

**The Carle Foundation
IRB Policy 301**

Subject	Research Submission Requirements				
Approval	Dec 2006	Review	Dec 2009	Revision	Dec 2009
Scope	These policies apply to all research submitted to IRB.				
Purpose	To identify the submission requirements for initial review.				

Statement of Policy

1. The primary source of information regarding a specific study is typically the documentation submitted by Investigators for initial and continuing review. The IRB relies on Investigators to provide accurate and complete information regarding a proposed research project. Therefore, this material must provide IRB members with enough information about a study to assess if it adequately meets the IRB's criteria for approval.
2. A submitted protocol will be scheduled for IRB review when staff has determined that the information and materials submitted present an adequate description of the proposed research and when the Scientific Review Committee has reviewed the protocol and determined that scientific merit and feasibility have been adequately addressed for the protocol to be reviewed by the Carle Institutional Review Board.

Specific Policies

1. **Submission Requirements for Initial Review.** Only submissions received two weeks prior to a scheduled IRB meeting will be considered at the meeting; any exceptions to this deadline must be approved by the IRB Chair or his/her designee.
 - a. **Required** Investigators applying for initial approval of a proposed research protocol must submit via the electronic submission system:
 - The appropriate initial review application
 - Research protocol in its entirety (including any amendments to the original), Investigator Brochure, device specifications and other documentation describing the research
 - Supporting material, such as examples of recruitment advertising, etc. If recruitment materials are to be broadcast, the IRB must review the final recording prior to use. Final review of such materials may occur through expedited review.
 - A web address and screen prints of any website used for recruiting subjects
 - Questionnaires & assessment instruments
 - A description of participant recruitment and enrollment procedures, including selection of subjects and how such selection is equitable
 - Proposed informed consent form, process and information sheets including how informed consent is approved, obtained and documented/maintained. Investigator must refrain from obtaining consent and enrollment for studies until **after** IRB has approved consent for the protocol)
 - HIPAA documents
 - A description of procedures to protect participant privacy
 - A description of procedures to maintain confidentiality, accuracy and integrity of data
 - Proposed subject instructions
 - For federally funded research, a copy of the federal grant application with budget
 - Information regarding any other IRB approvals, withdrawal of approval, or refusals to approve
 - For other funded research, a copy of the funding agreement
 - A copy of the Carle Investigator Agreement signed by the PI, as given here in the Appendix A
 - b. In addition, applicants may be required to submit, as appropriate:
 - Financial disclosure statement including any Conflicts of Interest
 - FDA Form 1572 (IND) or signed Investigator agreement (IDE)
 - Case report form sample
 - Documentation that the study has been reviewed and approved by other committees charged with oversight of research at Carle Foundation Hospital
 - For multi-center studies, documentation that the study has been reviewed and approved by other IRBs, and any instructions, forms or information to be presented to the local IRB
 - Evidence of continuing education and training in human subject protection, and knowledge of local and state law requirements when applicable.

Specific Policies (cont.)

- If the Principal Investigator has more than 20 open studies (includes studies conducted where Carle IRB has oversight **AND** all other sites outside of Carle IRB oversight), then submission of Appendix B (Research Resource Disclosure form available on IRBNet) is required to document the adequacy of resources to conduct the studies.

