Title: SARMC Institutional Review Board: Deviations from Protocol and/or Standard Operating Procedures

Policy Statement: Investigators are responsible for conducting human subject research in accordance with all applicable federal and state regulations, as well as SARMC IRB policies and procedures. During the conduct of the study, unintentional events or deviations from standard operating procedures and/or the protocol may occur or subsequently be discovered upon periodic reviews. If a protocol deviation is discovered by the Investigator and/or their research staff, it must be reported to the SARMC IRB (major deviations must be reported within 5 days of discovery; see sec. III below).

Procedure:

I. Protocol Deviations and/or Deviations from Standard Operating Procedures

A deviation occurs when there is a discrepancy between the protocol and/or standard operating procedures and the activities being performed for a study. While a deviation may or may not increase risk to subjects, it is particularly important that the IRB be notified immediately when the deviation could potentially cause increased risk to subjects or alter the outcome of a study. The Investigator must complete a Protocol Deviation Reporting Form for the IRB that includes the following:

A. when the deviation occurred;
B. how it was discovered;
C. what effect it has (if any) on current or future research subjects, and
D. the remedial action taken to avoid recurrence of the deviation.

II. IRB Authority

The IRB Chairperson or designee will expeditiously review deviations to determine whether the risk/benefit ratio has increased as a result of the deviation. Potential or real harm to any subjects will be assessed. If deemed necessary by the IRB Chairperson or designee, the report will be sent to the next convened full IRB meeting for review and assessment of further actions that may need to be taken. The range of actions may include revisions to the protocol, audit of the investigator, increase in frequency of continuing review, or additional protective measures requested by the IRB (i.e. observation of the informed consent process). If the IRB is notified of an excessive number of protocol deviations, it is within the authority of the IRB to conduct an inspection to promote integrity and compliance, and depending on the results of such an audit, to temporarily or permanently suspend the research.

III. Definitions

Deviations may be either minor or major in nature, and may or may not have a direct effect on individual subjects.
Major deviations: The deviation posed a significant risk of substantive harm to the individual research subject; the deviation has compromised the scientific integrity of the data collected for the study; or there is continuing occurrence of deviations that will lead to issues of non-compliance as stated in federal regulations. Major deviations must be reported to the IRB within 5 working days of the occurrence.

Minor deviations: The deviation has no substantive effect on the risks or benefits to the individual research subject(s); the deviation has no substantive effect on the data collected; or the deviation was an inadvertent error on the part of the research team or the subject. Minor deviations can be reported at continuing review or periodically as needed, at the discretion of the principal investigator or study sponsor.

IV. Examples

Major Deviations (please note: the list of examples is intended as a guide and is not all inclusive):

- Failure to obtain informed consent, i.e., there is no documentation of informed consent or informed consent obtained after initiation of study procedures
- Informed consent for IND/IDE studies obtained by someone other than individuals authorized by IRB to obtain consent, e.g. someone other than the investigator or person(s) authorized to obtain informed consent.
- Incomplete documentation of informed consent, including missing subject signature, missing witness signature or missing signature of person who obtained informed consent
- Enrollment of a subject who did not meet all inclusion/exclusion criteria
- Conduct of a research study not approved by the IRB
- Failure to perform a required lab test that, in the opinion of the PI, may affect subject safety or data integrity
- Drug/study medication dispensing or dosing error
- Study visit conducted outside of required timeframe that, in the opinion of the PI, may affect subject safety
- Failure to follow an approved safety monitoring plan
- Enrollment of subjects after expiration or suspension of IRB study approval
- Use of an invalid consent form, i.e. a consent form without an IRB approval stamp, or use of an outdated or expired consent form
- Enrollment of ineligible subjects (e.g., subject’s age was 6 months above age limit)

Minor Deviations (please note: the list of examples is intended as a guide and is not all inclusive):

- Implementation of unapproved procedures except for the purpose of subject safety
- Missing original signed and dated consent form (only a photocopy available)
- Missing pages of executed consent form
- Copy not given to the person signing the form
- Failure to follow the approved study procedure that, in the opinion of the PI, does not affect subject safety or data integrity
- Study procedure conducted out of sequence
- Failure to perform a required lab test
• Missing lab results
• Study visit conducted outside of required timeframe
• Failure of subject to return study medication
• Over-enrollment or over-accredual

Related Policies: SARMC Institutional Review Board: Purpose, Principles and Authority

Related Forms: Protocol Deviation Reporting Form

References:


http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html