

**The Carle Foundation
IRB Policy 303**

Subject	Documentation and Document Management		
Approval	Dec. 2006	Review	Jan 2010
		Revision	Oct 2009
Scope	These policies apply to all documents submitted for review of research under the jurisdiction of the IRB.		
Purpose	To provide guidance in documentation and document management relating to IRB.		

Statement of Policy

1. The IRB's files must be maintained in a manner that contains a complete history of all IRB actions related to review and approval of a protocol, including continuing reviews, amendments and adverse event reports. All records regarding a submitted study (regardless of whether it is approved) must be retained in an appropriate manner as required by regulatory requirements and/or institutional policy.
2. Records must be accessible for inspection and copying by authorized representatives of the Sponsor, funding department or agency, regulatory agencies and institutional auditors at reasonable times and in a reasonable manner.
3. Required documents must be submitted to the appropriate funding entity as required.

Specific Policies

1. **Confidentiality** All materials received by the IRB will be considered confidential and will be distributed only to meeting participants (regular members, alternate members and special consultants) for the purpose of review. All application materials will be stored in an IRB study file with access limited to IRB members and staff. Consultants and visitors will be expected to sign a Confidentiality Agreement.
2. **Study-Related Document Retention** The IRB Office must retain all records regarding an application in accordance with state and federal records retention requirements which currently require retention for at least 3 years after completion of the last non-exempt research activity for HHS-regulated studies. [45 CFR 46.115(b)] [21CFR 56.115(b)] [45 CFR 164.530] Adequate documentation of IRB activities will be prepared, maintained and retained in a secure location. All research related documents will be handled in the same manner. The following documents must be maintained:
 - a. Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, all approved sample consent forms or other documents given to potential or enrolled study subjects, progress reports submitted by investigators, and reports of injuries to subjects.
 - b. Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.
 - c. Records of continuing review activities.
 - d. Copies of all correspondence between the IRB and the investigators.
 - e. A list of IRB members in the same detail as described in §46.103(b)(3).
 - f. Written procedures for the IRB in the same detail as described in §46.103(b)(4) and §46.103(b)(5).
 - g. Statements of significant new findings provided to subjects, as required by §46.116(b)(5).
 - h. For research which is never conducted, e.g., either never approved, or approved but no subjects were ever enrolled, the records shall be retained for at least 3 years from the last IRB correspondence or action relating to such research. Records relating to research which is conducted shall be retained for at least 3 years after completion of the last non-exempt research activity for HHS-regulated studies.
 - i. For research deemed to be "Exempt" from further Carle IRB review, all records pertaining to the study shall be maintained for 3 years after such determination is granted.
 - j. For research involving FDA-regulated drugs, devices or biologics, records shall be maintained for at least six years after the date of completion of research activities.
 - k. In order to be compliant with HIPAA regulations, records for all studies involving PHI shall be maintained for at least six (6) years from the last IRB action.
3. **IRB Administration Documents** The IRB office must maintain and retain all records regarding IRB administrative activities that affect review activities per regulatory requirements. The IRB Office must retain all records regarding protocols that are approved or otherwise and the research initiated for an amount of time specified in regulatory documents after completion of the research.
 - a. Rosters of regular and alternate IRB members identified by name, earned degrees, representative capacity, and indications of experience sufficient to describe each regular and alternate member's chief anticipated contribution

Specific Policies (cont.)

to the IRB's deliberations; and any employment or other relationship between each member and the Carle Institutional Review Board and/or Carle Foundation Hospital (e.g., full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant).

Alternate members shall be included on the roster. In addition to the above information, the roster shall indicate the regular member for whom the alternate may substitute.

Current and obsolete membership rosters will remain in the IRB Office and then archived according to Carle Foundation Hospital policy.

The roster of IRB members must be submitted to the Office for Human Research Protections ("OHRP"). Any changes in IRB membership must be reported to the head of the department or agency supporting or conducting the research, unless the department or agency has accepted the existence of a Federalwide Assurance (FWA). In the latter case, changes in membership are to be reported to OHRP.

- b. Maintain current and obsolete copies of Policies and Procedures.
 - c. Delegation of specific functions, authorities, or responsibilities by the IRB Chairperson must be documented in writing and filed in the IRB Office.
4. **Destruction of Copies** All material received by the IRB, which is considered confidential and in excess of the required original documentation and appropriate controlled forms, will be collected at the end of the meeting and destroyed by a method deemed appropriate by the Institutional Official.
 5. **Archiving and Destruction** When allowed by regulations (no earlier than 3 years following completion of the research), all documents and materials germane to IRB determinations will be archived according to institutional policy. Archiving policies of the Carle Foundation Hospital will determine when such archived records may be destroyed.

Reference

[45 CFR 46.115] [21CFR 56.115(b)] [45 CFR 164.530]

Electronic Approval On File

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