Protection Program
(Last Updated: 01/29/2024)
This PowerPoint will guide you through how to create and submit a modification to an approved IRB protocol.
Getting started

1. Navigate to the IRB workspace
2. Select Submissions tab
3. Select All Submissions tab
4. Note: Filter by allows you to sort through your studies by name, PI first and last name, and submission type.
5. Open your study by selecting the folder symbol or the name of the study.
Creating a modification

1. Select Create Modification/CR
Modification/Update

1. Select Modification/Update***

2. Identify the modification scope (must select at least one option, or both if applicable):
   - Select Study team member information to add new study personnel
   - Select Other parts of the study for all other modifications to the protocol

*** Do not select Modification and Continuing Review unless you are confident that your study requires a continuing review. Most minimal risk studies approved after January 20, 2019 do not require a continuing review, but still must undergo an Administrative Check In (instructions on how to create and submit an Administrative Check In can be found here). To identify if your study requires a continuing review or an administrative check in, please reference your initial approval letter.
How to discard a modification

1. Once you select Save or Continue on the Modification/Continuing Review page, you will not be able to edit your purpose or scope on this page.

2. If an incorrect response was chosen for either “What is the purpose of this submission?” or “Modification scope” and the form has been saved, then click Exit to leave the submission and select Discard from the study record workspace. A new Modification/CR request will need to be created to continue with the modification request.
Complete the Modification Summary

1. Complete the Modification Summary page

IMPORTANT! Provide a brief summary of the modification and a revised copy of your protocol document. All modifications must be added to the written protocol. It is not sufficient to provide the modification in Question 3. The revised protocol must be attached to the Basic Study Information page. If the revised protocol is not provided, the modification will be returned.

2. Select Save and then Continue
Navigate the IRB Application to make edits

Once **Continue** is selected on the **Modification Summary** page, you will be brought to the application to make edits.

1. Use the page navigator on the left side of the screen to locate any pages that need to be edited. The page currently being viewed will be shown highlighted in orange. To view a specific page, click the desired page on the navigator.
2. Click **Save** after making any edits to ensure your work is saved.
3. Once all edits have been made and saved, click **Exit**.
How to attach your revised protocol

Modifications to approved procedures (e.g., participant enrollment, consent process, recruitment) require that you update your protocol document. Attach an updated protocol to the Basic Study Information page:

1. Navigate to the Basic Study Information page
2. Click Update on Attach the Protocol (this can be either Question 7 or 8)
3. Click Choose File and attach your revised protocol and then click OK
Adding/removing TAMU personnel

To add TAMU study team members:

1. Click +Add

   I am trying to add study personnel to an IRB protocol, why am I not able to locate them in the system?

   Some TAMU members (such as undergraduates, visiting scholars, and adjunct/affiliate professors) need to opt into their information being fed into Huron before they are active in the system. If you are not able to locate a member of your research team, have that individual visit the following website: [https://raes.dor.tamu.edu](https://raes.dor.tamu.edu). Note: It will take 24 hours before their information is active in Huron.

2. Complete the Add Study Team Member smart Form
   - Q1 – Type the name of the team member being added or click the ellipsis [...]  
   - Q2 – Identify the role of the team member  
   - Q3 – Identify if the team member will be involved in collecting consent.  
   - Q4 – Identify if the team member has a conflict of interest.

   Important! All personnel being added must have completed CITI training and log into the new Texas A&M SSO CITI URL

To remove study team members:

3. Click the X to the right of the team member.
How to attach new or revised study documents

If you need to add a new or revised study document in response to a clarification requested:

1. Navigate to the Local Site Document page

2. Select +Add to attach a new study document or Update to attach a revised study document. It is important that you select the correct option to ensure good document management.

3. Click Save, then Exit to navigate back to the study Workspace.
Submitting your modification to the IRB

Once you have finished editing the IRB application and saved all your edits:

1. Select Exit to be directed to the IRB Workspace

2. Click Submit

   IMPORTANT! The PI or PI Proxy must click Submit for the submission to be received by the IRB.

3. Click OK
Visit the FAQ webpage

Please take a moment to visit the frequently asked questions webpage Huron FAQ – Division of Research (tamu.edu) to learn more about Huron functionality.