



## Policy IRB301

<b>Subject</b>	Research Submission Requirements
<b>Category / Section</b>	Research / Institutional Review Board
<b>Owner</b>	Manager of Human Subject Protection
<b>Stakeholder/ Reviewer(s)</b>	
<b>Approver(s)</b>	Manager of Human Subject Protection; Executive Director of the Research Institute
<b>Review Frequency</b>	Annual
<b>Effective Date</b>	12/06
<b>Review Date</b>	04/11; 11/28/11; 01/23/12
<b>Revision Date</b>	10/11; 11/28/11; 01/23/12

### Scope of Policy (Identifies the entities that are covered under the policy)

<input checked="" type="checkbox"/>	All Carle Locations		Caring Place, The		SurgiCenter, LLC - Champaign
	Carle Hospital		Health Alliance		SurgiCenter - Danville
	Carle Physician Group		Home Care		SurgiCenter Recovery Centers
	Carle Foundation Physician Services		Home Infusion		Therapy Services
	AirLife		Hospice		Therapy Services - MTCH
	Arrow Ambulance		Medical Supply & Arabella Boutique		Windsor Court
	Auditory Oral School		Risk Management Company		Windsor of Savoy
	Cancer Center/Mills Breast Cancer Institute				

### Scope Exclusions

--	--

### Purpose

- A. To identify the submission requirements for initial and continuing reviews, proposed modifications, and other submissions to the Carle IRB.

### Definitions

- A. [Approved Terminology – AD100A](#) is a glossary of common terms that can be used in P & P's without defining them in the document.
- B. **Human Subjects Protection Office (HSP)** – Human Subjects Protection office at Carle, which supports the Carle IRB administratively.
- C. **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.
- D. **Minimal Risk** - The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
- E. **Principal Investigator** - The investigator/ researcher who is responsible for the conduct of a research study at an institutional site.
- F. **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.

### Statement of Policy

- A. The primary source of information regarding a specific study is typically the documentation submitted by the Principal Investigator for initial and continuing review. The Carle IRB relies on the Principal Investigator to provide accurate and complete information regarding a proposed research project. Therefore, this material must provide the Carle IRB

members with sufficient information to thoroughly assess if a study meets the IRB's criteria for approval.

- B. A submitted research study via IRBNet will be scheduled for IRB review when the HSP office 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 IRB.

### Procedure

- A. With limited exceptions, the Principal Investigator must be a Carle healthcare provider or non-visiting Carle staff who will serve as project supervisor at Carle. Students, interns, post-doctoral researchers, medical residents, and visiting faculty from other institutions may not serve as Principal Investigator, but should be listed as Co-Investigators or Key Research Personnel, if applicable. Exceptions to this requirement include: studies that have already been reviewed and approved by the Carle IRB prior to the revision date of this policy., studies initiated by a Carle employee who attends another educational institution (for example, a Carle nurse completing an MSN program), and studies conducted by a non-visiting faculty member at another institution (UIUC, for example) as long as a qualified Carle Responsible Investigator is identified.
- B. **Submission Requirements for Initial Review.** Only submissions received via IRBNet (the Carle IRB's electronic submission system) 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 designee.
1. A Principal Investigator applying for initial approval of a proposed research study must submit the following **required** information via IRBNet:
    - a. An application for review of research;
    - b. Research protocol in its entirety (including any amendments to the original), Investigator Brochure, device specifications and other documentation describing the research, as applicable, including:
      - A description of participant recruitment and enrollment procedures, including selection of subjects and how such selection is equitable;
      - A description of procedures to protect participant privacy;
      - A description of procedures to maintain confidentiality, accuracy and integrity of data;
      - Proposed subject instructions;
      - A clear delineation of data points to be collected during the course of proposed research, unless a separate data collection form is included in the submission;
    - c. Appendix A: Carle Investigator Agreement signed by the Principal Investigator;
    - d. IRB Registration Form;
    - e. Proposed informed consent form, process and information sheets including how informed consent is obtained and documented/maintained (only applicable if a waiver of informed consent or a waiver of documentation of informed consent is not requested);
  2. **In addition, Principal Investigators are required to submit the following materials appropriate for the study:**
    - a. Appropriate HIPAA document(s);
    - b. Supporting material, such as examples of recruitment or advertising flyers, etc. If recruitment materials are to be broadcast, the Carle 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;
    - c. Questionnaires & assessment instruments;
    - d. Data collection forms, unless the study protocol contains a detailed list of data points that will be collected in the course of research;
    - e. For federally funded research, a copy of the federal grant application with budget;
    - f. For multi-center studies, information regarding any other IRB approvals, withdrawal of approval, or refusals to approve;
    - g. Financial disclosure statement including any Conflicts of Interest;
    - h. FDA Form 1572 (IND) or signed Investigator agreement (IDE);
    - i. Case report form sample;
    - j. Documentation that the study has been reviewed and approved by other committees or staff charged with oversight of research at The Carle Foundation (Receipt of a study submission by the Carle IRB indicates that the study has been reviewed and approved by one of three Carle Review Committees described in Research Policy 104: Scientific, Feasibility, and Local Context Review of Human Subjects Research. Documentation of their review and approval are available to the Carle IRB upon request. Any issues related to human subjects protection identified by these committees will be electronically communicated to the Carle IRB);

