Summary of policy changes October 2020

A. Policy 2: Institutional Review Boards, Revised October 22, 2020

Change Rationale: Removed references to MSHA ex-officio IRB members as contract for IRB services for MSHA was terminated

Change Summary: Removed MSHA references

Changes Specifics:

1. Page 4, Section II.D, Non-voting Ex-officio Members, second paragraph, removed: "In addition, for the approved term of service, the Director of Pharmacy Services at Johnson City Medical Center Hospital shall also serve as a non-voting member of the ETSU/VA IRB." and the MSHA Representative in the following sentence.

B. Policy 6: Scientific Review, Revised October 22, 2020

Change Rationale: Removed reference to MSHA as contract for IRB services to MSHA was terminated

Change Summary: Removed reference to MSHA scientific review and minor updates to language for consistency with other policies

Change Specifics:

1. Page 1, Section I, updated the paragraph to read: "It is 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 that all human research projects are reviewed for scientific merit to ensure that risks to participants are minimized by using procedures that are consistent with sound research design, and that risks to participants are reasonable in relation to anticipated benefits, and the importance of the knowledge that may reasonably be expected to result from the study."
2. Page 1, Section II, first sentence, changed "ETSU and ETSU/VA" to "human research" protocols.
3. Page 1, Section II, last sentence, changed Department Head to Department Head.
4. Page 2, Section II, last sentence, updated reference to new protocol submission xform.
5. Page 2, Section II, deleted the second bullet point regarding scientific review for MSHA initial submissions.

C. Policy 7: Exempt Review, Revised October 22, 2020

Change Rationale: Remove old common rule exempt categories, as new submissions are reviewed in accordance with new common rule

Change Summary: Changed structure and formatting to be consistent with current IRB policies and procedures

Change Specifics:

1. Page 1, Section I, added "…if so, whether the research complies with applicable ethical standards." in place of regulatory references.
2. Page 1, Section I, added the following sentence at the end of the paragraph: "Researchers do not have the authority to make an independent determination that research involving human subjects is exempt and must obtain determination of exemption prior to beginning the research."
3. Page 1, Section II, added the following statement at the beginning of the paragraph: For proposed research, the investigator provides the ETSU IRB study specific information by completing the New Protocol Submission xform and providing the required attachments.
4. Page 1, Section II, clarified that the IRB Chair, or designee, will make the final determination regarding exempt status.
5. Page 1, Section II, updated statement to read: If the reviewer determines that the study is not eligible for exemption, the protocol will be considered for either expedited or full board review, as appropriate to the level of risk.
6. Page 1, Section II, added the statement: Reviewers may make the exemption determination, HIPAA privacy determination, request clarifications/modifications, or refer the project for other appropriate level of review.
7. Page 2, Section III is now Ethical Standards, which was previously Section V.
8. Page 3, Section IV, deleted 1991 Common Rule exempt categories and re-formatted the 2018 Common Rule exempt category descriptions.
9. Page 5, Section V is now Limitations for Exemptions, which was previously Limited IRB Review.
10. Page 5-6, Section V, incorporates the limitations for exempt determinations and specifies what types of studies are not eligible for exemption.
11. Page 6, Section VI is now Limited IRB Review, which was previously Modifications, and specifies limited IRB review requirements.
12. Page 6, Section VII is now Subsequent Review, instead of Modifications, and briefly addresses subsequent review requirements of exempt studies including modifications and administrative check-in.

D. Policy 9: Full Board Review, Revised October 22, 2020

Change Rationale: Updated to reflect current practice in preparation for AAHRPP re-accreditation

Change Summary: Refined the policy descriptions and definitions, updated formatting to be more consistent with other policies

Change Specifics:

1. Page 1, Section I is now Summary Policy, which was previously Section II.
2. Page 1, Section II is now Pertinent Definitions, which have been refined.
3. Page 1, Section III is now Convened IRB Meetings and describes the conduct of convened meetings, types of reviews assigned to the convened IRB, and timing.
4. Page 2, Section IV is now Initial Full Board Reviews and describes that investigators are invited to the meeting.
5. Page 2, Section V is now Primary Reviews and describes the primary review system utilized by the IRB and materials reviewed by the IRB.
6. Page 4, Section VI is now Committee Responsibilities and describes the committee review process and defines the approval criteria.
7. Page 6, Section VII is now Voting Actions and describes the possible actions that may be taken by the IRB and the associated procedures. Revised the actions to reflect the language used locally (i.e., approval with stipulations became approval pending modifications).
8. Page 7, Section VIII is now Other Considerations which describes the IRB determinations for risk level, review period, and vulnerable populations.
9. Page 8, Section IX is now Approval Notification and describes the process for notifying the investigator of IRB approval.

