



HRPP Policy Number: 801 Version: 4.0 Effective Date: 8/14/2025	Amending Human Subjects Research Activities	Supersedes Document Dated: 12/01/16, 7/12/19, 10/06/2020
Reviewed and Approved by: Tyler Ridgeway, Director, Research Integrity & Education	Reviewed and Approved by: Julia Dmitrieva, PhD, DU IRB Chair	

Section 8: Amendment of Human Subjects Research Activities

8.1 Requirement for Amendments

8.2 Submission Requirements

8.3 Assignment of Expedited Reviewer

8.4 Review of Amendment Requests to Research Originally Reviewed by Convened IRB

8.5 Possible IRB Protocol Amendment Determinations

8.6 Criteria for Approval of Amendments

8.7 Length of Approval Period

8.8 Notification of Investigators of IRB Determination

8.1 Requirement for Amendments

Modifications to consent forms or process, protocols, or procedures/study-related activity must be reviewed and approved by the IRB prior to making any changes in study procedures except when necessary to eliminate apparent immediate hazards to subjects. If modifications are made prior to IRB review to remove immediate hazards to subjects, the modification must be promptly reported to the IRB, and the modification(s) will be reviewed by the IRB Chair to verify that it was appropriate to implement prior to IRB review and approval.

8.2 Submission Requirements

All amendments must be submitted through IRBNet. The requirements for amendments are:

1. Completed amendment application.
2. Revised consent process described in protocol or document with changes highlighted or in tracked format, along with a clean copy, if applicable.
3. Updated IRB Application, including recruitment, enrollment, research personnel changes, and other study activities or procedures if modified.
4. Revised research subject materials, provided in tracked format along with a clean copy, if applicable.
5. Amendment requests must describe what modifications are proposed, why the changes are required, and if the changes pose any additional risks to the subjects.

Amendments may only be submitted after any prior amendment for the same protocol has been approved. If a protocol amendment is submitted while a prior amendment request is still under review for the same protocol, the new amendment request will be held and not reviewed until the previous amendment has been reviewed and a determination letter has been issued.

8.3 Assignment of Expedited Reviewer

Upon receipt, the IRB Compliance Analyst or designee will verify whether the amendment is appropriate for expedited review and ensure that all required documentation has been uploaded and the application is complete prior to review by an IRB-designated reviewer.

8.4 Review of Amendment Requests

Minor changes (those which involve minimal risk procedures and/or do not increase the risk or decrease the potential benefit to subjects) may be approved through an expedited review process. Typical changes considered to be minor include changes in personnel, non-significant changes in sample size (less than 10% change), an addition of a questionnaire that does not include sensitive or controversial questions, a change in the compensation schedule, an addition of a site, etc. Reviewers using the expedited review process must consider the following:



1. The amendment is a minor modification to previously approved research,
2. The regulatory criteria for approval are met.

At the reviewer's discretion, the amendment may be referred to the convened IRB. All amendments reviewed through an expedited process are included with the IRB agenda and in the minutes of the convened meeting.

Changes considered as more than minor will be referred for review at a convened meeting of the IRB. When amendments are reviewed by the convened IRB, all IRB members will be provided with a copy of all documents submitted by the PI. Each amendment to be considered will be assigned and presented by the assigned Primary Reviewer. IRB Compliance Analysts will assure that appropriate scientific expertise, local knowledge, and other expertise specific to the protocol(s) is present at the IRB meeting and at least one member who is knowledgeable about or experienced in working with such subjects, when research involving subjects who are vulnerable to coercion are reviewed, will be present at the IRB meeting. If a member with the appropriate expertise, knowledge, or experience in working with the specific vulnerable population cannot be present, the IRB staff will notify the IRB Chair to obtain a consultant, if needed. To be properly presented and discussed, a quorum of the members must be present for the entire presentation, discussion, and deliberation of the amendment request. Members not present for a substantial part of the discussion and deliberations should abstain from voting.

8.5 Possible IRB Amendment Determinations

Full Board Review

During a convened meeting, a Full Board Review will be presented by a Primary and Secondary Reviewer (if necessary) to the IRB members and one of the following determinations will be issued:

Approved: It is approved as written with no explicit conditions.

Approved with Modifications: The protocol was approved, requiring minor changes or simple concurrence of the PI. These will be identified to the PI and must be completed and documented prior to continuing the research.

Deferred: The information in the submitted documents has deficiencies that prevent accurate determination of risks and benefits. The deficiencies will be identified to the PI, who must address all concerns in a written response to be considered for re-review.

Expedited Review

Either the IRB Chair or a designated reviewer will render one of the following determinations for amendment submissions for projects that were initially reviewed and approved through expedited review, or the modifications proposed to a more than minimal risk project are minimal risk in nature:

Approved: It is approved as written with no explicit conditions.

Modifications Required: The amendment package in IRBNet is unlocked administratively, requiring minor changes. The modifications will be communicated to the PI through Project Mail correspondence and must be completed and documented prior to continuing the research.

Referred to Full Board: A designated reviewer for an expedited amendment may not render a decision of disapproval. Amendment disapprovals may only be rendered through Full Board Review at a convened meeting.



