FRIENDS RESEARCH INSTITUTE, INC.
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Subject: Post-IRB Approval Reviews
Division: IRB
Date: March 1, 2012

IRB Policy 111.4: PROTOCOL DEVIATIONS

Policy

A deviation is any difference in study conduct from the criteria or procedures prescribed in the approved protocol, which may or may not affect the participant's rights, safety, welfare, and/or the integrity of the study and resultant data. Deviations may result from the actions of the participant, investigator, or staff and may be unintended or intended.

Examples of deviation may include, but are not limited to:

- Enrollment of a subject who did not meet all inclusion/exclusion criteria;
- Performing study procedure not approved by the IRB;
- Failure to perform a required lab test or missing lab result;
- Drug/study medication dispensing or dosing error;
- Study visit conducted outside of required time frame;
- Failure to follow safety monitoring plan;
- Implementation of unapproved recruitment procedures;
- Failure to obtain informed consent, i.e., there is no documentation of informed consent, or informed consent is obtained after initiation of study procedures;
- Inappropriate documentation of informed consent, including: missing subject signature; missing investigator signature; copy not given to the person signing the form; someone other than the subject dated the consent form; individual obtaining informed consent not listed on IRB approved study personnel list.
- Use of invalid consent form, i.e., consent form without IRB approval stamp or outdated/expired consent form;
- Study procedure conducted out of sequence;
- Omitting an approved portion of the protocol;
- Over-enrollment;
- Enrollment of subjects after IRB-approval of study expired or lapsed;
- Any identified noncompliance with federal regulations, state laws, FRI policies and/or requirements or determinations of the IRB or provisions of the approved research study; and any event that requires prompt reporting according to the protocol or the study sponsor.

A protocol deviation is reportable to the IRB within 10 business days of the time the PI becomes aware of the event if the event is likely to adversely affect:

1. The rights and welfare of the research subject;
2. The safety of the research subject;
3. The integrity of the research data; and/or

4. The subject's willingness to continue study participation.

Such events should be reported to the IRB when they are discovered, whether they occur during the course of the study, after study completion, or after subject withdrawal or completion.

If a deviation occurs that is unlikely to affect the rights, welfare or safety of the research subject or the integrity of the research data, the deviation should be reported at the time of continuing review.

Commercially sponsored research agreements may require the PI to notify the sponsor of all unplanned deviations from IRB approved protocol procedures. Sponsor reporting requirements for deviations may differ from FRI IRB reporting requirements. It is the PI's responsibility to comply with the reporting requirements outlined in the signed contract.

The IRB will review the following:

1. The deviation's net effect on risk,
2. Why the deviation occurred,
3. What is being done to prevent future occurrences,
4. Whether participants were adversely affected by the deviation,
5. Whether the participants were or should be informed of the deviation,
6. Whether the deviation indicates additional risks for subjects,
7. Whether it alter the risk/benefit ratio of the study, and
8. Whether study or consent procedures be revised accordingly.

The IRB may note the occurrence of the deviation and the investigator's report of it, request more information, request protocol or consent form changes, or suspend enrollment or interaction with subjects if it believes that it is in the best interest of the subjects.

Responsibility

IRB Administrators and Chairperson (or designee) are responsible for preliminary assessments of protocol deviations. IRB Members are responsible for reviewing these reports, and determining their affect on human subjects and whether study or consent procedures should be revised accordingly.

Applicable Regulations and Guidelines

21CFR 56.108(a)(4)
45CFR 46.103(b)(4)(iii)