E. Policy 11: Continuing Review, Revised October 22, 2020

Change Rationale: Updated to reflect current practice in preparation for AAHRPP re-accreditation

Change Summary: Refined definitions, updated formatting, and minor corrections throughout

Change Specifics:

1. Page 1, Section I, refined the definitions for consistency with other policies.
2. Page 1, Section II, changed January 19, 2019 to 2018 Common Rule.
3. Page 2, Section II, added "4. ETSU is the IRB of record for a multi-site, collaborative research study" as a possible reason for requiring continuing review
4. Page 3, Section III.A, removed description of Primary Reviewer system and added reference to Policy 9 instead.
5. Page 4, Section III.A, refined description of documents to be reviewed during continuing review.
6. Page 4, Section III.A, last paragraph, changed second sentence to read: With special attention to the analysis of risk/benefit ratio, whether new information or

unanticipated risks have been discovered since the previous IRB review, and whether any new information regarding the risks and benefits should be provided to participants
7. Page 9, Section V.A, incorporated the asterisk note into the appropriate bullet point to describe when a data safety monitoring plan is required.
8. Page 9, Section V.A, added that the IRB may require a new protocol submission if IRB policies or requirements have changed such that it is deemed necessary rather than performing continuing review.
9. Page 10, Section V.C-D, added HHS regulatory reference in addition to FDA reference.
10. Page 10, Section V-VI, updated reference to xform 107 to Continuing Review/Study Closure xform 107.
11. Page 10, Section V, deleted prior subsection C. Protocol Summary, as a protocol summary/narrative is not required but instead incorporated into the NPS xform.

F. Policy 13: Informed Consent, Revised October 22, 2020

Change Rationale: Updated to reflect current practice in preparation for AAHRPP re-accreditation

Change Summary: Refined definitions, updated formatting, and minor corrections throughout

Change Specifics:
1. Page 1, Section I is now Summary Policy and added broad consent statement at the end.
2. Page 2, Section II is now Pertinent Definitions, which have been refined.
3. Page 3, Section III is now Informed Consent Process and generally describes the process required to obtain legally effective informed consent.
4. Page 4, Section III.A, describes how to determine the LAR when an adult subject cannot consent for themselves.
5. Page 5, Section III.B, describes who can provide parental permission when the subject is a child that cannot consent for themselves.
6. Page 5, Section III.C, describes the process and requirements when there are nonreading or non-English speaking subjects.
7. Page 6, Section IV is now Required Elements of Informed Consent and describes the basic, additional, and local requirements for consent.
8. Page 10, Section V is now Informed Consent Document and describes the general requirements for consent such as reading level, version date, payments, mandatory reporting, etc.
9. Page 14, Section V.I describes the VA Research Consent Form requirements.
10. Page 16, Section VI is now Documentation of Informed Consent and describes the requirements for obtaining signatures and dates and putting a copy in the study file and medical record, if applicable.

11. Page 17, VII is now Posting of Consents and describes the requirement to post a consent form on a public website for federally funded clinical trials under the new common rule.
12. Page 18, Section VIII is now Confidentiality/Anonymity and describes the requirements to maintain confidentiality and disclosure in the consent of who will access records including signed consent forms.
13. Page 20, Section IX, describes the IRB authority to observe the consent process.
14. Page 21, Section X is now Waiver of Informed Consent and describes the eligibility for waiving or altering some elements of consent.
15. Page 22, Section XI is now Waiver of Documentation of Consent and describes the eligibility for waiving signed consent.

G. Policy 18: Reporting Unanticipated Problems/Events, Revised October 22, 2020

Change Rationale: Updated to reflect current practice in preparation for AAHRPP re-accreditation

Change Summary: Refined definitions, updated formatting, and simplified language

Change Specifics:

16. Page 1, Section I, is now Summary Policy to summarize the policy and describe the purpose of the policy.
17. Page 1, Section II is now Pertinent Definitions and includes more definitions relevant to the policy.
18. Page 2, Section III is now Reportable Events and identifies which events require prompt reporting and provides examples; combines ETSU and VA reportable requirements.
19. Page 2, Section IV is now PI Responsibilities for Reporting and describes the PI's responsibilities for assessing, documenting, and reporting events and related changes.
20. Page 3, Section IV, no longer requires prompt reporting for external UPIRTSOs or any reporting for external adverse events.
21. Page 5, Section V is now IRB Review of Reports and describes the IRB review process for all adverse events.
22. Page 7, Section VI is now Additional VA Requirements and describes the additional VA requirements for reporting adverse events.

H. Policy 20: Emergency Use, Revised October 22, 2020

Change Rationale: Removed reference to MSHA as contract for IRB services to MSHA was terminated

Change Summary: Removed reference to MSHA applicability and formatting updates for consistency

Change Specifics:

1. Page 1, Section II.A, Scope, removed Legacy MSHA providers.

I. Policy 23: Special Requirements, Revised October 22, 2020

Change Rationale: Updated to reflect current practice in preparation for AAHRPP re-accreditation

Change Summary: Created a Summary Policy section, reorganized the sections, updated formatting, and minor corrections throughout

Change Specifics:

1. Page 1, Section I is now Summary Policy and describes the purpose of the policy.
2. Page 1, Section II, now lists the rearranged special requirements for various types of submissions.
3. Section II, deleted Intellectual Property section.
4. Section II, subheadings rearranged to C. Biohazards, D. Radioisotopes in Humans, E. Radiation Safety and were refined to describe the processes for each.

J. Policy 28: Community Outreach, Revised October 22, 2020

Change Rationale: Updated to reflect current practice in preparation for AAHRPP re-accreditation

Change Summary: Removed definitions, added summary policy, updated formatting, and minor corrections throughout

Change Specifics:

1. Page 1, Section I, deleted previous definitions.
2. Page 1, Section I is now Policy Summary and describes the purpose of the policy.
3. Page 1, deleted previous Section IV Mechanism to receive complaints.
4. Page 1, rearranged Sections and refined content.