

Guidance and Procedures Number: 8
Title: IRB Review Process – Expedited Review
Date of Last Revision: March 5, 2009

I. Introduction

The IRB may review certain applications on an Expedited basis if they meet specified criteria within 45 CFR 46.110¹ of the federal regulations. An Expedited review may be performed by the IRB Chair or by an experienced IRB member designated by the IRB Chair, based on the member's area of expertise. In reviewing the research, the reviewer may exercise all of the authorities of the full Committee except to issue disapproval. The reviewer may at any time refer the application to the full Committee if necessary. All Expedited protocols are reviewed at least once annually.

II. Expedited Review Eligibility – Initial Review

Protocols may be reviewed via an Expedited review process if they meet the following criteria [45 CFR 46.110(b)(1)]:

- a. Research poses no more than minimal risk² to subjects, as assessed by the reviewer;
AND
- b. Research for which each of the procedures falls within one of the Expedited review categories 1-7 as outlined by the Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA), as outlined at: <http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm>

The Expedited categories apply regardless of the age of subjects, except as noted.

III. General Restrictions on Eligibility for Expedited Review

Expedited review procedures may not be used where identification of the subjects and/or their responses would easily place them at risk of criminal or civil liability or be damaging to the subjects' reputation, financial standing, employability, etc., unless reasonable and sufficient protections will be implemented so that risks related to invasion of privacy and/or breach of confidentiality are no greater than minimal.

The Expedited review procedure may not be used for classified research involving human subjects.

¹ For research subject to FDA regulations, all references in this guidance to provisions of 45 CFR 46.110 include the corresponding provisions of 21 CFR 56.110 as well.

² *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests [45 CFR 46.102(i)].

IV. Expedited Review Eligibility – Continuing Review

- A. Continuing review of protocols may be conducted via an Expedited review process if it meets one of the following criteria:
1. Continuing research activities pose no more than minimal risk to subjects, as assessed by the reviewer; AND research met the criteria for initial Expedited review and continues to meet those criteria, AND all procedures continue to meet one or more of the Expedited review categories [1-7] as identified at initial/previous review.
 2. Research which was previously reviewed by the convened IRB, but meets the criteria for Expedited review and meets category 8(a), 8(b), or 8(c) for Expedited review as defined by OHRP and the FDA (<http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm>).
 3. Research which was previously reviewed by the convened IRB, but meets the criteria for Expedited review and meets category 9 for Expedited review as defined by OHRP and the FDA (<http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm>).

V. Expedited Review Eligibility – Modifications to an Approved Protocol

- A. An IRB may use the Expedited review procedure to review minor changes in previously approved research during the period (of one year or less) for which approval is authorized [45 CFR 46.110(b)(2)].
- B. Modifications to protocols previously approved by a convened IRB may be reviewed via an Expedited review process if they meet the following criteria:
- a. Modifications do not pose an increased risk to subjects; AND
 - b. Modifications constitute a minor³ change to previously approved research.
 - c. All added procedures fall within Categories (1)-(7) of research that may be reviewed using the expedited procedure (see Section II above).
- C. Modifications to protocols previously approved by the Expedited review process may be reviewed via Expedited review if they meet the following criteria:
- a. With the modifications, the research continues to pose no more than minimal risk to subjects.
 - b. The modifications do not involve any procedures that do not meet Expedited categories 1 through 7.

³ Any change that would materially affect the assessment of risks and benefits should not be considered minor [Institutional Review Board Guidebook: Chapter II. http://www.hhs.gov/ohrp/irb/irb_chapter2.htm#d1.]

D. Examples of changes to previously approved protocols that generally CAN be reviewed by Expedited review procedures:

- a. Administrative changes
- b. Minor consent form changes
- c. Minor changes to recruitment procedures, recruitment materials or submission of new recruitment materials to be used in accordance with approved recruitment methods
- d. Minor changes to study documents such as surveys, questionnaires or brochures
- e. New study documents to be distributed to or seen by subjects that are similar in substance to those previously approved
- f. 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
- g. Decrease in the number and volume of sample collections as long as they do not negatively alter the risk/benefit ratio of the study
- h. Editorial changes that clarify but do not alter the existing meaning of a document
- i. Addition of or changes in study personnel
- j. Addition of a new study site
- k. Translations of materials already reviewed and approved by an IRB

E. Examples of changes to previously approved protocols that generally CANNOT be reviewed by Expedited review procedures:

- a. Changes that adversely affect the risk/benefit ratio of the study or specifically increase the risk to subjects
- b. Changes in inclusion/exclusion criteria that impact the risk/benefit ratio of the study
- c. Significant changes in study design, such as the addition of a new subject population or the elimination of a study arm
- d. New risk information that is substantial or adversely affects the risk/benefit ratio of the study
- e. Significant changes to the study documents to be distributed to or seen by subjects
- f. 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.

VI. **Materials for Review**

Please refer to [HRPP Guidance & Procedure #7: Materials Required for IRB Review](#) for an outline of the materials required for Expedited review procedures.

