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 Co-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.

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

1. Some or all of the research appearing in the “Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review”, published by DHHS, and the reviewer finds:
   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.

2. Minor changes in previously approved research during the period (of 1 year or less) for which approval is authorized.

NOTE: A list of categories for expedited review are provided at the end of this SOP. For more information regarding expedited review criteria, see Reference Manual 2, section 2.3

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 using expedited procedures will undergo continuing review at intervals appropriate to the degree of risk at least annually.

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:

- The research involves no more than minimal risk.
- The research is not "classified" research.
- 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

- 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.
- All remaining research activities are limited to data analysis. Such determinations will be documented in the expedited review procedure; or
- 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

- The research is not "classified," and
- 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.

**REFERENCE:**
45 CFR 46.100, 21 CFR 56.110, 45 CFR 46.116, 45 CFR 46.117.

**PROCEDURE**

**Investigator:**

The investigator must submit copies as indicated below of all the materials, as applicable, required by a full board review. Some documents may not be required in a study considered for expedited review, i.e., consent form. (See SOP 2.10 Guidelines for Protocol Submission for document requirements.)

- A completed Expedited Review IRB coversheet
- Title Page with signatures of approval from the department chair and section chief, if applicable
- Study Application form
- The research protocol
- The informed consent document (as attachments, i.e., questionnaires, screening instruments, recruitment materials if applicable, the submission of standard screening instruments is not required)
- CITI completion certificate
- HIPAA form
- Financial disclosure forms

**IRB Office:**

**IRB Staff:**
- Documents receipt of Expedited application documents using date stamp;
- Forwards application to IRB Chair or designee for review.

**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 research 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 45.117.
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 investigator submits 17
copies (including original) of the revised protocol to the IRB Chairman as outlined in
SOP 2.01, Guidelines for Protocol Submission. 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 subcommittee is unable to satisfy its concerns
regarding the rights and wellbeing of the subjects, and/or crucial aspects of the
protocol or consent statement require clarification.

**REVISION HISTORY:**

<table>
<thead>
<tr>
<th>Date Revised</th>
<th>Reason For Change</th>
<th>Revised By</th>
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<tr>
<td>01/19/12</td>
<td>We do children’s research</td>
<td>Becky</td>
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<tr>
<td>04/09/15</td>
<td>Added IRB Office Staff responsibilities and expedited categories</td>
<td>Becky</td>
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EXPEDITED REVIEW CATEGORIES

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 expected 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. (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.)

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 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 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) uncanellated 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 HSS regulations for the protection of human subjects. 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 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.

NOTE: Although permitted by regulations to expedite a continuing review when no subjects have been enrolled, TCH IRB will continue to have these studies reviewed by the full board unless one of the other above conditions are met under 8, a-c.

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories 2 through 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.