The Christ Hospital IRB **Number:** 1.17
Submitted By: Erica Jones **Effective Date:** 11/08
Reviewed By: Steve Roberts, MD **Revised/Reviewed Date:** 09/22
Approved By: Steve Roberts, MD
(II.2.F.1)

STANDARD OPERATING PROCEDURE

Expedited Review

POLICY:

It is Christ Hospital policy that TCH IRB review qualified human subject research using expedited procedures in accordance with federal regulations. An expedited procedure refers to review of research involving human subjects by the IRB Chair or designee. Although investigators make a preliminary determination about whether research meets the criteria for expedited review procedures, the IRB makes the final determination. If the IRB does not concur with the investigator's determination, it may request modification to the research or require that the research be submitted for convened IRB review. At the discretion of the Chair, expedited review may be delegated to another IRB member provided the reviewer(s) selected for the delegated review are qualified, in the opinion of the chair, 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 study file.

The IRB may use an expedited review procedure to review any of the following:

- Research which (1) presents no more than minimal risks to human subjects, and (2) involves only procedures listed in one or more of the Expedited Research Categories below.
- Renewals or modifications to research previously-approved under expedited procedures provided the research continues to meet the Expedited Research Categories below and any modifications do not substantially increase risk to subjects.
- Minor changes in research previously-approved by the convened IRB
- Research granted exemption but requiring a limited IRB review under the TCH IRB Policy on Exempt Research.

The IRB may not use an expedited review procedure to conduct initial review any of the following:

- Research in which identification of the subjects 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
- Classified research involving human subjects
- Studies involving randomized use of non-FDA approved drugs, devices, or biologics. All such studies are reviewed by the convened IRB.

Expedited Research Categories

Category 1

Clinical studies of drugs and medical devices only when either condition below is met:

a) 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; or
b) Research on medical devices for which (1) an investigational device exemption application (21 CFR 812) is not required; or (2) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

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, 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.

Category 3

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

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; or
j) Sputum collected after saline mist nebulization.

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 include:

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.

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).

Category 6

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

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.

Category 8

Continuing review (i.e. renewal) 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.

Category 9

Continuing review (i.e. renewal) 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.

The expedited review procedure will apply to IRB applications for initial review, continuing review, and minor modifications of previously approved research as appropriate. A reviewer using expedited procedures will exercise all authorities granted to the IRB except the reviewer will not disapprove the research. 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. Also, consultants may assist the IRB in review of research undergoing expedited review.

Research approved initially via convened IRB review may later qualify for expedited review. This may occur if during the convened review, the reviewer finds that:

a) The research involves no more than minimal risk.
b) The research is not "classified" research.
c) The identification of the participants or their responses will not 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.

AND

a) The research is permanently closed to enrollment of new subjects, all subjects have completed all research-related interventions, and the research remains open only for long-term follow-up of subjects. Such determinations will be documented in the expedited review procedure.
b) All remaining research activities are limited to data analysis. Such determinations will be documented in the expedited review procedure; or
c) The convened IRB determines that the research involves no greater than minimal risk and that no additional risks have been identified. Such determinations will be documented in the minutes.

OR

a) The research is not "classified," and
b) Where no subjects have been enrolled and no additional risks have been identified.

A list of actions taken through the expedited review procedures will be provided to the convened IRB. 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.

Renewals/Continuing Review of Research

The IRB conducts continuing review of all applicable research at intervals appropriate to the degree of risk, but not less than once per year for:

- Non-exempt studies that are federally funded or regulated (e.g., FDA, VA)
- Renewals requiring review by the convened IRB

The IRB may require review more frequently than annually as it deems appropriate.

The IRB is not required to conduct renewal for the following:

- Research that is not federally funded or FDA- or VA-regulated and is eligible for expedited review under the the Revised Common Rule at 45 CFR 46.110.
- Research reviewed by the IRB in accordance with the limited IRB review described in § 46.104(d)(2)(iii), (d)(3)(i)(C), or (d)(7) or (8);
- Research granted exemption, including exempt research requiring a limited IRB review.
- Research that is not federally funded or FDA- or VA-regulated and required review by the convened IRB, but has progressed to the point that it involves only one or both of the following:
    - Data analysis, including analysis of identifiable private information or identifiable biospecimens (i.e., data analysis only)
    - Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care (i.e., clinical follow-up)

The IRB may require renewal for this research on a case-by-case basis as it deems appropriate. If renewal is required, the IRB must document the rationale for such requirement.

Ressearch not requiring continuing review is still subject to study status updates/check-ins per IRB SOP 1.01 Continuing Review.

REFERENCE:

21 CFR 56.110; 45 CFR 46.109; 45 CFR 46.110; 45 CFR 46.116; 45 CFR 46.117.

PROCEDURE

Investigator:

The investigator must submit the following through the web-based IRB submission system, Mentor IRB, as applicable, for IRB consideration through the expedited review mechansim: (See SOP 2.10 Guidelines for Protocol Submission for document requirements.)

- E-Application, incorporating a request for the following as applicable to the research:
    - HIPAA Request for Full or Partial Waiver
    - Waiver of Informed Consent
    - Waiver of Documentation of Informed Consent
- Protocol, if applicable
- Informed consent document, if applicable
- CITI completion certificate
- Questionnaires, screening instruments, recruitment materials, if applicable
- Financial Conflict of Interest (FCOI) disclosure, for funded research

IRB Office:

- Ensures that the submission is complete and is available in its entirety in Mentor IRB for IRB Chair or designee review
- Assigns the IRB Chair or designee as reviewer
- 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, IRB Meeting Minutes / Conducting IRB Meeting.

- New protocols are given a one-year approval, effective the date of the convened meeting, and expiring 12 months later on the first day of the 12th month. For example, new protocols approved by the convened IRB on March 9, 2021 will have an expiration date of March 1, 2022. Any expedited research that does not require continuing review will require an annual Status Update to confirm the current status of the research, training requirements and any updated FCOI disclosures.

IRB Chair or Designee:
Expedited initial or continuing review and modifications to approved research shall be carried out by the IRB Chair. At the discretion of the Chair, such review may be delegated to another IRB member provided the reviewer(s) selected for the delegated review are qualified, in the opinion of the chair, 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 study file.

Research reviewed by the expedited process must be reviewed using the same criteria the IRB uses to review research at a convened meeting. The criteria for review are:

1. Risks to subjects 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.
2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably 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 subjects would receive 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 reearch risks that fall within the purview of its responsibility.
3. Selection of subjects 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).
4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by 45 CFR 46.116.
5. Informed consent will be appropriately documented, in accordance with, and to the extent required by 45 CFR 46.117.
6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
8. When some or all of the subjects 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 subjects.

The Chair or designee(s) will review the research evaluating whether the research fits the applicability, and if so, will determine whether the research fits into one or more of the categories for expedited review. The Chair or designee(s) will mark the determination on the expedited review checklist. The recommendations usually fall into three categories.

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

b. Additional Information Requested: A letter is sent to the investigator, explaining what additional information is requested.

c. Protocol Requires Full Board Review: The investigator is notified that a full review is necessary and the revisions or clarifications necessary are outlined for the submission of the protocol for review by the full board. The decision to require full review is made if the protocol fails to meet the expedited review categories which are specified by federal regulations, if the reviewer is unable to satisfy their concerns regarding the rights and wellbeing of the subjects, and/or crucial aspects of the protocol or consent statement require clarification.