

**The Carle Foundation
IRB Policy 902**

Subject	Audits by Regulatory Agencies				
Approval	Dec 2006	Review	Sep 2010	Revision	Jun 2009
Scope	These policies and procedures apply to all IRBs in the Carle Foundation Hospital system.				
Purpose	To describe procedures for audits.				

Statement of Policy

1. Carle Foundation Hospital acknowledges that certain regulatory agencies have the authority to audit the operations of IRBs, and supports such audits as part of its continuing effort to maintain high standards for human research protections. Entities that may audit IRBs include: FDA, OHRP, JCAHO, and appropriate certified auditors of foreign countries where data from clinical research has been submitted in an application for drug or device approval. Sponsors or funding entities of research may also be authorized to audit specific documents and procedures.

Specific Policies

1. Preparing for an Audit

- a. For external audits involving OHRP or the FDA, the following must be notified immediately:
 - Chief Executive Officer
 - Institutional Official
 - Risk Management/Legal Counsel
 - IRB Chairperson
 - Directors of Research (Executive and Medical)
 - Vice President of Research
 - Chief Compliance Officer

2. Participating in an Audit

- a. IRB staff is expected to know and follow the procedures outlined by this Institution for the conduct of a regulatory audit.
- b. Prior to being granted access to IRB documentation, inspectors or auditors must exhibit proof of their authority or authorization to conduct the audit and to access IRB documents, and no entity other than those listed on the consent forms may have access to any document that includes subject identifiers.
- c. Auditors will be provided with adequate working area to conduct an audit and IRB staff and members must make every reasonable effort to be available and to accommodate and expedite the requests of such auditors.
- d. Documents may be copied and taken off-site only by individuals authorized in writing by the Senior Vice President, Legal Affairs to do so.

3. **Follow-up After an Audit.** Reports of the audit, either verbal or written, should be addressed by the Carle IRB Chairperson and Director of HSP, (with the assistance and support of Carle Foundation Hospital Administration), as soon as possible after the audit.

Reference

Corporate Compliance Policy CF607 Responding to Investigations by Governmental Agencies

Approval On File

*Approved by IRB Board Aug 2010

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