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Subject: IRB Communication and Notification
Division: IRB
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IRB Policy 113.1: IRB COMMUNICATION AND NOTIFICATION

Policy

It is important that staff, subjects, and other interested parties have a means of communicating information about the conduct of a research project directly to the appropriate institutional officials. It is vital that IRB members, and other officials with responsibility for oversight of research have open and ready access to the highest levels of authority within the institution. The researcher and his/her research staff interact with subjects; therefore it is vital that open and frequent communication with the investigative team be maintained.

The IRB is required by federal regulation and institutional policy to communicate certain actions to other entities that may have an interest in the status of the research being conducted under IRB supervision.

Investigator Notifications

1. Initial submission: The Investigator will be notified in writing of the IRB's decision as soon as possible after the meeting (within one week of the approval of the meeting minutes). For expedited reviews, investigators will receive written notification within three days of the review. If the approval is pending upon receipt and review of requested materials or responses from the Investigator or Sponsor, the IRB must receive the response within 60 days of the date of notification; however, this period may be extended if the Investigator/Sponsor communicates a need for an extension.

2. Renewals and revisions: Investigators will be notified in writing as soon as possible as to action taken by the IRB for any continuing reviews or revisions (within one week of the approval of the meeting minutes). For expedited reviews, investigators will receive written notification within three days of the review.

3. Notification of approval: Investigators will be notified in writing of the approval and provided with an IRB-approved version of the consent form. The IRB-approved consent form will be stamped with an approval date and expiration date. Each approval notice will contain a list of the "Principles to be Followed by Principal Investigators," which outlines the responsibilities of the investigator.

4. Disapproval: Correspondence will provide the reason(s) for disapproval and instructions to the Investigator for appeal of this decision.

Investigator Appeal of IRB Action

An Investigator may appeal the revisions required by the IRB in the protocol and/or informed consent form. This appeal must be in writing and submitted to the IRB Administrator. Investigators may also

appeal an IRB decision to disapprove a study. Any such appeal may be in writing or in person and must be reviewed by the full IRB at a convened meeting. If the appeal is denied and the study disapproved, the institution cannot override the IRB's decision.

Noncompliance

It is the responsibility of the IRB staff and members to act on information or reports received from any source that indicate a study being conducted at any facility under the jurisdiction of the IRB could adversely affect the rights and welfare of research subjects. Reports of non-compliance or adverse situations may be reviewed and investigated by the IRB, or referred to the appropriate FRI authority.

Investigator noncompliance may often be the result of communication difficulties; therefore the IRB and IRB Administrative Staff will attempt to resolve instances of noncompliance without interrupting the conduct of the study, especially if the rights and welfare of subjects may be jeopardized. However, if it becomes apparent that an Investigator is intentionally noncompliant, the IRB, through the IRB Chairperson, will notify the Investigator in writing, detailing the alleged noncompliance, specifying corrective action, and stating the consequences. Copies of such correspondence shall also be sent to the Sponsor, the individual's supervisor, and FRI's Institutional Official.

Should noncompliance continue, appropriate action will be determined at a convened meeting. Action by the IRB can include but is not limited to:

1. Halting the research until the Investigator is in compliance. If the research is halted, OHRP will be notified if the research is funded by a government agency, and FDA will be notified if the research involves an FDA regulated product or agent.
2. Requiring the Investigator to complete a training program.
3. Barring the Investigator from conducting further research.
4. Any other action deemed appropriate by the IRB.

When unapproved research is discovered, the IRB and FRI will act promptly to halt the research, ensure remedial action regarding any breach of regulatory or institutional human subject protection requirements, and address the question of the Investigator's fitness to conduct future human subject research.

The IRB's responsibility is to protect the rights and welfare of research subjects, who could be placed at risk if there is misconduct on the part of an Investigator or any member of the investigative team. It is, therefore, the duty of the IRB to be receptive to and act on good faith allegations of misconduct. Allegations of misconduct in science should be referred to FRI's Institutional Official for handling under FRI policies.

Communications to Others

1. The following incidents will be promptly reported to appropriate Institutional Officials, funding sources, department or agency heads, regulatory agencies (OHRP, FDA) and any other appropriate entity:

   a) Any unanticipated problems involving risks to human subjects or others
   b) Any instance of serious or continuing noncompliance with these regulations or the requirements or determinations of the IRB
   c) Any suspension or termination of IRB approval, and
   d) Any research that the IRB cannot approve under the terms of 21 CFR 50.24.

   The IRB Administrator will ensure prompt reporting of these incidents to the IRB and FRI's Institutional Official.

The Institutional Official will report these incidents to FRI's Board of Directors, OHRP, and the FDA (if appropriate).

If the IRB determines that it cannot approve a clinical investigation because the investigation does not meet the criteria in 21 CFR 50.24 Exemption from Informed Consent Requirements for Emergency Research, notification of disapproval will be conveyed to the Sponsor as well as the Investigator.

2. Device studies: If the IRB determines that a study submitted as a non-significant risk presents significant risk, the IRB must notify the Sponsor, FDA, and the Investigator.

3. IRB findings and actions will be reported to the Institutional Official each month by way of the IRB meeting minutes. The IRB Administrator will forward the approved minutes from all IRB meetings, within one week of the meeting, to the Institutional Official.

Responsibility

IRB Administrators are responsible for overseeing all IRB communications, and for generating appropriate correspondence in response to IRB meetings and decisions.

IRB Administrators are responsible for corresponding with other interested entities concerning the status of research under review by the IRB. IRB Chairperson (or designee) is responsible for ensuring appropriate discussion and IRB decision-making regarding un-approvable emergency research, risk assessment of investigational device, adverse event assessments and Investigator non-compliance.

Applicable Regulations and Guidelines

45 CFR 46.103, 109, 113
21 CFR 56.109, 113
21 CFR 50.24
21 CFR 812.66
OHRP Guidance on Reporting Incidents to OHRP (June 20, 2011)