

| | | |
|-------------------------------------------------------------------------------|-----------------------------------|------------------------------------------------------|
| SOP: FO 303 Version No: 1 Effective Date: 03/27/06 | IRB MEETING ADMINISTRATION | Supersedes Document Dated: 02/10/03 |
|-------------------------------------------------------------------------------|-----------------------------------|------------------------------------------------------|

1. POLICY

Except when an expedited review procedure is used, the IRB will review proposed research at convened meetings at which a quorum is present. The IRB will meet monthly, or at some frequency determined by IRB Chairperson and the IRB Administrator.

Specific Policies

1.1 Quorum

- 1.1.1 A quorum is defined as one half of the number of regular members plus one.
- 1.1.2 A quorum consists of regular and/or their alternate members and includes:
 - a) at least one member whose primary concerns are in scientific areas, and one member whose primary concerns are in nonscientific areas; and b) at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.
- 1.1.3 When FDA-regulated research is reviewed, there shall be one member who is a physician.
- 1.1.4 An alternate member may attend in the place of an absent regular member in order to meet the quorum requirements outlined above.
- 1.1.5 A special consultant(s) will not be used to establish a quorum.
- 1.1.6 If a member abstains from voting, the member may be used to establish a quorum.
- 1.1.7 If a member recuses him/herself from deliberations and voting, the member may not be used to establish quorum for the duration of review of the item from which the member is recused. A member experiencing a COI must recuse him/herself, and exit the meeting room until discussion and formal action has been taken.

1.2 Primary Reviewers

Prior to the meeting, the IRB Administrator and/or IRB Coordinator will designate the primary reviewers for each research proposal. The primary review team will consist of three members of the IRB – one of which should be a physician. The duties of the primary review team are described in SOP OR 203.

1.3 Meeting Materials Sent Prior to IRB Meetings

All IRB members will be sent study documentation required for review at least two (2) weeks in advance of the meeting to allow time for adequate review. These include:

- 1.3.1 Agenda: a meeting agenda will be prepared by the IRB Coordinator under the supervision of the IRB Administrator, and distributed to IRB members prior to each meeting. A copy of the agenda will be maintained on file with the meeting minutes.

The IRB Chairperson will ask members to declare any potential Conflict of Interest they may have with research that is about to be reviewed at the outset of each meeting. The IRB Chairperson will ask for a declaration of such conflict and this will be incorporated in the minutes of the meeting. The IRB minutes should specifically reflect such recusals as they occur during meetings.

1.3.2 Reviewer materials

A. All IRB members

- Agenda
 - To include an Announcement section describing IRB activities since the previous meeting (determinations for expedited or exempt protocols, compliance with conditional approvals, and actions taken by other IRB's under contractual arrangements with Sparrow Health System).
- Draft Minutes from previous meeting
- New Protocols
 - Application for Initial Review
 - Proposed Informed Consent Documents
 - Statement of research (if applicable)
 - Rationale for Waiver of Consent (if applicable)
- Progress Reports
- Application for Continuing Review
- Amendments and/or Revisions
- Termination, Suspension, and Completion notices
- Internal Adverse Events
- External Adverse Events
- Advertising intended to be seen or heard by potential subjects, including email solicitations and physicians letters

B. Primary review Team

- Materials sent to all IRB members (as listed above)
- Full Investigator's or Sponsor's protocol
- Copies of surveys, questionnaires, or videotapes
- Proposed informed consent document(s) and/or script as appropriate.
- Investigator Brochure (if one exists)
- Risk Assessment Form

1.4 Minutes

The 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." These requirements are minimal.

Good minutes should enable a reader who was not present at the meeting to determine exactly how and with what justification the IRB arrived at its decisions.

The minutes will include the Announcement section describing IRB activities since the previous meeting reported in the Agenda (determinations for expedited or exempt protocols, compliance with conditional approvals, and actions taken by other IRB's under contractual arrangements with Sparrow Health System).

1.4.1 Recording: The IRB Coordinator will take minutes of each meeting. Minutes will be written in sufficient detail to show the following:

- Meeting attendance; including status of each attendee (regular member, alternate members, consultant, etc.), and conflicts of interest, if any;
- Actions taken by the IRB on each agenda item requiring full IRB action, including, the basis for requiring changes in or disapproving the research;
- Summary of the discussion of controverted issues and resolution;
- Voting results, including number for, against and members who recused themselves and reason for recusal.

1.4.2 Approval: Draft 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 Coordinator and the minutes will be kept on file in the OROC office. The Chairperson, Co-Chair, or designated IRB member acting on behalf of the Chairperson shall sign and date final, approved minutes.
- The IRB Coordinator, under the supervision of the IRB Administrator, will maintain copies of the minutes, as well as the agenda and pertinent materials on file (see SOP FO 305).

A majority of members must vote in favor of an action for that category of 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.

The minutes of the IRB meeting along with an Executive Summary Report will be sent to the Medical Staff Executive Committee for review and acceptance following each IRB meeting.

1.5 Telephone Use [Currently not used at SHS, but policy stands as acceptable action should technology become available]

1.5.1 Convened meeting using speaker phone:

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 one 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.

1.5.2 Meetings Conducted Via Telephone Conference Calls:

On occasion, meetings may 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.

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

1.6 Voting

Members of the IRB vote upon the recommendations made by the primary reviewers according to the criteria for approval (see SOP RR 402 and 404). Members also will determine level of risk, the frequency of review for each protocol, monitoring of the investigative site, and whether third party assessment and follow-up will be needed.

If an IRB staff member is serving on the IRB as a voting member, that staff member will not be responsible for any administrative functions during that meeting. Specifically, he or she will not take minutes.

2. SCOPE

These policies and procedures apply to all research submitted to the IRB.

3. 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.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.103, 46.108

21 CFR 56.108, 56.109

FDA Information Sheets, 1998

5. REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

6. ATTACHMENTS

FO 303-A IRB Agenda/Minutes Template

7. PROCESS OVERVIEW

The policies in this section provide the framework to ensure that IRB meetings are conducted and documented in a consistent manner in order to meet federal and institutional requirements.

8. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

| Who | Task | Tool |
|-------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|
| <i>IRB Coordinator</i> | Complete agenda section of the IRB Agenda/Minutes Template. Complete Announcement section of the IRB Agenda/Minutes Template to include actions taken by other IRB's under contractual arrangements with Sparrow Health System, and/or actions taken between scheduled meetings. | IRB Agenda/Minutes Template |
| <i>IRB Coordinator</i> | Assemble reviewers' packets per SOP FO 304. | |
| <i>IRB Coordinator</i> | Attend meeting of the IRB. Using IRB Agenda/Minutes Template, record proceedings of the meeting. | IRB Agenda/Minutes Template |
| <i>IRB Administrator and/or IRB Chairperson or designee</i> | Provide IRB members with summary of expedited reviews conducted and any internal serious adverse event reports received since the last IRB meeting. | |
| <i>IRB Chairperson</i> | Chair meeting, using the IRB Agenda/Minutes Template as a guide. Ensure that all business is addressed, that proceedings are recorded, and that any member who has a conflict of interest does not participate in the IRB's consideration nor in voting for study determination, except as requested by the IRB. | |
| <i>IRB Coordinator</i> | Complete draft minutes in time to include in the reviewers' packets for the next meeting. | IRB Agenda/Minutes Template |
| <i>IRB Administrator</i> | Review/edit IRB Agenda and Minutes prepared by IRB Coordinator. Sit on the IRB Committee as a voting member. Prepare monthly Executive Summary of IRB actions for Medical Staff Executive Committee. | |