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 MODCR has a unique ID “MODCR.” This means you cannot “split” Mods from CRs like in the legacy system.
**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**

<table>
<thead>
<tr>
<th>Step 1</th>
<th>After logging into Click, find the desired study and click the <strong>Create Modification/CR</strong> button in the My Current Actions menu on the left side of the study page.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step 2</td>
<td>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.</td>
</tr>
</tbody>
</table>

**Modification / Continuing Review / Study Closure**

- What is the purpose of this submission?

  - Continuing Review
  - Modification
  - Modification and Continuing Review
  - Clear

  Consider your options carefully. Once you select a button, you cannot change the section later.

**Step 2**

Complete the **Modification Information SmartForm:**

**Modification Information**

1. Study enrollment status:
   - No subjects have been enrolled to date
   - Subjects are currently enrolled
   - Study is permanently closed to enrollment
   - All subjects have completed all study-related interventions
   - Collection of private identifiable information is complete

2. Notification of subjects: (check all that apply)
   - Current subjects will be notified of these changes
   - Former subjects will be notified of these changes

Attach files: If notifying subjects, add a description of how they will be notified to the Supporting Documents page.

3. **Summarize the modifications:**

More questions? Contact the Institutional Review Board at [irb@seattlechildrens.org](mailto:irb@seattlechildrens.org) or x77804.
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.