

The Carle Foundation

IRB Policy 202

Subject	Duties of IRB Members		
Approval	Dec 2006	Review	Jun 2009
Scope	These policies apply to IRB membership.		
Purpose	To delineate duties and responsibilities of IRB members.		

Statement of Policy

1. Each IRB member's primary duty is the protection of the rights and welfare of the individuals who are serving as the subjects of research. The IRB member must understand that he or she is not serving on the IRB to expedite the approval of research, but to advocate for the ethical treatment of research subjects. In order to fulfill their duties, IRB members are expected to be trained on and familiar with regulations governing human subjects protection, biomedical and behavioral research ethics, and the policies of Carle Foundation Hospital germane to human subject protection.

Specific Policies

1. Duty to the Carle Foundation Hospital
 - a. The IRB is appointed as an Institutional Committee. As such, IRB members serve Carle Foundation Hospital as a whole, rather than a particular department. Members must not allow their own interest or that of their department to supersede their duty to protect the rights and welfare of research subjects.
2. Term of Duty
 - a. The IRB Chairperson, regular IRB members, and their alternates are expected to commit to a two-year term and, during that time, to fulfill certain duties. 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.
3. Specific Duties
 - a. Scope of Review – In conducting the review of each proposed research study, or renewal of prior approved research studies, the IRB will consider at a minimum:
 - Scientific Merit – The IRB will consider the scientific merit of each study, including:
 - Whether the study procedures are consistent with sound research design;
 - The appropriateness of the study design given the hypothesis being tested;
 - Whether the study is designed in a manner likely to answer the question posed;
 - Whether the knowledge to be gained is sufficiently important to justify the risks involved;
 - Whether risks are minimized and benefits are optimized to the extent possible;
 - If placebos are used, whether the design is justified based on a lack of effective therapeutic intervention;
 - Whether study cohorts are sized reasonably; taking into consideration whether the number of participants is large enough to result in reliable, replicable results without exposing excessive numbers of participants to the risk of the research.

If vulnerable populations are used, additional scrutiny of study design, risks and benefits will occur to ensure additional required protections to such populations.

The IRB may consider the conclusions of other qualified entities or individuals for research projects which have already been submitted to qualified peer review, including multi-site studies and those receiving federal funding; however, the IRB will reach its own conclusions regarding scientific merit.

 - Regulatory Requirements – In order to approve a proposed research study the IRB shall determine that all of the requirements listed in 45 CFR 46.111 are satisfied
 - The study or study location has sufficient resources to safely conduct the study and provide for the needs of study subjects, including access to medical and psychological support and resources for communication such as translators, each as appropriate for the study in question.
4. Other Responsibilities
 - a. All IRB members are responsible for the following:
 - Review of IRB packet materials prior to the IRB meeting
 - Active participation in IRB meetings
 - Completing training and education regarding IRB responsibilities

Specific Policies (cont.)

b. Each class of IRB member shall have the following responsibilities:

- Nonaffiliated Member(s)
 - Nonaffiliated members are expected to provide input regarding their knowledge about the local community and be willing to discuss issues and research from that perspective.
- Non-scientific Members
 - Nonscientific members are expected to provide input on areas germane to their knowledge, expertise and experience, professional and otherwise. For example, members who are lawyers should 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 permit those members to assess whether the protocol adequately protects the rights and welfare of subjects.
- 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 scientific or non-scientific areas is required to assess whether the protocol adequately protects the rights and welfare of subjects.
- Chairperson
 - In addition to the above responsibilities (germane to the member's capacity), the Chairperson chairs meetings of the IRB. The Chairperson performs or delegates to an appropriate voting IRB member expedited review when appropriate. The Chairperson is empowered to suspend the conduct of a clinical trial deemed to place individuals at unacceptable risk, pending IRB 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 the IRB's requirements.
- The Chairperson may appoint a Co-chairperson or Associate Chairperson or Vice Chairperson to assist or act on behalf of the Chairperson in particular IRB matters and at IRB meetings, either as a general procedure, or on a case-by-case basis. The Chairperson 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 Director of the HSPP.
- The task of making the IRB a respected part of the institutional community falls primarily on the shoulders of the IRB Chairperson and individual IRB members. The IRB must be perceived as 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.

Reference

45 CFR 46, 21 CFR 56 and Carle IRB Policies

Approval On File

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