
**UNIVERSITY OF TENNESSEE COLLEGE OF MEDICINE
CHATTANOOGA INSTITUTIONAL REVIEW BOARD
INVESTIGATOR NON COMPLIANCE**

I. PURPOSE

To provide a procedure for addressing issues of investigator noncompliance reported to University of Tennessee College of Medicine Chattanooga Institutional Review Board.

II. SCOPE

Applies to all investigators and other research personnel involved in studies reviewed by UTCOMC IRB.

Personnel responsible:

IRB Members, IRB Administrator, section chair, IRB members.

III. BACKGROUND

The IRB has the authority 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: 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 report will be reviewed by the IRB Administrator/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 principal investigator (PI) 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 Chair.
3. Additional information regarding the report may be obtained by the IRB Chair/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 and/or other study personnel (current or former), as well as current and/or former research subjects participating in the study;
 - c. Request for relevant research records from the PI and/or study personnel;
 - d. IRB audit of the study; and

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- e. Other information as needed.
4. The IRB Chair/designee, may determine if a temporary hold on research activities is warranted or 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.
 5. If minor problems permitting corrective action are identified, the IRB Administrator 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.
 6. If serious problems meriting suspension of the study are identified by the IRB Chair/designee then the following individuals will be notified in writing within 48 hours of the determination: PI, UTCOMC department chair and/or division chief, sponsor, UTCOMC Vice Chancellor for Research (the Signatory Official named in UTCOMC's Federalwide Assurance held with OHRP), and appropriate officials of the institution in which the research is being conducted, as well as the appropriate federal department or agency head and OHRP when the research is conducted or supported by any federal agency that has adopted the Common Rule, and/or the Food and Drug Administration (FDA) when the research is FDA-regulated. 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.
 7. 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 satisfactory 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, department chair (or dean when the PI is the department chair) and/or division chief, sponsor, Vice Chancellor for Research, and appropriate officials of the institution in which the research is being conducted, as well as the appropriate federal department or agency head when the research is conducted or supported by any federal agency that has adopted the Common Rule, and/or the Food and Drug Administration (FDA) when the research is FDA regulated. 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.

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8. 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, department chair and/or division chief, sponsor, Vice Chancellor for Research, and appropriate officials of the institution in which the research is being conducted, as well as the appropriate federal department or agency head when the research is conducted or supported by any federal agency that has adopted the Common Rule, and/or the Food and Drug Administration (FDA) when the research is FDA regulated. The basis for the termination will be clearly delineated in these communications.
 9. 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 follow-up 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. Auditing, suspension or termination of other research studies conducted by the PI.
 10. Principal investigators may appeal the IRB's decision regarding corrective actions and the imposition of sanctions. Appeals will only be considered if a written request is submitted to the IRB Director within ten business days after formal notification of the PI regarding the action of the IRB. In the correspondence, the PI should identify the action that he or she wishes to appeal, and must explain clearly and completely the basis for the appeal. The IRB Director will confer with the appropriate section chair to determine whether the appeal warrants further consideration. If so, the appeal will be considered at the next meeting of the section of the Board that approved the original action being appealed. At the discretion of the IRB Director, the PI may be granted the opportunity to make a presentation to the Board regarding the issue. However, the presence of a personal attorney representing the PI will not be permitted. See IRB SOP: Appeal of IRB Decisions.
 11. Communications from the PI, FDA, OHRP, sponsor or other involved entities or persons regarding the suspension or termination of previously approved studies will be carefully evaluated by the IRB Chair or IRB Administrator/designee, and

SOP: UTCOMC IRB Investigator Non Compliance

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reviewed with the full Board in determining appropriate responses to instances of noncompliance.