

The Carle Foundation

Research Policy 106

Subject	Designation of Institutional Review Board				
Approval	Nov 2010	Review	Feb 2011	Revision	Feb 2011
Purpose	To ensure that all human subjects research at The Carle Foundation is reviewed by an appropriate Institutional Review Board (IRB) operating in accordance with federal regulations, state laws, and local policies.				

Statement of Policy

1. Prior to initiation, all human subjects research must be submitted to the Carle IRB (or an approved designated IRB) for review and approval, or determined to be exempt from IRB review according to federal regulations when:
 - a. The Carle Foundation is conducting or supporting the research, **or**
 - b. The research is conducted by or under the direction of any employee or agent of The Carle Foundation, **or**
 - c. The activities of an employee or agent of The Carle Foundation meet the criteria for “engaged in research” as defined by the Office for Human Research Protections (OHRP) Guidance on Engagement of Institutions in Human Subjects Research (Oct 2008), **or**
 - d. The research involves the use of The Carle Foundation’s non-public information to identify or contact human subjects.
2. All physicians, staff and agents of The Carle Foundation involved in the conduct, supervision, reporting or management of human subjects research without regard to funding or funding source must comply with this policy.
3. The Carle Foundation must ensure that the Carle IRB operates in accordance with federal regulations, state laws, and local policies.

Definitions

Engaged in Research – In general, The Carle Foundation is considered engaged in human subjects research when its employees or agents for the **purpose of the research** project obtain:

1. Data about the subjects of the research through intervention or interaction with them;
2. Identifiable private information about the subjects of the research; or
3. The informed consent of human subjects for the research.

The Carle Foundation – Includes all legal entities part of The Carle Foundation such as Carle Foundation Hospital, Carle Physician Group, Mills Breast Cancer Institute, and Carle Cancer Center.

Institutional Review Board (IRB) – Means any board, committee, or other group formally designated by an institution to review, to approve the initiation of, and to conduct periodic review of, biomedical research involving human subjects. The primary purpose of such review is to assure the protection of the rights and welfare of the human subjects.

Human Subjects Research – Research involving “human subjects” means any activity that either:

1. Meets the HHS definitions of “research” and “human subjects” (45 CFR 46.102 (d) and (f)); **or**
2. Meets the FDA definitions of “research” and “human subjects” (21 CFR 50.3, 21 CFR 56.102 (e), and 21 CFR 812.3 (p)).

Procedure

1. All human subjects’ research regardless of funding must be submitted to the Carle IRB unless otherwise permitted by this policy. The Institutional Official or designee will determine if a research study can be submitted to an outside IRB.
2. For federally funded research, the Institutional Official or designee is responsible for ensuring that The Carle Foundation’s Federalwide Assurance is properly amended in accordance with federal regulations and Research Policy 107 to reflect the additional IRB.
 - a. In such an event, the Institutional Official or designee is responsible for ensuring that use of the external IRB is documented in a written IRB Authorization Agreement or equivalent
 - b. The IRB Authorization Agreement or equivalent must be signed by the Institutional Official and be available to OHRP upon request.
3. Before designating an external IRB other than the Carle IRB, the Institutional Official or designee must determine that the other IRB:
 - a. Is in compliance with federal regulations, state laws, and local policies;
 - b. Has meeting space and sufficient staff to support the IRB’s review and recordkeeping duties.
 - c. Meets all IRB membership requirements according to 45 CFR 46.107:

Procedure (cont.)

- Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.
 - Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. No IRB may consist entirely of members of one profession.
 - Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.
 - Each IRB shall include 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.
 - No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.
 - An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB
- d. Possesses sufficient knowledge of the local research context to be able to ascertain the acceptability of proposed research in terms of The Carle Foundation's commitments, applicable law, and standards of professional conduct and practice.
4. The Institutional Official or designee is responsible for tracking all IRB Authorization Agreements to ensure that The Carle Foundation accounts for all its human subjects' research.

References

- 45 CFR 46
- 21 CFR 50, 56, 812
- FWA 00002292
- Office for Human Research Protections (OHRP) Guidance on Engagement of Institutions in Human Subjects Research (Oct 2008): www.hhs.gov/ohrp/humansubjects/guidance/engage08.html

Electronic Approval on File

Supersedes CCA policy 5306 and Carle IRB policy 203.

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