
STANDARD OPERATING PROCEDURE

Expedited Review Procedures

1.0 PURPOSE

This procedure establishes the process of using expedited procedures to review qualified human subject research in accordance with federal regulations.

2.0 POLICY

It is Christ Hospital policy that The Christ Hospital Institutional Review Board (TCH IRB) review qualified human subject research using expedited procedures in accordance with federal regulations. An expedited procedure consists of the review of research involving human participants by the IRB chair or one or more experienced reviewers designated by the IRB chair from among members of the IRB, who, in the opinion of the chair, have appropriate expertise, experience or other qualification to perform the review. A written record of the delegation is made and kept in the IRB records.

If the reviewer cannot approve the research (with or without modifications to secure approval) using expedited procedures, (s)he will refer it to the convened IRB for review. The requirements for informed consent process, or for altering or waiving the requirement for informed consent process, apply to research reviewed under the expedited procedure. Consultants may also assist the IRB in the review of research undergoing expedited review.

A list of actions taken through the expedited review procedures will be provided to the convened IRB on the monthly Exempt/Expedited Report (Chairman's Report). Any IRB member may request re-review of research that was approved using expedited procedures. Upon such requests, the research will be reviewed by the convened IRB.

3.0 DEFINITIONS

Minimal Risk: Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests ([45. CFR. 46.102\(j\)](#))

4.0 SCOPE

4.1 The expedited review procedure applies to:

4.1.1 Research granted exemption but requiring a limited IRB review under the TCH IRB Policy on Exempt Research,

- 4.1.2 Initial review of research which (1) presents no more than minimal risks to human participants, and (2) involves only procedures listed under expedited research Categories 1 through 7,
 - 4.1.3 Continuing review of research previously approved under expedited procedures provided the research continues to meet the expedited research categories,
 - 4.1.4 Continuing review of research previously approved by the convened IRB which is eligible for review under expedited research Category 8 or 9,
 - 4.1.5 Modifications to research previously approved under expedited procedures provided the research continues to meet the Expedited Research Categories and any modifications do not substantially increase risk to participants, and
 - 4.1.6 Minor modifications to research previously approved by the convened IRB provided the modifications do not substantially increase risk to participants.
- 4.2 The expedited review procedure does not apply to initial review of:
- 4.2.1 Research in which 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, 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,
 - 4.2.2 Classified research involving human research participants, or
 - 4.2.3 Studies involving randomized use of non-FDA approved drugs, devices, or biologics. All such studies are reviewed by the convened IRB.

5.0 OVERVIEW

Expedited [Research Categories](#)

5.1 [Category 1](#)

Clinical studies of drugs and medical devices only when condition (5.1.1) or (5.1.2) is met.

- 5.1.1 Research on drugs for which an investigational new drug application ([21 CFR 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;
- 5.1.2 Research on medical devices for which (i) an investigational device exemption application ([21 CFR 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.

5.2 [Category 2](#)

Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

- 5.2.1 From healthy, nonpregnant adults who weigh at least 110 pounds. For these participants, 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

- 5.2.2 From other adults and children, considering the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these participants, 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.

5.3 Category 3

Prospective collection of biological specimens for research purposes by noninvasive means. Examples:

- 5.3.1 Hair and nail clippings in a nondisfiguring manner;
- 5.3.2 Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
- 5.3.3 Permanent teeth if routine patient care indicates a need for extraction;
- 5.3.4 Excreta and external secretions (including sweat);
- 5.3.5 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;
- 5.3.6 Placenta removed at delivery;
- 5.3.7 Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
- 5.3.8 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;
- 5.3.9 Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; or
- 5.3.10 Sputum collected after saline mist nebulization.

5.4 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:

- 5.4.1 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 research participant or an invasion of the participant's privacy;
- 5.4.2 Weighing or testing sensory acuity;
- 5.4.3 Magnetic resonance imaging;
- 5.4.4 Electrocardiography; electroencephalography, thermography detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;

5.4.5 Moderate exercise, muscular strength testing, body composition assessment and flexibility testing where appropriate given the age, weight and health of the individual.

5.5 Category 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 46.104](#).)

5.6 Category 6

Collection of data from voice, video, digital, or image recordings made for research purposes.

5.7 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. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.104**(b)(2)** and **(b)(3)**.)

5.8 Category 8

Continuing review of research previously approved by the convened IRB as follows:

5.8.1 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

5.8.2 Where no subjects have been enrolled and no additional risks have been identified; or

5.8.3 Where the remaining research activities are limited to data analysis.

5.9 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.

6.0 PROCEDURE

6.1 Initial Review of Research

6.1.1 Investigator or Designee

The investigator/designee must create a new protocol through the web-based IRB submission system, Mentor IRB, as applicable, for IRB consideration through the expedited review mechanism. (Refer to [SOP 2.01, “Guidelines for New Protocol Submission”](#) for submission guidelines.)