VII. **Expedited Review Process**

- A. Based on pre-review of a protocol, the Administrator makes the initial determination of whether a submission may qualify for Expedited review.
- B. The Administrator forwards the submission to the IRB Chair/designee for review. The reviewer shall make the final determination of whether a submission for initial or continuing review meets the eligibility criteria outlined above and falls into one or more of the categories allowing review under the Expedited procedure. The reviewer shall make

the final determination of whether modifications to previously approved research meet the eligibility criteria outlined above. The reviewer provides comments in written form.

- C. The IRB Chair/designee may request additional review by other member(s) of the IRB with applicable expertise. The additional assigned reviewer provides comments in written form.
- D. The assigned reviewer(s) of an Expedited submission may exercise all of the authorities of the IRB except that the reviewer(s) may not disapprove the research. A reviewer may choose to consult with another member prior to making any determinations. If the reviewer finds that the research should not be approved, it must be referred to the full Committee for final determinations.

VIII. Possible Expedited Review Actions and Communications

The assigned reviewer(s) may make one of the determinations listed below. Approvals, concerns and suggestions are communicated to investigators following each step of review according to [HRPP Guidance & Procedure #12: IRB Review Process—Communication of IRB Actions](#).

- A. **Approval:** The submission is approved, and no changes to the submission are recommended.
- B. **Conditional Acceptance, contingent upon the reviewer's acceptance of requested modifications and/or clarifications:** The reviewer stipulates specific clarifications or modifications. Staff will notify the investigator of the reviewer's concerns in writing.
- C. **Referred for Full Committee Review:** The reviewer has determined that the submission may not be Expedited. Staff will prepare the study for Full Committee review. In addition, the reviewer may decide that a request for additional information should be sent to the investigator prior to the Full Committee review.

IX. Documentation of Expedited Review Procedures

Initial and continuing reviews conducted under Expedited review procedures are documented on the application materials by the IRB Chair/designee, and in the OPRS database by IRB staff. Documentation includes: (1) the Expedited category citation(s) and (2) any approved consent waivers or other regulatory determinations.

The convened Board is notified of all Expedited approvals issued since the last meeting within a designated section of each meeting agenda. This information is also included in the meeting minutes.

X. Review Frequency

If the IRB Chair/designee determines that a protocol previously reviewed under Expedited review procedures requires review more often than annually, review of the protocol will be referred for review by the convened IRB. *All determinations of requirements for review more often than annually will be communicated to the investigator in writing, and documented as a codicil on the approval notice for the research..*

XI. Timely Review Defined

Ideally, given that all necessary resources⁴ are available, the IRB and the staff aim to complete each action⁵ within two weeks of receipt date.

XII. Designation of Reviewers Other Than an IRB Chair

- A. By virtue of the qualifications and experience necessary for the position, IRB Vice Chairs are eligible to review on an Expedited basis.
- B. If needed to address considerations such as expertise, scheduling or submission volume, an IRB Chair, in consultation with the OPRS Director, OPRS Assistant Director and IRB Administrator, may identify other members with sufficient experience and expertise to review on an Expedited basis. Such determinations are based on active IRB service of at least one year, demonstrated knowledge and application of regulatory requirements and OPRS/IRB policies and procedures, and willingness to visit the OPRS office on a regular basis to conduct such reviews.
- C. Designation of a member other than a Chair or Vice Chair as eligible to review on an Expedited basis shall be confirmed via written communication among the following individuals as appropriate: the Chair, the designated member, the OPRS Director or Assistant Director and the IRB Administrator. Any changes to the designation shall be communicated in the same fashion. The IRB Administrator shall maintain all documentation related to such designations.
- D. The IRB Administrators are responsible for communication with eligible reviewers regarding review duties.

Regulations:

21 CFR 56.110
45 CFR 46.110

References:

DHHS Federal Register Notice: November 9, 1998 (Volume 63, Number 216), "Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) Through an Expedited Review Procedure."⁶

<http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm>
or <http://www.hhs.gov/ohrp/humansubjects/guidance/63fr60364.htm>

⁴ Necessary resources may include but are not limited to required Board member expertise and sufficient staffing.

⁵ Each action refers to each procedure required by the IRB/IRB staff. These include, but are not limited to, completion of a correspondence to the investigator and issuance of an approval notice.

⁶ The FDA version of this Federal Register notice is available at <http://www.fda.gov/oc/ohrt/irbs/expeditedreview.pdf>

OHRP Guidance on the Use of Expedited Review Procedures, August 11, 2003.
<http://www.hhs.gov/ohrp/humansubjects/guidance/exprev.htm>

OHRP Guidance on Continuing Review, January 15, 2007.
<http://www.hhs.gov/ohrp/humansubjects/guidance/contrev0107.pdf>

FDA, *IRB Information Sheets: Continuing Review After Study Approval*, September 1998.
<http://www.fda.gov/oc/ohrt/irbs/review.html>