

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 / Continuing Review / Study Closure

Please choose carefully; you cannot change your responses once you move past this page.

* What is the purpose of this submission?

Continuing Review

Modification and Continuing Review

Modification/Update

[Clear](#)

Modification scope:
If you are adding study team members and need to update documents (e.g. consent forms) as a result, please choose both boxes for Modification Scope below.

Study team member information

Other parts of the study

Active Modification for This Study Modification Type

Tips:
-Choose the purpose carefully; you cannot go back and change once you hit "continue"
-Avoid pairing a complex Mod with your CR to avoid a lapse
-Separate study team member mods from complex "other parts of the study" mods if you need to add team members quickly

Modification Form

- Step by step instructions are available in the Modifications Quick Guide on the [Click IRB Resources page](#)

Modification Information

1. Study enrollment status: **Tip: Make sure you answer this.**

No subjects have been enrolled to date

Subjects are currently enrolled

Study is permanently closed to enrollment

All subjects have completed all study-related interventions

Collection of private identifiable information is complete

2. Notification of subjects: (check all that apply)

Current subjects will be notified of these changes **Tip: Leave blank if you do not plan to notify subjects of the changes.**

Former subjects will be notified of these changes

Attach files: If notifying subjects, add a description of how they will be notified to the Supporting Documents page.

3. Summarize the modifications: **Tip: Be thorough and accurate.**

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 sites:		0	0
Study-wide:		0	

2. Research milestones at this investigator's sites: (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. Tip: Select the first four boxes to close your study

3. Check the items 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:

- Required research progress report*
*Click on Help Text to see required content
- If available: Sponsor's progress/annual report

Name
HRP-503_Logan_Study.docx

Help x

Tip: Read the Help Text for Question 4

Attach Files for Continuing Review

Include the following information in the attached report:

- Brief summary of research progress
- Explanation of each item left unchecked above
- If your study has lapsed, please provide the following information:
 - Why the lapse occurred
 - Whether any research activities occurred after the study has lapsed
 - What corrective action will be taken to prevent future lapses

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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)

- 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.

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

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:**

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

Use one of these templates:

- HRP-214A RNI Attachment

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.