

**The Carle Foundation
IRB Policy 302**

Subject	IRB Meeting Administration				
Approval	Dec 2006	Review	Dec 2009	Revision	Dec 2009
Scope	These policies and procedures apply to all research submitted to IRB.				
Purpose	To provide guidance in the proper conduct of IRB meetings.				

Statement of Policy

1. 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. IRB meetings may be held more frequently than monthly, as determined by the IRB Chairperson in consultation with the Director of HSP.

Specific Policies

1. Quorum

- a. A quorum is defined as one more than half of the number of regular voting members. A quorum may be established with members convened in person, or via audio, video, or Web conference; see Remote Attendance, below.
- b. A quorum includes regular members and alternate members designated to serve as voting members at the meeting in question, and must include at least one member whose primary concerns are in scientific areas, and one member whose primary concerns are in nonscientific areas.
- c. When FDA-regulated research is reviewed there shall be at least one voting member present who is a physician.
- d. An alternate member may attend in the place of an absent regular member in order to meet the quorum requirements outlined here.
- e. Special consultants may not be counted toward a quorum.
- f. Members who abstain from voting may still be counted toward a quorum.
- g. A member with a Conflict of Interest (COI) with any part of a study must be recused from voting in accordance with 45 CFR §46.107(e), may not participate in the discussion, and will only provide information at the request of the IRB. Members with COIs may not be counted as part of the quorum for the item(s) in question.

2. **Meeting Materials Sent Prior to IRB Meetings:** All IRB members will receive study documents required for review sufficiently in advance of the meeting to allow reasonable time for adequate review. These documents include:

- a. **Agenda** A meeting agenda will be prepared by the IRB staff and distributed to IRB members prior to each meeting. A copy of the agenda and attached materials will be maintained on file with the meeting minutes. The meeting agenda will remind members to declare at the outset of each meeting any potential COI they may have with research that is about to be reviewed. The Chairperson will ask for a declaration of such conflicts and the request and any responses will be reflected in the minutes of the meeting. The IRB minutes should also specifically reflect such recusals as they occur during meetings.
- b. **Research Documents**
 - To IRB Members:
 - A completed submission form
 - Proposed informed consent and assent document(s) and/or script as appropriate (with Carle Disclaimers)
 - Proposed HIPAA Authorization form or Waiver, if separate from the consent document
 - Full Investigator's or Sponsor's protocol
 - Complete Grant Proposal or Funding Agreement for funded research
 - Investigator Brochure (if one exists)
 - Copies of surveys, questionnaires, and other data collection instruments and measures
 - Recruiting and advertising materials intended to be seen or heard by potential subjects, including e-mail solicitations, physician letters, and Web site contents
 - Information regarding any study-related Web site
 - Any and all other information related to the research submitted by the Investigator.
 - Reviewer's Worksheet for primary reviewers [Note: The primary reviewer is responsible for completing the Reviewer's Worksheet for any study, approvable by the Expedited or Full Board review process, submitted for initial or continuing review and modifications that necessitate review]
 - On file in Office of Human Subject Protection; available for review at the convened meeting:
 - All materials sent to the IRB

Specific Policies (cont.)

- Copies of letters of assurance or cooperation with research sites
- Correspondence documenting IRB submissions, reviews, and outcomes of IRB reviews
- IRB Review of NIH-Approved Informed Consent Documents for NIH-Supported Multi-center Clinical Trials: For NIH-supported multi-center clinical trials the IRB must receive and review a copy of the NIH-approved sample informed consent document and the full NIH-approved Investigator's protocol, if available, as a condition for review and approval of the local informed consent document. Any deletion or substantive modification of information concerning risks or alternative procedures contained in the sample informed consent document must be justified in writing by the Investigator, approved by the IRB, and reflected in the IRB minutes.

3. **Use of Primary Reviewer(s)** The IRB designate one or more IRB members to take the lead on review of research projects. The use of lead or primary reviewer(s) is intended to facilitate review of protocols that may require particular expertise, or which have similar characteristics. All IRB members remain responsible for review of submitted materials and active participation in review and consideration of research. The Chair and each primary reviewer will encourage the participation of other members of the IRB in all discussion regarding the research. The primary reviewer is responsible for completing the Reviewer's Worksheet for each study reviewed.

a. **Selection of Reviewers** In selecting primary reviewer(s), the IRB staff, in consultation with the IRB Chair and members of the IRB as needed, will:

