

**The Carle Foundation
IRB Policy 406**

Subject	Categories of Action		
Approval	Dec 2006	Review	Jun 2009
Revision	Jun 2009		
Scope	These policies and procedures apply to all research under the jurisdiction of the IRB.		
Purpose	To state the categories of actions for the IRB-reviewed research.		

Statement of Policy

1. As a result of its review, the IRB may decide to approve or not approve the proposed research activity, or to specify modifications required to secure IRB approval of the research activity. When conducting expedited review, the Chairperson or designee can take any of the following actions except to not approve a study. A recommendation to not approve the study by the appointed reviewer in an expedited review shall be referred to the convened IRB for review and vote.

Specific Policies

1. Determinations – The IRB may, as a result of its review of research submitted for initial or continuing review, decide as follows:
 - a. Approval – The protocol and accompanying documents are approved as submitted. Final approval is effective on the day the study is approved by an action of the convened IRB (or, in the case of expedited review, Chairperson or designee responsible for reviewing the project).
 - b. Modifications Required – The IRB may request changes to any portion of the submission. The Investigator will need to submit the required changes and a new round of review will occur. A revised submission may receive expedited review if it qualifies. No activity on the research may occur until all additional required information is received and reviewed by the convened IRB and a final decision of approval is made.
 - c. Tabled – No action was taken by the IRB. No activity on the research may occur until all additional required information is received and reviewed by the convened IRB and a final decision of approval is made.
 - d. Not Approved – The proposal fails to meet one or more criteria used by the IRB for approval of research. As proposed, this research cannot be conducted.
2. Communication Regarding IRB Decision – The Investigator will be advised of the IRB's decision in writing, with the basis for the decision, and any additional information required.

Reference

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

Approval On File

Gopal Kulkarni, PhD
Director of Human Subject Protection

Anna Keck, PhD
Executive Director of the Research Institute

William Schuh, MD, PhD
Medical Director of the Research Institute

Carle IRB Contact:
Carle Foundation Hospital
Carle Institutional Review Board
611 West Park Street
Broadway Research Center (BWRC)
Urbana, IL 61801
Phone: 217-383-4366
Fax: 217-383-3993
Email: irb@carle.com
Web: www.carleconnect.com/irb.shtml