

The Carle Foundation

IRB Policy 203

Subject	Jurisdiction of the IRB				
Approval	Dec 2006	Review	Jun 2009	Revision	Jun 2009
Scope	These policies apply to all research conducted by Carle Investigators (any Carle Foundation/Carle Foundation Hospital employee, or member of the medical staff, receiving funds from Carle Foundation), or at Carle facilities.				
Purpose	To define the Jurisdiction of the Carle IRB.				

Statement of Policy

1. The Carle IRB reviews any proposal involving human subject research if conducted at CFH or an entity with a prior IRB Authorization Agreement with the Carle IRB. No human subject research may occur using facilities, staff or assets of Carle Foundation Hospital unless that research is exempt from review under federal regulations and these policies, has been approved by the Carle IRB, or has been approved by another IRB which has been granted jurisdiction over research conducted at Carle Foundation Hospital through a written agreement and registration on the Carle Federal Wide Assurance. The Carle IRB has jurisdiction over research performed at CCA, or by a CCA employee or representative, if the Carle IRB is the IRB of record for CCA. The IRB's decision regarding jurisdiction is final and cannot be overturned by administration or other committees.
2. Carle IRB review and approval of all research involving human subjects is required if:
 - a. The research is sponsored, in whole or in part, by Carle Foundation, Carle Foundation Hospital, or any of their affiliates, regardless of whether the research is conducted at Carle Foundation Hospital or at another institution;
 - b. The research is conducted by or under the direction of any Carle Investigator, employee, staff or agent of CFH;
 - c. The research is conducted by and/or at other institutions or organizations and that institution/organization has requested Carle IRB review, approval and oversight of the Research and the Carle IRB has accepted the request;
 - d. The research is being conducted by Carle Clinic Association (CCA) and the Carle IRB is the IRB of record for CCA;
 - e. The research is conducted using any property or facility of CFH; and/or the research involves the use of nonpublic information (including patient information) of Carle Foundation, Carle Foundation Hospital, or any affiliate or subsidiary of either of them, including use of such information to identify or contact potential research subjects;
 - f. CFH information, including identifiable patient information, is provided to an Investigator or used to identify possible study subjects;
 - g. CFH serves as a collating center or statistical center for analysis or retention of data gathered by other study sites; and/or
 - h. The Carle IRB also functions as the Privacy Board. Actions of the IRB in its role as the Privacy Board shall be conducted in accordance with CFH HIPAA and confidentiality policies.

Specific Policies

1. Impact of Approval of Study by Other IRBs
 - a. Many research studies are conducted at several institutions or sites simultaneously. This typically is a valid study design intended to permit timely accomplishment of enrollment goals and diversity of participants. Thus, many proposed research studies will be reviewed by multiple institutional review boards. Notwithstanding this review, review of the research by Carle IRB is required unless: (a) the other institutional review board which has reviewed the study is listed on the Carle Foundation Hospital Federal Wide Assurance; (b) a written agreement is in effect with that institutional review board, where the institutional review board formally accepts responsibility for oversight of that study at Carle facilities; and (c) the Carle IRB is advised of, and agrees through a formal action to, the oversight of such research at Carle facilities by that other institutional review board. If the Carle IRB agrees to permit another IRB to review, approve and oversee research otherwise under the jurisdiction of the Carle IRB, the Investigator for such research must, on a timely basis, provide to Carle IRB documentation of such review and all related correspondence.
2. Review by National Cancer Institute Central Pediatric IRB/Central Adult IRB
 - a. Studies may have already been reviewed by the Central IRB sponsored by the National Cancer Institutes. Review by the Central IRB does not fulfill the requirements of Carle Foundation Hospital for IRB review. However, the Carle IRB may take into consideration the peer and scientific review which has occurred in protocols already approved through the Central IRB, and may focus on addressing issues of local concern and ensuring local procedures and protocols will ensure equitable treatment of human subjects, adequate informed consent for potential subjects, and maintaining oversight of the conduct of the study at Carle facilities.

Specific Policies (cont.)

3. Review by Other National IRBs
 - a. Review of a study by a national IRB does not fulfill the requirements of Carle Foundation Hospital for IRB review. However, the Investigator is required to report to the Carle IRB any actions taken by such national IRB, and ensure that Carle IRB is apprised of any adverse event or similar reports submitted to the national IRB.
4. Review by Other Institutional IRBs
 - a. Review of a study by another institution's IRB does not fulfill the requirements of Carle Foundation Hospital for IRB review. However, the Investigator is required to report to the Carle IRB any actions taken by such institutional IRB, and ensure that Carle IRB is apprised of any adverse event or similar reports submitted to the institutional IRB.
5. Research exempt from IRB review is contained in 45 CFR 46.101(b)(1-6) and 21 CFR 56.104.

Reference

Carle IRB Policies

Approval On File

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