Title: SARMC Institutional Review Board: Expedited Review

Policy Statement: Expedited review of research involving human participants may be conducted by the IRB chairperson or by a designee. Expedited review will be conducted in accordance with the requirements set forth in 45 CFR 46.110.

Procedure:
I. Definition of expedited review
   A. Research activities involving no more than minimal risk and in which the only involvement of human subjects is in one or more of the categories listed in Section II are eligible for expedited review.
   
   B. Minimal risk is 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” [21 CFR § 56.102(I)].

   C. The initial determination of whether the review can be expedited is made by the IRB Chairperson or the Director of Research Integrity. Expedited review may be carried out by the Chairperson or Chairperson's designee. The reviewer may either approve the submission, or refer it to the full convened Board for review. The reviewer may not disapprove an expedited review.

   D. The requirements for informed consent (or for altering or waiving the requirement for informed consent) apply regardless of whether the research is reviewed by the full convened IRB or under the expedited procedure.

II. The following research is eligible for expedited review:
   A. Minor changes in previously approved research during the period (of one year or less) for which approval is authorized. Examples include, but are not limited to:
       1. Informational revisions - changes in the protocol with no potential impact on the risks for human subjects, such as:
a. changes in telephone numbers,
b. the addition or deletion of associates or staff,
c. the reduction in the number of research participants, or
d. the deletion of questions in a questionnaire.

2. Minor revisions - changes in the protocol that may impact the research participants, but do not significantly affect the risks to the participants, such as:
   a. increasing the size of the study sample,
   b. decreasing the amount of blood that is drawn or the frequency of blood draws, or
   c. revising the format of the consent form.

3. Revision with minimal risks to research participants, such as:
   a. adding a standardized test,
   b. changing the treatment,
   c. decreasing the drug dosage or the frequency of drug administration,
   d. changing the recruitment plan,
   e. adding a standard quality-of-life questionnaire,
   f. extending the time period of the study to include follow-up with the research participants,
   g. revising eligibility to include or exclude study participants,
   h. adding a research site,
   i. changing the principal investigator, or
   j. changing the consent form to include a newly identified side-effect or adverse event related to the study drug.

4. Surveys and Questionnaires

B. Continuing review of research previously approved by the convened IRB as follows:
   1. 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
   2. where no subjects have been enrolled and no additional risks have been identified; or
   3. where the remaining research activities are limited to data analysis.

C. The study of existing data, documents, records, pathological specimens, or diagnostic specimens. Existing data means the items existed before the research was proposed or was collected prior to the research for a purpose other than the proposed research.

D. Research on individual or group characteristics or behavior (including, but not limited to research on perception, cognition, motivation, identity,
language, communication, cultural belief or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

E. Collection of blood samples by finger, ear, or heel stick, or by venipuncture, in amounts not exceeding 550 milliliters in an eight-week period and not more than two times per week, from subjects 18 years of age or older who are in good health and not pregnant.

F. Collection of: hair and nail clippings in a non-disfiguring manner, deciduous teeth, and permanent teeth if patient care indicates a need for extraction.

G. Recording of data from subjects 18 years of age or older using non-invasive procedures routinely employed in clinical practice. It does not include exposure to electromagnetic radiation outside the visible range (for example: x-rays or microwaves).

H. Voice recordings, video, digital, or image recordings made for research purposes, such as investigations of speech defects.

I. Moderate exercise by healthy volunteers.

IRB members will be advised of all research proposals approved through the expedited review process at the next regularly scheduled IRB meeting. The IRB has the prerogative to discuss, rescind or amend expedited actions.

**Related Policies: Research Studies**

**Related Forms:** Expedited Review Application

[http://www.saintalphonsus.org/forms-and-resources](http://www.saintalphonsus.org/forms-and-resources)

**References:**

