FRIENDS RESEARCH INSTITUTE, INC.
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Subject: Responsibilities of Investigators
Division: IRB
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IRB Policy 114.1: RESPONSIBILITIES OF INVESTIGATORS

Policy

The PI has the ultimate responsibility for the conduct of a study, the ethical performance of the project, the protection of the rights and welfare of human subjects, adherence to any stipulations imposed by the FRI IRB. The PI must abide by the following principles when conducting research:

1. Perform the project by qualified personnel according to the approved protocol.
2. Do not implement changes in the approved protocol or consent form without prior IRB approval (except in a life threatening emergency, if necessary to safeguard the well being of a human subject).
3. Obtain informed consent from subjects prior to their enrollment into the research using only the currently approved consent form (unless this requirement was waived by the IRB).
4. Promptly report adverse consequences or unexpected side effects that are encountered in the course of the study, or new information, which could change the perception of a favorable risk/benefit ratio.
5. Report SAEs to the IRB within 48 hours of discovery, and 24 hours for deaths. For studies that have been determined by the IRB to be greater than minimal risk, these reports should be filed regardless of whether the SAE appears to be study related or is anticipated. For minimal risk studies, investigators must report only SAEs that they believe are possibly, probably, or definitely study-related. Follow up reports and a final written report should be sent to the IRB as soon as the investigator receives additional information regarding the event.
6. Request IRB renewal in advance of the expiration of the approval period.

Each approval notice given to Investigators will contain the above list of principles to be followed by Principal Investigators.

IRB Review of Research

All human subjects research that is conducted by (or under the direction of) any employee, of FRI, in connection with his or her institutional responsibilities, must be reviewed by the IRB.

Informed Consent

The Investigator must obtain informed consent from subjects prior to their enrollment into the research. The Investigator must use the informed consent document approved by the IRB. Approval and expiration dates are indicated on the consent document. Consent documents are valid only during the dates indicated on the form and/or approval notification; and the Investigator may use the forms only during the period for which they are valid.

Adverse Event Reporting

The IRB must be informed of any serious, unexpected or alarming adverse events that occur during the approval period. Investigators or Sponsors must also submit Sponsor-generated reports of adverse events occurring at other investigative sites.

Changes in Approved Research

Changes in approved research, during the period for which approval has already been given, may not be initiated without IRB review (or expedited review, where appropriate) and approval, except where necessary to eliminate apparent immediate hazards to human subjects. Investigators must submit requests for changes to the IRB in writing via the Application for an Amendment/Addendum. Upon receipt of the protocol change, the IRB Chairperson or the Chairperson's designee will determine if the revision meets the criteria for minimal risk. If the change represents more than a minimal risk to subjects, it must be reviewed and approved by the IRB. Minor changes involving no more than minimal risk to the subject may be reviewed by the expedited review process.

Periodic Reports

The length of time approval is given to a research protocol will be no more than one year, and is dependent on the risk involved with the research. Investigators are responsible for requesting renewal in anticipation of the expiration of the approval period. Investigators or their designees are required to provide a report regarding their investigation prior to the end of the approval period, or upon completion of the study. An IRB Application for Continuing Review will be available to the Investigator for this purpose.

On occasion, the IRB will request that the PI submit a periodic report prior to the date of the continuing review. Examples of these types of reports include an update regarding recruitment, an update regarding a new procedure, an update after the first subject has been medicated, etc. When this type of periodic report is requested, it will be stated in the approval letter, along with the due date of the report. It is the responsibility of the investigator to submit this report to the IRB prior to the due date.

Conflict of Interest

The protection of human subjects requires objectivity in communicating risks, selecting subjects, promoting informed consent, and gathering, analyzing and reporting data. Therefore, the IRB should consider conflict of interest issues in its deliberations of applications. All Investigators must reveal on their application to the IRB whether they or any other person responsible for the design, conduct, or reporting of the research has an economic interest in, or acts as an officer or a director of any outside entity whose financial interests would reasonably appear to be affected by the research.

Responsibility

IRB Administrator is responsible for tracking Investigator compliance with IRB requirements stipulated during the IRB's review of the Investigator's research, and for engaging appropriate Investigator sanctions when Investigators are not in compliance with IRB requirements.

IRB Chairperson (or designee) is responsible for facilitating Investigator compliance with IRB requirements through his/her management of IRB deliberations, and providing Investigators clear guidelines pertaining to that compliance through IRB communications to the Investigator.

Applicable Regulations and Guidelines

OHRP Guidance Investigator Responsibilities FAQ
FDA Guidance – Investigator Responsibilities (October 2009)