

Huron IRB Quick Reference Guide – How to Submit a Request for a Modification (MOD) and/or Continuing Review (CR).

This guide describes how to submit a request for a Modification (MOD) and/or Continuing Review (CR) on an IRB-approved, active study. These actions are defined as follows:

- **Continuing Review (CR)** – Requests a study closure or an extension of the approval period of your study.
- **Modification (MOD)** – Requests approval of changes to your study.
- **Modification and Continuing Review (MODCR)** – Requests both approval of changes and extension of approval.

Important:

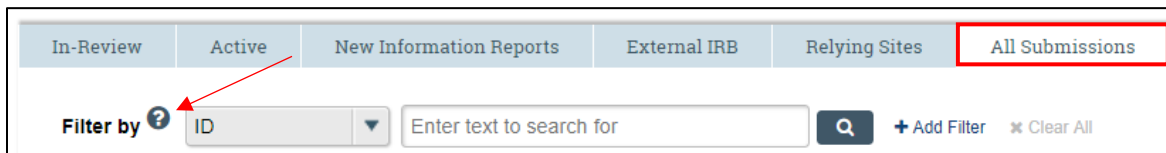
- For studies converted from the iRIS system, select the “Modification and Continuing Review” option if this is the first time you are updating your study for the IRB Office. This allows the ability for you to update information within the study that was not converted from iRIS. Studies converted from the iRIS system to the new Huron IRB system have the same Study ID number.
- For studies not converted from the iRIS system, please create a new study (rather than submit a “Modification and Continuing Review”).

Follow the steps below to submit a Modification (MOD) and/or Continuing Review (CR) request:

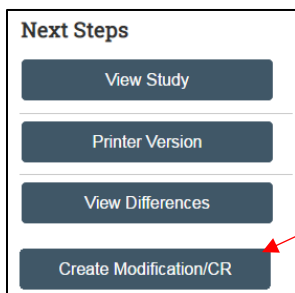
1. Navigate to the Study Workspace. This can be done by selecting the *IRB* tab, selecting the *Active* or *All Submissions* tab, and then selecting or searching for your study. Click the study name to display the Study Workspace.



Note: Click the **Filter by Help** button for quick search tips, including the wild card search using the “%” sign.



2. On the Study Workspace, select the **Create Modification/CR** activity.



3. Complete the series of screens (also known as the “SmartForm”). The screens displayed are based upon the purpose of the submission – **Continuing Review**, **Modification**, or **Modification and Continuing Review**.



Note: The purpose cannot be changed after completing this screen.

- a. For a **Continuing Review** request, specify the enrollment totals and complete the remaining questions to the best of your ability, then click the **Continue** button. On the next page, click the **Finish** button.
- b. For a **Modification** request, indicate the modification scope as outlined below.



Note: The scope cannot be changed after completing this screen.

- **Study team member information** – Select to update only study team member information (other parts of the study are not editable). When complete, click the **Finish** button on the last page to complete the request.
- **Other parts of the study** – Select to update only other parts of the study (study team member information is not editable). When complete, click the **Finish** button on the last page to complete the request.

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- Select both checkboxes to have the ability to update all information. When complete, click the **Finish** button on the last page to complete the request.
- c. For a **Modification and Continuing Review** request, complete the screens. When complete, click the **Finish** button on the last page.
4. After clicking the **Finish** button, you are returned to the applicable Workspace based on the purpose selected (Continuing Review, Modification, or Modification and Continuing Review).
 5. For a **Continuing Review** or **Modification and Continuing Review** request, select the **Submit** activity in the Workspace. In the *Submit* dialog box, click **OK** to complete the submission.

