Summary of policy changes March-May 2020

A. Policy 2: Institutional Review Boards, Revised March 27, 2020

Change Rationale: Removed statement that did not allow for video/teleconference convened meetings in order to conduct meetings during the COVID-19 pandemic of 2020

Change Summary: Edited structure and formatting for consistency throughout, edited to meet composition requirements of old and new common rule, removed statement that disallowed video/teleconference, added student member to campus IRB composition and allowed flexibility for member with medical expertise rather than solely MD.

Changes Specifics:

1. Page 1, Section I, added statement "Each IRB will be appropriately constituted for the volume and types of research to be reviewed at ETSU."
2. Page 1, Section II, added statement "The requirements for the composition of the IRB under the revised Common Rule vary slightly from the 1991 Common Rule. The composition of the ETSU and ETSU/VA IRB complies with both rules," and removed redundant references to both rules throughout.
3. Page 2, Section II.B, rearranged content for readability.
4. Page 3, Section II.C, second paragraph, added "one ETSU student representative."
5. Page 4, Section II.C, second paragraph, last sentence, changed MD to: "a medical degree or license (i.e., MD, DO, NP, PA)."
6. Page 4, Section II.C, deleted prior last paragraph.
7. Page 4, Section II.E, added "An alternate may substitute for the primary IRB member for an entire meeting or at any time during a meeting. Alternates and IRB members have equal responsibilities in terms of required education, service and time commitments, and participation. Alternates receive the same information that the regular members receive."
8. Page 6, Section II.G, deleted 3rd bullet and added last bullet stating "Current Volunteer Agreement in accordance with University policy."
9. Page 6, Section II.H, first sentence, added "…with the exception of student members, who shall serve terms of 1-3 years as their program duration allows."
10. Page 6, Section II.I, second sentence of first paragraph, added "Members are expected to attend no less than 50% of the convened IRB meetings annually."
11. Page 7, Section II.J, last sentence, added "Additionally, meetings may be canceled at the discretion of the IRB Chair."
12. Page 8, Section II.K, last sentence, edited #2 to state: "and 2) must have demonstrated understanding of human subject research regulations and local policy."

13. Page 8, Section III, first paragraph, deleted “Meetings are not conducted by videoconference or teleconference.”
14. Page 8, Section III, deleted paragraphs about composition when reviewing vulnerable populations; this is covered in IRB Policy 15.
15. Page 9, Section IV, deleted first 3 and last paragraphs.
16. Page 9, Section IV, added to new paragraphs to the beginning of section and minor edits to remaining paragraphs.

B. Policy 15: Vulnerable Populations, Revised March 9, 2020

Change Rationale: Updated to incorporate newly revised language from VHA Directive 1200.05, amended 3.05.20

Change Summary: Edited structure and formatting to be consistent throughout, revised language for consistency with amended VHA Directive 1200.05

Change Specifics:

1. Page 1, Section I, Replaced first paragraph with “It is the responsibility of the ETSU IRBs to ensure the procedures are in place in a research activities to protect the subjects taking part. This is especially true when a research activity targets vulnerable individuals as subjects. The ETSU and ETSU/VA IRB determines and documents that appropriate additional safeguards are in place to protect vulnerable populations as stipulated in the federal regulations and subjects likely to be vulnerable to coercion or undue influence due to other considerations or circumstances of the research activity itself.”
2. Page 1, Section I, moved bulleted list to second paragraph.
3. Page 1, Section I, deleted references to specific reviewer forms and stated “The appropriate checklist(s) section of the relevant reviewer xform will be completed…”
4. Page 2, Section II titled changed to “Research Involving Adults with Impaired Capacity to Consent”
5. Page 2, Section II, added opening paragraph that describes the policy application of this section.
6. Page 2, Section II, moved definitions to top of Section and removed unnecessary definitions.
7. Page 2, Section II, Requirements for VA studies, moved VA specific information to that section.
8. Page 4, Section II, Requirements for non-VA studies, moved non-VA specific information to that section.
9. Page
10. Page 4, Added Subsections A-D to organize the information and be consistent with other Sections throughout.

