

**UNIVERSITY OF TENNESSEE HEALTH SCIENCE CENTER
INSTITUTIONAL REVIEW BOARD
INVESTIGATOR NONCOMPLIANCE**

I. PURPOSE

To provide a procedure for addressing issues of investigator noncompliance reported to University of Tennessee Health Science Center Institutional Review Board.

II. SCOPE

Applies to all investigators and other research personnel involved in studies reviewed by UTHSC 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 46.108(a)(4) (previously 45 CFR 46.103(a)(5) under the pre-2018 Common Rule) and 21 CFR 56.108(b), IRBs must also have written procedures for promptly reporting to appropriate institutional officials and agency heads any serious or continuing noncompliance of investigators with federal regulations and local IRB policy, and any suspension or termination of research studies resulting from noncompliance.

In Accordance With:

For studies approved under the revised Common Rule:

45 CFR 46.108(a)(4); 45 CFR 46.113;

For studies approved under the Pre-2018 Common Rule:

[45 CFR 46.103\(b\)\(5\)](#)

For FDA-regulated studies

21 CFR 56.108(b).

OHRP Guidance on Reporting Incidences at

<http://www.hhs.gov/ohrp/compliance-and-reporting/guidance-on-reporting-incident/>

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.

IV. PROCEDURES

1. Upon receipt of a complaint or allegation of noncompliance, the IRB Director/designee will send a copy of the report to the Director or designee. 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);
 - 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.
2. The report will be reviewed by the IRB Director or designee. The Director and/or designee may consult with IRB administrative staff, IRB members and other knowledgeable consultants in reviewing the report.

3. The IRB Director/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 within 48 hours of the determination.
4. Additional information regarding the report may be obtained by the IRB Director and/or 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.
5. The IRB Director/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.
6. If minor problems permitting corrective action are identified, the IRB Director and/or 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.
7. If serious problems meriting suspension of the study are identified by the IRB Director, then the following individuals will be notified in writing within 48 hours of the determination: PI, Chair or Division Chief, Sponsor, Vice Chancellor for Research, and appropriate federal department or agency head when the research is conducted or supported by any federal agency that has adopted the Common Rule. The basis for the suspension will be clearly delineated in these communications. The Director and/or designee will communicate with the PI regarding the nature of the problems and request the formulation of appropriate corrective actions.
8. The nature of the problem and the corrective action plan formulated by the investigator will be reviewed by the full Board at the next convened meeting. If the Board accepts the corrective action plan and appropriate corrective actions are implemented, then the suspension will be lifted and the previously enumerated officials will be notified in writing within 48 hours of the determination that the corrective actions have been implemented. If the Board determines that there are deficiencies in the response of investigator requiring continuation of the suspension, then the following individuals will be notified in writing within 48 hours of the Board's determination: PI, Chair or Division

Chief, Sponsor, Vice Chancellor for Research, and appropriate federal department or agency head when the research is conducted or supported by any federal agency that has adopted the Common Rule. The basis for the continuing suspension will be clearly delineated in these communications. The Director and/or designee will communicate with the PI regarding the continuing nature of the problems and request the formulation of appropriate corrective actions.

9. If serious problems meriting termination of the study are identified, then the nature of the problem will be reviewed with the full Board at the next convened meeting. If the Board approves termination of the study, then the following individuals will be notified in writing within 48 hours of the Board's determination: PI, Chairman or Division Chief, Sponsor, Vice Chancellor for Research, and appropriate federal department or agency head when the research is conducted or supported by any federal agency that has adopted the Common Rule. The basis for the termination will be clearly delineated in these communications.
10. When problems are identified meriting suspension of a study, potential corrective actions that the Board may endorse include, but are not limited to, any of the following:
 - a. Requiring changes in study procedures or the informed consent process or disclosure;
 - 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;
 - f. Requiring that the investigator inform previously accrued subjects regarding the identified elements of noncompliance; and
 - g. Suspension or termination of other research studies conducted by the PI.
11. 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 Director and reviewed with the full Board in determining appropriate responses to instances of noncompliance.
12. A copy of all correspondence / reports will be maintained in the electronic IRB files for the study.