

SOP 402: EXPEDITED REVIEW

1. POLICY

The categories of human research that may be reviewed by the IRB Chair or IRB designee through an expedited review process include research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures in one or more of the specific categories listed in the regulations at 45 CFR 46.110 and 21 CFR 56.110.

The criteria for approval using the expedited procedure are the same as those for review by a convened IRB found in SOP 403; Initial Review-Criteria for IRB Approval. The IRB Chair or IRB designee cannot disapprove an item submitted for expedited review; the item must be presented to the convened IRB for determination.

Specific Policies

1.1 Research Categories Eligible for Expedited Review

The following human research categories are eligible for expedited review:

- (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, 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 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 non-disfiguring 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 non-research 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 of research 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.

1.2 Definition of Minimal Risk

Minimal risk is defined as when "...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) and 21 CFR 56.102 (i).

1.3 Expedited Review of Human Research Involving Prisoners

Expedited review procedures are not recommended for research involving prisoners. However, if the IRB chooses to use the expedited review procedure for research involving prisoners, the prisoner representative of the IRB shall be one of the designated IRB reviewers.

The Department of Defense prohibits the use of expedited review procedures for research involving prisoners.

SOP 501-Special Populations, includes additional guidance for these kinds of research projects.

1.4 Cautions

A. Activities listed in Section 1.1 are not deemed to be of minimal risk simply because they are included on the list of eligible research. Inclusion on this list merely means that the activity is eligible for review through the expedited review process when the specific circumstances of the proposed research involve no more than minimal risk to human participants.

B. The expedited review process may not be used where identification of the participants and/or their responses would reasonably place them at risk of

criminal or civil liability; be damaging to the participants' financial standing, employability, insurability, reputation; or be stigmatizing, 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. Furthermore, the expedited review process may not be used for classified research involving human participants.

1.5 Authority of the IRB Chair or IRB Designee

The IRB Chair or IRB designee may exercise all of the authorities of the IRB, except that he/she may not disapprove the research. A research project may be disapproved only after review by the convened IRB.

1.6 Notification of the IRB

When the expedited review process is used, the IRB office shall inform the Investigator of the expedited review decision, including the qualifying category for expedited review. All IRB members are informed of the actions taken by the IRB Chair or IRB designee at the next convened meeting. The meeting agenda reflects those items approved under an expedited review. IRB discussion of the expedited items is limited unless there are questions.

1.7 Documentation

If the research qualifies for expedited review, the IRB Chair or IRB designee shall document the justification for using the expedited procedure, his/her determination of risk, and actions taken by the reviewer on the reviewer checklist, along with any other findings required by applicable laws, regulations, codes, and guidance to be documented.

The IRB minutes shall include documentation of the studies that were reviewed via expedited review and any issues resolved relating to questions that IRB members raised concerning the research reviewed.

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

Modifications of the human research project that do not materially affect an assessment of the risks and benefits of the research project or substantially change the specific aims/design of the research project are considered minor (or non-substantive) changes and qualify for expedited review. Examples of additional items appropriate for expedited review:

- Board requested changes that require simple concurrence.
- Modifications as described in SOP 405: Modifications.
- Events reported on the Unanticipated Problem Form that the IRB Chair or IRB designee determines are not unanticipated problems involving risks to participants or others.
- Protocol deviations as SOP 407: Protocol Deviations and Unanticipated Problems.
- Miscellaneous items such as correspondence from the sponsor or investigator.
- IRB minutes contingently approved by the convened IRB.

- Changes in Key Study Personnel.

2. SCOPE

This SOP applies to all human participant research submitted to the IRB that qualifies for expedited review.

3. RESPONSIBILITY

3.1 The IRB Administrator is responsible for the initial identification of submissions that qualify for expedited review and for forwarding all such submissions to the IRB Chair or IRB designee. Submissions forwarded to the IRB Chair or IRB designee include the same materials that would be reviewed by the convened IRB. The IRB Chair or IRB designee is responsible for making the final determination of eligibility for expedited review and for documenting the expedited category.

3.2 The IRB Chair or IRB designee is responsible for conducting the expedited review.

3.3 The convened IRB is responsible for reviewing research projects initially reviewed under the Expedited categories that the IRB Chair or IRB designee recommends review by the convened IRB in accordance with the non-expedited review process.

3.4 The IRB Administrator is responsible for posting the expedited reviews to the agenda/minutes for presentation and review by the IRB.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.102

21 CFR 56.102

45 CFR 46.110

21 CFR 56.110

FDA Information Sheets, Guidance for Institutional Review Boards and Clinical Investigators, 1998, Frequently Asked Questions

OHRP Guidance Document, IRB Guidebook

OHRP Guidance on the Use of Expedited Review Procedures, August 11, 2003

5. REFERENCES TO OTHER APPLICABLE SOPS

SOP 301, Research Submission Requirements

SOP 405, Modifications

SOP 407, Protocol Deviations and Unanticipated Problems

SOP 501, Special Populations

6. ATTACHMENTS

203-A HSC Reviewer Checklist

203-A-1 NC Reviewer Checklist

7. PROCESS OVERVIEW

- 7.1 The IRB Staff confirms all documents are reviewed for submission per SOP 301: Research Submission Requirements.
- 7.2 The IRB Administrator assigns to the IRB Chair or IRB designee the submission to be reviewed.
- 7.3 The IRB Chair or IRB designee determines the eligibility for expedited review according to the Research Categories listed in Section 1.1 above. The IRB Chair or IRB designee considers the methods used to conduct the research, recruitment practices, participant population, confidentiality of data, involvement and training of the research staff, and feasibility of the research project when considering whether a research project is minimal risk.
- 7.4 The IRB Chair or IRB designee documents in the IRB's electronic information system minor revisions or requests for additional information. The IRB Administrator communicates the requests for information or revisions to the Investigator. When received, the IRB Administrator forwards the revisions to the IRB Chair or IRB designee for approval.
- 7.5 When approval is granted, the IRB Chair or IRB designee documents in the IRB's electronic information system the determination of risk including the expedited category. The IRB Administrator posts the expedited review approval to the next appropriate IRB agenda and generates an approval letter for the Investigator.
- 7.6 For other submissions that qualify for expedited review (continuing reviews as described in 1.1(8), final closure reports, modifications, miscellaneous items), the IRB Chair or IRB designee documents in the IRB's electronic information system minor revisions or requests for information, or if approved, indicates approval. The IRB Administrator then posts the expedited review approval to the next IRB agenda and generates an approval letter for the Investigator.
- 7.7 If the submission entails more than minimal risk, the IRB Chair or IRB designee documents in the IRB's electronic information system that the submission should be reviewed by the convened IRB review. The IRB Administrator posts the item to the next appropriate IRB agenda.

APPROVED BY: _____ **DATE:** 08/31/2014

NEXT ESTABLISHED REVIEW DATE: AUGUST 2016