Modification, Continuing Review, and Reportable New Information Forms

This Quick Guide will help me
- View the modification, continuing review/closure forms
- See what new information should be reported to the IRB within five business days
- For more information, see the Continuing Review Submission and the Modification Quick Guides on the Click IRB Resources page

Modification/Continuing Review/Study Closure Selection

Modification Form
- Step by step instructions are available in the Modifications Quick Guide on the Click IRB Resources page
Modification, Continuing Review, and Reportable New Information Forms

Continuing Review/Closure SmartForm

- Step by step instructions are available in the Continuing Review Submission Quick Guide on the **Click IRB Resources page**

### Continuing Review / Study Closure Information

1. Specify enrollment totals:

   - **Subjects Enrolled**
   - **Total**
   - **Since Last Approval**

   - At this investigator’s site: 3
   - **Total**: 0
   - Study-wide: 3

2. Research milestones at this investigator’s site: (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 (i.e., 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 discontinues IRB oversight.

3. Check the boxes that are true since the last IRB approval (initial review or last continuing review) for all sites involved in the study:
   - 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

4. Attachments:
   - 1. Required research progress report
   - 2. If available: Sponsor’s progress/annual report

### Tip: Select the first four boxes to close your study

### Tip: Read the Help Text for Question 4
Reportable New Information SmartForm

- When you have new information about your study that you need to report, click this button and fill in this form

Reportable New Information

Only the submitter of this form can respond to the IRB’s subsequent inquiries. This is due to the concept that anyone can report concerns. This is not an anonymous means of reporting concerns.

1. RNI short title: [uniquely identify this new information report]

2. Date you became aware of the information:

3. Identify the categories that represent the new information: (check all that apply)
   □ Risk: Information that indicates a new or increased risk, or a safety issue. For example:
     a. New information (e.g., an interim analysis, safety monitoring report, publication in the literature, sponsor report, or investigator finding) indicates an increase in the frequency or magnitude of a previously known risk, or introduces a new risk.
     b. An investigator brochure, package insert, or device labeling is revised to indicate an increase in the frequency or magnitude of a previously known risk, or to describe a new risk.
     c. Withdrawal, restriction, or modification of a marketed approval of a drug, device, or biologic used in a research protocol.
     d. Protocol violation/deviation that harmed subjects or others that indicates subjects or others might be at increased risk of harm. This can include deviations from normal practices by institutional persons/groups such as a laboratory or a pharmacy.
     e. Complaint of a subject that indicates subjects or others might be at increased risk of harm or at risk of a new harm.
   □ Risk of Harm/Harms: Any risk of harm or actual harm experienced by a subject or other individual that, in the opinion of the investigator, is unexpected and is related or possibly related to the research procedures.
     a. A risk of harm or actual harm is "unexpected" when its specificity or severity is inconsistent with risk information previously reviewed and approved by the IRB in terms of nature, severity, frequency, and characteristics of the study population.
     b. A risk of harm or actual harm is "related or possibly related" to the research procedures if, in the opinion of the investigator, there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research.
   □ Non-compliance: Non-compliance with the federal regulations governing human research or with the requirements or determinations of the IRB, or an allegation of such non-compliance.
     a. Non-compliance can result from system processes or the action/inaction of the investigator, study staff or other institutional persons/groups, including the IRB.
     b. But protocol deviations that result from the action/inaction of the investigator or study staff should be submitted as a Research Error (see Research Error box below).
   □ Audit: Audit, inspection, or inquiry by a federal agency.
   □ Report: Written reports of study monitors.
   □ Researcher error: Failure to follow the protocol due to the action or inaction of the investigator or research staff.
   □ Confidentiality: Breach of confidentiality.
   □ Unreviewed change: Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a subject.
   □ Incarceration: Incarceration of a subject is a study not approved by the IRB to involence prisoners.
   □ Complaint: Complaint of a subject that cannot be resolved by the research team.
   □ Suspension: Premature suspension or termination of the research by the sponsor, investigator, or institution.
   □ Unanticipated adverse device effect: Any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplement plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

Important: Information that does not fit into one of the categories above does not need to be reported to the IRB as new information.

4. Briefly describe the new information:

5. In the submitter’s opinion:
   a. Does this information indicate a new or increased risk, or a safety issue?
      □ Yes □ No
   b. Does the study need revisions?
      □ Yes □ No
   c. Does the consent document need revision?
      □ Yes □ No

If revisions are required, describe them above and submit a study modification for review.

6. Related studies and modifications:

7. Attach files containing supporting information:

Tips: View the RNI attachment or the help text to see if the RNI attachment is required.

To send the new information for review, you must select “Submit RNI” under “My Current Actions” on the next page.