

Guidance and Procedure: IRB Review Type - Amendments to Previously Approved Research (last updated September 3, 2011)

[Overview](#)

[Level of Review and Type of Modification](#)

[Investigator Responsibilities](#)

[Emergency Deviation from the Approved Protocol](#)

[Anticipated Deviation from the Approved Protocol](#)—Single Subject Exception

[IRB Review Process](#)

[References](#)

Overview

All amendments to currently approved research must be approved by the IRB prior to implementation, except when necessary to eliminate apparent immediate hazards to the human subjects (see below). Amendments or changes to the protocol are sometimes referred to as “modifications” or “addenda.” In webIRB they are referred to as “Amendments.” See [OHRPP Certification of Exemption from IRB Review](#) for information about modifying studies previously approved as exempt.

Level of Review and Type of Modification

Full Committee Review: Amendments that do not meet the criteria for expedited review must be reviewed by the Full Committee at a convened meeting. Researchers should allow approximately a month for a Full Committee review and approval of a major amendment.

Expedited Review: Amendments that meet the criteria for expedited review will be reviewed by a Chair or Chair designee according the Expedited Review procedures. Researchers should allow approximately one week for an expedited review and approval of a minor amendment reviewed by the expedited process.

Amendments to protocols that were initially reviewed using the Expedited procedures or by Full Committee may be reviewed by Expedited Review if the amendment fulfills the criteria below:

Protocols Initially Approved by Expedited Review Process that <i>May Be</i> Reviewed as Expedited	Protocols Initially Approved by Full Committee Review that <i>May Be</i> Reviewed as Expedited
<ul style="list-style-type: none"> The amendment continues to pose no more than minimal risk to subjects. The amendments do not involve any procedures that do not meet Expedited categories 1 through 7. 	<ul style="list-style-type: none"> Amendments do not pose an increased risk to subjects; AND Amendments constitute a minor change to previously approved research (see examples below). Any added procedures must fall within Categories (1)-(7) of research that may be reviewed using the expedited procedure.

Amendments that do not fulfill the above criteria may require Full Committee review.

The following table provides examples of **minor** changes (generally can be reviewed via Expedited Review) and **major** changes (generally reviewed by Full Committee pending upon the overall risk level) to previously approved protocols:

Minor Changes	Major Changes
<ul style="list-style-type: none"> • Administrative changes • Minor consent form changes • Minor changes to recruitment procedures, recruitment materials or submission of new recruitment materials to be used in accordance with approved recruitment methods • Minor changes to study documents such as surveys, questionnaires or brochures • New study documents to be distributed to or seen by subjects that are similar in substance to those previously approved • Changes in payment to subjects or the amount subjects are paid or compensated that are not significant enough to affect the risk/benefit ratio of the study • Decrease in the number and volume of sample collections as long as they do not negatively alter the risk/benefit ratio of the study • Editorial changes that clarify but do not alter the existing meaning of a document • Addition of or changes in study personnel • Addition of a new study site (in many but not all cases) • Translations of materials already reviewed and approved by an IRB 	<ul style="list-style-type: none"> • Changes that adversely affect the risk/benefit ratio of the study or specifically increase the risk to subjects • Changes in inclusion/exclusion criteria that impact the risk/benefit ratio of the study • Significant changes in study design, such as the addition of a new subject population or the elimination of a study arm • New risk information that is substantial or adversely affects the risk/benefit ratio of the study • Significant changes to the study documents to be distributed to or seen by subjects • New study documents to be distributed to or seen by subjects that include information or questions that are substantively different from materials already approved by the IRB. • New or revised financial conflict of interest management plans (e.g., change in PI or change to study design).

IMPORTANT NOTE: These above tables may be used as guidance for the investigators but the IRB will make the final determination of appropriate review level.

Please refer to [OHRPP Guidance & Procedure: IRB Review Level -- Full Committee Review](#) and [OHRPP Guidance & Procedure: IRB Review Level -- Expedited Review](#) for details.

Investigator Responsibilities

Evaluate Whether the Amendment is Minor or Major: The principal investigator should evaluate whether an amendment is a major or minor using the tables above as a guide. The determination depends on whether risks to participants are increased and the complexity of the changes. Major modifications require more intensive review than minor or administrative changes. [Contact the OHRPP](#) if you have questions about how to submit an amendment.

Submit the Amendment via webIRB: webIRB will direct you through the process. You will need to provide the IRB with complete descriptions of the amendment, including the rationale(s) for the amendment and the anticipated impact upon current and future subjects, as well as revised versions of any supporting materials related to the amendment (e.g., informed consent documents, questionnaires, sponsor protocol).

Submitting Amendments Resulting from Post Approval Events: If you are submitting an amendment as a result of an unanticipated problem, submit the Post-Approval Report through webIRB concurrently with the Amendment. Answer “Yes” to Item #9 of the amendment application. Or, if you have submitted the PAR prior to the amendment, refer to this in your amendment application. [Contact the OHRPP](#) if you have questions.

