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

Subject: Collaborative Research
Division: IRB
Date: March 1, 2012

IRB Policy 106.1: COLLABORATIVE RESEARCH

Policy

The IRB may enter into joint review arrangements, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort as allowed and upon entering into an IRB Authorization Agreement as provided for by OHRP.

The IRB may extend, for one or more research protocols, the applicability of its FWA to cover two types of collaborating individual investigators: collaborating independent investigators and collaborating institutional investigators.

OHRP notes that some human subjects research conducted by an assured institution may involve the following two types of collaborating individual investigators:

1. A collaborating **independent** investigator is:
   a. not otherwise an employee or agent of FRI,
   b. conducting collaborative research activities outside the facilities of FRI, and
   c. not acting as an employee of any institution with respect to his/her involvement in the research being conducted by FRI.

2. A collaborating **institutional** investigator is:
   a. not otherwise an employee or agent of FRI,
   b. conducting collaborative research activities outside the facilities of FRI,
   c. acting as an employee or agent of a non-assured institution with respect to his/her involvement in the research being conducted by FRI, and
   d. employed by, or acting as an agent of, a non-assured institution that does not routinely conduct human subjects research.

Extension of FWA

FRI will extend its FWA to cover a collaborating independent or institutional investigator provided that all of the following conditions are satisfied:

1. The principal investigator at FRI directs and appropriately supervises all of the collaborative research activities to be performed by the collaborating individual investigator outside FRI.

2. The extension of the coverage of the FWA is put in place by use of an appropriate written agreement, such as the sample Individual Investigator Agreement, for each collaborating individual investigator who will be engaged in the research being conducted by the assured institution. FRI will maintain the

Individual Investigator Agreement, or other written agreement used by the assured institution, on file and provide copies to OHRP upon request.

3. For collaborating institutional investigators, the appropriate authorities at the non-assured institution state in writing that the conduct of the research is permitted at their institution.

4. FRI and the responsible IRB designated under the FWA approve the extension of the assurance through either the Individual Investigator Agreement or other written agreement used by FRI.

5. The following documents are made available to the collaborating individual investigator: (a) The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects or Research; (b) the HHS regulations for the protection of human subjects at 45 CFR part 46 and the FDA regulations at 21 CFR 50, 56, 312, and 812, when appropriate; (c) the FWA and applicable Terms of the FWA for the assured institution; and (d) the relevant institutional policies and procedures for the protection of human subjects of FRI.

6. The collaborating individual investigator understands and accepts the responsibility to comply with the standards and requirements stipulated in the documents referenced in the preceding paragraph and to protect the rights and welfare of human subjects involved in research conducted under the Individual Investigator Agreement or other written agreement used by FRI.

7. The collaborating individual investigator agrees to comply with all other applicable federal, international, state, and local laws, regulations, and policies that may provide additional protections for human subjects participating in research conducted under the Individual Investigator Agreement or other written agreement used by FRI.

8. The collaborating individual investigator agrees to abide by all determinations of FRI's IRB and agrees to accept the final authority and decisions of the IRB, including but not limited to directives to terminate participation in designated research activities conducted under the Individual Investigator Agreement or other written agreement used by FRI.

9. The collaborating individual investigator agrees to complete any educational training required by FRI and/or the IRB prior to initiating research covered under the Individual Investigator Agreement or other written agreement used by FRI.

10. The collaborating individual investigator agrees not to enroll subjects in research under the Individual Investigator Agreement or other agreement used by the assured institution, prior to the research being reviewed and approved by the IRB.

11. The collaborating individual investigator agrees to report promptly to the IRB/IEC any proposed changes in the research conducted under the Individual Investigator Agreement or other agreement used by FRI. The collaborating institutional investigator agrees not to initiate changes in the research without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to subjects.

12. The collaborating individual investigator agrees to report immediately to the IRB any unanticipated problems involving risks to subjects or others in research covered under the Individual Investigator Agreement or other agreement used by FRI.

13. The collaborating individual investigator, when responsible for enrolling subjects, agrees to obtain, document, and maintain records of informed consent for each such subject or each subject's legally authorized representative as required under HHS regulations at 45 CFR part 46 and stipulated by the IRB.

14. The collaborating individual investigator acknowledges and agrees to cooperate with the IRB's in its initial and continuing review, record keeping, reporting, and certification for the research covered by the Individual Investigator Agreement, or other agreement used by FRI. The collaborating institutional investigator agrees to provide all information requested by the IRB in a timely fashion.

Responsibility

When FRI's IRB determines that it will rely on another institution's IRB review of a study, or vice versa, FRI's IRB Administrator will create an IRB Authorization Agreement. FRI's signatory official, and the other institution's signatory official will sign the document, and copies will be kept on file at both institutions. The IRB Administrator will also amend the FWA accordingly, when appropriate.

When FRI decides to extend, for one or more research protocols, the applicability of its FWA to cover collaborating individual investigators FRI's IRB Administrator will create an Individual Investigator Agreement. FRI's signatory official, and the individual investigator will sign the document, and copies will be kept on file at both institutions.

Applicable Regulations and Guidelines

45 CFR 46.114
45 CFR 46.103 (a)
45 CFR 46.103 (b)
OHRP Guidance on Extension of an FWA to Cover Collaborating Individual Investigators and Introduction of the Individual Investigator Agreement, January 31, 2005