Administrative Review

A designated reviewer or IRB staff member will render one of the following determinations for amendments submitted for exempt protocols:

Acknowledge: The amendment submission will be administratively reviewed and acknowledged as submitted with no explicit conditions.

Modifications Required: The amendment package in IRBNet is unlocked administratively, requiring minor changes. The modifications will be communicated to the PI through Project Mail correspondence and must be completed and documented prior to continuing the research.

Referred to Full Board: A designated reviewer will refer any amendment disapproval for an exempt protocol to the full board for review at a convened meeting.

8.6 Criteria for Approval of Amendments

In order to approve an amendment to research activities, the IRB will provide ethical and scientific scholarly review of all human subjects research to determine that all requirements are satisfied according to [45 CFR 46.111](#) Criteria for IRB approval of research.

8.7 Length of Approval Period

Amendment approvals do not change the approval period of full board review protocols or the Next Report Due dates of exempt or expedited protocols. Therefore, the expiration date and Next Report Due dates will remain the same as was determined for the protocol at the time of initial or continuing review.

8.8 Notification of Investigators of IRB Determination by Convened Board

For protocol amendments submitted for full board review, within five (5) working days after each IRB meeting, a letter is prepared and sent to the PI providing the IRB determination for their protocol. If a full approval is determined, an approval letter will be issued and requires no further action, and the PI can begin research. Letters giving approval with modifications required will contain a list of required conditions and a statement that PIs will not receive final approval until all required conditions have been met. The PI is required to respond within the IRBNet system by creating a new package for their responses within IRBNet.

Along with the determination, the IRB will determine whether the PI's responses to the explicit conditions will need to be reviewed for appropriateness and completeness at another IRB convened meeting, by the IRB Chair or other designated reviewer. Responses to clarifications that are directly relevant to regulatory criteria must be reviewed by the convened IRB. When the PI has responded appropriately and completely to all conditions, via IRBNet, the IRB may require that the responses be reviewed at the next convened meeting or may grant the IRB staff, at the time of the convened meeting, the authority to administratively grant final approval. The PI will be notified by a determination letter when full approval has been granted and amendment requests can be implemented.

For deferred protocols, the PI will be notified by letter, via IRBNet, which will include the reasons for protocol deferral. The entire submission, with all required documents, will need to be revised as needed and resubmitted for IRB review.

For disapproved amendments, the PI will be notified by letter that the amendment was disapproved and the reason(s) for the disapproval.

8.9 Notification of Investigators of IRB Determination by Expedited Review

Protocol amendments submitted for expedited review will be assigned to the IRB Chair or other



designated IRB reviewer. A preliminary review will be conducted by the IRB Compliance Analyst or other designated IRB staff member for appropriateness and completeness.

If an expedited amendment is complete and meets regulatory criteria for approval, an IRB determination letter will be issued to the PI via IRBNet, notifying them that the amendment has been granted full approval and can be implemented.

If an expedited amendment requires modification, a Project Mail will be issued through IRBNet to the PI notifying them of the IRB stipulations that must be addressed to grant full approval of the amendment request. The amendment package will be unlocked in IRBNet, and the PI is then responsible for addressing the stipulations as outlined in the Project Mail and re-locking the package for IRB re-review. Once the package is re-locked by the PI, the IRBNet system will automatically notify the IRB staff, and a re-review will be conducted to confirm that the amendment has been modified per the preliminary review. If all modifications have been addressed, an IRB determination letter will be issued to the PI notifying them that the amendment has been granted full approval and can be implemented.

If any requested modifications from the preliminary review have not been adequately addressed, a Project Mail will be issued through IRBNet to the PI and the amendment package will be unlocked again. The unlocking and re-locking procedure in IRBNet will continue until all stipulations have been addressed.

8.10 Notification of Investigators of IRB Determination by Administrative Review

Protocol amendments submitted for a project that was granted exempt status will be reviewed by an administrative review process by an IRB staff member for appropriateness, completeness, and to ensure that the proposed changes do not affect the risks of the exemption.

If an exempt amendment is complete and does not change the potential risk to the research participant, an IRB acknowledgement letter will be issued to the PI via IRBNet, notifying that the amendment has been acknowledged and can be implemented.

If an exempt amendment required modification or clarification, a Project Mail will be issued through IRBNet to the PI notifying them of the IRB stipulations that must be addressed to allow the amendment to be implemented. The amendment package will be unlocked in IRBNet, and the PI is then responsible for addressing the stipulations as outlined in the Project Mail and re-locking the package for IRB re-review. Once the package is re-locked by the PI, the IRBNet system will be automatically notify the IRB staff and a re-review will be conducted to confirm that the amendment has been modified per the preliminary review. If all modifications have been addressed, an IRB acknowledgement letter will be issued to the PI notifying them that the amendment has been reviewed and acknowledged and can be implemented.

If any requested modifications from the preliminary review have not been adequately addressed, a Project Mail will be issued through IRBNet to the PI and the amendment package will be unlocked again. The unlocking and re-locking procedure in IRBNet will continue until all stipulations have been addressed.