Section 15. **Unanticipated Problems Involving Risks to Subjects or Others**

The medical school complies with DHHS and FDA regulations that require organizations to have written policies and procedures for reporting unanticipated problems involving risks to subjects or others to the IRB, organizational officials, and relevant federal agencies and departments.

This section provides the policies and procedures of how unanticipated problems are managed for research for which the medical school IRB serves as the IRB of record. Unless specifically required by the IRB, the medical school IRB does not accept reports of adverse events that do not meet the definition of an unanticipated problem.

15.1 IRB Review

After a determination of a possible unanticipated problem involving risk to subjects or others, the report is placed on the agenda for the next convened IRB meeting and a primary reviewer assigned.

The primary reviewer is given the study file, current approved consent document (if applicable), previous reports of unanticipated problems, investigator's brochure (if one exists), event report, and recommendations from the IRB chair, or designee. All IRB members receive the event report and have full access to all materials upon request.

After review of the study and event report, the full IRB makes findings and recommendations based on the following considerations:

- Whether the reported event is an unanticipated problem according to the definition in this policy.
- The appropriate action(s), if any, in response to the report.
- Whether suspension or termination of study approval is warranted.

If the IRB finds that the event is not an unanticipated problem according to the definition in this policy, the IRB may recommend any of the following actions:

- No action.
- Requiring modifications to the protocol/research plan.
- Revising the continuing review timetable.
- Modifying the consent process.
- Modifying the consent document.
- Providing additional information to current participants (eg, whenever the information may relate to the subject's willingness to continue participation).
- Providing additional information to past subjects.
- Requiring additional training of the investigator and research staff.
- Other actions as appropriate given the specific circumstances.

If the IRB finds that the event is an unanticipated problem, according to the definition in the policy, the IRB may recommend any of the following actions:

- Requiring modifications to the protocol/research plan.
- Revising the continuing review timetable.
- Modifying the consent process.
- Modifying the consent document.
- Providing additional information to current participants (eg, whenever the information may relate to the subject's willingness to continue participation).
- Providing additional information to past participants.
- Requiring additional training of the investigator and research staff.
- Reconsidering approval.
- Requiring that current subjects re-consent to participation.
- Monitoring the research.
- Monitoring consent.
- Referral to other organizational officials and entities (eg, legal counsel, risk management, Institutional Official).
- Suspending the research approval.
- Terminating the research approval.
- Other actions as appropriate given the specific circumstances.

If a report suggests that participant safety is at risk, the IRB may immediately suspend or terminate the research. Any suspension or termination of research by the IRB must be promptly reported to the Institutional Official and relevant federal regulatory agencies through the Institutional Official. This should be done in writing.

If, after reviewing a report, the IRB finds that the event is an unanticipated problem, or that suspension or termination of approval is warranted, the IRB:

- Notifies the investigator in writing of its findings, with copies to the chair of the investigator's department, the investigator's immediate supervisor, and directors of other affected units
- Reports its findings and recommendations to the assistant dean for Research Compliance for further reporting to the appropriate federal officials, when required (see Section 18).