I. PURPOSE

The purpose of this SOP is to describe the process for using expedited review procedures.

II. POLICY STATEMENT

The IRB may approve human subjects research using expedited review procedures provided that the following criteria are met: the research activities (1) present no more than minimal risk to human subjects, and (2) if federally funded or FDA-regulated, involve only procedures listed in one or more of the specific categories listed in the regulations at Federal Register 63: 29748, 1998, 21 CFR 56.110, and 45 CFR 46.110. The IRB may also use expedited procedures to review and approve minor changes to previously approved research. Non-material changes and staff changes (except changes to the Principal Investigator) may be administratively reviewed. Adverse events not meeting prompt reporting criteria and staff removals may be auto-acknowledged, as appropriate.

III. SCOPE

These policies and procedures apply to all research submitted to the IRB(s) that qualifies for expedited review.

IV. DEFINITIONS

Amendment: Any change in the research activity from what was approved by the IRB, including, but not limited to, modifications to the protocol, consent document, recruitment material, or information included in the Investigator's Brochure.

Material Change: A modification to the research-related documentation that impacts the conduct of the research at sites overseen by CHOP or the assessment of the risks and benefits of the study. Non-material changes (e.g., staff changes) do not require IRB review or approval.

Minor Amendment: A proposed change in the research-related activities that does not materially affect assessment of the risks and benefits of the study and does not substantially change the specific aims, objectives, or design of the study. A modification may not be considered "minor" if the changes involve the addition of a procedure that is more than minimal risk or a procedure that cannot be reviewed under Expedited Categories 1-7 (Representative examples of minor modifications are included in the **SOP 401** Appendix 2).

Full Board Review: Review of proposed research at a convened Full IRB meeting at which a majority of the membership of the IRB is in attendance, including at least one member whose primary concerns are in non-scientific areas. For the research to be

approved, it must receive the approval of a majority of those members attending the meeting.

Review Using Expedited Procedures: Review of proposed research by the Chair, CPHS or their designee. The designee must be an experienced IRB member/alternate.

Expedited Review Categories: The listing of procedures and categories of research published periodically by the Secretary HHS in the Federal Register (See Appendix 1).

Expanded Expedited Review Categories: The procedures and categories of research not listed in the Federal Register Expedited Review Categories but that have been determined by the CHOP IRB to present no more than minimal risk and are otherwise eligible for expedited review. This provision does not apply to research that is funded by the federal government or to clinical investigations of FDA-regulated products.

Experienced IRB Member/Alternate: A member is considered experienced after completing the IRB member training in accordance with **SOP 102** and after serving as a member of an IRB for at least 6 months. Alternatively, a member can be considered experienced with at least 1 year of IRB work experience in an IRB.

Minimal risk: Defined 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...." (§46.102(i)). The IRB interprets "minimal risk" to be calibrated to the life of normal, healthy children and "daily life" to be those activities to which most children are exposed. The IRB may determine that procedures that are considered minimal risk for normal healthy children constitute greater than minimal risk for populations that are vulnerable by virtue of their condition or circumstances.

Relying Institution: The institution that has assigned another IRB to serve as the Reviewing IRB under an IRB Authorization Agreement.

Reviewer: The Chair, CPHS or their designee who is responsible for providing a review of all submitted materials (described in **SOP 301)**, documenting the review on the appropriate evaluation form, and taking an action on behalf of the IRB. The reviewer must be an experienced IRB member/alternate.

V. PROCEDURES

A. Establishing Applicability of Expedited Review Procedures

1. Expedited review procedures may be used when the research presents no more than minimal risk to human subjects, and when the procedures involved are limited to those in a listing of minimal risk procedures (Appendix 1: A and B).

2. Expedited review procedures will not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects 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.

3. The IRB will apply the same requirements for informed consent, as well as for its waiver, alteration, or exception for research reviewed using expedited procedures as for research reviewed by the convened IRB.

B. Expedited Review Procedures

1. Pre-review procedures to ensure completeness of the submission will be followed in accordance with **SOP 105.**

2. The Chair or designee (the reviewer) will have access to all materials submitted in eIRB as described in **SOP 301**.

3. Reviewer Responsibilities:

   (a) The reviewer discloses conflicting interest with any submission sent for review. If there is a conflict of interest, the submission will be reassigned to another member.

   (b) The reviewer evaluates the research using the criteria described in **SOP 402**.

   (c) The reviewer documents their review and determinations.

   (d) The reviewer establishes the continuing review frequency (as applicable) and any other requirements as described in **SOP 105.**

   (e) At any time, the reviewer may forward the submission to the full board.

4. The reviewer exercises all of the authorities of the IRB as described in **SOP 406**, except that they may not disapprove the research. A research protocol may only be disapproved after review by a convened IRB.

C. Post Review Procedures

1. Expedited review actions will be reported in the agenda for the next convened meeting via the agenda in the IRB electronic management system. This report will include actions taken by the reviewer. Members will have access to the complete submission and all review materials and IRB members will have an opportunity to ask questions or raise concerns.

2. The investigator will be notified of the IRB's determinations in accordance with **SOP 105.**

VI. ROLES AND RESPONSIBILITIES

Title	Responsibility
Director, HSR	Director, Human Subjects Research (or designee) is responsible for triaging new submissions and determining eligibility for expedited review or delegating this authority.
Chair, CPHS	The Chair (or designee) is responsible for reviewing submissions eligible for expedited review or selecting a designee.
Analyst, IRB	IRB Analyst is responsible for processing and assisting the reviewer with studies eligible for expedited review.