- Take into consideration the type of research being reviewed, any unique scientific or clinical implications of the research, the typical characteristics of participants in such research, and the knowledge and expertise of the IRB member(s) in such areas; when the reviewing member(s) feel that they need an outside expertise in a particular area, they will request the Chair to invite person(s) with such expertise. The Chair shall provide such resources to the members in order to better accomplish the review functions.
- Ensure that no primary reviewer has any conflict of interest with respect to the research project.

b. **Primary Reviewer Process**

- In the case of initial reviews, all IRB members shall receive a copy of all materials described in Section 2 of this policy. In the case of continuing reviews, all IRB members shall receive at least a protocol summary and a status report on the progress of the research that includes the information specified in IRB Review of Research Policy 404 Continuing Review.
- Subject safety is of the greatest importance. If, while reviewing study reports, a member of the IRB believes that immediate action is needed to protect study subjects, the member shall notify the Chair of the facts and the basis for the concern. The Chair may, as appropriate, take action prior to the IRB meeting to protect subjects. The Chair will advise the convened IRB of the action at the next meeting, and the convened IRB may take such other action(s) as may be appropriate at that time. For reviews that do not require immediate intervention, the primary reviewer(s) shall be prepared to discuss any concern(s) noted in the review. This would include a summary of the nature of the concern(s) in general terms, and a description of any possible or apparent causative or contributory factors. Other members of the IRB will be encouraged to ask questions and a full discussion of all concerns shall occur prior to any action by the convened IRB.
- Upon conclusion of the discussion, the convened IRB as a whole shall consider the proposed research in accordance with standard IRB procedures. The IRB may, by majority vote as provided in federal regulations and institutional policies and procedures, take any action authorized with respect to such research.

4. **Minutes**

a. **Recording** Consistent with federal regulations for the protection of human subjects [45 CFR 46.115(a)(2)] at least one IRB staff member 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, 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;
- Recusal/absence from meeting and return to meeting, as appropriate;
- Voting results, including number for, against, abstaining, and recused; and reasons for abstention and recusal.

Minutes must expressly reflect the consideration of each requirement for IRB review and approval for each protocol considered at the meeting. The minutes shall demonstrate that all regulatory requirements for review of research have been considered. 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.

Specific Policies (cont.)

Minutes also must include references to: determinations and review of the measures described in the protocol to protect the privacy of subjects and maintain the confidentiality of data; the informed consent approval/denial/waiver process; review and approval/denial of protocol amendments, document separate deliberations, actions and votes for each protocol undergoing initial and continuing review.

- b. **Approval** Draft minutes will be distributed to members on or before the next IRB meeting for review. Approval will be requested at the next scheduled meeting.
- Corrections requested by the IRB will be made by an IRB staff member and the minutes will be printed in final form and made available to members at the following meeting. The Chairperson of the IRB, or designee, shall sign and date final, approved minutes.
 - The IRB office will maintain copies of the minutes, as well as the agenda and pertinent materials.

5. Remote Attendance

- a. Convened meeting using remote technology: If an IRB member is not able to be physically present during a convened meeting, but is available by telephone, interactive Webcasting, interactive videoconference, or other technology which permits real-time interaction of meeting participants, the meeting can be convened using remote distance technology. The member who is not physically present will be connected to the rest of the members. All attendees must be able to discuss the protocol even if not physically present. Members participating remotely may vote, provided they have had an opportunity to review all the material the other members have reviewed.
- b. Meetings conducted via conferencing technology. On occasion, meetings may be convened via conferencing technology. A quorum (as defined in this policy) must participate for the conference call meeting to be convened. To allow for appropriate discussion to take place, all members must be connected simultaneously. Polling individuals (i.e., individually contacting members not concurrently participating on the call) is not acceptable. No voting by proxy will be permitted.

6. **Voting:** Each member of the IRB must consider the criteria for approval or continuing approval of each protocol reviewed, taking into account the 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. Each member's vote will reflect that member's conclusions regarding these factors, and a determination that, based on these criteria, the research shall be approved, tabled, disapproved, modified, or otherwise disposed.
- a. At the discretion of the IRB Chair, voting may be by a show of hands, written ballot, or voice vote. The IRB meeting minutes will record the number of votes in favor, not in favor, abstained, and recused, but will not identify individuals.
- b. 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 or otherwise serve as an administrative resource to the other IRB members during the conduct of the meeting.
7. **Guests:** Investigators, research staff and other individuals may attend IRB meetings only if invited by the IRB committee and/or HSP Office. Invited attendees must sign a Confidentiality Agreement with the Carle IRB before beginning of the meeting.

Reference

[45 CFR 46.115(a)(2), and Carle IRB Policies

Electronic Approval On File

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