Policy 25: Non-compliance
Revision Date: March 29, 2009, revised June 11, 2010, revised 9/17/15, revised 9.14.18, revised March 2, 2021

I. Summary Policy

It is the policy of both the East Tennessee State University Campus Institutional Review Board (ETSU IRB) and the East Tennessee State University/Veterans Affairs Institutional Review Board (ETSU/VA IRB) that investigators engaged in the conduct of human subjects research on behalf of ETSU or under the purview of the ETSU IRBs follow all applicable rules, regulations, and policies for the duration of the research. This policy addresses the process that the IRB follows to manage allegations and findings of non-compliance. All members of the research community are responsible for reporting to the ETSU IRB any concerns or allegations of potential noncompliance. Reports may come from any category of research reviewed and may include anyone involved, or not directly involved, in the research process/study. The IRB, as part of their oversight responsibilities (45 CFR 46.113 and 21 CFR 56.113), must establish procedures for the evaluation of all non-compliance and the prompt reporting of any serious or continuing non-compliance with the federal regulations or institutional policies.

II. Definitions

A. Non-compliance: Failure to comply with applicable regulations, laws, agreements, policies, or the determinations or requirements of the IRB. Examples may include:

i. Failure to obtain IRB approval;
ii. Inadequate or non-existent procedures for the informed consent process;
iii. Inadequate supervision;
iv. Failure to follow recommendations made by the IRB;
v. Failure to report adverse events or protocol changes;
vi. Failure to provide ongoing progress reports; or
vii. Protocol deviations.

B. Serious Non-compliance: Non-compliance that any other reasonable Investigator would have foreseen as compromising the safety, rights, or welfare of a participant, research study staff, or others; or noncompliance that presents genuine risk of reputational harm to the institutions involved or to the institution's Human Research Protection Program. Examples may include:

i. Conducting non-exempt research without IRB approval;
ii. Enrollment of subjects that fail to meet the inclusion or exclusion criteria of the protocol, that in the opinion of the IRB Chair or convened IRB, increase the risk to the subject; or
iii. Enrollment of research subjects while study approval has lapsed; or
iv. Serious protocol deviations that may place subjects at increased risk from the research.

C. **Continuing Non-compliance:** A pattern of repeated actions, omissions, or instances taken by an Investigator that indicates a deficiency in the ability or willingness of an Investigator to comply with applicable federal regulations, laws, policies, agreements, or determinations or requirements of the IRB, or the prolonged persistence of noncompliance occurring after its identification, awareness, or implementation of a corrective action intended to effectively resolve the noncompliance.

D. **Research Misconduct:** Any fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

E. **Whistle-blower:** An individual who reports sensitive information to the ETSU IRB regarding potential non-compliance issues or research activities that have potentially placed participants or others at increased risk in relationship to the conduct of the research.

F. **Allegation of non-compliance:** An unproven assertion of non-compliance.

G. **Finding of Non-compliance:** Non-compliance determined by the IRB to be true.

III. Reporting of Non-Compliance

Allegations of non-compliance can come from a number of different sources. Potential sources include investigators, members of the research team, study sponsors, regulatory bodies (OHRP, FDA), participants and their families, institutional personnel or committees, the media, the public, or anonymous sources. Additionally, the IRB can identify non-compliance during its review or audit of research studies.

Research personnel are required to report all non-compliance to the IRB within 5 working days. For VA studies, the written report of noncompliance must also be made to the Associate Chief of Staff for Research (ACOS/R) within 5 working days. The reporting party should submit documentation to the IRB, including any supporting information from other sources (e.g. study sponsor, regulatory body, members of the research team, research subjects), involved in or having information related to the allegation of non-compliance (e.g. who, what, when, where, and why) and what actions were taken and will be taken to ensure subjects or others were not or are not harmed.

IV. Procedures for Allegations of Non-compliance

1. IRB staff members who receive verbal reports of alleged non-compliance will collect as much information as possible while completing the IRB Non-Compliance Form. The IRB Staff forward all allegations of non-compliance to the HRPP Director and IRB Chair, or designee, on the day of receipt.

2. The HRPP Director promptly forwards the allegation to the Vice Provost for Research (VPR). If the allegation involves research at the VA, the HRPP Director notifies the VA Administrative Officer (AO), Research Compliance Officer (RCO), and the Associate Chief of Staff for Research (ACOS/R).

3. The IRB Chair and Director (or their designees) will promptly contact the complainant, the respondent, and the PI, as necessary, to compile information and to obtain a greater understanding of:
    A. The facts surrounding the allegation; and
    B. Whether the allegation is true.