- k. Evidence of continuing education and training in human subject protection, and knowledge of local and state law requirements when applicable;
- l. Appendix B: Research Resource Disclosure, 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), in order to document the adequacy of the Principal Investigator's resources for conducting those studies;
- m. Appendix C: Children and Neonates as Research Subjects, if minors will be enrolled in the research;
- n. Appendix D: HUD Supplement to Research Application, if a protocol involves the use of a Humanitarian Use Device (HUD) as defined by the FDA.
- o. Appendix H: Human Biological Material, if human biological material will be collected or used for research purposes.
- p. Appendix K: Co-Investigators and Key Research Personnel, as necessary.
- q. Appendix T: Carle Tissue Repository Request, if research involves the use of tissues supplied by the Carle Tissue Repository.

### C. Submission Requirements for Continuing Review

1. The Principal Investigator requesting renewal of an approved research project must submit, via IRBNet, 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 Principal Investigator and/or Key Research Personnel to submit any additional information the Carle IRB/ HSP office may request after the pre-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: [www.carleconnect.com/ResearchDeadlines.shtml](http://www.carleconnect.com/ResearchDeadlines.shtml)). Submission requirements for continuing review **must include all actively used documents**, including, but not limited to the following:
  - a. A completed Continuing Review of Research Form, which contains the following information:
    - **Significant New Findings** Any statements of significant new findings provided to subjects during the course of the study will be reviewed.
    - Progress Report. Each Carle IRB member has full access, via IRBNet, to the research study on the agenda for the upcoming IRB meeting and shall review a protocol summary and a progress report prepared and submitted by the Principal 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 Conflict of Interest disclosure as applicable;
      - Updated assessment of the risk-to-benefit ratio which takes into account the above factors.
  - b. Consent Document. If the research is still open for accrual, 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.
  - c. IRB Registration Form.
  - d. 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. 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 Carle IRB must still receive and review reports of local, on-site unanticipated problems involving risks to subjects or others and any other information needed to ensure that its continuing review is substantive and meaningful. The Carle IRB has the right and authority to decline to approve a renewal or continuation application regardless of the conclusions of the DSMB/DMC.

- e. Grant applications will be reviewed by the HSP office to verify that there have been no changes.
  - f. Documentation of appropriate Investigator training which meets the requirements of Research Policy 102: Education Requirements for Investigators and Key Research Personnel Involved in Research and any applicable grant requirements must be submitted with the continuing review materials.
  - g. All other currently approved study documents for which the Principal Investigator seeks continued approval for use in the research.
- D. Submission Requirements for Other Submission Types** The completed appropriate form, available on IRBNet, based on the submission type and required attachments must be submitted via IRBNet.
1. Modification Request Form
    - a. Any documents modified must be included in the submission using a “tracked changes” function in addition to a “clean copy” without tracked changes so that reviewers can clearly see the proposed changes.
    - b. If the proposed modifications involve changes to the information included in the IRB Registration Form, an updated IRB Registration Form must be included with this submission.
  2. Project Closure Form
    - a. Refer to Carle IRB Policy 405—Project Closure or Transfer—for other specific requirements for project closure requests.
  3. Prompt Reporting Form
    - a. Refer to Carle IRB Policy 801—Unanticipated Problems and Other Events Requiring Prompt Reporting—for other specific requirements for reporting specific events to the Carle IRB.
- E. Action Taken if Documentation is Inadequate or Additional Information is Required.** If the Carle IRB or HSP office staff determines that the submitted documents are not adequate, the Principal Investigator 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 the Carle IRB or the HSP office staff will not be reviewed by the Carle IRB. Submissions which, upon consideration by the Carle IRB, require more information shall be tabled until sufficient information is provided.

**Attachments** N/A

**Other Related Links** N/A

#### **References**

- 45 CFR 46.111
- 21 CFR 56.111
- Carle IRB Policies
- Research Policy 102: Education Requirements for Investigators and Key Research Personnel Involved in Research
- Research Policy 104: Scientific, Feasibility, and Local Context Review of Human Subjects Research

#### **Electronic Approval on File**

Kyle Galbraith, PhD  
Management of Human Subject Protection

Anna Keck, PhD  
Executive Director of the Research Institute

R. Bruce Wellman, MD  
CEO of Carle Physician Group  
Institutional Official

Carle IRB Contact:  
Carle Foundation Hospital  
Carle Institutional Review Board  
611 West Park Street  
Broadway Research Center (BWRC)  
Urbana, IL 61801  
Phone: 217-383-4366

Fax: 217-383-3993  
Email: [irb@carle.com](mailto:irb@carle.com)  
Web: [www.carleconnect.com/irb.shtml](http://www.carleconnect.com/irb.shtml)