

P&P: RR 402 Version No: 1.4 Effective Date: 1/21/2019	EXPEDITED REVIEW	Supersedes: CPHS Policies and Procedures 6/1/2013
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1. POLICY

An expedited review procedure consists of a review of research involving human subjects by an IRB Chair, or by one or more experienced reviewers designated by the Chairperson from among the members of the committees.

In order to be eligible for expedited review, all aspects of the research must include activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures included in one or more of the specific categories listed in the regulations at Federal Register Volume 63, No 216.

Specific Policies

1.1 Important Definitions

- 1.1.1 **Minimal risk** is defined by 45 CFR 46.102 as 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.
- 1.1.2 **Children** are defined by 45 CFR 46.402 as persons who have not yet attained the legal age for consent to treatment or procedures involved in the research, under the applicable law of jurisdiction in which the research is conducted (be it local, national, foreign or domestic).

1.2 Applicability

- 1.2.1 A study is presumed to be minimal risk if it meets one of the categories listed in the regulations at Federal Register Volume 63, No 216. The Secretary will evaluate the list at least every 8 years and amend it, as appropriate, after consultation with other federal departments and agencies and after publication in the Federal Register for public comment. If the CPHS Reviewer decides that a study involving activities described in the Federal Register presents greater than minimal risk to subjects, justification must be documented.
- 1.2.2 The categories in this list apply regardless of the age of subjects, except as noted.
- 1.2.3 Unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal, the expedited review procedure may not be used where identification of the participants and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, insurability, reputation, or be stigmatizing.
- 1.2.4 The expedited review procedure may not be used for classified research involving human subjects. Furthermore, UC Berkeley policy prohibits investigators from conducting research involving human subjects that is considered classified by the U.S. government.

- 1.2.5 The expedited procedure may not be used for research involving prisoners, unless the prisoner representative of the IRB is one of the designated reviewers.
- 1.2.6 The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of whether the research is reviewed by the convened IRB (the full committee) or by expedited procedures.

1.3 Expedited Review Categories (this information is quoted directly from the regulations at Federal Register Volume 63, No 216.)

- (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, 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.

1.4 Authority of the IRB Chair and Designee

The IRB Chair may exercise all of the authorities of the IRB, except that he or she may not disapprove the research application. A research application may be disapproved only after review by the convened IRB. The Designee may exercise authority as permitted and specified by the Chair.

1.5 Notification of the IRB

The OPHS staff provide IRB members with a list of all new applications, continuation applications, and amendments approved under expedited review by month. In general, the list is provided to members at the next convened meeting. If the list cannot be provided by then, it is provided at the next possible convened meeting.

1.6 Documentation

When research is reviewed by expedited procedures, IRB records must include documentation of the research, the permissible category or categories of expedited review that apply (for example, survey research per F(7)), and that the research is minimal risk.

CPHS must document the rationale for an expedited reviewer's determination under §46.110(b)(1)(i) that research appearing on the expedited review list described in §46.110(a) is more than minimal risk.

1.7 Additional Items That May be Reviewed by the Chair or IRB Designee

Minor changes: An IRB Chair/Designee may use the expedited review procedure to review minor changes in research protocols that were previously approved via expedited and/or full committee review during the period for which approval is authorized. Any protocol revision that presents more than a minimal risk of harm to the subjects must be reviewed by the full committee at a convened meeting.

Limited review: Research for which limited IRB review is a condition of exemption under §46.104(d)(2)(iii) or (d)(3)(i)(C): The IRB Chair/Designee must determine that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data (§46.111(a)(7)).

2. SCOPE

These policies and procedures apply to all non-exempt human subjects' research and exempt research for which limited IRB review is a requirement.

3. RESPONSIBILITY

OPHS staff are responsible for facilitating the review of expedited applications and pre-reviewing submissions that qualify for expedited review, as well as providing a list of protocols reviewed under expedited procedures to IRB members at convened meetings. Staff will consult with the IRB Chair/Designee and/or OPHS Director as necessary in order to determine if an application may be reviewed by expedited procedures.

The IRB Chair/Designee is responsible for the review and approval of all applications eligible for expedited review.

Other IRB members may be consulted and/or conduct reviews as needed or requested by the IRB Chair based on their specific expertise. An ad hoc consultant may also be asked to review the research, if the Chair/Designee, OPHS Director, or a senior staff member feels that the research activities involve issues that necessitate the additional consultation of

someone with relevant expertise outside the realm of the IRB members. It is important to note that a consultant does not have authority to vote or take action on a research study.

4. REVIEW PROCESS OVERVIEW

Expedited Review of New Study, Amendment, and Renewal

In general, OPHS staff coordinate the review process and perform a preliminary check of applications that appear to qualify for expedited review. If additional information or clarification is necessary, the responsible staff member initiates correspondence to the investigator. When the investigator responds, the staff member verifies that all items have been addressed and the application is complete. The application and response are then routed to the IRB Chair/Designee at which point he or she will review the research. If any concerns are identified, the Chair/Designee will return the application along with his or her comments to the staff member who communicates these comments to the investigator in writing. If there are no concerns, or the concerns have been addressed, the IRB Chair/Designee will approve the research.

After the application is approved, all approved informed consent, parent permission, and assent documents (English and foreign language) will be made available to the investigator along with the protocol approval letter. Any foreign language translations of approved consent documents must be submitted, either with initial application materials, as responsive materials to a conditional approval by the IRB, or as an amendment after initial approval of the research and English consent documents.

If there are any issues that cannot be resolved or if the Chair/Designee determines that the application does not meet the criteria for review by expedited procedures, the application must go to the full committee (convened IRB) for review. The IRB Chair/Designee cannot disapprove a study via the expedited review process.

5. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.109

21 CFR 56.109

45 CFR 46.102

45 CFR 46.110

21 CFR 56.110

Federal Register Volume 63, No 216

45 CFR 46.111

21 CFR 56.111

45 CFR Subparts B, C & D

OHRP Guidance on the Use of Expedited Review Procedures (Aug 2003)

FDA Information Sheets, 1998

The Belmont Report