CARILION CLINIC INSTITUTIONAL REVIEW BOARD
Standard Operating Guidelines

Title: 1.6: General Administration: MAINTENANCE OF IRB OFFICE RECORDS	
Original Date: January 2006	**Date of Last Revision:** 1-08, 8-14, 8-23
Primary Sponsor: Human Research Protections Office	**Approved By:** Director of the Human Research Protections Office

Objective:

To establish recordkeeping and retention requirements for Institutional Review Board (IRB) and Human Research Protections Office (HRPO) related records, including requirements for written procedures as dictated by federal regulations.

General Description:

The Carilion Clinic Human Research Protections Office (HRPO) shall prepare and maintain adequate documentation of IRB activities.

Procedure:

The following records will be maintained in the IRB office or in designated storage areas:

IRB Policies and Procedures and Standard Operating Guidelines

A complete listing of all HRPO and IRB Policies/Procedures and Standard Operating Guidelines will be maintained in the HRPO office. These will be available upon request as appropriate.

IRB Records/Study Files

The IRB maintains a record for each research proposal it receives for review. Each file will contain the following, when applicable:

- Research application with all attachments
- Protocol and any amendments to protocol
- Advertising materials
- Approval letter(s)
- Approved Informed Consent Forms
- Continuing review records
- Progress reports (Changes/Updates) submitted by investigators
- Reports of adverse events
- Scientific evaluations that may accompany the proposal
- Investigator brochure
- Statements of significant new findings provided to subjects
- Correspondence
  - Correspondence to and from the investigator
  - Correspondence to and from the sponsor or any regulatory agency

- Letters of Agreement
- Certificate of Confidentiality
- IRB Authorization Agreement

Documentation of Expedited Reviews

The IRB will maintain complete documentation of expedited research. The investigator's research application and/or protocol is used to determine justification that the study meets the conditions of the expedited review category that has been determined by the IRB.

Documentation of Exemptions

The IRB will maintain documentation of verified exemptions. The investigator's research application and/or protocol is used to determine justification that the study meets the conditions of the expedited review category that has been determined by the IRB.

Documentation of Quality Assurance/Quality Improvement

The IRB will maintain documentation of all applications resulting in approval as Quality Assurance or Quality Improvement. The investigator's QA/QI application and/or research application and/or protocol is used to determine justification that the study meets the conditions of Quality Assurance or Quality Improvement as determined by the IRB.

Documentation of Emergency Use of a Test Article

Emergency use reports, which include written certifications of exceptions from informed consent for emergency use and/or exemptions from IRB review for emergency use of a test article, shall be maintained. The file will include the investigator's request, patient information, justification of need for the research treatment, and the IRB's acknowledgement of the emergency use.

Auditing Reports

Files will be maintained for each audit initiated by the IRB and will include documentation of audit results, copies of all correspondence with the investigator and copies of all correspondence with institutional officials, the IRB, the sponsor and any regulatory agencies.

IRB Membership

A list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution.

Education and Training Records

All individuals involved in human subjects research under the jurisdiction of the Carilion IRB, including but not limited to investigators, study personnel, board members and IRB staff, must provide proof of completion of educational requirements as mandated by the Carilion IRB. Copies of completed educational requirements will be maintained, along with any additional educational and training opportunities that are provided by the IRB.

Meeting Minutes

Documentation will be kept in accordance with Carilion IRB Standard Operating Guideline titled: 1.7: General Administration: Documentation of IRB Meeting Minutes.

Access and Retention Period

IRB records are stored in locked offices in the Human Research Protections Office space, in the IRB electronic submission system PRIS3M, and/or on the secure, password protected HRPO shared drive. Record access is limited to:

- Institutional officials
- IRB members
- IRB staff
- Officials of federal regulatory agencies conducting reviews such as the OHRP and FDA
- Research investigators (reasonable access to files related to their research)
- Appropriate accreditation bodies

All other access to IRB records is limited to those who have legitimate need for them, as determined by IRB staff.

Records relating to research that is conducted shall be retained for at least three years after the research has been concluded. All records shall be accessible for inspection and copying by authorized representatives of the department or agency at reasonable times and in a reasonable manner.