

SPARROW HEALTH SYSTEM
INSTITUTIONAL RESEARCH REVIEW COMMITTEE

**POLICY: EXPEDITED REVIEW OF MINOR CHANGES IN A PREVIOUSLY
APPROVED STUDY**

PURPOSE: The purpose of this policy is to provide guidelines, pursuant to 45 CFR § 46.110(b)(2), for defining minor revisions with minimal risks* to research participants that may be reviewed and approved by expedited review procedures. According to Federal guidelines, *"An IRB may use the expedited review procedure to review....(2) minor changes in previously approved research during the period (of one year or less) for which approval is authorized."*

PROCEDURE: The expedited review procedure allows the IRRC Chair and/or a qualified member of the IRRC to review the revision and determine approval. A revision cannot be disapproved by expedited review; however, the Chair or IRRC member may recommend that the revision be reviewed by the full IRRC.

1. The key determining factor for revisions that would qualify for expedited review is the amount of risk to the study participant based on the definition of minimal risk. This initial determination must be made by the IRB Administrator and/or IRRC Chair or designated IRRC member. See definitions below.
2. The revision approval will only be effective until the expiration date of the most recent continuation review.
3. All members of the IRRC must be informed of revisions to study protocols approved by the expedited review procedures. Notification of these revisions will be placed in the Announcement section of the IRRC agenda as well as the minutes.

DEFINITIONS: For purposes of this policy, the following definitions shall apply:

1. **INFORMATIONAL REVISIONS** involve changes in the protocol with no potential impact on the risks for human subjects. Many of these changes are editorial changes within the protocol. Examples include:
 - 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 include changes in the protocol that may impact the research participants, but do not significantly affect the risks to the participants. Examples of these changes include:
 - a. adding to the population,
 - b. decreasing the amount of blood that is drawn or the frequency,
 - c. adding nonsensitive questions to a questionnaire,
 - d. revising the format of the consent form,
 - e. changing telephone numbers or contact persons on the consent form, or
 - f. other minor revisions to the consent form.

*According to Federal guidelines, 21 CFR § 56.102(i), "*Minimal Risk* means that 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."

APPLICABLE REGULATIONS AND GUIDELINES:

45 CFR § 46.110(b)(2)
21 CFR § 56.110(b)(2)
21 CFR § 56.102(i)