# IRB Policy 34: Reporting 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

**INSTITUTIONAL REVIEW BOARD REPORT OF FINDINGS**

## I. Purpose / Background

This policy establishes guidelines for the Office for the Protection of Human Research Subjects (OPHRS) to ensure prompt reporting in response to findings of a East Tennessee State University Institutional Review Board (IRB) or East Tennessee State University/VA IRB of those events listed in Federal regulations. These regulatory requirements may be found in 45 CFR 46.103(b)(5)(i) and 21 CFR 56.108(b)(1).

## II. Summary Policy

A. Decisions by IRB Chair for VA studies only

The VA IRB Vice-Chair will report via memorandum to the VA Facility Director (directly), the ACOS/R and the RCO within 5 business days of an IRB determination to suspend or terminate any VA research study. A copy of the memorandum will be kept on file with the R&D Service and IRB.

B. Decisions by convened IRB

If the IRB determines that an event represents:

a. An unanticipated problem involving risks to subjects or others,
b. A serious or continuing noncompliance with research regulations or determinations of the IRB, or
c. A suspension or termination of IRB approval,

the HRPP Director will prepare a draft report within three (3) workdays after the IRB meeting at which the determination occurred.

For VA studies, when the IRB reviews either a local SAE or serious problem that are both unanticipated and related to the research, the IRB must notify the VA facility Director and the ACOS/R&D in writing within 5 business days after its convened meeting if:

(a) Actions were taken to eliminate apparent immediate hazards to subjects; or

(b) The IRB determined that the incident was serious and unanticipated and related to the research, or there was insufficient information to make the determination; or

(c) Protocol or informed consent modifications were warranted.

For VA studies, when the IRB determines that serious or continuing non-compliance occurred, the IRB must notify the VA facility Director and the ACOS/R&D within 5 business days after making its determinations.

For VA report of a local death that is both unanticipated and related, the IRB must notify the VA facility Director and the ACOS/R&D of its determinations within 5 business days of the determinations.

For VA studies, when receiving a report of a suspension or termination of VA research, if the IRB determines that the suspension or termination meets either of these criteria; (a) Resulted from a local adverse event(s), local noncompliance, or other local issue(s); or (b) Requires local action (in addition to the suspension/termination) to ensure the safety, rights, or welfare of local human research subjects, personnel, or others or the effectiveness of the local HRPP; then

(a) The IRB must notify the VA facility Director and the ACOS/R&D within 5 business days after the determination;

(b) The VA facility Director must report the suspension/termination to ORO within 5 business days after receiving the IRB's notification.

## III. 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. Federal Support, if any.

## IV. Report Distribution

The HRPP Director in consultation with the IRB chair and the Vice Provost for Research (VPR) will finalize non-VA reports within seven (7) working days after

the IRB meeting at which the final determination occurred. VA reports will be finalized within five working days after the IRB meeting at which the final determination occurred.

For studies done under ETSU's assurance, the VPR will send the report to the following:

a. The IRB (as a information item with the agenda),
b. OHRP (whenever the research is subject to OHRP regulation)
c. FDA (whenever the research is subject to FDA regulation),
d. Department of Veterans' Affairs AO* and VA 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),
e. Other Federal Agencies* that are a signatory to "The Common Rule" who conduct or oversee the research.
f. Investigator.

In addition, when the report involves unauthorized use, loss, or disclosure of individually identifiable patient information, the notification will be sent to the VA Privacy Officer. When the report involves violations of VA information security requirements, the report will be sent to the VHA Information Security Officer. (Refer to Policy 18 for immediate reporting requirements)

For reports (serious or continuing non-compliance, suspensions or terminations, and UPIRTSOs) that are not subject to submission to FDA or OHRP, the VPR will provide a written response to the IRB's determinations. The response will include whether the VPR accepts the actions taken by the IRB, or requires additional actions on behalf of the institution.

The HRPP Director will report to the following if the IRB or the VPR deems appropriate:

a. Departmental chair, program director and supervisor of the investigator,
b. Other organizations involved with the research,
c. The sponsor,
d. The funding agency,
e. The Research and Sponsored Programs offices.

For studies done under the assurance of Mountain States Health Alliance or the VA, that institution forwards the report to entities as noted above. A copy of the

correspondence must be provided to the Vice Provost for Research, ETSU, who ensures that reporting requirements have been met.

*The VA AO forwards the report to the Research and Development Committee and the ACOS/Research.

The VA facility Director must report to ORO within 5 business days after receiving notification of any situation that is reportable to ORO under Handbook 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:

(a) Any research-related citation or determination of regulatory noncompliance issued by any State or Federal agency; or

(b) Any situation covered by this Handbook that has generated media attention or Congressional interest.

The VA Facility Director must report the following circumstances related to research information security incidents to ORO within 5 business days after taking or becoming aware of such action(s), regardless of the IRB determination:

(1) Provision of an Issue Brief for VA Central Office regarding the incident;

(2) Any notification to individual(s) of an information breach or provision of credit monitoring as required by the Network Security Operations Center (NSOC);

(3) Any breach notification required under the Health Information Technology for Economic and Clinical Health (HITECH) Act;

(4) Any notification to or from the Office of Inspector General (OIG) regarding the incident.

Sources: Appendix A, Memo from Deputy Under Secretary for Health Operations and Management (DUSHOM) and Chief Research and Development Officer (CRADO) dated February 6, 2007