

## Guidance and Procedure: IRB Review Level – Expedited Review

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## Introduction

This guidance outlines the criteria and process for IRB review conducted by expedited procedures.

The IRB may review applications using Expedited review procedures if they meet specified criteria within the federal regulations, as noted below. An Expedited review may be performed by the IRB Chair and/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.

## Categories of Research That May Be Reviewed By Expedited Review

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

- Research poses ***no more than minimal risk to subjects***, as assessed by the reviewer;  
**AND**
- Research for which ***each of the procedures falls within one of the DHHS Expedited review categories 1-7*** and the Food and Drug Administration (FDA):
  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 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***.
  2. ***Collection of blood samples*** by finger stick, heel stick, ear stick, or venipuncture as follows:

- a. from healthy, nonpregnant 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 children<sup>2</sup>, 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.
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.

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 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.

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). (**NOTE:** Some research in this category may be exempt from the HHS regulations for the protection of human subjects. [45 CFR 46.101\(b\)\(4\)](#). This listing refers only to research that is not exempt.)
6. ***Collection of data from voice, video, digital, or image recordings made for research purposes.***
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.***

**NOTE:** Some research in this category may be exempt from the HHS regulations for the protection of human subjects. [45 CFR 46.101\(b\)\(2\)](#) and (b)(3). This listing refers only to research that is not exempt.

8. **Continuing review of research previously approved** by the convened IRB as follows:
  - 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**.
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**.

**General Restrictions:** 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

## Initial Review Process and Communications

**Submission:** Investigators are required to submit a complete application via webIRB, including all required supporting documentation.

**Materials for review:** All documents outlined in [Materials Required for IRB Review](#) are provided to designated expedited reviewers via webIRB.

### IRB Pre-Review Process:

- IRB staff will conduct an initial pre-review for completeness, and determine whether a submission may qualify for Expedited review.
- The staff forwards the submission to the IRB Chair and/or designee for review.
- The reviewer makes the final determination of whether initial, continuing review, and modification submissions meet the eligibility criteria and falls into one or more of the categories listed above.
- The reviewer provides comments in written form.
- 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.
- 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.

**Possible IRB Actions:** The assigned reviewer(s) may make one of the determinations listed below:

- **Approved:** Acceptable as is. No changes are required. Criteria for IRB approval met.
- **Accepted Pending Modifications:** Minor specific changes are required.
- **Referred for Full Committee Review:** The reviewer may determine that the submission may not be expedited. The reviewer may also decide that additional information must be provided by the investigator prior to review by the convened Board.
- **Not Human Subjects Research**
- **Not Engaged in Human Subjects Research**

**NOTE:** *Only the Full Committee may disapprove a study if the criteria for IRB approval are not met.*

**Communication with Investigators Regarding IRB Actions:** Approvals, concerns and suggestions are communicated to investigators following each step of review; see [IRB Review Process and Communication of Results of IRB Review](#) for details.

**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. *The IRB will communicate to the investigator in writing and document on the Approval Letter all determinations of requirements for review more often than annually.*

**Timely Review:** The IRB and the staff aim to respond to the investigator within one week of receipt of the IRB submission. Depending upon the type of review (i.e., initial, amendment, continuation) expedited review approval may take from one to three weeks.

**Documentation of Expedited Review Procedures:** Regulatory determinations for initial and continuing reviews conducted under Expedited review procedures are documented in the webIRB application and on the IRB approval notices.

For protocols reviewed using expedited review procedures, the designated reviewer(s) designate the applicable expedited review category (ies) in webIRB when they electronically submit their Expedited Review Activity Form.

Expedited reviewers document any disagreement with the protocol-specific information supporting any waiver of informed consent or documentation of consent or the inclusion of vulnerable subjects in the research in the “Additional Comments” section of the Expedited Review Activity Form.

IRB staff include conditions on IRB approval notices to document the applicable expedited review category(ies), approved waiver(s) of informed consent or documentation of consent, and criteria for inclusion of vulnerable subjects in the research.

**IRB Approval Notice:** In addition, the Approval Notice will contain all regulatory determinations, the IRB approval period, and the list of funding sources for the research in addition to PI and study identifying information and other information as needed.

## Post-Initial Review

**Continuing Review:** The IRB must review ongoing research at least annually, unless the IRB requires more frequent review for a particular protocol. For more information, please see [IRB Review Process – Continuing Review](#).

**Amendments to Approved Research:** 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. For more information, please see [IRB Review—Amendments](#).

**Post-Approval Reporting:** The Principal Investigator must submit to the IRB all post approval reports that meet the submission criteria within the proper timeframe, as described in the OHRPP document [Post Approval Reporting Requirements \(PAR\)](#).

## Designation of Reviewers Other Than an IRB Chair

- By virtue of the qualifications and experience necessary for the position, IRB Chairs and Vice Chairs are eligible to review on an Expedited basis. If needed to address considerations such as expertise, scheduling or submission volume, an IRB Chair or Vice Chair may identify other experienced members with sufficient experience and expertise to review on an Expedited basis. “Experienced” members must have active IRB service of at least one year and demonstrated knowledge and application of regulatory requirements and OHRPP/IRB policies and procedures.
- Designation of a member other than a Chair or Vice Chair as eligible to review according to the criteria for Expedited review procedures shall be confirmed via written communication among the following individuals as appropriate: the Chair, the designated member, the OHRPP 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. The IRB Administrators are responsible for communication with eligible reviewers regarding review duties. Because of their experience and qualifications, the IRB Assistant Directors and the IRB Administrators may serve as voting members and may be designated by the Chair to review Expedited studies as needed.

## References

### ***DHHS Regulations***

- Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research: [45 CFR 46.110](#)
- Criteria for IRB Approval of Research: [45 CFR 46.111](#)
- November 9, 1998 Federal Register [list of research eligible for expedited IRB review](#)

### ***FDA Regulations & Guidance***

- Criteria for IRB Approval of Research: [21 CFR 56.111](#)
- Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research: [21 CFR 56.110](#)

### ***OHRP Guidance***

- [Guidance on the Use of Expedited Review Procedures](#) – August 11, 2003
- [Guidance on Written IRB Procedures](#) – July 1, 2011
- [Guidance on IRB Continuing Review of Research](#) – November 10, 2010
- Desk Manual: Guidance for UCLA OHRPP Staff Designated to Conduct Review by the Expedited Procedures

### ***UCLA OHRPP Guidance***

- [Post Approval Reporting Requirements \(PAR\)](#).
- [IRB Review Process and Communication of Results of IRB Review](#)
- [Materials Required for IRB Review](#)