

The Carle Foundation

Research Policy 104

Subject	Scientific, Feasibility, and Local Context Review of Human Subjects Research			
Approval	Apr 2011	Review		Revision
Purpose	To define the responsibilities of the Research and Protocol Feasibility Review Committees (“Review Committee”) and the process for reviewing all proposed human subjects research studies that will be conducted in part or in whole at The Carle Foundation prior to submission to an IRB.			

Policy Statement

1. The Review Committee(s) reviews all human subjects’ research studies that will be conducted in part or in whole at The Carle Foundation.
2. The proper conduct of human subject’s research requires the commitment of a variety of resources, including professional and staff time, space, equipment and supplies. It also requires assurance that the proposed human subject’s research has scientific merit. In order to preserve and maintain the viability of human subjects research and to promote a responsible research environment, all research protocols must undergo advance review by a Review Committee and can proceed only upon receiving Review Committee approval.
3. **If the study will be reviewed by the Carle IRB**, then the Carle IRB has the responsibility of reviewing the research for its local context to fulfill Carle’s responsibilities under the regulations and its Federalwide Assurance with the Federal government.
4. **If the study will not be reviewed by the Carle IRB**, then the Review Committee(s) will also be responsible for the review of local context for studies that will be submitted to an external IRB. If there are local context concerns, they will be communicated to the external IRB at the time of initial submission to ensure that the external IRB has sufficient knowledge of local context of the research regardless of its geographical location. This includes, but is not limited to, understanding the patient population, community attitudes, local requirements and state laws, and size and complexity of Carle as it pertains to the proposed research.
5. No research may proceed until all approvals are in place, including but not limited to, approvals from the Review Committee and the IRB, and, where applicable, signed contract(s) with the Sponsor.
6. The Review Committee(s) role is not intended to substitute or interfere with the IRB’s role as defined in 45 CFR 46 or 21 CFR 56.

Definitions

Federalwide Assurance – An agreement with OHRP as described in 45 CRF 46.103 that assures that an Institution will comply with federal regulations for the protection of human subjects whenever it engages in non-exempt human subjects research that is federally conducted or supported.

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

- a. Meets the DHHS definitions of “research” and “human subjects” (45 CFR 46.102 (d) and (f); **or**
- b. Meets the Food and Drug Administration (FDA) definitions of “research” and “human subjects” (21 CFR 50.3, 21 CFR 56.102 (e), and 21 CFR 812.3 (p).

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 research involving human subjects. The primary purpose of such review is to assure the protection of the rights and welfare of the human subjects.

IRBNet – An online submission system that the Carle Scientific Review Committee and the Carle Institutional Review Board is utilizing.

Principal Investigator – The investigator/ researcher who is responsible for the conduct of a research study at an institutional site.

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.

Procedures

1. The Principal Investigator, sponsor or designee delivers the new proposed research protocol and any related study materials, including the Investigator Brochure and contract to one of Carle’s Review Committee’s:
 - a. Carle Cancer Center Review Committee (Oncology clinical trials; submitted via the Cancer Center Research Office),
 - b. Non-Cancer Clinical Trials Review Committee (non-oncology clinical trials; submitted via the Manager of Clinical Trials), or
 - c. Carle Scientific Review Committee (for all other research at Carle, submitted via IRBNet through the Research Office).

Procedures (cont.)

2. Each Review Committee meets on a regular basis in order to timely consider the feasibility and scientific merit of proposed studies prior to submission of any proposal to an IRB. Each Review Committee has its own specific standard operating procedures. The Principal Investigator may be asked to meet with the Review Committee, but in any event must be available upon reasonable request to answer questions from the Review Committee.
3. The scope of the Review Committee's review of the proposed research may include, but is not limited to:
 - a. Investigator interest in the research
 - b. Investigator experience in the therapeutic area
 - c. Sponsor enrollment expectations and adequate subject population at Carle
 - d. Adequate and appropriate staffing, equipment and resources
 - e. Protocol design
 - f. Competing research studies at Carle
 - g. Sponsor contract
 - h. Budget matters
 - i. Medical and scientific merit
 - j. Statistical analysis including subject numbers and justification
 - k. Potential risks and benefits to subjects/patients
 - l. Local context, if the study will be submitted to an external IRB
4. The composition of each of the Review Committee is as following:
 - a. Carle Cancer Center Review Committee: Cancer Center staff, Principal Investigator or Co-Investigator, Patient Advocate*, and VP of Medical Subspecialties, a designee by the Institutional Official. The committee is charged with evaluating the proposed protocols' operational feasibility. Designees review the protocol for departmental feasibility. Comments are noted on the protocol feasibility review form as well as in the meeting minutes.
 - b. Non-Cancer Clinical Trials Review Committee: Medical Director of Clinical Trials, VP of Research and Chief Academic Officer, Executive Director of the Research Institute, Manager of Clinical Trials, and other Clinical Trials staff.
 - c. Carle Scientific Review Committee: The core of the committee consists of the Chair, Co-Chair, Administrative Coordinator, Biostatistician(s), Clinical and/or Basic Scientist(s). Depending on the focus of the proposed research study, at least one expert member from a clinical specialty area below will be required to review the proposed study and to attend the meeting when that proposed study is discussed: Oncology/Hematology, Gastrointestinal, Genetics/Genomics, Stem cells, Cardiovascular, Imaging, Medical Informatics, Pathology, Database, Other: as required.
5. If any department other than the Principal Investigator's department is involved, the research protocol and feasibility will either be reviewed by the other department's manager or designee and a support letter/statement from the manager or designee will be submitted to the Review committee.
6. Each Review Committee may seek guidance or advice from others with expertise that it deems necessary or helpful for the proper evaluation of the proposed research.
7. The Review Committee informs the Principal Investigator about the review outcome. The review outcome can include approval to proceed, request for modification, request for more information, or disapproval.
8. All review comments are documented in a feasibility review form, which is uploaded onto IRBNet for proper documentation. To meet Joint Commission requirements the study protocol, consent template, and HIPAA Authorization must also be uploaded into IRBNet for record retention.
9. Any concerns regarding local attitudes or context will be reported by the Principal Investigator to IRB of records in the initial submission.

NOTE: If there are any changes in local context issues arise during the study, they will be documented and reported to the IRB of record by the principal investigator during a modification or continuing review submission.

References

OHRP guidance on IRB Knowledge of Local Research Context (July 21, 2000): www.hhs.gov/ohrp/policy/local.html

Electronic Approval On File

*Supersedes CFH 104 and CCA 5305.

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