

Policy Number: 8

Title: IRB Review Process – Expedited Review

Date of Last Revision: February 11, 2008

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 following Expedited review categories as outlined by the Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA):

Expedited Categories 1-7

Category 1

Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

- (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases

¹ For research subject to FDA regulations, all references in this policy 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)].

the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for Expedited review.)

- (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

Category 2

Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

- (a) From healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
- (b) From other adults and children³, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

Category 3

Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

Category 4

Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for Expedited review, including studies of cleared medical devices for new indications.) Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing

³ *Children* are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted [45 CFR 46.402(a)].

or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

Category 5

Research involving materials (data, documents, records, or specimens) that have been collected; or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

Category 6

Collection of data from voice, video, digital, or image recordings made for research purposes.

Category 7

Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

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.

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 of the Expedited review categories [1-7 above].

2. Research which was previously reviewed by the convened IRB, but meets the criteria for Expedited review and meets one of the following categories for Expedited review as defined by OHRP and the FDA:

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(a) Where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or

(b) Where no subjects have been enrolled and no additional risks have been identified; or

(c) Where the remaining research activities are limited to data analysis.

3. Research which was previously reviewed by the convened IRB, but meets the criteria for Expedited review and meets the following category for Expedited review as defined by OHRP and the FDA:

Expedited Review Category 9

Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

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 minor⁴ change to previously approved research.

⁴ 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.]

- 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.
- 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 [OPRS/IRB Policy 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 [OPRS/IRB Policy 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. Please refer to [OPRS/IRB Policy 9: IRB Review Process—Full Committee Review](#) for details

regarding further steps. In addition, the reviewer may decide that a request for additional information should be sent to the investigator prior to the Full Committee review. Please refer to [OPRS/IRB Policy 12: IRB Review Process —Communication of IRB Actions](#) for details regarding further steps.

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 resources⁵ are available, the IRB and the staff aim to complete each action⁶ 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

⁵ Necessary resources may include but are not limited to required Board member expertise and sufficient staffing.

⁶ 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.

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."⁷

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

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

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>

⁷ The FDA version of this Federal Register notice is available at <http://www.fda.gov/oc/ohrt/irbs/expeditedreview.pdf>

Attachments:

- OPRS-38 UCLA IRB/OPRS IRB Reviewer Checklist
- OPRS-40 UCLA IRB/OPRS Informed Consent Checklist
- OPRS-41 UCLA IRB/OPRS Checklist for involvement of children
- OPRS-42 UCLA IRB/OPRS Checklist for involvement of pregnant women and fetuses
- OPRS-43 UCLA IRB/OPRS Checklist for involvement of prisoners
- OPRS-44 UCLA IRB/OPRS Checklist for waiver of informed consent
- OPRS-45 UCLA IRB/OPRS Checklist for waiver of signed informed consent
- OPRS-46 UCLA IRB/OPRS Checklist for waiver of parental permission
- OPRS-47 UCLA IRB/OPRS Checklist for waivers of informed consent & HIPAA authorization