

SPARROW HEALTH SYSTEM
INSTITUTIONAL RESEARCH REVIEW COMMITTEE

POLICY: REPORTED PROPOSED CHANGES IN RESEARCH PROTOCOL

PURPOSE:

To ensure prompt reporting to the IRB of changes in research activity and to ensure that IRB approval has been granted before implementation of the changes.

Proposed changes in a research protocol must ordinarily be reviewed and approved by the IRB prior to implementation of the change. An exception to this rule is a suspension of or other change in a protocol that is necessary to eliminate a hazard to the subjects enrolled in the protocol. In these cases, prompt notification to the IRB of the changes is required. For this purpose, the following policy is instituted:

- A. The principal investigator is responsible to inform the IRRC within 48 hours, of:
 1. Any suspension or changes in the research environment or new information indicating greater risk to the human subjects than existed when the protocol was previously reviewed and approved. Any suspension of or other change made in the protocol for safety reasons.
 2. Any local adverse event, or other problem, subject to the IRRC's policy: *IRB Reporting of Unexpected Internal Adverse Event*.
- B. All other changes should be promptly submitted to the IRRC for review following the regular schedule for monthly IRB meetings; including changes in the investigative team, unless this change might adversely affect the rights and welfare of the human subjects, in which case, reporting this change to the IRB needs to be done within 48 hours.

PROCEDURE:

The principal investigator must submit a completed [Application for Revision and/or Amendment](#) form, to request approval of a change of research protocol, as stipulated above. The application will include, but is not limited to, the following information:

1. Title of Research Protocol and Sparrow ID#
2. Category of proposed change(s)
3. Description of, and justification for, proposed change(s)
4. Risk to subjects
5. Changes to consent.

Minor changes involving no more than minimal risk that occur during the period for which approval is in force, may be reviewed by an expedited review process by the IRB Chairperson, if determined appropriate, otherwise the changes will go before the full Committee. (See *IRRC Policy: Expedited Review of Minor Changes in a Previously Approved Study.*)

SCOPE:

These policies and procedures apply to all research submitted to the IRB.

RESPONSIBILITY:

IRRC staff is responsible for promptly notifying the IRB Chair, or designee, of receipt of an Application for Revision and/or Amendment form that indicates a change in the protocol that may cause greater risk to the human subjects.

The IRB Chair, or designee, is responsible for preliminary assessments of the changes and indicating appropriate action.

APPLICABLE REGULATIONS AND GUIDELINES:

45 CFR 46.103
45 CFR 46.113
21 CFR 56.108
21 CFR 56.113
OHRP Guidelines
FDA Information Sheets, 1998

ATTACHMENT:

Application for Revision and/or Amendment of a Project Involving Human Subjects