11. Page 6, Section III, added opening paragraph that describes policy application of this section.
12. Page 6, Section III, deleted prior paragraph 2.
13. Page 6, Section III, revised Subsections A-G to organize the information and be consistent with other Sections throughout.
14. Page 10, Section III.D, added subsection heading for Waiver of Parental Permission and added details.
15. Page 11, Section III, added new subsections F. Children who Turn 18 While on Study and G. Pregnant Minors and Minor Parents.
16. Page 11, Section IV, edited opening paragraph and added second paragraph describing policy application of this section.
17. Page 12, Section IV, added Definitions subsections with pertinent terms defined for this section.
18. Page 13, Section IV, added subsection A. IRB Submission and Review to describe how these protocols are reviewed and documented.
19. Page 13, Section IV, 1. Research involving pregnant women or fetuses, changed to "B" for consistency and deleted g from list.
20. Page 14, Section IV, For VA studies section, replaced prior c with new VA Directive language.
21. Page 14, Section IV, previous subsection A. Neonates became C. Research Involving Neonates.
22. Page 16, Section IV. C, removed inconstant numbering and change previous #6 to subsection D. Research involving after delivery: the placenta, the dead fetus or fetal material.
23. Page 17, Section IV, added subsection header E. Research involving Human Fetal Tissue to organize content.
24. Page 18, Section V, added opening paragraph to give context to the importance of additional protections for prisoners subjects.
25. Page 18, Section V, added Definitions subheading and added Minimal Risk definition for prisoners.
26. Page 18, section V, edited subsections A-H for consistency and to organize the information.
27. Page 18, Section V, added A. IRB Submission and Review to describe review process and requirements.
28. Removed outdated references as necessary throughout.

C. Policy 17b: Conflicts of Interest for IRB Members, Revised April 22, 2020

Change Rationale: Remove old references to IRB paper review packets

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

Change Specifics:

1. Page 1, Section I, is now policy Summary stating: "Federal regulations do not permit an IRB member or consultant of the IRB to participate in the review of research in which he/she has a conflict of interest, except to provide information requested by the IRB. This requirement helps to ensure that financial or other interests do not compromise the rights and welfare of human research subjects. This policy describes when IRB members, staff, or consultants are considered to have a conflict of interest, the procedures that must be followed for disclosure, and IRB review of research when a conflict exists. Henceforth, reference to an "IRB member" in this policy refers to an appointed IRB member, consultants of the IRB, or IRB staff involved during the review of an IRB submission. This policy applies to all IRB submission review types including initial review, continuing review, review of modifications, review of unanticipated problems involving risks to participants or others, and review of non-compliance with the regulations or IRB determinations."
2. Page 1, Section II, is now pertinent Definitions defining the terms: Conflict of Interest, Financial Conflict of Interest, Non-financial Conflict of Interest, and Immediate Family.
3. Page 2, prior Section I. Responsibility became Section III. Removed numbering. Changed previous number three to state: "IRB staff are responsible to inform Consultants of this policy, and Consultants are responsible for disclosing any conflict of interest to the IRB prior to providing any requested consultation or review recommendations."
4. Page 2, prior Section II. Actions Taken with Conflicting Interests became "Section IV. Disclosure and Documentation of COI." Removed subsection headings and combined information. Prior introduction incorporated into Section IV and added more examples of potential COIs:

   "3) Has a board or executive relationship related to the research, regardless of compensation.

   4) Has responsibility for Institutional business development, such as raising funds or garnering support for research.

   5) Has proprietary interest related to the research including, but not limited to, a patent, trademark, copyright or licensing agreement.

   6) Is involved in research utilizing competing technology, intellectual property, or resources such that the ability to render an objective assessment is compromised."
5. Page 2, Section IV, second paragraph, added statement: "IRB members who realize they have a conflict of interest when first assigned an item for review at an upcoming IRB meeting must notify the IRB Chair or staff immediately so that the item can be reassigned prior to the meeting."

6. Page 3, Section IV, third paragraph, added statement: “If the IRB Chair has a conflict, he or she may not chair the meeting during the consideration of the item in which the conflict resides must leave the room during the discussion and vote. Any IRB member may recuse him/herself from review of a specific protocol for any reason, including a conflicting interest not specifically described by this policy.”
7. Page 3, Section IV, last paragraph, added statement: “If an alternate is present for the IRB member with the conflict, the alternate can vote and be counted toward the meeting quorum for that review item only.”

D. Policy 20: Emergency Use of a Test Article, Revised April 17, 2020

Change Rationale: More clearly delineated the responsibilities of the physician/investigator and IRB.

Change Summary: Added definitions, identified procedures for the investigator and IRB, updated references, resources, and links throughout.

