OBJECTIVE

To describe policies and procedures the Institutional Review Board (IRB) follow for handling allegations of noncompliance, independent verification of non-compliance, and the suspension and/or termination of research.

GENERAL DESCRIPTION

The ethical conduct of research is a shared responsibility. It requires cooperation, collaboration, and trust among the institution, investigators and their research staff, the participants who enroll in research, IRB members, and IRB staff. The primary responsibility of the IRB is to ensure protection of the rights and welfare of research participants. In performing that responsibility, the IRB Office will review and investigate all reports of non-compliance. Continuing and serious non-compliance issues will be reported to the appropriate institutional officials, funding agencies, and federal agencies. IRB staff, IRB members, or IRB consultants do not participate in alleged noncompliance reviews if they have a conflict of interest. (See the *Conflicts of Interest* SOP.)

The convened IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with institutional policy, the IRB approval, that has been associated with serious or continuing noncompliance, or that has been associated with substantive harm to the rights and welfare of human subjects. Any suspension or termination of approval shall include a statement of the reason for the IRB action.

The IRB reports the suspension or termination promptly to the investigator and appropriate institutional official(s). If the research is funded by an extramural agency, federal regulations dictate whether the funding agency must be informed that IRB approval has been suspended or terminated. Principal investigators (PIs) are responsible for informing the funding agency of any suspension or termination of funded research.

Definitions

Noncompliance is defined as conducting research in a manner that disregards or violates federal regulations or institutional policies and procedures applicable to human research. Noncompliance with IRB policies and/or federal requirements may involve a range of issues from relatively minor, administrative, or technical violations to more serious violations that may pose a risk to participants and/or violate their rights and welfare.

Continuing noncompliance is a persistent failure to adhere to the laws, regulations, or policies governing human research.

Serious noncompliance is a failure to adhere to the laws, regulations, or policies governing human research that may reasonably be regarded as:

1) Involving substantive harm, or a genuine risk of substantive harm, to the safety, rights, or welfare of human research participants, research staff, or others; or
2) Substantively compromising the effectiveness of a facility's human research protection or human research oversight programs.

A *suspension* of IRB approved research is a temporary interruption in the enrollment of new subjects, activities involving previously enrolled participants, or other research activities.

A *termination* of IRB approval refers to a permanent halt in the enrollment of new participants, activities involving previously enrolled subjects, or other research activities.

RESPONSIBILITY

Execution of SOP: Principal Investigator (PI)/Research Personnel, Institutional Review Board (IRB) Office Staff, IRB Members, IRB Chairs, Institutional Official

PROCEDURES

A. Reporting of Non-Compliance to the IRB

1. Investigator should self-report any incidents of non-compliance to the IRB Office within one business day of discovery.

2. Researchers, university students, or employees who have knowledge of, or concerns about research conducted without IRB approval and/or not being conducted as approved by the IRB Office, should contact the IRB Office to discuss concerns within one business day of discovery.

3. The IRB Office will notify the investigator within one business day of IRB notification that there has been a potential incident of non-compliance.

4. All research activities must halt until an investigation has been conducted by the IRB Office and the investigator has been notified of the IRB's determination. Researchers will receive an official determination memo that will provide details regarding corrective action plan and conditions for re-initiating study. The only exception to this requirement is where halting

treatment or study intervention would be an immediate hazard to human participants. The investigator must notify the IRB Office immediately for review regarding participants' continued welfare.

B. Investigation and Verification of Non-Compliance

1. The Post-Approval Monitor will initiate an investigation within three business days of receiving a report of any potential non-compliance.

2. The Post-Approval Monitor will review the information presented, as well as other sources of information. After consultation with the IRB Director, the Post-Approval Monitor will determine if further investigation is necessary.

3. If further investigation is necessary, additional assistance may be requested from the IRB members, IRB staff, or administration.

4. The IRB Office may implement verification of the protocol using sources other than the investigator without first contacting the investigator; however, the investigator will be given the courtesy of being informed prior to verification whenever feasible and appropriate.

C. Minor Incidents of Non-Compliance

1. If the Post-Approval Monitor, in agreement with the Director, believes that the non-compliance is not serious and is not a continuing problem, the Post-Approval Monitor will consult with the Director to determine the necessary corrective measures required from the investigator(s).

2. The convened IRB will be notified of any incidents of minor non-compliance and the corrective actions prescribed by the Post-Approval Monitor.

3. If the investigator is not in agreement with the findings of the Post-Approval Monitor and the prescribed corrective action, the investigator may appeal the matter via the procedures outlined in the "Appeal of IRB Actions and Determinations" SOP.

E. Continuing or Serious Incidents of Non-Compliance

1. The investigator must notify the IRB Office immediately if halting treatment or study intervention would be an immediate hazard to human participants.

