FRIENDS RESEARCH INSTITUTE, INC.
1040 Park Avenue, Suite 103
Baltimore, MD 21201

Subject: Functions and Operations
Division: IRB
Date: March 1, 2012, Revised: January 12, 2016

IRB Policy 104.4: DOCUMENTATION AND DOCUMENT MANAGEMENT

Policy

IRB files are maintained in a manner that contains a complete history of all IRB actions related to review and approval of a protocol, including continuing reviews, and amendments. 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.

Records are 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.

Document Retention

1. The IRB Office will retain all records regarding an application (regardless of whether it is approved) for at least three years. For all applications that are approved and the research initiated, the IRB Office will retain all records regarding that research for at least three years after completion of the research.

2. Study-related documents: Adequate documentation of each IRB's activities will be prepared, maintained and retained in a secure location. Retained documents include:

    a) Copies of all original research protocols reviewed, scientific evaluations, if any, that accompany the proposals, approved consent documents, recruitment materials, progress reports submitted by Investigators, documentation of findings used to waived informed consent determinations and documentation of findings used for not approving a research protocol.
    b) Agendas and minutes of all IRB meetings.
    c) Copies of all submitted amendments, monitoring reports, site visit reports, serious adverse events, deviations, and unanticipated problems involving risks to research participants and other continuing review activities.
    d) Copies of all correspondence between the IRB and the Investigators.
    e) Statements of significant new findings provided to subjects.
    f) Reports of any complaints received from subjects.

IRB Administration Documents

The IRB Office will maintain and retain all records regarding IRB administrative activities that affect review activities for least three years. The IRB Office will retain all records regarding protocols that are approved and the research initiated for at least three years after completion of the research.

Retained documents include:

1. 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 to the IRB's deliberations; and any employment or other relationship between each member and the IRB and FRI (e.g., full-time employee, part-time employee, member of Board of Directors, paid or unpaid consultant). Current and obsolete membership rosters will remain in the IRB Office.

2. Current and obsolete of the Standard Operating Policies and Procedures.

3. Current and obsolete Federalwide Assurances with OHRP.

4. Current and obsolete IRB registrations.

Destruction of Copies

All material received by the IRB members, which is considered confidential and in excess of the required original documentation and appropriate controlled forms, will be destroyed by a method such as shredding the paper.

Archiving and Destruction

After three years, all documents and materials germane to IRB determinations will be archived according to institutional policy. Archiving policies of FRI will determine when such archived records may be destroyed.

Responsibility

The IRB Administrator is responsible for maintaining complete files on all research reviewed by or submitted to the IRB and for all applicable regulatory compliance requirements.

Applicable Regulations and Guidelines

45 CFR 46.115
21 CFR 56.115