4. If, in the opinion of the IRB Chair and HRPP Director, the alleged non-compliance is not true, the IRB Chair (or designee) will document the outcome of all communications and discussions in writing. The IRB Chair or Director (or designees) will communicate the outcome of these discussions to the complainant, the respondent, and the PI, and copies will be placed in the IRB file. Information will be provided to the IRB as an informational item on the agenda of the subsequent meeting.

5. If the IRB Chair and HRPP Director determine that the alleged non-compliance is true, it will be handled as a finding of non-compliance.

V. Procedures for Findings of Non-compliance

1. IRB staff members who receive verbal reports of apparent non-compliance will collect as much information as possible while completing the IRB Non-Compliance Form. If the non-compliance is neither serious nor continuing and a corrective action plan is in place the staff member documents those findings and provides the form to the Director for review. Otherwise, the report is given to the IRB Chair.

2. If, in the opinion of the IRB Chair, the finding of non-compliance might be serious or continuing, the IRB Chair or designee may suspend research activities immediately if the Chair believes participants may be exposed to immediate harm until such time that the full IRB can convene.

3. If the Chair determines that a suspension is merited, then notification of the suspension, (following IRB Policy 26: Suspension) effective immediately, will be forwarded per IRB Reporting Policy (Policy 34). If the Chair suspends the research because of findings or alleged findings of serious or continuous non-compliance, the convened IRB will vote to confirm or reverse that decision at the subsequent convened IRB meeting.

4. An audit of the records may be necessary to determine the nature of serious or continuing non-compliance. The HRPP Director, IRB Chair, and IRB Coordinator (or designees) will gather information. The following may be charged for review:
    - Review protocols in question
    - Review FDA audit report of the investigator/study, if appropriate
    - Review any relevant documentation, including the ICD, case report forms, subjects' investigational and/or medical files, etc., as they relate to the investigator/s execution of his/her study involving human subjects
    - Interview participant(s) involved in the study

- Interview appropriate study or hospital personnel, if necessary

5. The HRPP Director, IRB Chair, or IRB Coordinator may consult with other institutional units such as the Radiation Safety Sub-Committee, Office of Research and Sponsored Programs Administration, research offices of affiliated or relying institutions, and the Privacy Officer concerning the reported non-compliance.

6. The HRPP Director prepares a written report of the findings of any such audit or consultation. Based on the information provided, the IRB Chair or designee will determine if the report of non-compliance might be serious or continuing non-compliance.

7. If the IRB Chair or designee determines that the non-compliance is clearly neither serious nor continuing, the IRB Chair or designee may accept the report as presented or recommend a corrective action plan with documentation to be completed within 60 days of the initial report of noncompliance. The Chair or designee's decision will be reported to the IRB for acknowledgement at its next convened meeting, and if a VA study, the decision will be reported to the VA facility director, RCO, and ACOS/R within 5 days of the determination.

8. If the IRB Chair or designee determines that the non-compliance might be serious or continuing, the documentation is forwarded to the convened IRB for review within 30 days of the initial report of noncompliance. All IRB members will receive the:
    - Copy of the report of the allegation
    - any additional documentation provided in the original complaint
    - the preliminary audit findings (previously reviewed by the IRB chair)
    - narrative description of the project
    - currently approved consent document

9. The IRB will then:
    - review the information provided above;
    - vote on the information provided as indicated below, or defer the vote and gather additional information if needed from the investigator or others involved;
    - vote on whether the non-compliance is serious; and
    - vote on whether the non-compliance is continuing;

10. After voting, the IRB is required to consider the following range of possible actions:
    - Suspension of IRB approval of the research
    - Termination of IRB approval of the research
    - Notification to current participants (required when such information might relate to participants' willingness to continue to take part in the research)

In addition to the required considerations above, the IRB optionally may consider the following possible actions:

- no action;

- modification of the research protocol;
- modification of the information disclosed during the consent process;
- providing additional information to past participants;
- requiring current participants to re-consent to participation;
- modification of the continuing review period;
- monitoring of the research;
- monitoring of the consent process;
- obtaining more information pending a final decision, such as requiring an audit; and/or
- referral to other organizational entities (e.g., legal counsel, institutional official).

The convened board's determination may not be altered by a higher authority.

If the IRB determines that serious or continuing noncompliance occurred, the IRB minutes will document the IRB determination along with information as to whether remedial actions are needed to ensure present and/or future compliance.

VI. Report of Findings

Reporting Policy 34 is followed for reporting serious or continuing non-compliance.

References:
VHA Directive 1058.01, October 22, 2020
45 CFR 46.108(a)(4)
21 CFR 56.108(b)(2)