

Expedited Review of Research

I. **Policy Statement:**

Human research activities may not be initiated until an IRB has reviewed and approved a proposal in accordance with applicable Federal regulations. Tasks such as data collection, access to medical records for the purpose of research, recruitment, and participant screening (including the collection of contact information for a potential participant) may not be undertaken until IRB review and approval has been completed. When an investigator intends to implement new research, an application that is inclusive of the current protocol and all supporting documents, must be submitted to the IRB for consideration. When received, the IRB will determine the appropriate category of review for the proposed research, which may include an exempt or expedited process or full board consideration. Determinations regarding the described process and documentation of informed consent and HIPAA authorization, inclusion of vulnerable populations and other applicable investigational drug, device or biologic criteria will also be considered during the application of established criteria for approval of newly proposed research.

This policy will describe the procedure for the expedited review of research conducted by the Trinity Health West Region IRB (THWR IRB). It will set forth the parameters for IRB review of new applications, modifications, and continuing review reports through an expedited procedure.

This policy applies to all human subject research submitted to the THWR IRB for consideration and implementation within the Trinity Health West Region.

II. **Definitions:**

Child: per HHS regulations, a person who has not attained the legal age form consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted ([45 CFR 46.402\(a\)](#)).

Expedited Review: A review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in [45 CFR 46.110](#).

Minimal Risk: 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.

III. **Equipment:** None

IV. **Procedure:**

The IRB permits the use of expedited review procedures for eligible human subject research activities, as defined by federal regulations ([45 CFR 46.110](#)).

A. Eligibility for Expedited Review

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

1. Research that involves no more than minimal risk and meets the criteria for an expedited review categories authorized by [45 CFR 46.110](#) and [21 CFR 56.110](#).
2. Minor changes to previously approved research during the period for which approval is authorized.
3. Research for which limited IRB review is a condition of exemption under [45 CFR 46.104\(d\)\(2\)\(iii\)](#), or [\(d\)\(3\)\(i\)\(C\)](#).

B. Categories of Research that may be reviewed through the Expedited Review Process

When intending to use any of the expedited review categories authorized by federal regulations, the following must be considered:

1. The activities should not be deemed to be of minimal risk only because they are listed in one of the categories. The identified activities are eligible for review through an expedited procedure WHEN the specific circumstances of the proposed research involve no more than minimal risk to a human subject.
2. The categories apply regardless of the age of the subject, except when noted otherwise.
3. The expedited review procedure may not be utilized when identification of the 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. The only exception is when reasonable and appropriate protections will be implemented so that the risks related to an invasion of privacy and/or breach of confidentiality are no greater than minimal.
4. The expedited review procedure cannot be applied for classified research involving human subjects.
5. The standard requirements for informed consent (including a request for a waiver or alteration) apply regardless of the type of IRB review.
6. Categories 1 through 7 pertain to initial submissions, modifications to previously approved research and continuing reviews.
7. Categories 8 and 9 only apply to continuing review.

Research Categories Eligible for Expedited Review are as follows:

1. Clinical studies of drugs and medical devices only when the following conditions are met:
 - a. Research on drugs for which an Investigational New Drug (IND) application (IND) 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 an Investigational Device Exemption (IDE) application is not required or the medical device is approved (cleared) for marketing and the medical device is being used in accordance with its approved (cleared) labeling.
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
 - a. Collected 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. Collected 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 non-invasive 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 gum base or wax or by applying a diluted 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 sub gingival 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.

Of note, FDA and OHRP agree that the following procedures are considered noninvasive when considered in the context of expedited research:

- a. Vaginal swabs that do not go beyond the cervical os.
 - b. Rectal swabs that do not go beyond the rectum; and
 - c. Nasal swabs that do not go beyond the nares.
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.
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 46.101\(b\)\(4\)](#). This listing in this policy 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 the HHS regulations for the protection of human subjects. [45 CFR 46.101\(b\)\(2\)](#) and [\(b\)\(3\)](#). This listing in this document refers only to research that is not exempt.
8. Continuing review of research previously approved by the convened IRB as follows:
 - a. Where the research is permanently closed to the enrollment of new subjects; all subjects have completed all research-related interventions; and 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 IND application or IDE where categories two (2) through eight (8) above 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.

