CARILION CLINIC INSTITUTIONAL REVIEW BOARD
Standard Operating Guidelines

Title: 2.11: Review of Research: STUDY COMPLETION; ENDING IRB OVERSIGHT	
Original Date: January 2006	**Date of Last Revision:** 9-11, 8-23
Primary Sponsor: Human Research Protections Office	**Approved By:** Director of the Human Research Protections Office

Objective:

To provide Carilion Institutional Review Board (IRB) members and staff as well as investigators and their staff guidance on when previously approved research is no longer subject to IRB oversight.

General Description:

Regulations 45 CFR 46.109(e) and 21 CFR 56.109(e) require that IRBs conduct continuing review of ongoing research involving human subjects at intervals not less than once per year. IRB oversight must continue through the data analysis phase if the analysis work involves identifiable data. Acknowledging that data analysis can take years to complete and is often accomplished by external parties, this policy was developed to meet the regulatory requirements and provide adequate protection to subjects while minimizing the burden to the IRB and investigators. IRB oversight is not necessary if the researcher only retains de-identified data after data analysis is complete.

Definitions

Direct Identifier: any data that, either alone or when combined with other data available at the same institution, would allow a person to establish the identity of an individual.

Indirect Identifier: any data that, either alone or when combined with other data available at the same institution, would not allow a person to establish the identity of an individual. Also included under the definition of an indirect identifier is any data that involves the utilization of a code that can identify an individual only with the use of a key or link.

Anonymized: data that has been stripped of all direct and indirect identifiers.

External Party: any organization or individual outside of this institution or any organization for which the Carilion IRB serves as the IRB of record.

Procedure:

Conclusion of Study Documentation

A request to end IRB oversight of a study must be submitted in the Carilion IRB electronic submission system PRIS3M using a Conclusion Form. Data should be kept according to the IRB protocol. A report of study results should be included in the conclusion submission, if available.

Cessation of IRB Oversight

IRB oversight may end if one of the following applies:

- All study activity is complete, including data analysis
- Activity is limited to analysis of anonymized data
- No local subjects have been enrolled
- All local subjects are deceased
- The convened IRB votes to close a study based on any of the following:
  - Study has been previously suspended due to an adverse event, noncompliance or other risk to human subjects
  - Other conditions as deemed appropriate

IRB oversight must continue if any of the following apply:

- Subjects are being screened, recruited, enrolled
- Subjects are receiving treatment or study intervention
- Subjects are being followed/data is being collected/reviewed