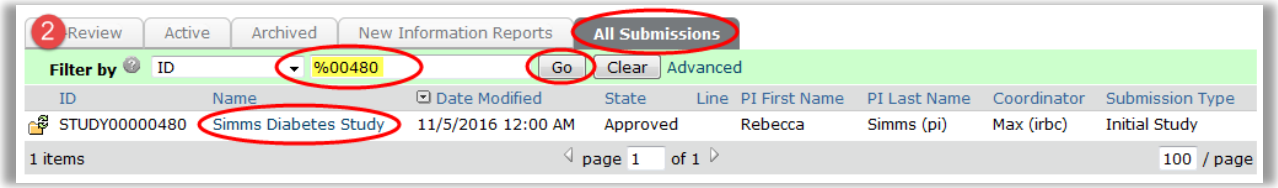
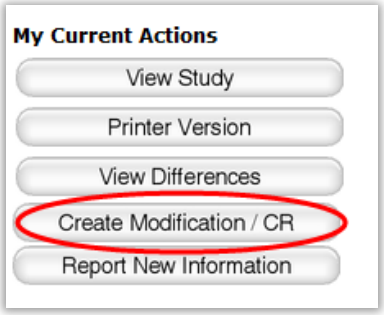
Continuing Review Submission

This Quick Guide will help me to know

- **How to submit a Continuing Review in Click IRB**
- **Tips for avoiding common errors**

How do I submit a Continuing Review (CR)?

1	Log into Click IRB. Navigate to the study that you wish to submit a CR for. **Navigation Hint:** Once in Click IRB, click on the **IRB** module in the upper left corner of the screen. Next, click the **All Submissions** tab, enter search criteria for the applicable study (e.g., using the ID/IRB# and wildcard (%) symbol), click **Go**, and then click on the link to the study.  
2	Click on **Create Modification/CR**. 

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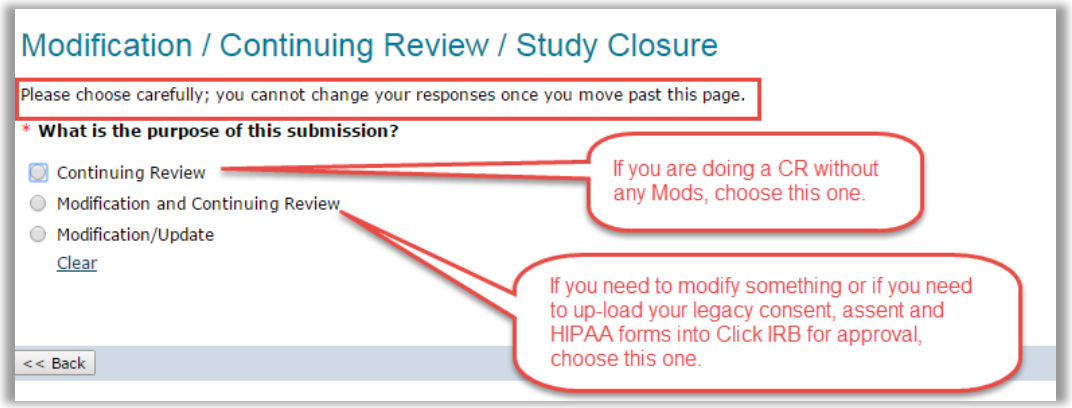
3

On the first page of the SmartForm, select the purpose of the submission. Select either **Continuing Review** or **Modification and Continuing Review**.

Hints:

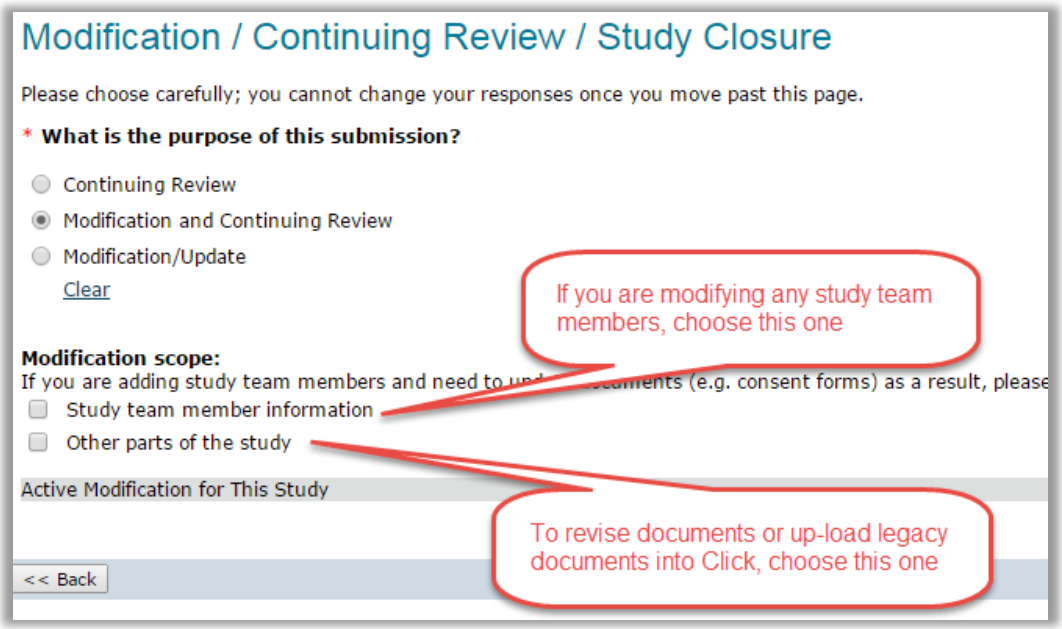
- Choose carefully; you cannot change your responses to this question once you move past this page. If you select the wrong purpose, you may end up having to discard your submission.
- If your CR will be accompanied by a modification, you will need to choose **Modification and Continuing Review**. You should also choose this option if you need to attach legacy consent, assent, and HIPAA forms into Click IRB for the first time.



