

**The Carle Foundation
IRB Policy 901**

Subject	Quality Assurance/Quality Control				
Approval	Dec 2006	Review	Jun 2009	Revision	Jun 2009
Scope	These policies and procedures apply to all aspects of the Carle IRB.				
Purpose	To develop and implement a Quality Assurance/Quality Control Procedure for HSP operations.				

Statement of Policy

1. Quality assurance (QA) and quality control (QC) of the daily operations of the Carle IRB ensures effective support of the Board's mandate. Therefore, the QA/QC operation consists of three components:
 - a. Regular review and assessment of policies and procedures (IRB General Administration Policy 101 Compliance with Policies and Procedures Manual).
 - b. Ensuring the Carle IRB staff has the required education, experience and training to perform their duties appropriately (IRB General Administration Policy 103 Training and Education).
 - c. Ongoing assessment of Carle IRB operations and outputs.

Specific Policies

1. Ongoing assessment of Carle IRB operations and outputs is conducted through QC monitoring and QA auditing (internal and external). QC monitoring involves periodic, real time checks of specific Carle IRB operations, documents and records. The Director of HSP performs these QC steps on a routine basis.
2. Internal auditing is a retrospective assessment of Carle IRB operations through document and record review. Internal audits may be horizontal, where a particular function is assessed across several studies (e.g., minute-taking); or they may be vertical, where a particular study is audited in whole or in part (e.g., high-risk research). Internal auditing is performed on at least a bi-annual basis.
3. Sponsors or other responsible agents (e.g., contract research organizations) periodically conduct an audit of their studies reviewed by the Carle IRB. In addition, Food and Drug Administration inspections provide additional assessment of the quality of Carle IRB operations (refer to IRB Quality Assurance Policy 902 Audits by Regulatory Agencies). These audits are considered external audits.
4. Carle IRB management (IRB Chair, Directors for Research, and Director of HSP) discusses the results of QC, internal/external QA audits and regulatory inspections. The considerations of adverse findings derived from these activities are used to determine the root cause(s) and to develop and implement a corrective and preventive actions (CAPA) plan to improve the effectiveness of the Carle IRB Human Subject Protection.

Reference

<http://www.hhs.gov/ohrp/qi/> (QA /QI for Human Research Protection Programs)

Approval On File

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