6.1.2 **IRB Office**

- 6.1.2.1 Ensures that the submission is complete and is available in its entirety in Mentor IRB for IRB Chair or designee review.
- 6.1.2.2 Confirms that all documentation is contained within the Mentor profile of all key research personnel for reviewer consideration. (Refer to [SOP 2.01, “Guidelines for New Protocol Submission”](#) for document requirements.)
- 6.1.2.3 Assigns the IRB Chair or designee as reviewer including the “Chair Expedited Review – Initial Review” checklist to the reviewer.
- 6.1.2.4 Communicates all IRB determinations through Mentor IRB in a notification letter sent to the Principal Investigator and any research coordinator(s) as outlined in SOP 1.04, “Conducting IRB Meetings / IRB Meeting Minutes”.
- 6.1.2.5 Sets expiration date in Mentor following review and approval:
 - 6.1.2.5.1 New protocols requiring continuing review are given a one-year approval. For ease of tracking, the expiration date of applicable studies is set for the first day of the month of the following year that approval was granted (e.g., if approval is granted on January 7, 2026, the expiration date will fall on the January 1, 2027).
 - 6.1.2.5.2 New protocols that do not require continuing review will require a Status Update within two years to confirm the current status of the research and that training requirements remain current, and for review of any updated FCOI disclosures. For ease of tracking, the expiration date is set for the first day of the month of two years following the date approval was granted (e.g., if approval is granted on January 7, 2026, the expiration date will fall on the January 1, 2028).

6.1.3 **IRB Chair or Designee**

Expedited initial review of research shall be carried out by the IRB chair. At the discretion of the IRB chair, such review may be delegated to another IRB member provided that the reviewer(s) selected for the delegated review are, in the opinion of the chair, qualified to review the submission by virtue of appropriate expertise, experience, or other qualification. A written record of the referral is made and kept in the IRB record.

Research reviewed by the expedited process must be reviewed using the same criteria the IRB uses to review research at a convened meeting, as follows.

- 6.1.4 Risks to participants are minimized (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risks, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
- 6.1.5 Risks to research participants are reasonable in relation to anticipated benefits (if any) to research participants, and the importance of the knowledge that may be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies that subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility. (Refer to [21 CFR 56.111\(2\)](#))
- 6.1.6 Selection of participants is equitable. In making this assessment, the IRB should take into account the purposes of the research and the setting in which the research will be conducted, and should be particularly cognizant of the special problems of research involving vulnerable populations such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons. (Note: The Christ Hospital does not conduct research on prisoners.)
- 6.1.7 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 [45 CFR 46.116](#).
- 6.1.8 Informed consent will be appropriately documented, in accordance with, and to the extent required by, [45 CFR 46.117](#).
- 6.1.9 When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of research participants.
- 6.1.10 When appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.
- 6.1.11 When some or all research participants are likely to be vulnerable to coercion or undue influence, additional safeguards have been included in the study to protect the rights and welfare of these participants.

The Chair or designee(s) will evaluate whether the research fits into one or more of the categories for Expedited Review and mark the determination on the reviewer checklist as follows.

- 6.1.12 Approved: An approval letter is sent to the investigator following the expedited review.

- 6.1.13 Additional Information Requested: A letter is sent to the investigator explaining the additional information requested.
- 6.1.14 Protocol Requires Full Board Review: The investigator is notified that a full review is necessary and the necessary revisions or clarifications are outlined for the submission of the protocol for Full Board Review. The decision to require full review is made if:
 - 6.1.14.1 The protocol fails to meet the expedited review categories specified by federal regulations,
 - 6.1.14.2 The reviewer is unable to satisfy his/her concerns regarding the rights and wellbeing of the research participants, and/or
 - 6.1.14.3 Crucial aspects of the protocol or consent statement require clarification.

Note: This procedure describes IRB review for the Initial Review (only) of a proposed research protocol. Procedures for other types of Expedited Review (i.e., Continuing Review, and Minor Modifications of Research Protocols) are outlined in [SOP 1.01](#), “Continuing Review”; [SOP 2.03](#), “Proposed Amendments/Modifications in Previously Approved Research Studies”; and [RM 03](#), “Continuing IRB Review of Existing Research Protocols”.

7.0 REFERENCES

- 7.1 [IRB Standard Operating Procedures](#)
 - 7.1.1 SOP1.01 Continuing Review
 - 7.1.2 SOP 1.04 Conducting IRB Meetings / IRB Meeting Minutes
 - 7.1.3 SOP 2.01 Guidelines for New Protocol Submission
 - 7.1.4 SOP 2.03 Proposed Amendments/Modifications in Previously Approved Research Studies
- 7.2 [IRB Reference Manual](#)
 - 7.2.1 RM 03 Continuing IRB Review of Existing Research Protocols
- 7.3 Code of Federal Regulations
 - 7.3.1 U.S. Department of Health and Human Services (HHS):
 - 7.3.1.1 [45 CFR 46.109](#)
 - 7.3.1.2 [45 CFR 46.110](#)
 - 7.3.1.3 [45 CFR 46.116](#)
 - 7.3.1.4 [45 CFR 46.117](#)
 - 7.3.1.5 [Expedited Review: Categories of Research that may be Reviewed Through an Expedited Review Procedure \(1998\)](#)
 - 7.3.2 U.S. Food and Drug Administration (FDA)
 - 7.3.2.1 [21 CFR 56.110](#)
 - 7.3.2.2 [21 CFR 312](#)
 - 7.3.2.3 [21 CFR 812](#)
- 7.4 AAHRPP Domains and Elements: [II.2.F.1](#)