

**The Carle Foundation  
IRB Policy 408**

<b>Subject</b>	Research Defined				
<b>Approval</b>	Nov 2010	<b>Review</b>	Apr 2011	<b>Revision</b>	Apr 2011
<b>Purpose</b>	To inform the Principal Investigator and other Key Research Personnel that the Carle Institutional Review Board (Carle IRB) may require verification from sources other than the Principal Investigator that no material changes have occurred to IRB-approved research without IRB approval.				

**Statement of Policy**

1. The Principal Investigator and other Key Research Personnel are expected to provide the Carle IRB with all relevant information in a timely manner regarding the conduct of the research approved by the Carle IRB. In order to ensure compliance and the protection of human subjects, the Carle IRB may, at any time, require verification of information from sources other than the Principal Investigator that no material changes have occurred to IRB-approved research without IRB approval.
2. Requiring independent verification may be based on The Carle foundation's routine audit plan or any legitimate concern that may include, but is not limited to, the following:
  - a. Studies being conducted by Key Research Personnel who have previously failed to materially comply with regulations and Carle IRB policies, including non-responsiveness to requests for information;
  - b. Studies for which the Key Research Personnel's conduct was suspect in light of information provided during continuing review or audit;
  - c. Complaints from any IRB of record or research subjects that appear not be adequately addressed by the Key Research Personnel;
  - d. Studies in which an IRB of record discovers previously undisclosed information that should have been reported to the IRB of record;
  - e. Studies in which the Key Research Personnel has disclosed or failed to disclose significant conflict(s) of interest; or
  - f. Studies that exhibit high-risk profiles such as unexpected frequencies or severity of reported serious adverse events, high participant dropout rates or involving an unusual level or types of risks to subjects.
3. The details of the independent verification will be worked out on a case-by-case basis, but may include conducting an audit by the Carle IRB, the Compliance Department or designee before reporting findings to the Research Compliance Committee and other parties in accordance with Research Policy 122. This review may include, but is not limited to:
  - a. Communications between the Key Research Personnel and any regulatory agency
  - b. DSMB reports
  - c. Site monitor reports – Sponsor/CRO audits, reports or correspondence
  - d. Grant applications
  - e. Research subject records
  - f. Patient medical records.
4. The Carle IRB shall maintain documentation of any requests and the outcome of an independent verification performed under this policy in accordance with federal and state laws, and The Carle Foundations records retention requirements.
5. Requirements for independent verification may occur due to allegations of noncompliance. Any allegations of noncompliance, including those regarding the protection of human subjects, must be reported and investigated in accordance with The Carle Foundation's Code and Research Policy 108 and Carle IRB policy 801. The Compliance Department will coordinate any for-cause audits with the Human Protections Administrator, the Carle IRB, and other applicable parties.

**Definitions**

**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.

**The Carle IRB** – The Internal IRB to The Carle Foundation.

**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.

## Definitions (cont.)

**Key Research Personnel** – Investigators and other individuals who contribute the scientific development or execution of a research study or research project in a substantive, measurable way, whether or not they receive salaries or compensation under the grant. These individuals participate in the conduct, reporting, supervision and management of human subject's research.

**Principal Investigator** – The investigator/researcher who is responsible for the conduct of a research study at an institutional site.

## Procedures

1. The Carle IRB, in the course of performing a review, may request an independent verification from a source other than the Principal Investigator.
2. If an independent verification is requested, the Carle IRB notifies in writing the Principal Investigator, Human Protections Administrator, Institutional Official, VP of Research and Chief Academic Officer, and the Research Integrity Officer. This notice must contain:
  - a. A brief summary of the request
  - b. A reason for the request
  - c. The scope of the request including a general description of independent sources of verification.
3. Carle IRB will work out the details and initiate the verification process with the Human Protections Administrator.
4. Once the independent verification has been completed, the Carle IRB will review the results and decide on the appropriate actions.
5. The Carle IRB will notify in writing the Principal Investigator, Human Protections Administrator, Institutional Official, VP of Research and Chief Academic Officer, the Research Integrity Officer, and the Research Compliance Committee when the independent verification has been resolved.
6. The Carle IRB will not give final approval to the research study until it has received and reviewed the independently verified information and found it satisfactory.
7. If the independent verification results in findings of noncompliance, the Carle IRB will follow IRB policy 801 to ensure proper corrective action and reporting.

## References

45 CFR 46.103(b)(4)(ii)

Carle IRB Policy 801: Unanticipated Problems and Other Events Requiring Prompt Reporting

Research Policy 108: Reporting Adverse Events, Unanticipated Problems Involving Risks to Subjects or Others, and Noncompliance.

Research Policy 121: Verification from Sources Other Than The Principal Investigator That No Material Changes have Occurred to IRB-Approved Research

Research Policy 122: Research Monitoring and Auditing Program

## Electronic Approval on File

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