4

If you chose **Modification and Continuing Review** in Step 3, select the scope of the Modification.

Hint: You can choose either one or both, depending on what changes you wish to make. Choose carefully because the scope cannot be changed once you move past this page.



Click **Continue**.

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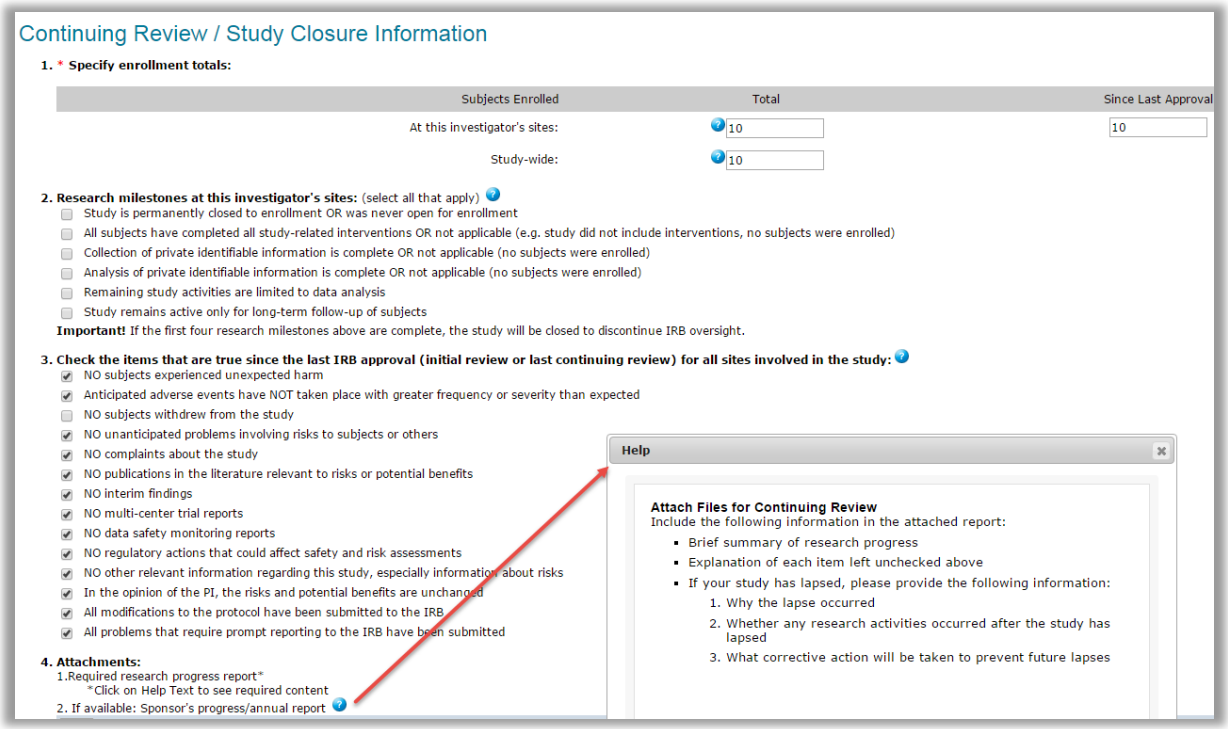
On the second page of the SmartForm, fill in the appropriate information. For example:



5

Hints:

Question 1:

- When determining enrollment totals, use the number of subjects who consented to participate or whose records/data/specimens you have obtained (e.g., if the study has waivers). Include subjects who were consented but failed screening or withdrew from the study.
- Include all subject populations in one grand total (e.g., children, parents, etc.).
- In the "At this investigator's sites" boxes, include the number of subjects enrolled under Seattle Children's IRB approval.
- In the "Study-wide" box, include the number of participants enrolled at all sites everywhere (including those enrolled under Seattle Children's IRB approval). If a multi-site study, contact the Coordinating Center/Sponsor for this information. If they do not provide it, answer to the best of your knowledge.
- Be sure all enrollment totals are consistent numbers reported at your previous CR. If there are inconsistencies, provide an explanation in the attachment in Question 4.

