UNIVERSITY OF TENNESSEE GRADUATE SCHOOL OF MEDICINE
INSTITUTIONAL REVIEW BOARD
INVESTIGATOR NONCOMPLIANCE

I. PURPOSE

To provide a procedure for addressing issues of investigator noncompliance reported to University of Tennessee Graduate School of Medicine Institutional Review Board (UTGSM IRB).

II. SCOPE

Applies to all personnel involved in the review of studies by UTGSM IRB.

Personnel Responsible:

IRB administrative staff and IRB members

III. BACKGROUND

The IRB has the authority to place research activities on hold, as well as to suspend or terminate approval of research that is not being conducted in accordance with the IRB policies or federal regulations for the protection of human subjects. Federal regulations require that institutions develop written policies and procedures for handling complaints and/or reports of noncompliance with the regulations or the policies of the IRB.

Under federal regulations at 45 CFR 46.103(b)(5) and 21 CFR 56.108(b), IRBs must also have written procedures for promptly reporting to appropriate institutional officials and agency heads any unanticipated problems involving risks to subjects or others, any serious or continuing noncompliance of investigators with federal regulations and local IRB policy, and any suspensions or termination of research studies resulting from non-compliance.

In Accordance With:

45 CFR 46.103(b)(5); 45 CFR 46.113; 21 CFR 56.108(b).
OHRP Guidance on Reporting Incidences at
https://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/index.html#Q8

Definitions:

Noncompliance means violation of federal regulations or local IRB policies or determinations regarding protection for the rights and welfare of human subjects.

Temporary hold means discontinuation of previously approved research, directed by the IRB, pending further investigation of alleged instances of noncompliance and/or implementation of minor corrective action.

Suspension means discontinuation of previously approved research, directed by the IRB, following determination of instances of serious noncompliance, and pending formulation and implementation of substantial corrective action.

Termination means closure of previously approved research, directed by the IRB, following determination of instances of serious noncompliance for which implementation of corrective action is not appropriate.

Serious Noncompliance means a noncompliance that, as judged by the convened IRB, significantly increases risk to study participants, significantly decreases expected benefits, or compromises the Human Research Protection Program (HRPP) integrity.

Continuing Noncompliance means a pattern, judged by the convened IRB that indicates a strong likelihood that noncompliance will continue without intervention.

IV. PROCEDURES

The UTGSM IRB will use the following guidelines for determining the type of noncompliance observed and the appropriate procedural actions required. This determination will be key in assessing the overall impact of the noncompliance as well as the proper punitive actions required for the noncompliance.

Noncompliance designations & examples:

Serious noncompliance

- Conducting human subject research without IRB approval
- Enrollment in a research study without consent
- Enrolling subjects outside of inclusion/exclusion criteria
- Major changes to protocols without IRB approval (not valid if change made to prevent imminent distress to research subjects)

Continuing noncompliance

- Consistently late submissions of reportable events
- Repeated lapse of research study approval from IRB
- Repeated lack of adherence to approved IRB protocols
- Repeated informed consent discrepancies

- Upon receipt of a complaint or allegation of noncompliance, the IRB Assistant Director/designee will send a copy of the report to the Chairperson. The possible types of complaints covered under this policy include, but are not limited to the following:
  a. Verbal or written complaints from subjects in research;

b. Reports of protocol noncompliance (including information from monitoring letters or sponsor correspondence). Reports will include a designation of the type of noncompliance from examples listed above;
c. Failure of the investigator to file reports required by the IRB;
d. Publications written by investigators without IRB approval of the referenced study; and
e. FDA or local IRB audits or reports regarding an investigator or a study

- The report will be reviewed by the IRB Chairperson/designee. The Chairperson /designee may consult with IRB administrative staff, IRB members and other knowledgeable consultants in reviewing the report.

- The IRB Chairperson/designee will determine whether a temporary hold on research activities is required to protect the rights and welfare of subjects until the complaint/report is investigated and resolved. If a temporary hold is necessary, the PI will be notified in a timely fashion.

- Additional information regarding the report may be obtained by the IRB Chairperson/designee including, but not limited to, the following:
  a. Interview or written inquiry directed to the author(s) of the complaint/report;
  b. Interview or written inquiry directed to the PI or other study personnel;
  c. Request for relevant research records from the PI or study personnel;
  d. IRB audit of the study; and
  e. Other information as needed

- The IRB Chairperson/designee may determine that a compliance audit is merited. If so, the audit will be conducted in a timely manner according to the SOP on IRB audits of research studies (SOP 30).

- If minor problems permitting corrective action are identified, the IRB Chairperson/designee will communicate with the PI regarding the nature of the problems and request the formulation of appropriate corrective actions. If appropriate corrective actions are implemented, then the matter will be considered resolved and any temporary hold on the research will be lifted.

- If serious problems meriting suspension of the study are identified, then the following individuals will be notified in writing: PI, Chairman or Division Chief, Sponsor, Assistant Vice Chancellor for Research, and appropriate federal department or agency head. The basis for the suspension will be clearly delineated in these communications. The Chairperson/designee will communicate with the PI regarding the nature of the problems and request the formulation of appropriate corrective actions. If appropriate corrective actions are implemented, then the suspension will be lifted and the previously enumerated officials will be notified.

- If serious problems meriting termination of the study are identified, then the following individuals will be notified in writing: PI, Chairman or Division Chief,

Sponsor, Assistant Vice Chancellor for Research, and appropriate federal department or agency head. The basis for the termination will be clearly delineated in these communications.

- The results of the investigation will be reported to the full IRB Board at the next convened meeting.

- The Chairperson/designee will determine whether any additional sanctions should be imposed. Additional sanction may be formulated in consultation with the full Board. These may include, but are not limited to:
  a. Suspension or termination of other research studies conducted by the PI;
  b. Directing the investigator to destroy or surrender data and/or specimens gathered from previously accrued subjects;
  c. Requiring more frequent continuing review of the study;
  d. Scheduling for-cause audits of the research study;
  e. Requiring that the research activity and/or informed consent process be monitored by an individual designated by the IRB; and
  f. Requiring that the investigator to inform previously accrued subjects regarding the identified elements of noncompliance.

- Communications from the PI, FDA, OHRP, sponsor or other involved persons regarding the suspension or termination of previously approved studies will be carefully evaluated by the IRB Chairperson/designee in determining appropriate responses to instances of noncompliance.

- A copy of all correspondence / reports will be kept in the IRB files.