Section 16. Non-compliance

As part of its commitment to protecting the rights and welfare of human subjects in research, the medical school reviews all reports and allegations of non-compliance and takes any necessary action to ensure the ethical conduct of research.

All Investigators and other study personnel involved in human subject research are required to comply with all laws and regulations governing their research activities, as well as with requirements and determinations of the IRB.

This section provides definitions and the policies and procedures of how complaints and allegations of non-compliance are managed by the IRB.

16.1 Definitions

- **Non-compliance**: Non-compliance is defined as failure to adhere to federal, state, or local regulations governing human subject research, organizational policies related to human subject research, or the requirements or determinations of the IRB. Non-compliance may be minor or sporadic or it may be serious or continuing.

- **Serious non-compliance**: Serious non-compliance is defined as non-compliance that, in the judgment of the convened IRB, creates an increase in risks to subjects, adversely affects the rights, welfare or safety of subjects, or adversely affects the scientific integrity of the study. Willful violation of regulations, policies, or procedures may also constitute serious non-compliance.

- **Continuing non-compliance**: Continuing non-compliance is defined as a pattern of non-compliance that, in the judgment of the convened IRB, suggests a likelihood that instances of non-compliance will continue unless the IRB or organization intervenes.

- **Allegation of Non-Compliance**: Allegation of Non-Compliance is defined as an unproved assertion of non-compliance.

- **Finding of Non-Compliance**: Finding of Non-Compliance is defined as an allegation of non-compliance that is proven true or a report of non-compliance that is clearly true. (For example, a finding on an audit of an unsigned consent document, or an admission of an investigator of that the protocol/research plan was willfully not followed, represent reports of non-compliance that would require no further action to determine their truth and would therefore represent findings of non-compliance.) Once a finding of non-compliance is proven, it must be categorized as non-compliance, serious non-compliance, or continuing non-compliance.

16.2 Reporting

Investigators and research staff are required to report instances of possible non-compliance. The investigator is responsible for reporting any possible non-compliance by research staff to the IRB. However, any individual or employee may report observed or apparent instances of non-compliance to the medical school IRB. In such cases, the reporting party is responsible for making these reports in good faith, maintaining confidentiality and cooperating with any IRB and/or organizational review of these reports.

If an individual, whether investigator, research staff, or other individual, is uncertain whether there is cause to report non-compliance, the individual may contact the IRB manager or IRB chair directly to discuss the situation informally.

Reports of non-compliance must be submitted to the IRB within seven (7) working days of discovery of this non-compliance. The report must include a complete description of the non-compliance including any personnel involved.

Complainants may choose to remain anonymous.

16.3 Review of Allegations of Non-compliance

All allegations of non-compliance are reviewed by the IRB chair or designee, who reviews the report or allegation and may request additional information or an audit of the research in question.

When the Chair or designee determines that non-compliance did not occur because the event was within the limits of an approved protocol/research plan for the research involved, the determination is reported in writing to the investigator and, if applicable, the reporting party. The determination letter is copied to the Institutional Official in cases where the Institutional Official and any other parties had been notified previously of the allegation or event.

If in the judgment of the IRB chair or designee, the report or allegation does represent non-compliance, the non-compliance is processed according to Section 16.4 (Review of Findings of Non-compliance).

If in the judgment of the IRB chair or designee, any allegation or findings of non-compliance warrants suspension of the research before completion of any review or investigation to ensure protection of the rights and welfare of participants, the IRB chair may suspend the research as described in Section 8 with subsequent review by the IRB.

The IRB chair or designee may determine that additional expertise or assistance is required to make these determinations and may request assistance from HRPP/IRB staff or form an ad hoc committee to assist with the review and fact gathering process. When an ad hoc committee assists in the review process, the IRB Chair or designee is

responsible for assuring that minutes of the meetings are generated and kept to help support any determinations or findings made by the ad hoc committee.

16.4 Review of Findings of Non-compliance

16.4.1 Non-compliance that is Not Serious or Continuing

If the IRB Chair or designee determines that the non-compliance occurred, but the non-compliance does not meet definition of serious or continuing non-compliance, the determination is reported in writing to the investigator and, if applicable, the reporting party. The IRB chair reviews any corrective and preventative actions taken or proposed by the investigator and determine if the actions are sufficient or if additional actions may be necessary. In the event that additional actions may be warranted, the matter is referred to the convened IRB for review.

16.4.2 Serious or Continuing Non-compliance

If the Chair or designee determines that non-compliance has occurred and that the non-compliance may meet the definition of serious or continuing non-compliance, the report of non-compliance is referred for review by the IRB at the next available convened meeting. However, the IRB chair or designee may use discretion and call an emergency IRB meeting should the circumstances warrant an urgent meeting.

All initial findings of potential serious or continuing non-compliance referred to the IRB is reviewed at a convened meeting.

At this stage, the IRB may:

- Find that there is no issue of non-compliance.
- Find that there is non-compliance that is neither serious nor continuing and that an adequate corrective and/or preventive action plan is in place.
- Find that there is serious or continuing non-compliance and modify or require a corrective and/or preventive action plan.
- Find that additional information is required to make a final determination. In this instance, the committee will request additional information, and indicate whether such information will be reviewed by the full committee or a subcommittee. If by a subcommittee, a report is written by the subcommittee for review by the convened IRB for final determination.

16.4.3 Final Review

The IRB makes a final determination as to whether the non-compliance is serious or continuing. Upon a finding of serious or continuing non-compliance, possible actions by the IRB include, but are not limited to:

- Request a corrective and/or preventive action plan from the investigator.
- Verification that subject selection is appropriate.
- Observation of informed consent.

- Require an increase in data and safety monitoring of the research activity.
- Request a directed audit of areas of concern.
- Request a status report after each participant receives intervention.
- Modify the continuing review cycle.
- Require additional investigator and staff education.
- Notify current subjects (eg, if the information about the non-compliance might affect their willingness to continue participation).
- Require modification of the protocol/research plan.
- Require modification of the information disclosed during the consent process.
- Require current subjects to re-consent to participation.
- Suspend the study.
- Terminate the study.

In cases where the IRB determines that the event of non-compliance also meets the definition of unanticipated problem involving risks to subjects or others, it is managed according to Section 15.

The investigator is informed of the IRB determination and the basis for the determination in writing. If the IRB determines that the non-compliance was serious or continuing, the results of the final review will be reported as described below in Section 18.