Question 2:

- Check all boxes that apply. If you are still enrolling, no boxes should be checked.
- If you wish to close your study, the first 4 milestones must apply. If you check the first 4 boxes, your study will be closed.
- For chart review studies, individuals whose records/data/specimens you use are considered subjects.

Question 3: For a definition of "unanticipated problem", see **HRP-001** in the Click IRB Library.

Question 4:

- Read the Help Text! Providing all items listed in the Help Text will speed up your review. If your study is lapsed, be sure to provide the required information.
- See below for more information on what a summary of research progress should look like.

Click **Continue**.

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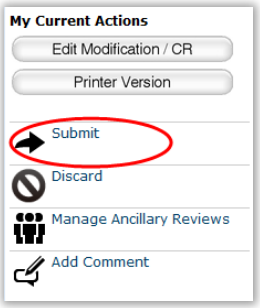
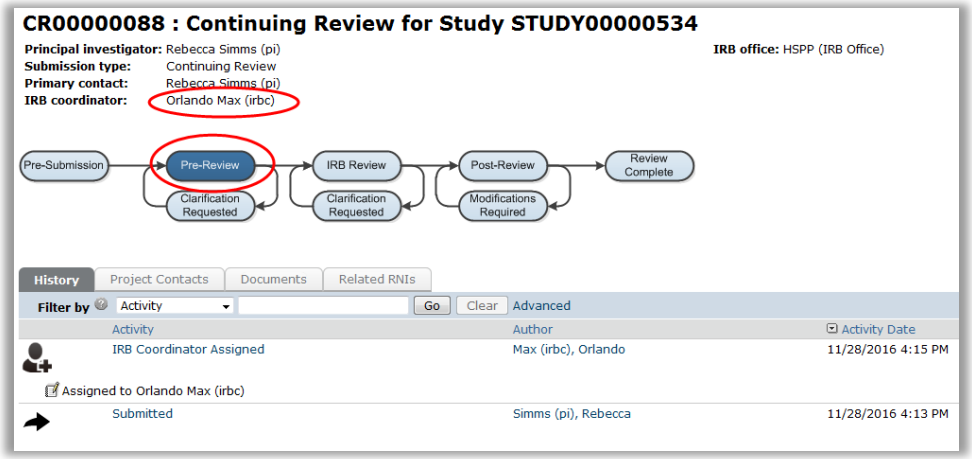
6	Click **Save and Close**. If you chose **Modification and Continuing Review** in Step 3, reference the "Modifications" Quick Guide on the IRB website for help with submitting the modification.
7	Click **Submit**, and confirm your login credentials. Only the PI and PI proxy(ies) can submit.  **Hints:** • You will know the CR has been submitted to the IRB when the dark blue bubble on the item's workflow moves from "Pre-Submission" to "Pre-Review." • When the CR is assigned to an IRB Analyst, his/her name will appear next to the "IRB Coordinator" item at the top of the page. 

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What does a summary of research progress look like?

- Information does not contradict the information provided in the CR SmartForm.
- Explains any boxes that were not checked in Question 3 the CR SmartForm.
- Briefly summarizes how the study is going.

For example:

STUDY00000411 RAINYDAYS
Progress Report

Study is progressing according to the approved IRB protocol. In the past year, we enrolled 10 participants. One family withdrew from the study as they decided the time commitment was too much for them at this time. We plan to create some recruitment materials to increase our enrollment in the coming year and will be submitting these as a modification request when they are completed. The study has not experienced any problems and we anticipate meeting our enrollment and retention goals.

How do I get my consent and assent forms re-stamped with new approval dates?

If your consent and assent forms are already in Click IRB: you do not need to re-attach them. HSPP staff will re-finalize the documents when they review your CR and the documents will get new stamped approval dates.

If you have legacy consent and assent forms that are not yet in Click IRB: be sure to submit a "Modification and Continuing Review" (see Step 3 above) and specify the modification scope as "Other parts of the study" (see Step 4 above). This enables you to upload your consent and assent forms to Click IRB. Reference the "Attaching New and Revised Documents" Quick Guide to ensure that you upload the documents properly.

More questions? Contact the Institutional Review Board by email or at x77804.