



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

**Subject:** Functions and Operations  
**Division:** IRB  
**Date:** March 1, 2012

## **IRB Policy 104.3: ADMINISTRATIVE REVIEW AND DISTRIBUTION OF MATERIALS**

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### **Policy**

The efficiency and effectiveness of the IRB is dependent upon each member's receipt of materials for review. Each member should have adequate time for thorough assessment of each proposed study, and documentation that is complete and clear enough to allow for an adequate assessment of study design, procedures, and conditions.

### **Exemptions**

The IRB Administrator will review Claims for Exemption submitted by Investigators in consultation with the IRB Chairperson. If granted, such Claims of Exemption will be filed, and a report of exemptions provided to the full IRB.

### **Incomplete Submissions**

Incomplete applications will not be accepted for review. Incomplete submissions will be returned and will not be scheduled for review until the Investigator has provided all necessary materials as determined by the IRB Administrator. The IRB Administrator will notify the submitting Investigator of any documentation or additional information necessary for the application to be scheduled for review.

### **Scheduling for Review**

Complete applications will be placed on the agenda for the earliest meeting possible for review by the full IRB as described in IRB Meeting Administration.

### **Distribution to Members Prior to IRB Meetings**

Copies of application materials described in Research Submission Requirements will be distributed to all IRB members, generally at least ten (10) days prior to the meeting. Each regular member of the IRB attending the meeting will receive a copy of the initial application material. If Consultants are scheduled to attend, they will only receive copies of material that pertain to their requested input. The originals of submission materials will be retained in the IRB Office and available for the IRB meeting.

### **Confidentiality**

All material received by the IRB will be considered confidential and will be distributed only to meeting participants for the purpose of review. All application materials will be stored in an IRB study file with access limited to the IRB members and staff. Consultants and visitors will be expected to sign

Confidentiality Agreements.

### **Responsibility**

The IRB Administrator is responsible for providing complete review material packets to IRB members and other relevant parties. IRB Chairperson (or designee) is responsible for supporting and assisting the IRB Administrator in determining priority of submissions.

### **Applicable Regulations and Guidelines**

21 CFR 56.109

45 CFR 46.109