

SOP: 303 Effective Date: 12/06/2021	EXPEDITED REVIEW	Supersedes Document Dated: 08/21/2020
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1. POLICY:

The Secretary of the Department of Health and Human Services and the Food and Drug Administration have established and published in the Federal Register a list of categories of research that may be reviewed by the IRB through an expedited review procedure. (See Section 5 below for links to the current list of expedited review categories.) An IRB may use the expedited review procedure to review either or both of the following:

- A. Some or all of the research appearing on the list, unless the reviewer determines that the study involves more than minimal risk. (If the reviewer determines that the study involves more than minimal risk, the reviewer’s rationale for this determination shall be documented in accordance with applicable HRPP policies. See SOP 203: Documentation and Records Management.)
- B. Minor changes in previously approved research appearing on the list during the period for which approval is authorized.

These policies and procedures apply to all Human Subjects Research activities regulated by the Food and Drug Administration and the Department of Health and Human Services that qualify for expedited review categories.

2. DEFINITIONS

- 2.1 *Administrative Review.* A review conducted by a Human Research Protection Program (HRPP) Protocol Analyst to determine if a submission contains all of the necessary paperwork and supporting documents and ensures that all required elements are complete.
- 2.2 *Expedited Review.* Review procedures for certain categories of research established by the Department of Health and Human Services and the Food and Drug Administration which do not require review by a convened quorum of the convened IRB. Categories eligible for Expedited Review are outlined in Section 3.1 of this SOP.
- 2.3 *Expedited Reviewers* – Experienced (by serving one year or more on the IRB, training by HRPP staff or a board member, or through daily job duties) reviewers who are voting IRB members assigned to conduct Expedited Review. All voting and alternate IRB members serving for one year or more on the IRB are automatically Expedited Reviewers, unless indicated to the IO by the IRB Chair.
- 2.4 *Full Review.* Level of review pertaining to research activities that must be evaluated by a quorum of the convened IRB.
- 2.5 *Minimal Risk.* Level of risk in which 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 of a normal healthy person living in a safe

environment or during the performance of routine physical or psychological examinations or tests.

- 2.6** *Minor Changes.* Changes to a protocol that do not increase risk or burden to participants.

3. PROCEDURES

3.1 Expedited Review Procedures for Initial Protocol Applications

3.1.1 HRPP Support Staff, enters a submitted protocol into the data management system, records training status of the research team members, and forwards the request to a Protocol Analyst.

3.1.2 A Protocol Analyst conducts administrative review on the Application. The Protocol Analyst documents any concerns and the appropriate category of Expedited Review, if appropriate, on the Checklist, special review form(s) as appropriate, and in the data management system. Once complete, the request is routed to an Expedited Reviewer, depending on the research proposed in the protocol application.

(a) The assigned Expedited Reviewer will determine if the protocol qualifies for Expedited Review under any of the following categories for Initial Review:

- (i) **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.

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.

- (ii) **Category 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, as defined in 45 CFR 46.402(a), 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.

(iii) **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.

(iv) **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 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.

(v) **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).

(vi) **Category 6:** Collection of data from voice, video, digital, or image recordings made for research purposes.

(vii) **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.

(b) The assigned Expedited Reviewer will determine if the protocol qualifies for Expedited Review under any of the following categories for Continuing Review:

(i) **Category 8:** Continuing review of research previously approved by the convened IRB as follows:

A. where (1) the research is permanently closed to the enrollment of new subjects; (2) all subjects have completed all research-related interventions; and (3) 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.

(ix) **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.

3.1.3 The Expedited Reviewer can choose to consult with another IRB Member or an outside consultant with appropriate expertise. The Expedited Reviewer must have experience in terms of professional competence related to human research protections or conduct of research with human subjects.

3.1.4 The Expedited Reviewer will conduct a review of the research which includes, but is not limited to the criteria outlined in 45 CFR 46.111 and/or 21 CFR 56.111:

- (a) A determination that risks to participants are minimized;
- (b) A determination that risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result;
- (c) A determination that selection of participants is equitable;
- (d) A determination that informed consent will be sought from each prospective participant or the participant's legally authorized representative, in accordance with and to the extent required by 46 CFR 46.116 and/or 21 CFR 50;

- (e) A determination that informed consent will be appropriately documented, in accordance with and to the extent required by 46.117 and/or 21 CFR 50.27;
- (f) A determination that when appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects;
- (g) A determination that when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data;
- (h) A determination that when some or all subjects are likely to be vulnerable to coercion or undue influence (such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons), additional safeguards have been included in the study to protect the rights and welfare of subjects; and
- (i) A determination of the scientific or scholarly validity of the research.
 - (1) Such validity is determined by the experience of an Investigator, a review by a funding agency, a separate peer review process, or by a thesis/ dissertation committee (in the case of graduate student research). These processes help to ensure that:
 - A. The research procedures are consistent with sound research design;
 - B. The research design is sound enough to reasonably expect the research to answer its proposed question; and
 - C. The knowledge expected to result from the research is of importance to the scientific or scholarly discipline.
 - (2) Should IRB Reviewers disagree with the scientific or scholarly validity assessment, the application should be reviewed either by an IRB Member with appropriate expertise or a consultant whose expertise is germane to the research.