2. Submission Requirements for Continuing Review

- a. Investigators requesting renewal of an approved research project must submit, via the electronic submission system, all pertinent materials sufficiently in advance of scheduled IRB meetings. It is recommended that such submissions be made in advance of two scheduled IRB meetings. This will allow the Investigator(s) and/or research staff to submit any additional information the IRB may request after the first review. Submissions qualifying for expedited review will be accepted per the discretion of the IRB Chair or designee. (Note: Please refer to the current scheduled IRB Submissions and Meeting timetable at: <http://www.carleconnect.com/ResearchDeadlines.shtml>). Submission requirements for continuing review include:
- A completed Continuing Review of Research form with required documents
 - Consent Document. The currently approved consent document shall be reviewed to ensure that the information is still accurate and complete. The Investigator shall advise the IRB in writing whether he/she believes new findings that may relate to the subject's willingness to continue participation have developed, and whether any additional or revised information should be provided to subjects in an updated consent document.
 - Current approved protocol including any amendments to the protocol since initial review: Amendments and addenda to a research protocol must be approved prior to implementation. A separate cover letter describing in detail each change and all appropriate documentation (a copy of an approved consent form and IRB approval letter, as well as any documentation explaining the reason for the change(s)) must accompany the continuing review application.
 - Continuing review of Data Safety Monitoring Board /Data Monitoring Committee ("DSMB/DMC")-monitored clinical trials: When a clinical trial is subject to oversight by a DSMB or DMC whose responsibilities include review of adverse events, interim findings and relevant literature, in conducting continuing review, the IRB may rely on a current statement from the DSMB/DMC indicating that it has reviewed study-wide adverse events, interim findings and any recent literature that may be relevant to the research, in lieu of requiring that this information be submitted directly to the IRB. However, the IRB must still receive and review reports of local, on-site adverse events, serious adverse events, or unanticipated problems involving risks to subjects or others and any other information needed to ensure that its continuing review is substantive and meaningful. The IRB has the right and authority to decline to approve a renewal or continuation application regardless of the conclusions of the DSMB/DMC.
 - Progress Report. Each IRB member shall receive and review a protocol summary and a progress report prepared and submitted by the Investigator which sets forth clearly:
 - The number of subjects accrued to date and since the last review
 - Adverse event experience summary
 - Unanticipated problems involving risks to subjects or others;
 - Withdrawal of subjects since last review;
 - Complaints about the study since the last review;
 - A summary of recent literature relevant to the research;
 - Amendments, changes in personnel, training of personnel and new COI disclosure as applicable;
 - Updated assessment of the risk-to-benefit ratio which takes into account the above factors.
 - Grant applications will be reviewed by the Office of the IRB to verify that there have been no changes.
 - Documentation of appropriate Investigator training which meets the requirements of these Policies and any applicable grant requirements must be submitted with the continuing review materials.
 - **Significant New Findings** Any statements of significant new findings provided to subjects during the course of the study will be reviewed.
 - Checklists. Checklists will be used to assist the IRB in the Continuing Review process

Refer to IRB Review of Research Policy 404 Continuing Review

3. Submission Requirements for Other Submission Types

The completed appropriate form based on the submission type and required attachments must be submitted via the electronic submission system.

- a. Modification
- b. Notification

Specific Policies (cont.)

- c. Closure
 - d. Prompt Reporting
4. **Action Taken if Documentation is Not Adequate or Additional Information is Required.** If the IRB or IRB staff determines that the submitted documents are not adequate, Investigators may be required to submit additional information, or their presence may be required to answer questions or explain the details of the study. Submissions which do not include required information or are determined inadequate by IRB staff will not be reviewed by the IRB. Submissions which, upon consideration by the IRB, require more information shall be tabled until sufficient information is provided.

Reference

45 CFR 46.111 and Carle IRB Policies

Electronic Approval On File

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Human Subject Protection
Institutional Review Board

Appendix A: Carle Investigator Agreement^{v1}

As an investigator at Carle Foundation Hospital (CFH), I, _____ would like to participate in research for which initial review and continuing oversight is provided by the Carle Institutional Review Board (Carle IRB) directly, or, as provided in the Institutional Review Board Authorization Agreement with the Carle IRB. I understand that one of the conditions of my participation in such research is my acknowledgement and acceptance of my responsibilities under this Agreement and applicable federal, state and local laws, regulations, ethical guidelines, and other policies and principles, as described here in.

A. Statement:

1. I acknowledge that I have read
 - this Agreement,
 - Office for Human Research Protections (OHRP)-approved Federalwide Assurance (www.hhs.gov/ohrp/humansubjects/assurance/filasurt.htm),
 - federal research regulations
 - (45 CFR 46: www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm;
 - 21 CFR part 50 & 56: www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm)
 - the applicable requirements under HIPAA (www.hhs.gov/ocr/privacy/hipaa/understanding/index.html),
 - the Belmont Report (<http://ohsr.od.nih.gov/guidelines/belmont.html>),
 - the Carle IRB Policies (www.carleconnect.com/ResearchPolicies.shtml), and
 - CITI guidelines for responsible conduct of human research (www.citiprogram.org).

I understand and hereby accept my responsibilities for satisfying the intent and procedures in these documents, for fully complying with them, and for protecting the rights and welfare of human subjects involved in research conducted under this Agreement.
2. I will comply with other federal, state, or local laws or regulations as they may relate to research covered by this Agreement
3. I will abide by determinations of the Carle IRB, and other IRBs with which Carle IRB has an agreement for providing oversight, and acknowledge that the authority and decisions of the Carle IRB are final. I will abide by policies, procedures, and decisions of the Carle IRB as they may apply.

