IRB Policy 34: Reporting to Institutional Officials and Regulatory Agencies Policy
Revision Date: March 27, 2009, revised June 11, 2010, revised January 27, 2011, revised 9/23/13, revised 9/17/15, revised 4/2/18, revised 9/14/18, revised March 2, 2021

I. Purpose

This policy establishes guidelines for the Office for the Protection of Human Research Subjects (OPHRS) to ensure prompt reporting in response to findings of either the East Tennessee State University Campus Institutional Review Board (ETSU IRB) or East Tennessee State University/VA (ETSU/VA) IRB of those events listed in Federal regulations found in 45 CFR 46.108(a)(3)(iii)-(4) and 21 CFR 56.108(b)(1).

II. Summary Policy

Federal regulations require the IRB to promptly report the following determinations to applicable regulatory agencies, i.e. Office of Human Research Protections (OHRP), Food and Drug Administration (FDA), Department of Defense (DoD), and the ETSU and/or VA Institutional Official:

- Unanticipated problems involving risk to subjects or others (UPIRTSOs)
- Serious or continuing non-compliance with Federal regulations, IRB polices, or with determinations of the IRB
- Suspensions or terminations of IRB approval

The HRPP Director will prepare a draft report within three (3) workdays after the IRB meeting at which the determination occurred and will share with the Vice Provost for Research and IRB Chair for comments, as appropriate. The finalized report will be disseminated to appropriate institutional representatives and regulatory agencies within the required timeframes.

III. Procedure

Immediately following the IRB meeting at which a determination that require prompt reporting occurred, the HRPP Director will prepare the event report and will share the draft report with the Vice Provost for Research and IRB Chair for review and comments. The HRPP Director in consultation with the IRB Chair and VPR will finalize the report within five (5) working days after the IRB meeting at which the final determination occurred. Once the report is finalized, it is signed by the ETSU Institutional Official and distributed as described in Section V of this policy. Documentation of the event report and notification letters are saved to the IRB study file and also maintained in the administrative records of the OPHRS and Office of the Vice Provost for Research.

IV. Report Contents

The report will contain:

a) A summary of the event,
b) The findings of the organization,
c) Actions taken by the organization or IRB,
d) Reasons for the organization's or IRB's actions, and
e) Plans for continued investigation or action,
f) Project title,
g) Principal Investigator,
h) The assigned ETSU IRB number, and
i) Federal Support details including the grant project title and assigned ORSPA number, if any.

V. Report Distribution

For studies done under ETSU's assurance, the Vice Provost for Research will send the report to the following:

a) The IRB that made the determination (as an information item with the agenda)
b) The Principal Investigator, and Project Director if applicable (for multisite or grant funded research, for example)
c) Department Chair or supervisor of the Principal Investigator
d) OHRP, if the research is subject to HHS or FDA regulations, or subject to a HHS federal wide assurance
e) FDA, if the research is subject to FDA regulation
f) If the research is conducted or supported by any other Federal agency that is a signatory to The Common Rule, the report is sent to OHRP and/or the agency head, as required by that agency.
g) Office of Research and Sponsored Programs Administration (ORSPA) to report to the appropriate sponsor, if funded
h) Privacy Officer of a Covered Entity, if the event involved unauthorized use, loss, or disclosure of patient health information from that covered entity
i) Information Security Officer of an organization, if the event involved violations of information security requirements of that organization
j) Quillen VA Administrative Officer and Facility Director (whenever the research involves the use of shared facilities or VA employees or agents with appointments at both East Tennessee State University and the James H. Quillen Veterans Affairs Medical Center)
k) Appropriate administrative officials at external sites where the research is conducted or for whom the ETSU IRBs serve as the IRB of Record
l) Others deemed appropriate by the VPR

Reporting to a regulatory agency is not required if the event occurred at a site that was not subject to the direct oversight of the organization, or the agency has been notified of

the event by the investigator, sponsor, another organization, or other mechanisms.

For studies done under the assurance of Mountain States Health Alliance (MSHA) or the Quillen VA, the Vice Provost for Research distributes the report prepared by the HRPP Director to that institution, and their Institutional Official forwards the report to appropriate entities as noted above. A copy of the correspondence must be provided to the Vice Provost for Research, who ensures that reporting requirements have been met.

VI. Additional Reporting Requirements for VA Research

For VA research conducted under the VA assurance, the Vice Provost for Research will provide a copy of the finalized event report to the VA Facility Director, Administrative Officer, Research Compliance Officer, and Associate Chief of Staff for Research within five (5) business days of the IRB determination to be forwarded to the VA Research & Development Committee and the VA Office of Research Oversight within 5 business days of receiving the notification.

In addition, when the reportable event involves unauthorized use, loss, or disclosure of individually identifiable patient information or involves violations of VA information security requirements, the report will be submitted in accordance with VHA Directive 1058.01, Section 11. (Refer to Policy 18 for immediate reporting requirements.)

The VA Facility Director must report to ORO within 5 business days after receiving notification of any situation that is reportable to ORO under VHA Directive 1058.01. The VA Facility Director must ensure that ORO is notified by e-mail or telephone as soon as possible, but no longer than 2 business days, after becoming aware of any research-related citation or determination of regulatory noncompliance issued by any State or Federal agency.

References:

45 CFR 46.108
21 CFR 56.108
Guidance on Reporting Incidents to OHRP (2011)
Appendix A, Memo from Deputy Under Secretary for Health Operations and Management (DUSHOM) and Chief Research and Development Officer (CRADO), dated February 6, 2007
VHA Directive 1058.01, October 22, 2020