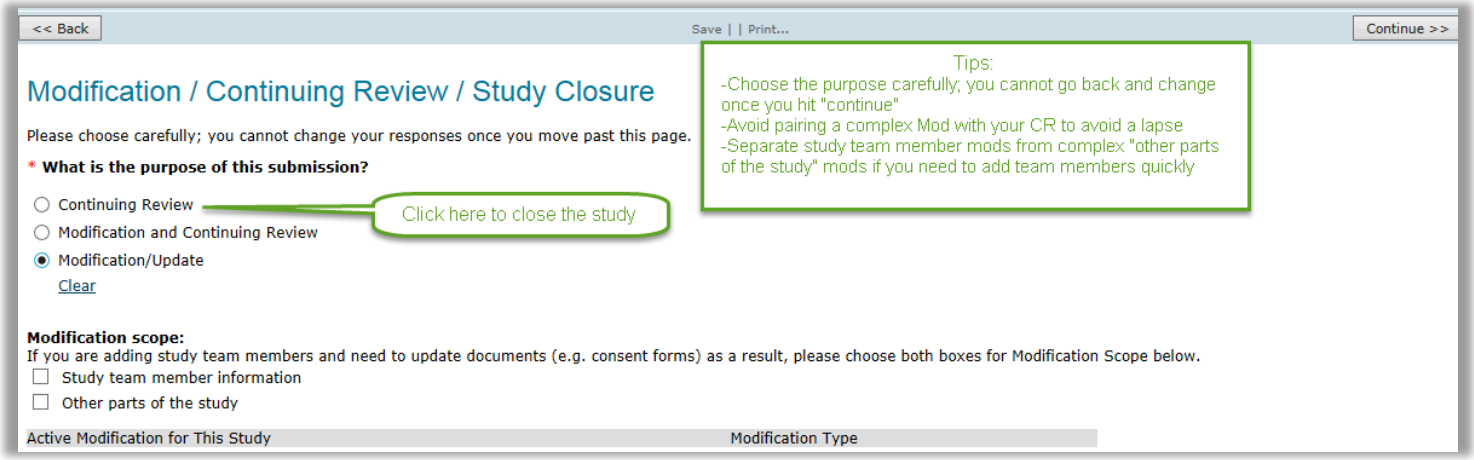
Modification, Continuing Review, and Reportable New Information Forms

This Quick Guide will help me

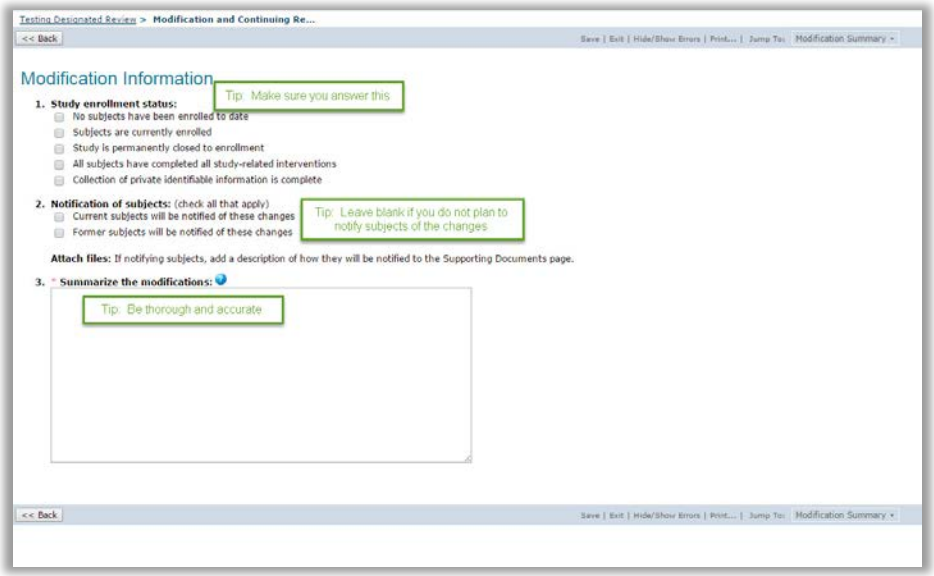
- View the modification, continuing review/closure forms
- See what new information should be reported to the IRB within five business days
- For more information, see the Continuing Review Submission and the Modification Quick Guides on the Click IRB Resources page

