

## Summary of policy changes January 2020

### **A. Policy 21: IRB Reliance, Version January 7, 2020**

Change Rationale: The new reliance policy replaces the external reliance policy and complies with the new common rule cooperative research regulation and conforms to AAHRPP I9 standards.

Change Summary: A new policy was developed which describes the ETSU policy for IRB reliance. The prior Policy 21 focused solely on External IRB and has been adapted into Policy 21a: External Reliance procedure. This new policy addresses when ETSU serves as the IRB for external sites as well as external IRB reliance.

Change Specifics: Substantively changed from prior Policy 21, External Reliance.

### **B. Policy 14: HIPAA Policy, Revised January 24, 2020**

Change Rationale: Added definition of research to comply with AAHRPP Standard I.1.

Change Summary: Added definition of research

Change Specifics:

1. Page 1, Section I, Pertinent Definitions, added, "H. "Research" means a systematic investigation including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge."

### **C. Policy 17a: Investigator Conflict of Interest, Revised January 31, 2020**

Change Rationale: To facilitate timely review, allow for expedited review of COI management plans for protocols determined to be minimal risk.

Change Summary: Allow expedited/Chair review of COI management plans for expedited protocols. Clarify VA COI disclosure requirements. Add statement to comply with AAHRPP Standard I.1.

Change Specifics:

1. Page 1, Section I, removed "or the VAMC" from the Covered Individual definition.
2. Page 3, Section II, Changed first sentence to read: "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) is to establish procedures for reporting and managing conflict of interest as it pertains to human subjects research conducted at ETSU and James H. Quillen VAMC."

3. Page 3, Section II, changed sentence two to read: "This policy is congruent with policies set forth in the ETSU Faculty Senate Handbook."
4. Page 4, moved the following paragraph from Section IV.D. to Section II: "The IRB's evaluation of the management plan is documented in the IRB minutes and/or protocol file which are maintained in accordance with IRB Policy 30. The management plan is maintained in both the IRB protocol file and the Vice Provost for Research/ or VA Research and Development Office files. The ETSU Significant Conflict of Interest Form is maintained in the Vice Provost for Research files. The VA Conflict of Interest Form is maintained in the VA Research and Development Office files."
5. Page 4, Section III, For VA studies, sentence one, removed "all research personnel" and replaced with "all listed investigators."
6. Moved the following sentence from Section III,#3 to Section III, top of page 5 with added reference to Admin check in: "In addition, the investigator must submit a revised Conflict of Interest Form within ten days of any change from previous disclosures and annually disclose any changes on the Continuing Review xForm or Administrative Check-in xForm."
7. Page 5, Section III, add the following heading to number section: "If a potential conflict of interest is identified, the following steps will be followed:"
8. Page 5, Section III, 1) combined statements for readability.
9. Page 5, Section III, moved prior #6 to #2 for the process to be in order.
10. Page 5, Section III, moved prior #7 to #3 for the process to be in order.
11. Page 5, Section III, moved prior #2 and part of #1 to #4 for the process to be in order and added the parenthetical: or IRB Chair, if the protocol is determined to represent minimal risk and is eligible for expedited review
12. Page 6, end of Section III, added the following paragraph: "When a conflict of interest is newly identified for approved studies, the above steps should be followed. The conflict of interest and accompanying management plan may be reviewed by either the expedited procedure or referred to the full board."
13. Page 6, Section IV, Moved prior section C to first paragraph. Removed capital letter sections throughout section for readability.
14. Page 6, Section IV, removed the statement: The IRB may accept the plan, request modifications, or disapprove the research.
15. Page 6, Section IV, added:

"The IRB Chair or convened board can:

  - accept the plan as proposed,
  - request modifications in the management plan, and approve the plan with those changes, or
  - request changes in the management plan, and defer review until a revised plan is received.
  - An IRB Chair may refer the review to the convened board."

16. Page 6, Section IV, revised prior section A to read:

“When the study involves human subjects research, the IRB makes the final determination as to whether the COI management plan is appropriate. Based on the significance of the conflict and the potential adverse effects on the protection of subjects, the IRB may take the following actions to manage, reduce, or eliminate conflict of interest:

- 1) Disclosure to subjects through the informed consent process,
- 2) Monitoring research through oversight/audit,
- 3) Modify research protocol and/or ICD,
- 4) Disqualification from participating in research,
- 5) Appointment of a non-conflicted Principal Investigator,
- 6) Removing the investigator from the subject selection process.
- 7) Requiring disclosure in all publications/presentations resulting from the research,
- 8) Divestiture of significant conflict of interest,
- 9) Severance of relationship that create actual or potential conflicts, or
- 10) More frequent continuing review.

The convened IRB has the authority to disapprove research.”

17. Page 7, Section V, Added the statement to beginning of section: “To ensure research compliance with this policy, the HRPP has the authority to conduct a retrospective review and issue a mitigation report if necessary.”