Submitting Amendments at Continuation Review: Amendments should be submitted concurrently with continuing review application. Although the continuing review application and the amendment(s) will be reviewed at the same time, webIRB requires that these be submitted as separate but linked applications. See [webIRB PI and Study Team Quick Reference Guide #4: Amendments, Continuing Reviews and PARs](#). Or contact the OHRPP office for assistance.

Include the Required Materials: Requirements for Amendment are indicated in the webIRB Application, and in the [Materials Required for IRB Review and Approval](#) guidance document on the OHRPP website.

Wait for IRB Approval Notice before implementing any proposed modifications, unless as described above the amendment is needed for patient safety.

Emergency Deviation from an Approved IRB Protocol

If a deviation is required to eliminate an apparent immediate hazard to a research subject or group of subjects, then the researcher should make whatever changes are needed to protect the safety and welfare of the subjects and may do so without prior IRB review. However, a post approval report needs to be submitted via webIRB to the IRB within three days of the emergent variance.

Anticipated Deviation from the Approved Protocol —Single Subject Exceptions

If an investigator anticipates the need to deviate from the previously-approved protocol for a particular subject, the investigator should submit a request for a “Single Subject Exception.” Two examples of the most common sorts of these requests are to change the schedule of the procedures or to waive an inclusion or exclusion criteria for one subject. This is submitted to the IRB as a Post-Approval Report through webIRB. The following information will be requested:

- Whether the sponsor has approved the request for a protocol exception for this subject, and to provide any documentation from the sponsor of their approval.
- A description of the protocol criteria for which the Principal Investigator is seeking exception, and an explanation why the requested exception is appropriate or necessary.
- Whether the exception increases the risk or lowers the potential benefits for the subject.
- Whether an amendment will be submitted to reflect the protocol exception for future subjects.
- Whether the current informed consent document adequately covers the exception, and if not, a revised consent form is requested.

IRB Review Process

IRB Pre-Review Process: IRB staff will conduct an initial pre-review for completeness, and make an initial assessment of the appropriate level of IRB review required.

- **Minor changes** in previously approved research will be forwarded to the Chair or his/her designee for consideration under the expedited review procedures. If the Chair or his/her designee determines that the amendments do not qualify for review under the expedited review procedures, the amendments will be forwarded to the Full Committee for review.

- **Major changes** in a previously approved Expedited study research will be forwarded Chair or his/her designee for consideration under the expedited review procedures if the study continues to fit under the expedited categories. If the Chair or his/her designee determines that the amendments do not qualify for review under the expedited review procedures, the amendments will be forwarded to the Full Committee for review.
- **Major changes** in a previously approved Full Committee study will be forwarded to the Full Committee. The Full Committee will determine if the amendment represents an increased risk to human subjects or is more than a minor change or it may determine the amendment fits into an expedited category.

Review and Approval Criteria: The criteria for reviewing and approving an amendment are the same as those for initial review. Therefore, the IRB (or the Chair or designated member of the IRB for protocols reviewed under the expedited review procedures) must determine that all of the following requirements are satisfied:

- Risks to subjects continue to be minimized and reasonable in relation to anticipated benefits;
- Selection of subjects continues to be equitable;
- Informed consent is sought or waived in accordance with [45 CFR 46.116](#) as well as [21 CFR 50.25](#) for FDA-regulated research.
- Informed consent will be documented or documentation waived in accordance with [45 CFR 46.117](#) and [21 CFR 50.27](#) for FDA-regulated research.
- The research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects, when appropriate;
 - There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data, when appropriate; and
 - Appropriate safeguards for vulnerable subjects are provided.
 - If multi-site research, the study management of information relevant to protection of subjects is adequate.

Review of Recruitment, Screening and Consent Documents: When reviewing the recruitment, screening and/or consent documents, the IRB will ensure the following:

- The currently approved or proposed documents are complete, accurately reflect the information in the study application, and meet all the regulatory and University criteria for approval.
- Any new findings that may relate to the subject's willingness to continue participation are provided to the subject in an updated informed consent form or addendum to the informed consent form.

Period of Approval for Amendments: The approval period does not normally change following IRB approval of an amendment to a protocol. For example, if the new, renewal, or continuing approval is issued on January 1, 2010, the protocol will have an expiration date of December 31, 2010. If an addendum is approved during the approval period time, the protocol will still have an expiration date of December 31, 2010, unless an amendment is submitted at the time of continuing review, or if the investigator submits a continuing review application along with amendment and requests a change in expiration date as part of the continuation review.

Related Documents

- [OHRPP Guidance: IRB Review Level – Full Committee Review](#)
- [OHRPP Guidance: IRB Review Level – Expedited Review](#)
- [OHRPP Guidance: Certification of Exemption from IRB Review](#)
- [OHRPP Guidance: Post-Approval Reporting Requirements](#)
- [OHRPP: Criteria Required by Federal Regulations for IRB Approval of a Human Research Study](#)