

## The Carle Foundation IRB Policy 601

<b>Subject</b>	Notice of IRB Decisions to Investigators		
<b>Approval</b>	Dec 2006	<b>Review</b>	Sep 2010
<b>Revision</b>	Jun 2009		
<b>Scope</b>	These policies and procedures apply to all research under the jurisdiction of the Carle IRB.		
<b>Purpose</b>	To describe procedures for communicating with investigators about IRB decisions.		

### Statement of Policy

1. Notice of Carle IRB decisions will be provided to Investigators in writing in a timely manner.

### Specific Policies

1. **Investigator Notifications.** Please refer to [IRB Review of Research Policy 406 Categories of Action](#).
2. **Investigator Appeal of IRB Action**
  - a. **Required Revisions.** An Investigator may appeal the revisions required by the IRB to the protocol and/or informed consent form. This appeal must be in writing and submitted to the Office of the Institutional Review Board prior to the date specified in the letter advising the Investigator of the required revisions. The appeal should explain the concerns of the Investigator and/or Sponsor regarding the requested revisions.
  - b. **Disapproval.** Investigators may also appeal an IRB decision to disapprove a study. Any such appeal must be in writing and must address the concern(s) addressed in the notice of disapproval. Appeals of disapproval must be reviewed by the IRB at a convened meeting. The Investigator may ask to attend the IRB meeting to address concerns regarding the protocol. If the appeal is denied and the study rejected, the disapproval is final, and no administrator or department can override the IRB's decision.
3. **Noncompliance.** Investigator noncompliance with federal regulations, IRB directives or the approved study protocol will result in the IRB Chairperson notifying the Investigator in writing, detailing the alleged noncompliance, specifying corrective action(s) required, and stating the consequences. Copies of such correspondence may also be sent to the Sponsor, the individual's supervisor, and institutional and regulatory authorities as appropriate.
4. **Scientific Misconduct.** Allegations of misconduct in science should be referred to the IRB Chairperson or Institutional Official for handling under Carle Foundation Hospital policies.

### Reference

45 CFR 46, 21 CFR 56 and Carle IRB Policies

### Approval On File

\*Approved by IRB Board Aug 2010

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