C. Process of Expedited Review

1. An expedited review must be performed by the IRB Chair or by an experienced IRB member designated by the IRB Chair, i.e., a member with demonstrated knowledge and application of research ethics in human subject protections of at least one year.
2. The reviewers have access to and review the same materials that are available for a convened IRB review.
3. The criteria for approval using the expedited procedure are the same as those for review by a convened IRB.
4. The reviewers may exercise all the authorities of the IRB except that the reviewers may not disapprove the research.
5. A research activity may be disapproved only after review performed in accordance with convened IRB procedures.
6. The reviewer will make **one** of the following determinations regarding the application:
 - a. Approved as minimal risk research.
 - b. The research is exempt from the requirements outlined in [45CFR46](#).
 - c. The proposed activity is not research or not human subjects research and does not require IRB review (Examples: case study, quality improvement/quality assurance),
 - d. Revisions and/or additional information required.

- e. Forward to the convened IRB.
- 7. Documentation of the review action taken by the reviewer, and any specific findings required by federal regulations must be documented in the reviewer notes in electronic IRB platform (IRB Manager).
- 8. In all cases, the expedited reviewer reserves the authority to refer any item to a medical reviewer and/or to the Convened IRB for review. The expedited reviewer provides specific rationale for the referral, including, but not limited to items appearing on the expedited review list that the reviewer has assessed as potentially more than minimal risk.

D. IRB Oversight of Expedited Review

IRB members are advised of research proposals which have been reviewed by the expedited procedure with a listing provided with each convened meeting agenda. This information is also included in the meeting minute history. Any member can request to review the entire IRB record associated with items reviewed by the expedited review procedure.

E. Modifications to Previously Approved Research using the Expedited Procedure

1. When the research was initially approved by a convened IRB.

Modifications to applications previously approved by a convened IRB may be reviewed by the expedited review process if they meet the following criteria:

- a. Modifications do not pose an increased risk to subjects.

AND

- b. Any additional procedures fall within categories 1-7 of research that may be reviewed using the expedited procedure.
- c. Modifications constitute a minor change to previously approved research.
- d. Minor Modifications: Any modification that does not materially affect the assessment of risks and benefits.

2. When the research was initially approved through an Expedited Procedure

Modifications to applications previously approved by Expedited review process may be reviewed using Expedited review if they meet the following criteria:

- a. With the modification implemented, the research would continue to pose no more than minimal risk to subjects,

AND

- b. The modifications do not involve any procedures that do not meet Expedited categories 1 through 7, or procedures that do not meet exemption categories 1 through 6.

F. Continuing Review of Research using the Expedited Procedure

- 1. The "Continuing Review of Research" policy outlines the criteria for research that requires, or does not require continuing review and, when applicable, the frequency for continuing review.
- 2. For research requiring continuing review, the continuing review may be conducted by the Expedited review process if it meets one of the following criteria:
 - a. Continuing research activities pose no more than minimal risk to subjects, as assessed by the reviewer, **AND** the research met the criteria for initial expedited review and continues to meet those criteria, **AND** all procedures continue to meet one or more of the expedited review categories [1-7] as identified at initial/previous review.
 - b. Research which was previously reviewed by the convened IRB but meets the criteria for expedited review and meets category 8(a), 8(b), or 8(c) for expedited review as defined by the Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA).

- c. Research which was previously reviewed by the convened IRB and the convened IRB determined the study meets category 9 for expedited review as defined by OHRP and the FDA.

G. Expedited Review with Vulnerable Populations

1. Subpart B: Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research

- a. Clinical studies of drugs or devices (Expedited Category 1) that involve participant contact with pregnant women, human fetuses or neonates will be forwarded to the Convened IRB for review and determination.
- b. The Convened IRB will determine whether Expedited procedures may be used for continuing review of these studies in accordance with [45 CFR 46.110](#).
- c. Proposed research projects involving the collection of data through noninvasive procedures (Expedited Category 4), may be reviewed by an IRB medical reviewer (provider) for assessment of the level of risk.
- d. In all cases the Expedited Reviewer reserves the authority to refer any study involving Subpart B to a medical reviewer and/or the convened IRB for review.

2. Subpart C: Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects.

Research involving prisoners as subjects requires review by a prisoner representative of the IRB and must be forwarded to a convened IRB for review and determination.

Exception: Research aimed at involving a broader subject population that only incidentally includes prisoners may be reviewed by the expedited procedure for purposes of determining exemption from [45 CFR 46](#).

3. Subpart D: Additional Protections for Children Involved as Subjects in Research.

- a. Research involving children as subjects will be reviewed using Expedited procedures providing the research is no greater than minimal risk in accordance with [45 CFR 46.404](#).
- b. In all cases, the Expedited Reviewer reserves the authority to refer any study involving Subpart D to a medical reviewer and/or the convened IRB for review.

V. Ministry Specific Related Addendums, Procedures, and/or Policies:

A. Saint Agnes Medical Center: None

B. Saint Alphonsus Health System: None

VI. Additional Approval: Not applicable.