

The Carle Foundation

IRB Policy 406

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| Subject | Categories of Action and Communication of the Carle IRB's Decision to the Principal Investigator | | | | |
| Approval | Dec 2006 | Review | Apr 2011 | Revision | Apr 2011 |
| Scope | This policy applies to all research under the jurisdiction of the Carle IRB. | | | | |
| Purpose | To state the categories of action for Carle IRB-reviewed research and to describe the procedures for communicating with the Principal Investigator about the Carle IRB determinations. | | | | |

Statement of Policy

1. As a result of its review, the Carle IRB may decide to approve, not approve, table, specify modifications required for Carle IRB approval, request additional information regarding the proposed research activity, or acknowledge the submission.
2. When conducting expedited review, the Chair or designee can take any of the following actions except to not approve a research study. A recommendation to not approve the research study by the appointed reviewer in an expedited review shall be referred to the convened IRB for review and vote.
3. Notice of the Carle IRB's decisions will be provided to Principal Investigator in writing via IRBNet in a timely manner.

Definitions

Human Subjects Protection Office (HSP) – Human Subjects Protection office at Carle, which supports the Carle IRB administratively.

Institutional Official – The individual designated as the Signatory Official on the Federal Wide Assurance on file with the Office for Human Research Protections or his/her designee.

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.

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. As a result of its review of the research study submitted for initial review, continuing review, for proposed modifications or other submissions to previously approved research, the Carle IRB's determination will consist of one of the following categories of actions:
 - a. *Approval* – The protocol and accompanying documents are approved as submitted. Final approval is effective on the day the study is approved by an action of the convened IRB (or, in the case of expedited review, Chairperson or designee responsible for reviewing the project).

Note: Research approved by the Carle IRB may be disapproved by the Institutional Official or the VP of Research and Chief Academic Officer, if it is deemed that this study is not in the best interest of The Carle Foundation and/or due to concerns that a study puts human subjects at significant risk of harm. However, the Institutional Official or the VP of Research and Chief Academic Officer may not approve the research if it has not been approved by the Carle IRB. The Institutional Official, the VP of Research and Chief Academic Officer and the Research Integrity Officer have full access via IRBNet to all research reviewed by the Carle IRB (via expedited or full board review) including decision letters, agendas and minutes. They are also invited to attend the monthly convened Carle IRB meeting(s).
 - b. *Modifications Required* – The Carle IRB may request changes to any portion of the submission. The Principal Investigator will need to submit the required changes and a new round of review will occur. A revised submission may receive expedited review if the submission meets the OHRP criteria for expedited review or if the Carle IRB determines that this re-submission may be reviewed via expedited review procedures. No research activity may occur until all additional required information is received and reviewed by the IRB and a final decision of approval is made.
 - c. *Tabled* – No action was taken by the Carle IRB. No research activity may occur until all additional required information is received and reviewed by the IRB and a final decision of approval is made.
 - d. *Not Approved* – The proposal fails to meet one or more criteria used by the Carle IRB for approval of research. As proposed, this research study cannot be conducted.
 - e. *Acknowledged* – Involves two categories 1.) The Carle IRB acknowledges receipt of the submission, but the submission is administratively reviewed and does not qualify for expedited or full board review procedures.

Examples of items that may be acknowledged include, but are not limited to, approval letters from other IRBs that also provide oversight for a given study or new publications resulting from studies overseen by the Carle IRB. 2.) The Carle IRB acknowledges receipt of the submission of a prompt reporting and it has been reviewed and accepted by the IRB chair or designee according to IRB policy 801: Unanticipated Problems and Other Events Requiring Prompt Reporting. If the prompt reporting is a potential noncompliance it will be handled according to Research Policy122: Research Monitoring and Audit Program.

2. Communication Regarding the Carle IRB's Decision – The Principal Investigator will be notified of the Carle IRB's decision in writing via IRBNet, with the basis for the decision, and any additional information required.
3. Investigator Appeal of Carle IRB's Decision
 - a. *Required Revisions.* A Principal Investigator may appeal the revisions required to the submitted research study by the Carle IRB. This appeal must be in writing and submitted to the Carle IRB via IRBNet as part of the submitted research study. The appeal should explain the concerns of the Principal Investigator and/or Sponsor regarding the requested revisions.
 - b. *Disapproval.* A Principal Investigator may appeal the Carle IRB decision to disapprove a study. Any such appeal must be in writing via IRBNet as part of the submitted research study and must address the concern(s) addressed in the notice of disapproval. Appeals of disapproval must be reviewed by the convened IRB. The Principal Investigator may ask to attend the IRB meeting to address concerns regarding the research study. If the appeal is denied and the study rejected, the disapproval is final, and no administrator or department can override the Carle IRB's decision.

References

45 CFR 46
21 CFR 56
Carle IRB Policies

Electronic Approval on File

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