

**The Carle Foundation
IRB Policy 602**

Subject	IRB Communication with Other Entities				
Approval	Dec 2006	Review	Sep 2010	Revision	Jun 2009
Scope	These policies and procedures apply to all research under the jurisdiction of the Carle IRB.				
Purpose	To describe the requirements of communication with relevant entities involved in research oversight.				

Statement of Policy

1. The Carle IRB is required by federal regulation and institutional policy to communicate certain actions to entities that may have an interest in the status of the research being conducted.

Specific Policies

1. **Communications to Others.** The purpose of this policy is to ensure prompt reporting to appropriate Institutional Officials, funding sources, agency heads, governmental and/or regulatory agencies and any other appropriate entity of:
 - a. Any unanticipated problems involving risks to human subjects or others
 - b. Any instance of serious or continuing noncompliance with these regulations or the requirements or determinations of the IRB
 - c. Any suspension or termination of IRB approval, and
 - d. Any research that the IRB cannot approve under the terms of 21 CFR 50.24.
2. **Prospective Emergency Research.** If the IRB determines that it cannot approve a clinical investigation because the investigation does not meet the criteria, per 21 CFR 50.24 Exemption from Informed Consent Requirements for Emergency Research, notification of disapproval will be conveyed to the Sponsor as well as the Investigator.
3. **Device Studies.** If the IRB determines that a study submitted as a non-significant risk presents significant risk, the IRB must notify the Sponsor, FDA, and Investigator.
4. **Unexpected or Serious Adverse Events.** The Investigator must notify the IRB and other entities as stipulated in IRB 801: Unanticipated Problems and Other Events Requiring Prompt Reporting.
5. **Suspension of a Study for-cause.** The IRB will notify the Institutional Official, and FDA when the study involves an FDA regulated product and federal Agency Head if the research is federally funded, as appropriate.

Reference

45 CFR 46, 21 CFR 56, 21 CFR 50.24 and Carle IRB Policies

Approval On File

*Approved by IRB Board Aug 2010

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