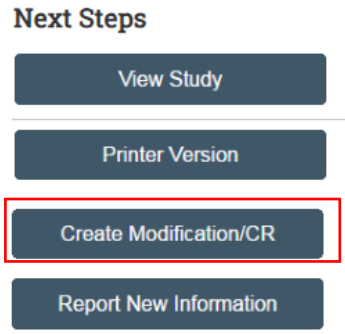
UT Health San Antonio | Enterprise Research Management System (ERMS)

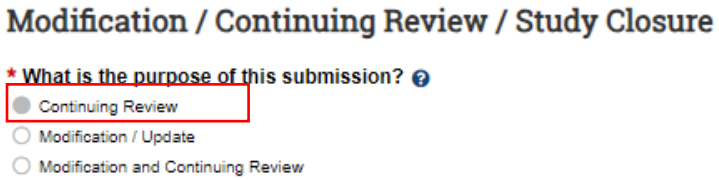
Quick-Guide - UT IRB Continuing Review

1. On the IRB page, navigate to the **Active** tab, and select the approved study.

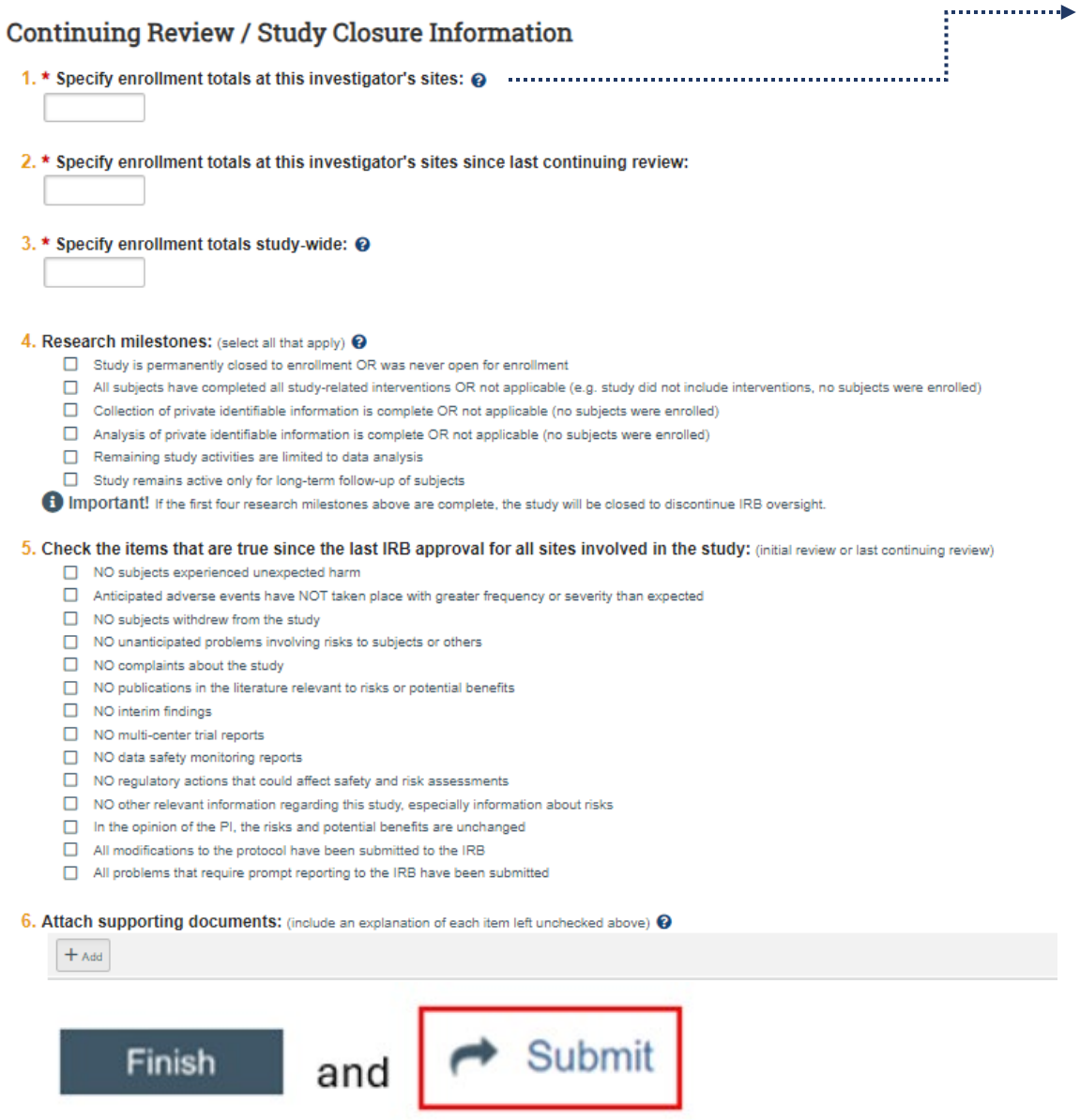
2. Select Create Modification/CR.



3. Select Continuing Review.



4 Complete the Continuing Review Information.



Continuing Review / Study Closure Information

1. * Specify enrollment totals at this investigator's sites:

2. * Specify enrollment totals at this investigator's sites since last continuing review:

3. * Specify enrollment totals study-wide:

4. Research milestones: (select all that apply)
   - ☐ Study is permanently closed to enrollment OR was 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)
   - ☐ Remaining study activities are limited to data analysis
   - ☐ Study remains active only for long-term follow-up of subjects

   Important! If the first four research milestones above are complete, the study will be closed to discontinue IRB oversight.

5. 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

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

   + Add

5 Finish and Submit

Need Help?

Enrollment Totals

Enrollment: Total number of participants consented (including screen failures and withdrawals) or number of medical records reviewed since the start of the study.

At this investigator's sites: All sites at which the sIRB PI is responsible for the research, including all research locations identified for the study. This does not include participating sites under a separate site PI.

Study-wide: All sites everywhere that are conducting this protocol, including participating sites.

Research Milestones

Read each option carefully because some of the options contain two different statements. If either statement is true, check the box.

Usually, the second statement in each option is intended for studies that do not involve interventions or enrollment of subjects, such as chart review and secondary data analysis studies.

Attach Files for Continuing Review

Include the following information:

- Explanation of each item left unchecked above (e.g. include protocol deviations and reasons for withdrawals; upload DSMB reports, if applicable)
- Brief summary of research progress
- Sponsor's progress report or annual report, if available