Modification/Continuing Review/Study Closure Selection



Modification Form

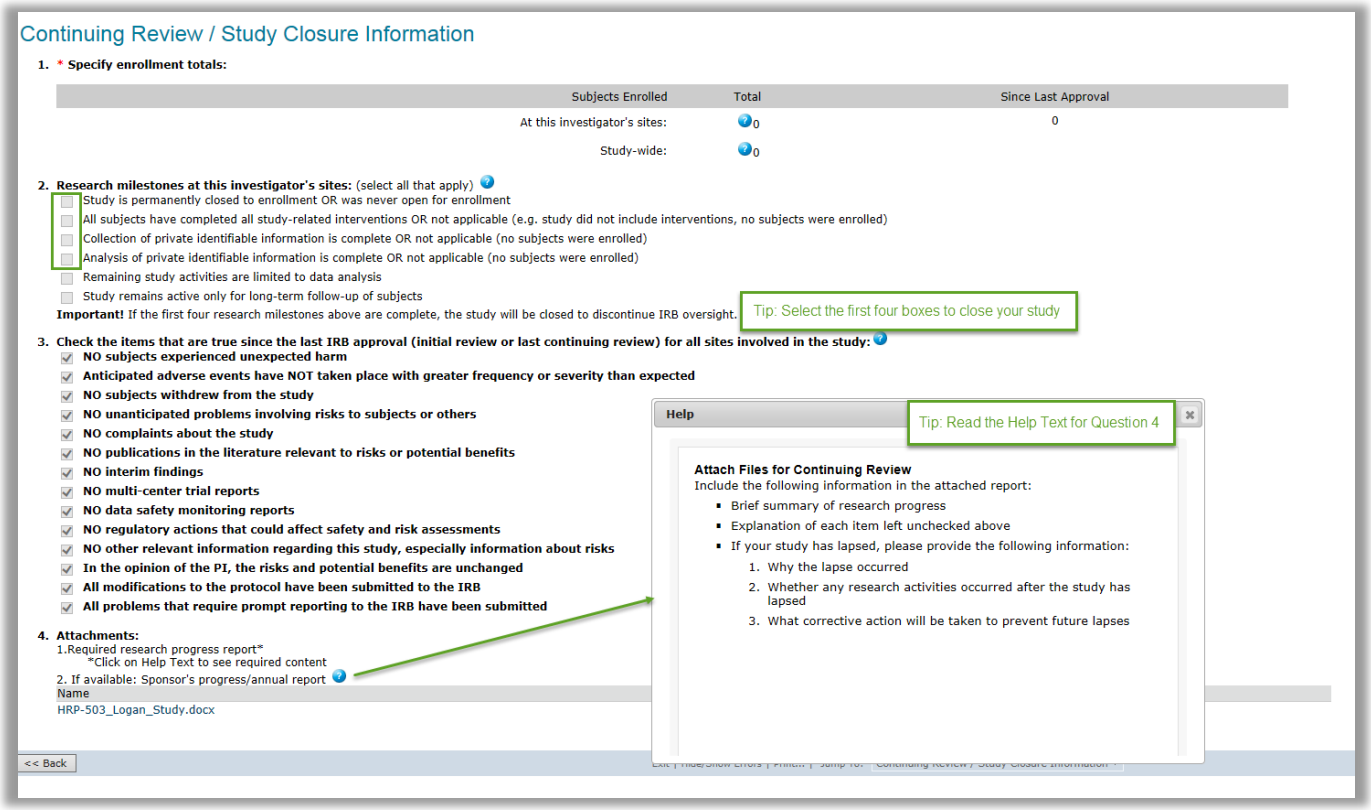
- Step by step instructions are available in the Modifications Quick Guide on the Click IRB Resources page



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



Modification, Continuing Review, and Reportable New Information Forms

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

Report New Information

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)

Tips:
-Information that does not fit one of these categories does not require reporting
-If the information needs to be reported, you should do so within five business days

- ☐ **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 uncovers 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 or 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.
  - **f.** Any changes significantly affecting the conduct of the research.
- ☐ **Risk of Harm/Harm:** 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 Researcher Error (use Researcher 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 in a study not approved by the IRB to involve 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 supplementary 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 Clear
   - b. * **Does the study need revision?** ○ Yes ○ No Clear
   - c. * **Does the consent document need revision?** ○ Yes ○ No Clear

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

6. **Related studies and modifications:**

Add

ID	Short Title	Investigator	State	IRB Office	
STUDY00000152	PLAT-03	Colleen Annesley	Approved	HSPP (IRB Office)	Remove

7. **Attach files containing supporting information:**

Add

Name
There are no items to display

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

Use one of these templates:

- **HRP-214A RNI Attachment**

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