FRIENDS RESEARCH INSTITUTE, INC.
1040 Park Avenue, Suite 103
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Subject: Quality Assurance
Division: IRB
Date: March 1, 2012

IRB Policy 115.1: QUALITY ASSURANCE

Policy

Quality assurance and control of the daily operations of the IRB ensure effective support of the IRB's mandate. Therefore, the QA program consists of three components:

1. Training and continuing education of IRB staff.
2. Interactions with the IRB community outside the FRI jurisdiction.
3. Regular review and assessment of procedures.

The IRB has the authority to implement a QA program and to act on identified deficiencies by implementing corrective action via revisions to the Standard Operating Policies and Procedures.

FRI acknowledges that certain regulatory agencies have the authority to audit the operations of the IRB, and support such audits as part of its continuing effort to maintain high standards for human research protections. Entities that may audit IRBs include: FDA, OHRP, JCAHO, and appropriate certified auditors of foreign countries where data from clinical research has been submitted in an application for drug or device approval. Sponsors or funding entities of research may also be authorized to audit specific documents and procedures.

Preparing for an Audit

For audits involving OHRP or FDA, the following must be notified immediately:

1. FRI's Institutional Official
2. IRB Chairperson
3. IRB Administrator

Those designated to participate in the audit are required to follow the steps outlined by this institution for preparing the site for an audit.

Participating in an Audit

IRB staff (and members if applicable) is expected to know and follow the procedures outlined by this Institution for the conduct of a regulatory audit.

Prior to being granted access to IRB documentation, inspectors or auditors must exhibit proof of their authority or authorization to conduct the audit and to access IRB documents. No entity other than those listed on the consent forms may have access to any document that includes subject identifiers.

Auditors will be provided with adequate working area to conduct an audit and IRB staff and members must make every reasonable effort to be available and to accommodate and expedite the requests of such auditors.

Documents may be copied and taken off-site only by individuals authorized in writing by the IRB Chairperson to do so.

Follow-up After an Audit

Reports of the audit, either verbal or written, should be addressed by the IRB Administrator in conjunction with the Institutional Official, as soon as possible after the audit.

Responsibility

The IRB Administrator is responsible for the establishment, implementation and oversight of the QA program.

The Institutional Official is responsible for all regulatory agency matters regarding regulatory compliance, participating as needed in regulatory agency audits, and providing support in responding to and correcting audit findings. The Institutional Official may delegate or appoint individuals to participate in audits on his/her behalf.

The IRB Supervisor and/or Administrator is responsible for all formal regulatory agency correspondence and interactions, establishing logistical support during regulatory agency audits, serving as key institution contact during such audits, and drafting responses to regulatory agency correspondence received following such audits.

IRB Chairperson, Members and Staff are responsible for participating in regulatory agency audits as determined by the Administrator, and in fully cooperating with government officials during their participation in such audits.

IRB Chairperson is responsible for assisting the IRB Administrator in formal responses to regulatory agency audits and in implementing policy and procedure changes indicated by such audits.

Applicable Regulations and Guidelines

21 CFR 56.115
45 CFR 46.115
FDA Information Sheet Guidance – FDA Institutional Review Board Inspections (January 2006)
OHRP Compliance Oversight Procedures for Evaluating Institutions (October 14, 2009)