This quick guide provides instructions for how to close a non-exempt study in Click.

**WHO:**
- Principal Investigators (PI) and/or PI Proxy
- Study team

**WHEN:**
- Creating and submitting a closure.

**HOW:**
1. Click the “IRB” tab to access your IRB submissions.

2. Select the “Active” tab to access your IRB approved studies.
3. Open the study that you would like to close by selecting the folder icon or name (title). This will display the study workspace.

4. From the study workspace, select “Create Modification/CR.”

5. On the Modification / Continuing Review/ Study Closure SmartForm page, select “Continuing Review” for the purpose of the submission and select “Continue.”
6. Complete Questions 1-5 on the Continuing Review SmartForm page and click “Continue.” To close a study, the first four milestones in Question 2 must be complete and selected. You must acknowledge that the study will be closed.

**Continuing Review / Study Closure Information**

1. *Specify enrollment totals:

<table>
<thead>
<tr>
<th>Subjects Enrolled</th>
<th>Total</th>
<th>Since Last Approval</th>
</tr>
</thead>
<tbody>
<tr>
<td>At this investigator’s sites:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study-wide:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2. **Research milestones:** (select all that apply)
   - Study is permanently closed to enrollment OR never open for enrollment
   - All subjects have completed all study-related interventions OR not applicable (e.g., study did not include interventions, no subjects were enrolled)
   - Collection of private identifiable information is complete OR not applicable (no subjects were enrolled)
   - Analysis of private identifiable information is complete OR not applicable (no subjects were enrolled)
   - Data analysis activities are limited to data analysis
   - Study remains active with no future follow-up of subjects

3. *I acknowledge that this study will be closed: ☐*

4. *Check the items that are true since the last IRB approval for all sites involved in the study: (initial review or last continuing review)*
   - NO subjects experienced unexpected harm
   - Anticipated adverse events have NOT taken place with greater frequency or severity than expected
   - NO subjects withdrew from the study
   - NO unanticipated problems involving risks to subjects or others
   - NO complaints about the study
   - NO publications in the literature relevant to risks or potential benefits
   - NO interim findings
   - NO multi-center trial reports
   - NO data safety monitoring reports
   - NO regulatory actions that could affect safety and risk assessments
   - NO other relevant information regarding this study, especially information about risks
   - In the opinion of the PI, the risks and potential benefits are unchanged
   - All modifications to the protocol have been submitted to the IRB
   - All problems that require prompt reporting to the IRB have been submitted

   **Comments:**

5. **Attach supporting documents:** (include an explanation of each item left unchecked above)

   - Use one of these templates:
     - HRP-527 - Template - Explanation(s) for Items Left Unchecked in Question 4
     - HRP-528 - Template - Closure Report
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Note
- Complete and attach HRP-528 – Template – Closure Report.
- For Question 4, if any items have been left unchecked, complete the HRP-527 – Template – Explanation(s) for Items Left Unchecked in Question 4 and upload to the supporting documents.
- Upload any additional supporting documents (e.g. data safety monitoring plan).

7. When you have completed the continuing review SmartForm you can either:
   a. Save and exit out of the SmartForm.
   b. Select “Finish” on the Final Page of the SmartForm.
   c. This will take you to the Continuing Review workspace.
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Continuing Review (Renewal) Submission Process

8. If you would like to continue to edit the submission, from the continuing review workspace, select “Edit Modification/CR” to open the submission to edit.

9. When the submission is ready to be submitted:
   a. Navigate to the continuing review workspace (My Inbox, IRB: Submissions).
b. PI (or PI Proxy) clicks “Submit” to submit the Continuing Review.

Note
- The system only allows the PI or the PI Proxy to submit the Continuing Review.