FRIENDS RESEARCH INSTITUTE, INC.
1040 Park Avenue, Suite 103
Baltimore, MD 21201

Subject: Functions and Operations
Division: IRB
Date: March 1, 2012

IRB Policy 104.2: IRB MEETING ADMINISTRATION

Policy

Except when an expedited review procedure is used, or the study qualifies for exempt status, the IRB will review all proposed research at convened meetings at which a quorum is present. The IRB will meet every four weeks, or as necessary (at a frequency determined by the IRB Chairperson and the IRB Administrator) to adequately review initial and continuing research.

Quorum

1. A quorum is defined as one half of the number of regular members plus one.

2. A quorum includes at least one member whose primary concerns are in scientific areas, and one member whose primary concerns are in nonscientific areas.

3. Staff and/or special consultant(s) will not be used to establish a quorum.

Primary Reviewer System

A primary reviewer system may be used for new submissions, protocols involving vulnerable populations, and for continuing reviews.

Although the primary reviewer system is utilized, all IRB members will receive all submission materials. For protocols involving vulnerable subject populations, the IRB Chairperson and/or Administrator will assign the advocate for the particular vulnerable subject population as the primary reviewer. All IRB members will be responsible for an in-depth review of the protocol and other submission materials. In addition, the primary reviewer will be responsible for an in-depth review of the protocol as it relates to the vulnerable subject population.

For initial and continuing reviews, the IRB Chairperson and/or Administrator may assign a primary reviewer, to provide an in-depth review of the study. The IRB member with the most relevant expertise regarding a specific protocol will be assigned as the study's primary reviewer. This member will receive a copy of the complete protocol including any modifications previously approved by the IRB, in addition to the rest of the submission materials. All other IRB members will receive same information. Upon request, any IRB member will have access to the complete IRB protocol file and relevant IRB minutes prior to or during the convened IRB meeting. The primary reviewer will be responsible for an in-depth review of the protocol and the initial or continuing review information, and will lead the discussion regarding the protocol at the convened meeting.

Meeting Materials Sent Prior to IRB Meetings

All IRB members will be sent the required review documentation sufficiently in advance of the meeting to allow time for adequate review. These include:

1. Agenda: a meeting agenda will be prepared by the IRB Administrator and distributed to IRB members prior to each meeting.

2. Educational material: All members will be provided with educational material, such as an article, guidance document, or selected text from the SOPs/regulations/etc. to keep them apprised of current human research protections issues.

3. Minutes of previous meetings: All members will be provided with previous meeting minutes to review and comment. Minutes will be voted upon during the following meeting to approve, require changes, or defer.

4. Reviewer materials: All IRB members will receive a complete copy of the submitted materials for each study. Upon request, any IRB member will have access to the complete IRB protocol file and relevant IRB minutes prior to or during the convened IRB meeting.

5. Summary of recent expedited reviews and exemption approvals.

6. A packet of reviewer forms to guide the IRB members in their review of each protocol.

Minutes

1. Federal regulations for the protection of human subjects [45 CFR 46.115(a)(2)] require that "Minutes of IRB meetings… shall be in sufficient detail to show attendance at the meeting; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution." IRB members representing vulnerable populations should be noted in the minutes.

2. Recording: The IRB Administrator will take notes of each meeting. An audio recording of each meeting may also be used if appropriate to aid in the preparation of written minutes, but the written meeting minutes will be the official record. Minutes will be written in sufficient detail to show the following:

    a) Meeting attendance; including names of attendants, their affiliation status with FRI, status as scientist/non-scientist, and their role on the IRB (i.e., Children's Advocate).

    b) Actions taken by the IRB on each agenda item requiring full IRB action, including, the basis for requiring changes in or disapproving the research, the level of risk and the approval period; and special considerations for Parts B, C and D of the Common Rule.

    c) Summary of the discussion of controverted issues and resolution;

    d) Voting results, including number for, against, abstentions (reason why) and members who recused themselves and reasons for recusals.

    e) Use of the primary reviewer system.

3. Approval: Minutes will be distributed to members at the next IRB meeting for review and approval.

Corrections requested by the IRB will be made by the IRB Administrator or designee. The IRB Administrator shall sign and date final, approved minutes.

4. The IRB Administrator will maintain copies of the minutes, as well as the agenda and pertinent materials on file. One hard copy and one electronic copy will be maintained.

5. A majority of members must vote in favor of an action in order for that action to be accepted by the IRB. Only regular and alternate members acting in place of absent regular members may vote. The vote will be recorded in the minutes. Members with a conflict of interest will recuse themselves from the discussion and voting and such will be noted in the minutes. Maintenance of a quorum after recusals will be noted in the minutes.

Telephone and/or Video-Conferencing

1. Convened meetings using speakerphone: Should a member not be able to be physically present during a convened meeting, but is available by telephone, the meeting can be convened using a speakerphone. The member who is not physically present will be connected to the rest of the members via speakerphone. In this manner, all members will be able to discuss the protocol even though a member is not physically present. Members participating by such speakerphone call may vote, provided they have had an opportunity to review all the material the other members have reviewed.

2. Meetings Conducted Via Telephone or Video Conference Calls: Meetings may also be convened via a telephone conference call. A quorum (as defined above) must participate for the conference call meeting to be convened. To allow for appropriate discussion to take place, all members must be connected simultaneously for a conference call to take place -- "telephone polling" (where members are contacted individually) will not be accepted as a conference call.

Voting

1. Members of the IRB vote according to the criteria for approval. Members also will determine level of risk, and the frequency of review for each protocol. Members may vote for, against, or abstain from voting.

2. Members not present at the convened meeting, nor participating in a conference call, may not vote on an issue discussed during a convened meeting (no voting by proxy).

Responsibility

IRB Administrator is responsible for IRB meeting procedural conduct and documentation. IRB Chairperson (or designee) is responsible for IRB meeting review conduct and leadership.

IRB Chairperson or Administrator is responsible for assigning primary reviewers for initial submissions, protocols involving vulnerable subject populations, and continuing reviews.

Applicable Regulations and Guidelines

45 CFR 46.115
21 CFR 56.115
FDA Information Sheets, Frequently Asked Questions,1998