

Human Research Protections Program

Instructions for creating and submitting a Continuing Review or Closure

Purpose: This guidance document is for use by HSC Investigators, Department Leadership, and Research staff. Please review this guidance in its entirety before beginning. If you require further assistance, the HRPO contact information is found at the end of this document.

Creating a Continuing Review

1. Sign in to Huron IRB (<https://irb.health.unm.edu>) and navigate to the applicable study homepage.
2. Select “Create a new modification/Continuing Review/ Closure”.
 - a. **What is the purpose of this submission:** select “Continuing Review”.


Modification / Continuing Review / Study Closure

To continue or close the study, choose 'Continuing Review'.

*** What is the purpose of this submission?**

- Continuing Review
 Modification / Update

3. Continue



The screenshot shows a web browser window with the title 'Continuing Review for Study'. The page content includes the heading 'Modification / Continuing Review / Study Closure' and the question '* What is the purpose of this submission?'. The 'Continuing Review' radio button is selected. At the bottom of the page, there is a section titled 'Active Continuing Review For This Study' with a sub-heading 'Continuing Review for Study'. A 'Continue' button is circled in red in the top right corner of the browser window.

4. **Continuing Review/Study Closure Information page:**
 - a. **Section 1. Specify enrollment totals:** a subject is enrolled if they have completed the informed consent **or** if consent is waived, a subject is enrolled once their data has been collected for the research.
 - i. **If this is not the first continuing review:**
 1. Enter the total **overall** and **SINCE** the last continuing review was submitted. You will need to navigate back to the previous continuing review and verify the enrollment information submitted then to ensure you correctly enter the enrollment information this year.
 2. **At this investigator's site:** enter the **total of** last year's enrollment total + since last year's CR enrollment numbers. Fill in the total for “since last Continuing Review Approval”.

3. Study-Wide: for sponsored studies, you may need to reach out to the Sponsor to capture the study-wide total, including your site. If this is the only site for this study, this total should match “At this investigator’s site”.
- ii. If this is the first continuing review:
 1. The total includes all subjects that have complete the informed consent. If informed consent is waived, subjects are enrolled once their data is collected for research purposes.
 2. Study-Wide: for sponsored studies, you may need to reach out to the Sponsor to capture the study-wide total, including your site. If this is the only site for this study, this total should match “At this investigator’s site”.
- b. **Section 2. Research Milestones**: Check all of the boxes that are true for your study
- 2. 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
- i. If the first milestone is checked, then either or both boxes 5 & 6 must be checked (other boxes can be checked also – just not the first four).
 - ii. If the second milestone through the fifth milestone is checked, the first milestone must be also checked.
- c. **Section 3. Check the items that are true since the last IRB approval for all sites involved in the study: (initial review or last continuing review)**
- 3. 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
- Important!** An explanation is required for each item left unchecked.
- d. **Section 4. Attach supporting documents**: Attach a completed HRP-508 Continuing Review Supporting Information document that includes an explanation **for each item left unchecked from section 3**. You can download the template from the Huron IRB library.

3. 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
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- NO other relevant information regarding this study, especially information about risks
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Important! An explanation is required for each item left unchecked.

4. Attach supporting documents:

Attach the completed HRP-508 Continuing Review Supporting Information document that includes an explanation of each item left unchecked. Download template from the IRB Library. ?

Name

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5. Continue

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6. Submit for HRRC Review.

Creating a Closure

1. Sign in to Huron IRB (<https://irb.health.unm.edu>) and navigate to the applicable study homepage.
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Modification / Continuing Review / Study Closure

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*** What is the purpose of this submission?**

- Continuing Review
- Modification / Update

b.

c. Continue

You Are Here: ▶

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Modification / Continuing Review / Study Closure

To continue or close the study, choose 'Continuing Review'.

*** What is the purpose of this submission?**

- Continuing Review
- Modification / Update

Active Continuing Review For This Study

Continuing Review for Study

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d.

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- b. **Section 2. Research Milestones:** to close the study with the HRRC, the first four research milestones must be true and checked in this section.
- i. Box 6 cannot be checked
 - ii. Complete the acknowledgment following the milestones.
- c. **Section 3. Check the items that are true since the last IRB approval for all sites involved in the study:** (initial review or last continuing review)
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5. Submit for HRRC Review.

Troubleshooting Help

If you run into issues creating the modification, revising study documents, or submitting the modification for review, please reach out to the HRPO and a member of our staff will schedule a consult to assist you further.

Human Research Protections Office Contact Information

Phone: 505-272-1129

Email: HSC-HRPO@salud.unm.edu