

**The Carle Foundation  
IRB Policy 403**

<b>Subject</b>	Ongoing Oversight				
<b>Approval</b>	Dec 2006	<b>Review</b>	Jun 2009	<b>Revision</b>	Jun 2009
<b>Scope</b>	These policies and procedures apply to all research submitted to the IRB.				
<b>Purpose</b>	To provide guidance in conducting ongoing IRB oversight of research.				

**Statement of Policy**

1. Once approved, each research project is subject to ongoing oversight and continuing review by the IRB.
2. Oversight includes review of, but may not be limited to, the following activities:
  - a. Site Visits and Third-Party Verification
  - b. Collection and Review of Data
  - c. Serious and Unexpected Adverse Events
  - d. Amendments
  - e. Significant New Findings
  - f. Revised protocols and informed consent documents
  - g. Reports from Employees, Staff and Faculty
  - h. Noncompliance
  - i. Unanticipated Problems
  - j. Internal and External Audits

**Specific Policies**

1. Site Visits and Third Party Verification
  - a. The IRB has the authority to observe, or to have a third party observe, the informed consent process of research it has approved, and to verify that the study is being conducted as required by the IRB and in accordance with the Institutional policies and procedures and site-specific procedures, as appropriate. IRB staff or members may perform site visits or use another party to verify information.
  - b. Investigators may be asked to submit copies of signed informed consent forms or other documents to ensure their compliance with IRB requirements. The IRB may conduct interviews with screened and/or enrolled subjects as deemed necessary.
2. Collection and Review of Data
  - a. The IRB may determine that collection and review of data is necessary or appropriate to evaluate potential flaws in study design, to identify early trends in data, and to monitor risks to human subjects.
3. Serious and Unexpected Adverse Events
  - a. Any event that is serious and unexpected must be reported to the IRB per IRB Reporting Responsibilities of Investigators and Sponsors Policy 801 Unanticipated Problems and Other Events Requiring Prompt Reporting. If the Chairperson determines that action may be needed to protect the safety of research subjects due to the nature or frequency of reported adverse events, he/she may take such action and/or the full IRB or designated subcommittee will review the adverse events and study in question to determine action, if any, by the IRB. The IRB, or designated subcommittee, will review summaries of all safety reports and serious adverse events as soon as possible at a convened meeting.
4. Unanticipated Problems
  - a. All unanticipated problems must be reported promptly to the IRB per IRB Reporting Responsibilities of Investigators and Sponsors Policy 801 Unanticipated Problems and Other [Events Requiring Prompt Reporting](#).
5. Amendments
  - a. **Following IRB approval**, proposed changes in approved research may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject (46.103(b)(4)(iii)). Deviations from protocol, where necessary to eliminate apparent immediate hazards to human subjects, may be implemented by the investigator but must be promptly reported to the IRB. Investigators should describe to the IRB the immediate hazard identified and provide to the IRB any analysis or theory of the reason for the hazard. Reports of deviations should also include recommendations regarding changes to the research project to avoid similar risk of harm to other subjects. Documentation regarding review and approval or denial of amendments to protocols or informed consent documents must be maintained in accordance with IRB – Functions and Operations Policy 303 Documentation and Document Management and noted in meeting minutes.

**Specific Policies (cont.)**

6. Significant New Findings
  - a. Investigators have a responsibility to promptly bring to the IRB's attention, per IRB Reporting Responsibilities of Investigators and Sponsors Policy 801 Unanticipated Problems and Other Events Requiring Prompt Reporting, any data which could reasonably impact the risk/benefit evaluation.
7. Reports from Employees, Staff and Faculty
  - a. The IRB will exercise oversight on information or reports received regarding the rights and welfare of research subjects.
8. Ensuring Compliance
  - a. The IRB has the authority to ensure prompt reporting of any serious or continuing noncompliance with applicable regulations or the requirements or determinations of the IRB. All credible reports of inappropriate involvement of human subjects in research must be reported to the IRB per IRB Reporting Responsibilities of Investigators and Sponsors Policy 801 Unanticipated Problems and Other Events Requiring Prompt Reporting.

The IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB policies, is not in compliance with federal regulations, or has been associated with unexpected serious harm to subjects. All such suspension and or terminations will be reported to the appropriate Institutional Official, funding and regulatory agencies.

**Reference**

45 CFR 46, 21 CFR 56, and Carle IRB Policies

**Approval On File**

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