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

IRB Policy 103.3: DUTIES OF IRB MEMBERS

Policy

Each IRB member's primary duty is the protection of the rights and welfare of the individual human beings volunteering to participate in research. The IRB member must understand that he or she is not serving on the IRB to expedite the approval of research, but rather to be a gatekeeper between the Investigator and the research subjects. In order to fulfill their duties, IRB members are expected to be knowledgeable about the regulations governing human subjects protection, biomedical and behavioral research ethics, and the policies of FRI regarding human subjects protection.

Duty to the Institution

The IRB must be perceived to be fair and impartial, immune from pressure either by the institution's administration, the Investigators whose protocols are brought before it, or other professional and nonprofessional sources. Members must not allow their own interest to supercede their duty to protect the rights and welfare of research subjects.

Term of Duty

Regular IRB members and Chairpersons are expected to commit to a five-year term and to fulfill certain duties during that time. These duties will be described prior to appointment and each IRB member is expected to fully understand the duties of IRB members prior to accepting appointment as an IRB member.

Specific Duties

All members are expected to review the materials provided, regardless of affiliation or specialty area:

1. Nonaffiliated member(s): Nonaffiliated members are expected to provide input regarding their local community and/area of advocacy, and be willing to discuss issues and research from that perspective.

2. Non-scientific members: Nonscientific members are expected to provide input on areas relating to their knowledge, expertise and experience, professional and otherwise. For example, members who are lawyers might present the legal views of specific areas that may be discussed, such as exculpatory language or state requirements regarding consent. Non-scientific members should advise the IRB if additional expertise in a non-scientific area is required to adequately assess a protocol.

3. Scientific members: Scientific members are expected to contribute to the evaluation of a study on its scientific and statistical merits and standards of practice. These members should also be able to advise the IRB if additional expertise in a non-scientific area is required to assess a protocol.

4. Chairperson: In addition to the above responsibilities, Chairpersons chair meetings of the IRB. Chairpersons may perform expedited review or delegate to an appropriate voting member when appropriate. They are also empowered to suspend the conduct of a clinical trial if it is deemed to place individuals at unacceptable risk, pending review. The Chairperson is also empowered, pending IRB review, to suspend the conduct of a study if he/she determines that an investigator is not following IRB requirements.

5. The Chairperson may appoint a Co-chairperson or Associate or Vice Chairperson to assist or act on behalf of the Chairperson in particular IRB matters and at IRB meetings. The Chair person also may delegate any of his/her responsibilities as appropriate to other qualified individual(s). Such documentation must be in writing and maintained by the IRB Administrative Office.

Responsibility

The IRB Administrator (or equivalent) is responsible for clearly articulating all IRB members' duties to potential and current IRB members. IRB Members are responsible for fulfilling their duties as specified.

Applicable Regulations and Guidelines

OHRP IRB Guidebook
FDA Information Sheets FAQ, section II, question 17.