

Click IRB Quick Guide

Submitting Modifications



Key Points about Modifications

- When a study is changing after initial approval, submit a request for modification.
- There are two types of modifications in Click: changes to 1) study team, and 2) other parts of the study.
- For version control purposes, Click only allows you to have one modification of each type open at once.
- There is no limit to the number of changes per modification.
- Update study documents at the same time if impacted by modifying your study team. (For example, if you are adding a study team member who is listed by name on the consent form.) To do this in Click, you submit two types of modifications: 1) a study team modification to add or remove team members, and 2) other parts of study modification to update document(s).

How Modifications Relate to Continuing Reviews (CR's)

- There can be modifications pending with the IRB for a study, and a Continuing Review can be submitted (e.g. you can have a modification of each type open and you are still able to submit a CR).
- Modifications and CRs submitted together as a MODCR cannot be split apart in Click. If you need to split them apart, you will withdraw the MODCR and resubmit as separate submissions.

Note the Mod/CR has a unique ID "MODCR"
This means you cannot "split" Mods from CRs
like in the legacy system

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IRB > Testing Mod/CR > Modification and Continuing Review #1 for Study STUDY00000335

Pre-Review

MODCR00000006 : Modification and Continuing Review #1 for Study STUDY00000335

Principal investigator: Tara pi
Submission type: Modification and Continuing Review
Primary contact: Tara pi
IRB coordinator:
IRB office: HSPP (IRB Office)

Entered IRB: 11/5/2015 10:12 AM
Approval:
Effective:
Modified: 11/5/2015 10:12 AM

Pre-Submission -> Pre-Review -> IRB Review -> Post-Review -> Review Complete
Clarification Requested
Modifications Required

My Current Actions

View Modification / CR
Printer Version
View Differences
Assign Line
Assign Coordinator
Manage Ancillary Reviews

History Project Contacts Documents IRB Assignment Details Reviews Related RNIs

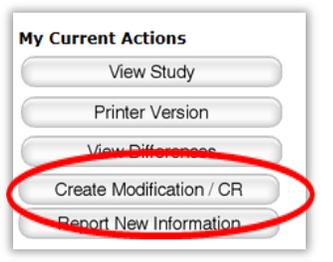
Filter by Activity Go Clear Advanced

Activity	Author	Activity Date
Submitted	pi, Tara	11/5/2015 10:12 AM

Modification Strategy Tips

- Think carefully when selecting the type of modification, and read the form fully.
- Pause before submitting a study team modification to make sure none of your documents need to change as well. If any document needs to change, you are required to submit an “other parts of study” modification too, and it is recommended that the two modifications be submitted at the same time.
- When completing the form, be specific in the **Summarize the Modifications** field about the changes you are making. For example, include the names of study team members that you are adding or removing, to document the changes you made.

To Submit a Modification

<p>Step 1</p>	<p>After logging into Click, find the desired study and click the Create Modification/CR button in the My Current Actions menu on the left side of the study page.</p>	 <p>My Current Actions</p> <ul style="list-style-type: none"> View Study Printer Version View Differences Create Modification / CR Report New Information
<p>Step 2</p>	<p>Make the appropriate selection between “Modification” or “Modification and Continuing Review.” Once you move forward from this screen, you cannot change the type of this modification.</p> <div data-bbox="430 934 1291 1186" style="border: 1px solid #ccc; padding: 10px; margin: 10px auto; width: 80%;"> <p>Modification / Continuing Review / Study Closure</p> <p>* What is the purpose of this submission?</p> <p> <input checked="" type="radio"/> Continuing Review <input type="radio"/> Modification <input type="radio"/> Modification and Continuing Review <input type="button" value="Clear"/> </p> <div style="border: 1px solid green; padding: 5px; margin: 5px auto; width: 60%; color: green; font-size: small;"> <p>Consider your options carefully. Once you select a button, you cannot change the section later.</p> </div> </div>	
<p>Step 2</p>	<p>Complete the Modification Information SmartForm:</p> <div data-bbox="430 1281 1274 1858" style="border: 1px solid #ccc; padding: 10px; margin: 10px auto; width: 80%;"> <p>Modification Information</p> <p>1. Study enrollment status:</p> <ul style="list-style-type: none"> <input type="checkbox"/> No subjects have been enrolled to date <input type="checkbox"/> Subjects are currently enrolled <input type="checkbox"/> Study is permanently closed to enrollment <input type="checkbox"/> All subjects have completed all study-related interventions <input type="checkbox"/> Collection of private identifiable information is complete <p>2. Notification of subjects: (check all that apply)</p> <ul style="list-style-type: none"> <input type="checkbox"/> Current subjects will be notified of these changes <input type="checkbox"/> Former subjects will be notified of these changes <p>Attach files: If notifying subjects, add a description of how they will be notified to the Supporting Documents page.</p> <p>3. * Summarize the modifications:</p> <div style="border: 1px solid #ccc; height: 100px; width: 100%;"></div> </div>	

Step 3

Click **Continue** to access the Basic Information SmartForm. Make the desired modifications using the appropriate page (e.g., update your study SmartForm record, which could include updating or adding documents), then **Save and Exit**.

Step 4

From the Modification page, click **Submit** in the My Current Actions menu

Pre-Submission **MOD00000092 : Modification #2 for Study STUDY00000373**

Entered IRB: **Principal investigator:** Rebecca Simms (pi)
Approval: **Submission type:** Modification
Effective: **Primary contact:** Beth Loots
Modified: 12/27/2015 3:16 PM **IRB coordinator:**

Pre-Submission → Pre-Review → IRB Review → Post-Review → Review Complete
Clarification Requested (between Pre-Review and IRB Review)
Clarification Requested (between IRB Review and Post-Review)
Modifications Required (between Post-Review and Review Complete)

My Current Actions

- Edit Modification / CR
- Printer Version
- View Differences
- Submit** (circled in red)
- Discard

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