VII. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.110(b)(1)(2)	21 CFR 56.110(b)(1)(2)
OHRP Guidance for Expedited Review https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-expedited-review-procedures/index.html#:~:text=OHRP%20policy%20provides%20that%20any,46.110(b)(2)	FDA Guidance for IRBs, Clinical Investigators, and Sponsors on 'IRB Continuing Review After Clinical Investigation Approval' https://www.fda.gov/regulatory-information/search-fda-guidance-documents/irb-continuing-review-after-clinical-investigation-approval

VIII. REFERENCES TO OTHER APPLICABLE SOPS

SOP 105: IRB Review Processes	SOP 402: Criteria for Initial IRB Approval
SOP 301: Research Submission Requirements	SOP 406: Categories of Action

IX. ATTACHMENTS

The IRB Reviewer Forms are embedded in the electronic IRB management system.

Appendix 1: Expedited Review Categories

Appendix 2: Administrative, Modifications

X. REVISIONS:

07-07-2006: Initial approval

10-09-2007: This revision incorporates revisions based on AAHRPP recommendations, changes in IRB office responsibilities, inclusion of the definitions of Major Amendment and Minor Amendment, and inclusion of an Appendix. The Appendix lists the types of modifications to research-related activities, approved by the full board and requiring full board approval for continuing review, that will be considered major (requiring full board review) and those which would be considered minor.

06-09-2010: This revision removes redundant information found in other SOPs and updates the link to the IRB reviewer forms.

07-08-2010: This revision updates the policy to include information requested as part of the AAHRPP certification process including addition of the Expedited Review Categories (Appendix 1).

09-04-2012: This revision updates the policy to reflect CHOP's FWA where the "box was unchecked" and CHOP's expanded expedited review categories.

09-25-2018: Minor edits to align with current SOPs and definitions, allow for the administrative review of staff changes, and editorial changes.

06-10-2022: Minor administrative edits to align with current processes

XI. APPROVAL:

Approval Indicator: Approved by Amy Schwarzhoff and Barbara Engel on 06/10/22
Amy Schwarzhoff, Director, Human Subjects Research and Barbara Engel, Chair, CPHS

XII. APPENDIX 1: Expedited Review Categories

Inclusion on this list indicates that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects. The categories in this list apply regardless of the age of subjects, except as noted.

A. Research Categories Published in the Federal Register* (for federally funded or FDA-regulated research)

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 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 46.104(d). This listing refers only to research that is not exempt.) Additional Note: if the research proposed is utilizing materials collected for research purposes (e.g.: an approved IRB protocol), category 5 will also apply to this research.

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 46.104(d)(2) and (d)(3)(i). 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.

*Source: 63 FR 60364-60367, November 9, 1998

B. Expanded Categories of Minimal Risk Research Procedures as Established by the CHOP IRB (for research that is neither federally funded nor subject to FDA regulations)

1. Skin biopsy not requiring suturing.
2. Ionizing radiation exposure that does not exceed 100 mrem (1 mSv) per year.
3. Blood draws via an indwelling catheter, regardless of frequency.
4. Blood sampling (that meets the NIH policy) for children that is limited to no more than 5 mL/kg on a single day or 9.5 mL/kg over the course of 8 weeks and for adults to no more than 10.5 mL/kg or 550 mL, whichever is less, over the course of 8 weeks.
5. Obtaining additional blood, CSF or bone marrow at the time of a clinically indicated procedure.

6. Obtaining additional endoscopic biopsies, other than esophageal biopsies, during the course of a clinically indicated gastrointestinal endoscopy.

7. Broncheoalveolar lavage (and the collection of the resulting BAL fluid) in individuals with an existing artificial airway.

8. Prolongation of clinically indicated sedation or general anesthesia for up to 30 minutes.

XIII. APPENDIX 2: ADMINISTRATIVE AND MINOR MODIFICATIONS

A. Administrative Modifications and Updates

Non-material changes to research-related documentation, previously approved by the IRB, do not require IRB review and only require acknowledgment of receipt by the IRB. These changes will not affect the conduct of the research at CHOP or CHOP's Relying Institutions. Examples of administrative modification include, but are not limited to:

1. Research sponsor clarification and notification memos;

2. DSMB or other reports with recommendations of no change to the research;

3. Typographical or editorial corrections to study documents, including consent forms, recruitment materials, protocols, etc.;

4. Additions and removals of study team members, other than the Principal Investigator, and changes to their designated roles/responsibilities; and

5. Study closure notifications.

B. Submissions that may be auto-acknowledged include:

1. Removal of study team members as long as the assigned responsibilities are appropriately addressed;

2. Adverse events not meeting prompt reporting criteria, as appropriate; and

3. Study closure notifications, as appropriate.

C. Minor Modifications

Proposed modifications (amendments and responses to IRB requested modifications) to research-related activities approved by the convened IRB may be considered to be minor changes provided that they are limited to one or more of the categories below. The reviewer will make the final determination whether expedited procedures may be used to review the proposed changes as listed below:

1. Change in appropriately credentialed study personnel;

2. Change qualifying for exemption or expedited review;
3. Increase/decrease in subject number;
4. Changes to inclusion or exclusion criteria without increase in risk to subjects;
5. Changes in the dosage form (e.g., tablet to liquid) but not route of administration;
6. Addition of Principal Investigators at external institutions (Relying Institutions) conducting research previously approved by the CHOP IRB that present no additional risks to subjects;
7. Changes to informed consent documents that are supported by the protocol;
8. Changes in the number of study visits without increase in risk to subjects; and
9. Change in remuneration (i.e., payments and reimbursement) to subjects;
10. Changes requested by the convened board as part of an approval with modification.