

The Carle Foundation

IRB Policy 405

Subject	Project Closure or Transfer		
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 procedures for closure of a research study or transfer of research oversight to an external IRB.		

Statement of Policy

1. The completion, transfer, or termination of a research study are considered changes in activity and must be reported to the Carle IRB via IRBNet, the online submission system. Once all non-exempt research activities have ceased at the location(s) over which the Carle IRB has oversight, the submission of a Project Closure Form and supporting verification of the closure or transfer, allows the Carle IRB to close its files.

Definitions

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

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

A research study may be closed with the Carle IRB when all non-exempt research activities have been completed or the oversight has been transferred to an external IRB of record.

1. Project Closure
 - a. In addition to the submission of a Project Closure, adequate verification of one of the following may be required to close a study with the Carle IRB:
 - A final report from the study base which clearly states that all non-exempt research activities have ceased at the location(s) over which the Carle IRB has oversight;
 - A permanent study closure notice form is issued by the sponsor or study base; or
 - Other documentation that the study is complete and that all non-exempt research activities have ceased.
 - b. All closures must be submitted via IRBNet, the online submission system.
 - c. By submitting a Project Closure Form, the Principal Investigator is formally attesting to the fact that all non-exempt research activities have concluded at the location(s) over which the Carle IRB has oversight.
 - d. Project closures are an administrative procedure conducted by the HSP office on behalf of the Carle IRB. If the HSP office has questions or concerns, they may refer project closure requests to the convened IRB. The Principal Investigator will receive a letter via IRBNet notifying him/her that the study has been closed with the Carle IRB. Until this letter is received, Carle IRB oversight will be maintained.

Note: If a study has been closed by the Carle IRB due to expiration of IRB approval, the Principal Investigator must resubmit the study for initial review before any research activity may occur again.
2. Transfer of research oversight to an external IRB
 - a. In addition to the submission Project Closure Form via IRBNet, the Principal Investigator is obligated to provide the following to the Carle IRB:
 - Clarifications addressing any outstanding issues related to human subject protection;
 - Confirmation that all study documents have been received by the Carle IRB;
 - Copy of protocol approval letter from the IRB to which the study is being transferred.
 - b. Project transfers are an administrative procedure conducted by the Carle Human Subject Protection office on behalf of the Carle IRB. If the Carle Human Subject Protection office has questions or concerns, they may refer project transfer requests to the convened IRB. The Principal Investigator will receive a letter via IRBNet notifying him/her that the study has been closed with the Carle IRB. Until this letter is received, Carle IRB oversight will be maintained.

c. Even after transfer, the Principal Investigator is still obligated to provide all relevant records of the study for institutional audits or investigations.

References

21 CFR 56.108
21 CFR 56.109
45 CFR 46.103
45 CFR 46.109

Electronic Approval on File

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