FRIENDS RESEARCH INSTITUTE, INC.
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Subject: General Administration
Division: IRB
Date: March 1, 2012

IRB Policy 101.3: MANAGEMENT OF IRB PERSONNEL

Policy

Competent staff function to provide consistency, expertise, and administrative support to the IRB, and serve as a daily link between the IRB and the research community. Thus, the IRB staff is a vital component in the effective operation of FRI's human subjects protection program. A high level of professionalism and integrity is expected.

Job Descriptions and Performance Evaluations

Members of the IRB staff should have a description of the responsibilities expected of their positions. The performance of IRB staff will be reviewed according to current FRI policy.

Staff Positions

Staffing levels and function allocation will be determined according to policy, management assessment of support requirements, and budget constraints.

Hiring and Terminating IRB Staff

The human resource policies of FRI determine the policies for recruiting and hiring staff.

Documentation

The policies of FRI determine the means of identifying, documenting and retaining formal staff interactions (such as performance reviews).

IRB Administrator Functions

The IRB Administrator is instrumental in ensuring that the IRB meets their primary responsibility of protecting the rights and welfare of human research subjects by:

1. Ensuring that submitted research is reviewed efficiently and consistent with federal regulations by:
   a) Having thorough knowledge of and ability to apply HHS/FDA federal regulations.
   b) Assuming responsibility for the education of IRB members and staff regarding the conduct of research.
   c) Helping the IRB Chairperson to determine which studies are eligible for expedited review, or qualify for exemption from continuing IRB oversight.
   d) Providing a pre-review of submitted materials, to help the investigators address human subjects

protections issue before they are brought to the IRB.
   e) Conducting site visits as appropriate.
   f) Effectively communicating with investigators, sponsors, and IRB members.
   g) Obtaining and distributing information required for Chairperson or IRB review
   h) Providing data entry to computer tracking system, generating letters, creating files and mailing notices to investigators.
   i) Maintaining, filing, and archiving systems that allow access to open and closed studies.

2. Maintaining accurate records of IRB actions by:
   a) Periodically reviewing IRB policies and procedures to ensure appropriate functioning of the IRB.
   b) Preparing Agendas for IRB meetings.
   c) Preparing Minutes for IRB meetings.
   d) Preparing and sending timely letters to the investigators, informing them of the IRB's review of their study.
   e) Documenting communications with sponsors, investigators, regulatory entities, and any others involved in the conduct of submitted research.
   f) Maintaining an accurate and comprehensive database of reviewed and approved research.
   g) Maintaining records of expedited reviews, risk determinations, and any other activities that result in a review or action by IRB members.

3. Maintaining accurate files, both paper and electronic.

4. Ensuring that Investigators and Sponsors are informed of the actions and findings of the IRB by:
   a) Reviewing IRB SOPs on a regular basis to ensure accurate information and disseminating changes to investigators, IRB members and staff.
   b) Providing direction and consultation to investigators regarding current issues and ethical concerns associated with the implementation of regulations, policies, and procedures.
   c) Assuming content responsibility for the IRB website.
   d) Notifying investigators and other appropriate entities of IRB actions.

5. Ensuring that the Institutional Official is informed of the actions and findings of the IRB by providing him/her with the IRB minutes of each meeting, after they have been approved by the IRB Chairperson.

6. Ensuring that continuing review of approved research is conducted appropriately and in a timely manner by:
   a) Making investigators aware of due dates for submission of renewal and other reports.
   b) Ensuring that information submitted by investigators is adequate for effective review.
   c) Entering SAE reports into database and preparing a report for each IRB meeting.

7. Serving as IRB Interface for subjects, investigators, sponsors and regulatory agencies by:
   a) Answering questions and supplying information when requested, and conveying IRB actions to appropriate individuals.
   b) Screening subject inquiries and resolving issues when possible, and conveying results of interactions with subjects to investigators, sponsors, and IRB members as directed.
   c) Serving as the IRB liaison during audits by regulator entities or sponsors.

8. Overseeing adequacy of IRB membership by:
   a) Providing support to the Institutional Official in the recruitment of IRB members.
   b) Providing training and continuing education of IRB members.
   c) Maintaining IRB membership logs and coordinating submissions to regulator agencies.
   d) Ensuring that a quorum is present, maintained, and documented during convened meetings.
   e) Keeping members apprised of their responsibilities regarding conflicts of interest.

9. Supporting the daily operations of the IRB.

IRB Chairperson Functions

The IRB Chairperson:

1. Directs the full-committee meetings,
2. Performs Expedited Reviews, with the aid of the IRB Administrator, or delegates the review to appropriate IRB members, and
3. Determines whether protocols are exempt from IRB review, with the aid of the IRB Administrator.

Applicable Regulations and Guidelines

IRB staff performance standards, management guidelines, and expectations will be established according to FRI policy.