Change Specifics:

1. Page 1, Section I. Summary Policy, removed reference to ETSU IRB, as that board does not review FDA-regulated studies.
2. Page 1, Section I, added: “This policy describes the process and procedure to assess the appropriateness of the emergency use of a test article, and the subsequent process for physicians and the IRB to obtain and review emergency use. This policy describes responsibilities of the physician/investigator when an emergency requires a patient be treated with an investigational test article such that there is not sufficient time to obtain IRB review and approval at a convened meeting. Expedited review of Emergency Use is not permitted.
3. Page 1, Replaced prior Section II. Definition with “Section II. Scope and Responsibility” which states:

   > “Scope: This policy applies to treating physicians affiliated with ETSU, JHQVAMC, and legacy Mountain States Health Alliance seeking to use investigational agents for the purpose of providing clinical treatment (non-research purposes), in an emergency context where there is insufficient time to obtain IRB review. This procedure also applies to OPHRS staff and the ETSU IRBs.
   >
   > Responsibility: It is the responsibility of the IRB, OPHRS staff, and all physicians seeking to carry out procedures covered in this policy to understand and comply with this policy.”

4. Page 1, Replaced prior Section III. Emergency Use with “Section III. Definitions,” updated the definition for Emergency Use, and defined the terms: test article, immediately life-threatening disease or condition, IDE, Emergency IDE, IND,

Emergency IND, life-threating condition(device context), and serious disease or condition (drug context).

5. Page 2, Prior Section VI. Regulations became "Section IV. Emergency Use Requirements." Changed section formatting and updated references to DHHS, FDA, and VHA regulations.
6. Page 3, Section IV. Emergency Use Requirements, added: "NOTE: Emergency use of a test article is different than using a test article for a single patient under an Expanded Access Treatment Use IND. If there is sufficient time to obtain IRB review, or the patient is not in an Immediate Life-Threatening Situation, then the Expanded Access IND path may be followed. Prospective IRB review of the treatment plan and other materials is required prior to administering an investigational agent under the Expanded Access Treatment Use IND program."
7. Page 3, Section V is now "Emergency Use Procedure for Physician/Investigator" and includes a step-by-step process for physician/investigators to follow in the event of an Emergency Use, with FDA references, and IRB contact information to ensure compliance with this policy.
8. Page 8, Prior Section III. Emergency Use became "Section VI. Emergency Use Procedure for IRB Review." Updated the formatting, added references to the newly developed Emergency Use Report Form, added reference to IRB Policy 25: Noncompliance, and added statement that Emergency Uses would be reported to the convened IRB.
9. Page 9, Prior Section IV. Subsequent Use became Section VII. Updated paragraph to include reference to FDA regulation and guidance. Added statement: "If an IND or IDE application for subsequent use has been filed with the FDA and FDA disapproves the application, the investigational agent may not be used even if an emergency exists."
10. Page 10, Prior Section V. Emergencies for which Informed Consent is not Feasible became Section VIII. Updated references to "independent" physician, referenced current Section IV for IRB review procedure, and other minor edits.

E. Policy 27: Complaints, Concerns, and Suggestions, Revised April 22, 2020

Change Rationale: Incorporated information to meet AAHRPP standards.

Change Summary: Revised policy to not only focus on complaints, but also describe how concerns or suggestions to PIs, the IRB, or the HRPP are handled. Clearly delineated investigator and IRB responsibilities when handling complaints, concerns, or suggestions.

Change Specifics:

1. Page 1, prior Section II. Summary Policy became Section I. Added the following to beginning of paragraph: "Complaints, concerns, and suggestions about the

conduct of specific human research studies or about the ETSU Human Research Protection Program or IRBs are taken very seriously. All complaints, concerns, or suggestions regarding the conduct of human research at ETSU are brought to the attention of the HRPP Director, IRB Chair, and/or the Vice Provost for Research. The complaints or concerns will be investigated and handled appropriately as described in this Policy."

2. Page 1, Section I, end of paragraph, added: "Complaints and concerns might also include reports of any attempts to unduly influence individuals responsible for the oversight of human research (e.g., IRB chairs and members, OPHRS staff)."
3. Prior Section I. Definitions was deleted.
4. Prior Section IV. How to File a Complaint was deleted.
5. Page 1, Section II is now "Submitting a Complaint." The section describes who may submit a complaint, concern, or suggestion regarding human subjects research and who may receive those complaints. The section notes: "All complaints related to human subjects research conducted under the purview of the ETSU IRBs should be brought to the attention of the HRPP Director, IRB Chair, or VPR."
6. Page 1, Section II, added information about receiving and handling complaints, concerns, or suggestions in relation to the IRBs or HRPP.
7. Page 2, Section III is now "Investigator Responsibilities." The section describes the responsibilities of the PI when responding to complaints, concerns, or suggestions including documentation and reporting requirements.
8. Page 2, Section IV is now "HRPP/IRB Responsibilities." This section incorporated prior Section III. Actions Taken, and it describes the HRPP and IRB responsibilities when responding to complaints, concerns, or suggestions about a particular PI or protocol or generally about the IRB or HRPP. Complaints are handled confidentially and do not become part of the study file, but documentation is maintained by the OPHRS.