- 3.1.5 If it is determined that the submitted documents are not adequate, the Investigators may be required to submit additional information, answer questions, or explain the details of the study and/or revise the application. Incomplete or inadequate submissions will not be approved.
- 3.1.6 A PI's responses to a request for additional information and/or application revisions are reviewed by a Protocol Analyst and an Expedited Reviewer. If the application is in order, the IRB Reviewer may approve the protocol by signing the Protocol Review Form.
- 3.1.7 Expedited Reviewers may exercise all the authority of the IRB in reviewing the research, except they may not disapprove the research. Research that cannot be approved via expedited procedures must be reviewed by the convened IRB.
- 3.1.8 If an issue requiring institutional approval (e.g., legal matter, public relations, payment), the IRB approved application is then routed to the Institutional Official (IO) or his/her designee to be reviewed for institutional approval. If approved, the IO or his/her designee will indicate approval through memo or an electronic message.
- 3.1.9 Once an initial protocol application is approved, HRPP Support Staff will enter the approval in the electronic system and add the protocol to the agenda for the next meeting of the appropriate IRB as a reported item. Staff will archive the approved consent document(s) and generate the approval letter. Copies of the approval letter and approved consent document(s) will be sent via e-mail or electronic data management system to the Investigator and Key Personnel.

3.2 Expedited Review Procedures for Revision and Continuing Review Requests

- 3.2.1 Beginning July 19, 2018, annual Continuing Review is no longer required by default for ongoing research originally approved through Expedited Review. This release from pre-2018 Common Rule requirements also applies to studies that have completed study interventions and are merely analyzing study data or involve only observational follow up in conjunction with standard clinical care. However, the Purdue IRB maintains the authority to mandate Continuing Review on these protocols if necessary for purposes of monitoring risk to participants and/or in cases of noncompliance.
- 3.2.2 No less than every (3) years, the PI will receive notification from the HRPP regarding the open study. At this time the PI will be notified of his/her responsibilities and provided with the most up to date processes and forms. The IRB or the Expedited Reviewer may elect to require more

frequent continuing review as a condition of initial approval or may impose such requirement at a subsequent time.

- 3.2.3 For studies undergoing Continuing Review, HRPP Support Staff completes intake of the revision or continuing review request, enters it into the data management system, records training status of the research team members, and forwards the request to a Protocol Analyst.
- 3.2.4 A Protocol Analyst conducts administrative review on the submission. The Protocol Analyst documents any concerns and the appropriate category of Expedited Review, if appropriate, on the Checklist and in the electronic system. Once complete, the request is routed to an Expedited Reviewer.
- 3.2.5 Expedited Reviewers can be the IRB Chair or other experienced IRB member. The Expedited Reviewer can choose to consult with another IRB Reviewer or an outside consultant with appropriate expertise.
- 3.2.6 The Expedited Reviewer will conduct a review of the research which includes, but is not limited to the criteria outlined in 45 CFR 46.111 and/or 21 CFR 56.111 and is stated in sections 3.1.2. and 3.1.4 of this SOP as well as procedures included in SOP 304: Continuing Review and SOP 305: Amendments Requests.
- 3.2.7 If it is determined that the submitted documents are not adequate, the Investigators may be required to submit additional information, answer questions, or explain the details of the study and/or make revisions to the application. Incomplete or inadequate submissions will not be approved.
- 3.2.8 The Investigator's responses to a request for additional information and/or application revisions are reviewed by a Protocol Analyst and an Expedited Reviewer. If the application is in order, the Expedited Reviewer may approve the revision request or continuing review request in the electronic system.
- 3.2.9 If necessary, the IRB approved revision request or continuing review request is then routed to the IO or his/her designee to be reviewed for institutional approval. If approved, the IO or his/her designee will indicate approval by memo or electronic message.
- 3.2.10 Once the revision request or continuing review request is approved, HRPP Staff will enter the approval in the electronic system and assign the protocol to the agenda for the next IRB meeting as a reported item. HRPP Staff will also finalize the approved consent document(s), if any, and generate the approval letter. Copies of the approval letter and approved consent document(s) will be sent via e-mail or available in the electronic data management system to the Investigator.

4. RESPONSIBILITY

HRPP Support Staff is responsible for completing intake processes of the protocol submissions (initial applications, revision requests and/or continuing review requests), entering it into the data management system, forwarding the request to a Protocol Analyst for administrative review, entering the approval into the data management system, placing the approved submission on the next IRB meeting agenda and notifying the Investigators of the submission's approval.

Protocol Analysts are responsible for overseeing the review process for expedited review as well as conduct administrative review on protocol submissions.

The IRB Chair or other experienced IRB member designated by the IRB Chair to conduct expedited review are responsible for conducting review and granting IRB approval of all submissions that qualify for expedited review. Additionally, they are responsible for determining the need for consultation with other IRB Members, HRPP Support Staff or consultants.

The IO or his/her designee is responsible for conducting further appropriate review and granting institutional approval when required.

5. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.110

21 CFR 56.110

6. REFERENCES TO OTHER APPLICABLE SOPs

302 Initial Review

304 Continuing Review

305 Amendment Requests