

# The Carle Foundation

## IRB Policy 102

<b>Subject</b>	Policies and Procedures Maintenance		
<b>Approval</b>	Dec 2006	<b>Review</b>	Feb 2011
		<b>Revision</b>	Feb 2011
<b>Scope</b>	These policies apply to all Carle IRB members, staff, and other personnel involved in or responsible for human subject research at The Carle Foundation.		
<b>Purpose</b>	To provide guidance for creating and maintaining current and accurate policies and procedures for the Carle IRB and/or the Human Subject Protection (HSP) office.		

### Statement of Policy

1. The Carle IRB is to maintain and follow written policies that comply with applicable laws and regulations, as well as describe the functions and operations of the Carle IRB. These policies, which follow the regulations and guidance of the Office for Human Research Protections, Food and Drug Administration, and the International Conference on Harmonization, are supported by The Carle Foundation institutional policies and ensure that the rights and welfare of the human subjects of research will be overseen and protected in a uniform and consistent manner, regardless of changes in research or IRB personnel.
2. The Carle Human Subject Protection (HSP) office is to maintain and follow written procedures to support the daily functions and operations of the Carle IRB. These procedures describe the administrative duties of the HSP office as well as steps taken by the HSP office to support the Carle IRB in its review of research submissions, proposed modifications to approved research, reports of unanticipated problems and other events requiring prompt reporting, or any other submissions to the Carle IRB.

### Specific Policies

1. Review, Revision and Approval of Carle IRB Policies
  - a. Changes to regulations, federal guidelines, ethical standards or scientific or research practice, as well as other policies of The Carle Foundation, may require a new policy or a revision to a previously issued policy.
  - b. Policies will be reviewed by the appropriate official(s) of The Carle Foundation no less frequently than annually, and as appropriate to ensure continued compliance with law, regulation and ethical standards.
  - c. The Vice President of Research and Chief Academic Officer, after consultation with the Chairperson and other members of the Carle IRB, has the power to approve new or revised policies affecting the Carle IRB prior to implementation of those policies.
  - d. Documentation of review and approval is indicated by electronic signature of the Vice President of Research and Chief Academic Officer through the internal SharePoint document review system.
2. Review, Revision and Approval of HSP Procedures
  - a. Changes to regulations, federal guidelines, Carle IRB policies, or other policies of The Carle Foundation, may require a new written procedure or a revision to a previously approved written procedure.
  - b. Written procedures will be reviewed by the HSP Manager no less frequently than annually, and as appropriate to ensure continued compliance with regulations and Carle IRB policies as well as to ensure that written procedures are reflective of the daily workflow of the HSP office.
  - c. The HSP Manager has the power to approve new or revised written procedures prior to the implementation of those written procedures.
  - d. Documentation of review and approval of HSP written procedures is indicated by signature of the HSP Manager. A signed copy of all approved HSP written procedures will be maintained and available for review in the HSP office.

### Reference

45 CFR 46  
 21 CFR 50, 56  
 Carle IRB Policies

### Approval On File

\*Approved by IRB Board Aug 2010

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