



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

Subject: General Administration

Division: IRB

Date: March 1, 2012

IRB Policy 101.1: POLICIES AND PROCEDURES MAINTENANCE

Policy

FRI's IRB recognizes that Standard Operating Procedures (SOPs) provide the framework for the ethical and scientifically sound conduct of human research, and that adherence to established SOPs helps to ensure high quality and integrity of the review process, regardless of changes in personnel. The IRB hereby establishes the procedures for development and maintenance of SOPs covering IRB operations.

Review, Revision, Approval of Policies and Procedures

1. Changes to regulations, federal guidelines, or research practices as well as the policies and procedures of the IRB or FRI may require a new SOP or policy, or a revision to a previously issued SOP or policy.
2. New or revised policies will be reviewed and approved by the IRB Administrator, with input from the IRB Staff and FRI's Medical Director.

Policy Dissemination and Training

1. When new or revised policies are approved, they will be disseminated to the appropriate individuals & departments.
2. Training will be provided to all IRB members and staff on any new or revised policy.
3. Each new IRB member or staff employee must review all applicable SOPs and policies prior to undertaking any responsibilities at the IRB.

Responsibility

1. The Institutional Official is responsible for granting final approval (as appropriate) to new and revised IRB policies.
2. The IRB Department is responsible for developing and periodically reviewing and modifying (as appropriate) IRB standard operating policies and procedures.
3. IRB members and staff are responsible for reviewing IRB standard operating policies and procedures, and providing feedback upon their content. IRB members and staff may also participate in the development of new policies as needed to reflect IRB operations.

Applicable Regulations and Guidelines

21 CFR 56.108, 56.115

45 CFR 46.108, 46.115

OHRP Guidance on Written IRB Procedures (July 1, 2011)