

## Summary of policy changes October 2021

### **A. Policy 10: Modifications, Revised October 22, 2021**

Change Rationale: Provide flexibility and authority to knowledgeable IRB staff to review modification to previously exempt research

Change Summary: Revised to remove requirement for IRB Chair review of modifications to exempt research and allow IRB Coordinators to administratively review

Changes Specifics:

1. Page 3, Section VII. Exempt Research, second sentence, replaced IRB Chair with "IRB Coordinator" and edited to state administrative approval for these types of changes.
2. Page 3, Section VII., edited third sentence to begin with "If the requested change(s) appear to increase risk, decrease safety, or renders the study ineligible for exemption,"
3. Page 3, Section VII., added new statement at the end of the paragraph that says "If changes to the study change the previously determined review level, the approval letter will document the review level, including the appropriate expedited category(ies), as applicable."

### **B. Policy 30: Record Keeping, Revised October 22, 2021**

Change Rationale: Streamline finalization process for IRB Minutes

Change Summary: Removed policy requirement for various ETSU and VA signatures from institutional officials

Changes Specifics:

1. Page 4, Section II, B. Minutes, last paragraph, removed sentences and lists of ETSU and VA institutional officials required to sign IRB Minutes.
2. Page 4, Section II, B. Minutes, last paragraph, added statement that says "The IRB Chair signs the IRB-approved minutes, and the administrative office that supports the IRB retains a copy of the final minutes."