B. Reporting:

1. I will report promptly to the Carle IRB, proposed changes in research activities under this Agreement. The changes shall not be initiated without prior Carle IRB review and approval, except where necessary to eliminate apparent immediate hazards to the subjects, in which case, these actions will be promptly communicated in writing to the Carle IRB within the prescribed time.
2. I will report immediately to the Carle IRB, on proper forms, any injuries to subjects (including but not limited to serious and unexpected adverse events, such as deaths, or illnesses) or unanticipated problems involving risks to subjects or others.
3. I will inform the Carle IRB about the progress of the approved studies periodically, and as requested, including reporting any studies that have lapsed for lack of obtaining continuing Carle IRB approval for any reason. I will cease all non-exempt research activities in such studies until reapproved by the Carle IRB. I understand that any violations in this regard are reportable as noncompliance to the institutional official(s) and

relevant regulatory agencies.

C. Other Responsibilities:

1. As a designated Principal Investigator, I will assume overall administrative responsibility for all aspects of each study approved under this Agreement.
2. I will attend any required training, and meet the educational requirements as per the policies of the Carle IRB, before conducting any research under this Agreement. I will attend other educational and training requirements that the Carle IRB deems appropriate, and will be responsible for following the updated policies and information regarding the conduct of research under this Agreement.
3. I understand that the Carle IRB has documents it regularly uses in providing oversight for research, such as appropriate forms and relevant procedures, which I agree to use, unless specific written approval is granted by the Carle IRB for use of any other document(s) for the conduct and/or reporting of research activities.
4. I will obtain Informed Consent, document Informed Consent, and maintain records of signed Informed Consent and HIPAA authorization forms from each prospective subject, or his or her legally authorized representative, as required by applicable federal, state and local regulations.
5. I acknowledge and agree to cooperate in the Carle IRB's responsibility for initial and continuing IRB reviews and approvals, record keeping, reporting, and certification. I will, in a timely manner, provide all the necessary information for progress reports used in the Carle IRB's continuing review process.
6. I will provide the Carle IRB, its designated auditor(s), and other regulatory agencies, with all the information they deem appropriate to assist them in carrying out their responsibilities under this Agreement. This includes, but is not limited to, any conflicts of interest with the research activities, on my behalf and those of my research staff, any complaints received from the study subjects and/or staff.
7. I will communicate in a timely manner with the representatives of the Carle IRB, appropriate regulatory agencies, and other investigators who may be participating in the study(ies), issues pertaining to the protection of human subjects in order to better protect the rights and welfare of the subjects.
8. If I conduct research under an investigational new drug or device subject to Food and Drug Administration (FDA) regulations, I will comply with all investigator (or investigator-sponsor, if appropriate) responsibilities described in FDA Form 1572, 21 CFR Parts 312 and 812, other applicable regulations, or successor provisions.
9. I will not accrue subjects on the study under this Agreement prior to approval and without certification of Carle IRB review and approval. Provision of any emergency medical care without prior full board review is permitted under applicable federal regulations. However, research data may not be used from such interventions.
10. Neither I, nor my research staff, will attend Carle IRB meeting, except when invited to provide information upon request.
11. Presentations and publications resulting from this research shall acknowledge Carle appropriately.
12. I will cooperate with any inquiry by the Carle IRB into research compliance in a study in which I participate under this Agreement, including but not limited to providing research records and related information upon request. In the event the Carle IRB deems me to have failed to comply with this Agreement, I agree to take action(s) that the Carle IRB deems appropriate, including but not limited to termination of my participation in designated research activities.

I understand my primary responsibility is to the well-being of research subjects and their interests take precedence over the research. It is my responsibility to abide by the federal research regulations, the HIPAA regulations, the Carle IRB policies, and this Agreement. In the event of serious or continuing noncompliance with any of these requirements, the Carle IRB will report such noncompliance to OHRP, other federal departments or agencies that sponsor the research or have jurisdiction over it, such as FDA, the sponsor of the research, and institutional officials as appropriate, and take all appropriate action(s) in order to enforce compliance with the

required regulations.

Principal Investigator Signature: _____

Date: _____

Print Name: _____

Title: _____