2. If the Post-Approval Monitor, in agreement with the Director, determines there are non-compliance practices or other circumstances that may immediately jeopardize the safety and welfare of human participants, the Post-Approval Monitor and the Director will convene a subcommittee comprised of the IRB Chair, 1st Vice Chair, and 2nd Vice Chair. The action of this subcommittee is based on a majority vote of the members of the subcommittee present. The Director or Post-Approval Monitor will only vote in cases of tied results. If the Director or Post-Approval Monitor are unable to secure all three subcommittee members, he or she may approach the Institutional Official for further guidance and action.

3. If the Post-Approval Monitor believes the report of non-compliance has possible merit and is serious and/or continuing, the Post-Approval Monitor will recommend that the Director:
    a. convene an emergency meeting of the IRB to review the concerns, or
    b. that the situation be discussed at the next scheduled, convened IRB

4. The convened IRB makes the determination whether the reported incident of non-compliance is substantiated and, if so, whether the noncompliance is serious or continuing based on the materials compiled during the inquiry. If the noncompliance is serious or continuing and the research is federally funded, the IRB Office will promptly report the incident(s) to the applicable agencies within one month of the IRB determining that the noncompliance is serious or continuing.

5. The convened IRB may take a variety of actions, depending on the outcome of the review, including but not limited to:
    a. Prescribe a corrective action plan that the investigator must comply with in order to maintain approval of the protocol submission.
    b. Determine that the investigator may not use the data collected for publication.
    c. Suspend or terminate IRB approval or disapprove continuation of the research submission. (See Procedure Section G of this SOP.)

6. The Post-Approval Monitor will report the decision of the convened IRB in a memorandum to the Principal Investigator within 5 business days after the convened IRB meeting. The investigator's immediate supervisor, faculty advisor/dissertation chair (for student researchers), the Institutional Official, the Office of Sponsored Programs (in the case of funded research), and the Office of Clinical Research (in the case of a clinical trial) will be copied on the correspondence.

7. If the researcher is not in agreement with the findings of the convened IRB, the researcher may appeal the matter via the procedures outlined in the *Appeal of IRB Actions and Determinations* SOP.

F. Incidents of Non-Compliance with Extenuating Circumstances

1. If the Post-Approval Monitor, in agreement with the Director, determines there are extenuating circumstances where time is a limiting factor and it is a more than minor incident of non-compliance, the Post-Approval Monitor and the Director may convene a subcommittee comprised of the IRB Chair, 1st Vice Chair, and 2nd Vice Chair. This subcommittee is convened on a case-by-case basis solely on the discretion of the Post-Approval Monitor and the Director. Principal Investigators may submit a formal declaration of these extenuating circumstances to the Post-Approval Monitor directly for review. This process cannot be used for continuing or serious incidents of non-compliance.

G. Suspension or Termination of IRB Approval

1. If the convened IRB decides to suspend or terminate research, the IRB Office will provide a memorandum of any actions and determinations made by the convened IRB.

2. This memorandum may include, but is not limited, to the following:
    a. An explanation of the extent of the suspension in terms of enrollment, recruitment, interventions, interactions, and data analysis;
    b. The reasons for the suspension, an explanation of the reasons for the decision, and an offer to the investigator to respond to the convened IRB in writing;
    c. A request for a description of any procedures needed to protect the rights and welfare of current subjects if the suspension involves currently enrolled subjects;
    d. A description of whether follow-up of subjects for safety reasons is permitted or required.
    e. A corrective action plan, if applicable, to reinstate research activities.

3. If the investigator is not in agreement with the findings of the convened IRB, the investigator may appeal the matter via the procedures outlined in the *Appeal of IRB Actions and Determinations* SOP.

G. Reporting and Recordkeeping

1. The Institutional Official will report cases of serious and/or continuing noncompliance to applicable regulatory or funding agencies, such as the Food and Drug Administration and the Office for Human Research Protections. This reporting is to occur within one month after the

convened IRB at which the matter was discussed and adjudicated, unless the matter is under appeal or at the advice of counsel. Further reporting may be delayed if the researcher indicates intent to appeal the decision, and if the Institutional Official approves a delay in reporting until the appeal has been heard.

2. The decision regarding the incident of non-compliance will be reflected in the meeting minutes of the convened IRB.

3. All reports of non-compliance will be tracked via a non-compliance tracking file. That file will contain the name of the Principal Investigator, the project title, IRB protocol number (if assigned) and pertinent information associated with the non-compliance investigation as determined by the Post-Approval Monitor.

4. A separate file for the applicable report will be created to store all documents associated with the non-compliance investigation. In the instance of multiple reports associated with the same study, the Post-Approval Monitor may, at their discretion, store the non-compliance records in one file.

5. Record of the determinations and documentation associated with the non-compliance will be retained for seven years following the last date of correspondence associated with the incident of non-compliance.

REFERENCES

45 CFR 46.103(b)(5)
45 CFR 46.113
21 CFR 56.108(b)(2)
21 CFR 56.108(b)(3)
21 CFR 56.113