

# Policy 25: NON-COMPLIANCE

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## I. Purpose

It is the policy of both the ETSU IRB and the ETSU/VA IRB to establish policy and procedures for addressing the process that the IRB follows to manage allegations and findings of non-compliance.

## II. Definitions

**A. Non-compliance:** Failure to comply with Federal regulations, ETSU IRB Policy, VHA Handbook 1200.5, or the determinations or requirements of the ETSU 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:** An action or omission taken by an Investigator that any other reasonable Investigator would have foreseen as compromising the rights and welfare of a participant. 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 risk from the research

For VA studies an additional definition applies.

Serious noncompliance is any failure to adhere to requirements for conducting human research that may reasonably be regarded as:

(1) Presenting a genuine risk of substantive harm to the safety, rights, or welfare of human research subjects, research personnel, or others, including their rights to privacy and confidentiality of identifiable private information; or

(2) Substantively compromising a facility's HRPP.

**C. Continuing Non-compliance:** A pattern of repeated actions or omissions taken by an Investigator that indicates a deficiency in the ability or willingness of an Investigator to comply with Federal regulations, ETSU IRB Policy, or determinations or requirements of the ETSU IRB

For VA studies, an additional definition applies. Continuing non-compliance is a persistent failure to adhere to the laws, regulations, or policies governing human research. .

**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. Summary Policy**

It is the policy of both the ETSU IRB and the ETSU/VA IRB to establish procedures for addressing allegations and findings of non-compliance by faculty, staff, and students of East Tennessee State University or the James H. Quillen Veterans Affairs Medical Center (at Mountain Home), any individual conducting research under the auspices of the IRB or the IRB with the ETSU Human Research Protection program (HRPP) requirements, as distinct from scientific misconduct. These may come from any category or research reviewed and may include anyone involved or not directly involved in the research process/study. Allegations of non-compliance or complaints regarding investigators or stemming from research protocols will be internally audited and forwarded to the appropriate officials. 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.

### **IV. 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. 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 were not or are not harmed.

For VA studies, members of the research community must report possible non-compliance with VA or other Federal requirements related to human research or IRB requirements or determinations to both the Associate Chief of Staff for Research (ACOS for R) and the IRB. VA personnel, including WOC and IPA appointees, must ensure that the IRB is notified, in writing, within 5 business days after becoming aware of any apparent serious or continuing non-compliance with IRB or other human research protection requirements.

### **V. 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 Chair or his/her 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 AO and the Associate Chief of Staff for Research (ACOSR).

3. The IRB Chair and Director (or their designees) will promptly contact the complainant, the respondent, and the PI to compile information and to obtain a greater understanding of:

A. The facts surrounding the allegation;

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 HRPP 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.

## **VI. Procedures for Findings of Non-compliance**

A. IRB staff members who receive verbal reports of findings 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.

B. If, in the opinion of the IRB Chair, the finding of non-compliance might be serious or continuing, the IRB Chair or Chair's 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.

C. If the Chair determines that a suspension is merited, then notification of the suspension, (following IRB Suspension Policy) 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 IRB meeting.

D. 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 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

- E. 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, research offices of affiliated institutions, and the Privacy Officer concerning the reported non-compliance.
- F. The IRB Director prepares a written report of the findings. 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.
- G. If the IRB Chair or the 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. The Chair's or designee's decision will be reported to the IRB for acknowledgement at its next convened meeting.
- H. If the IRB Chair or designee determines that the non-compliance might be serious or continuing, the documentation is forwarded to the fully convened IRB for review in the following section.
- I. Reviews will take place at the convened meeting.
- J. 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
- K. The IRB will then:
  - review the information provided in J 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;
- L. 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 of 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 schedule;
- monitoring of the research;

- monitoring of the consent process;
- obtaining more information pending a final decision, such as requiring an audit;
- referral to other organizational entities (e.g., legal counsel, institutional official)

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

For VA studies, the convened IRB must review any such notifications at the earliest practicable opportunity, not to exceed 30 business days after the notification. The IRB Chair may take interim action as needed to eliminate apparent immediate hazards to subjects. The convened IRB must determine and document whether or not serious or continuing noncompliance actually occurred.

If the IRB determines that serious or continuing noncompliance occurred:

(a) A documented IRB determination is also required as to whether remedial actions are needed to ensure present and/or future compliance.

The VA facility Director must ensure timely implementation of remedial actions in response to identified noncompliance or as otherwise found warranted by ORO.

(1) Except where remediation requires substantial renovation or fiscal expenditure, hiring, legal negotiations, or other extenuating circumstances, remedial actions must be completed within 120 calendar days after any determination of noncompliance.

(2) Where remedial actions cannot be completed in 120 calendar days, the VA facility Director must provide ORO with an acceptable written justification and an acceptable timeline for completion.

## **VII. REPORT OF FINDINGS**

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

In addition, for VA studies, the IRB must track the determinations for use in the VA facility Director Certification.

References:

VHA Handbook 1058.01, June 15, 2015

