Summary of policy changes October 2019

A. Policy 3 Roles and Responsibilities, revised 10.8.19

Change Summary: Further define Unaffiliated Investigators to be consistent with OHRP guidance on extending your FWA to cover collaborative investigators

Change Specifics Page 5:

1. Unaffiliated Investigator section now reads: "Unaffiliated Investigators are any research study staff that are not employees, students, or agents of ETSU or the Quillen VAMC, or any institution for whom these services are provided by contractual agreement. Investigators and physicians in private practice settings who are not acting as employees or agents of the institutions under the approved Federalwide Assurances noted in this policy are subject to all of the usual human protection requirements and responsibilities. Such investigators must be under the direction or supervision of an affiliated Principal Investigator and will be required to sign an Unaffiliated Investigator Agreement (UIA), agreeing to comply with all educational requirements and to be bound by the human protection policies of the ETSU and ETSU/VA IRBs. A copy of the fully executed document will be returned to the investigator to be added to the research records. The original copy will be maintained in the IRB Administrative records, along with the curriculum vitae for the investigator."

B. Policy 5 Research Activities, revised 10.8.19

Change Summary: Delegate authority for reviewing Form 129s (for non-VA studies) to knowledgeable IRB Staff

Change Specifics:

1. Page 3, Section II, revised to read "The IRBs delegate this decision to the IRB Chair, Vice Chair, or knowledgeable IRB Staff. The Chair or Vice Chair, Vice Chair, or IRB Staff completes Form 113 to determine whether a proposal submitted to the IRB is human research according to DHHS or FDA regulatory definitions."
2. Section II, removed "as defined in FDA regulations," (redundant)
3. Section II, second paragraph reads: "The IRB, or its delegates, has the sole authority to make a final determination of whether a proposed activity is human research according to DHHS or FDA regulatory definitions. Unless an investigator is familiar enough with these regulations to be certain that the activity does not represent human research, the activity should be submitted to the IRB for a determination."
4. Section II, third paragraph, removed Chair or Vice Chair

5. Page 4, Section II, third paragraph, VA now reads: “For VA submissions, the ETSU/VA IRB Chair or Vice Chair will make the determination, and a determination of “not human subject research” will be forwarded to the VA R&D Office rather than the submitter.”
6. Section III, Deleted “The IRB, or its delegates, has the sole authority to make a final determination of whether a proposed activity is human research according to DHHS or FDA regulatory definitions. Unless you are familiar enough with these regulations to be certain that the activity does not represent human research, the activity should be brought forward to the IRB for a determination.” (redundancy)

C. Policy 8, Expedited Review, revised 10.22.2019

Change Summary: Remove old rule expedited language and add language about how investigators are notified about approvals

Change Rationale: Per ORO site visit, revised to include written procedure of how investigators and RDC are notified of expedited approvals

Change Specifics:

1. Section III, Deleted “…or in the absence of the Chair, Vice Chair; or two or more…” and added, “or designated”
2. Section IV, #2 now reads: “If the Chair or the expedited reviewers cannot approve the study consistent with expedited review procedures, the proposal will be recommended for review by the convened IRB.”
3. Section IV, #3 replaced “non-expedited” with “full board review” and added “and described in Policy 9.”
4. Section IV, #4 replaced “advised” with “informed” and added “via the approved IRB minutes.”
5. Page 3, Section V, Removed all old 1991 common rule language and reformatted Final Rule language.
6. Section V, Expedited Category 3, added examples (k)-(m) consistent with OHRP correspondence.
7. Section VII, Deleted previous #6 regarding data safety monitoring, as its not applicable to minimal risk research.
8. Section VII, Deleted Broad Consent language (not allowed at our institution).
9. Page 13, Section VII, Added “Investigators are notified in writing of expedited review determinations. For VA studies only, investigators are informed of the review decision and expedited category(ies) in the approval letter.”
10. Section VIII, Replaced “advised” with “informed” and “expedited agenda” with “expedited review list.”
11. Page 14, Section VIII, Added “For VA studies only, the expedited review eligibility category(ies) for expedited approvals will be documented in the minutes; and the VA Administrative Officer (AO) distributes the ETSU/VA IRB minutes to the members of the VA R&D Committee.”

D. Policy 10, Modification Policy, revised 10.16.2019

Change Summary: Delegate authority to knowledgeable IRB staff to administratively review and approve study staff changes

Change Specifics:

1. Section V, Deleted "Examples of minor modifications may include, but are not limited to, the following: Administrative changes, such as correction of typographical error(s) and Revision of phone number(s)"
2. Section VII, Deleted "For studies subject to the 2018 Common Rule, when a modification is submitted on an exempt study that underwent limited IRB review, the IRB Chair must determine in the modification request impacts the determinations made during the limited review. If so, then the IRB Chair must determine if the modification renders the study ineligible for continuing exempt status and if so, the modification will not be approved. The investigator will be notified in writing that he may withdraw the modification request and continue the study as previously determined to qualify under exemption guidelines or submit the study for appropriate review and approval through an expedited or full board review."
3. Page 4, Section IX, Changes in Study Sites or Investigators now reads "Changes in study sites, investigators, or study staff must also be submitted to the IRB. All newly assigned principal investigators of previously approved studies must show proof of having completed required education and submit a current CV for the purpose of assessment of qualifications. Modifications to PIs will be reviewed by the IRB Chair or Vice Chair. All other study staff changes will be reviewed and administratively approved by qualified IRB staff. IRB Staff may refer study staff changes to the IRB Chair for review if the changes require assessment of qualifications of the new investigators (i.e., interventional research or federally-funded research). Modifications that propose changes in addition to study staff will be reviewed by the IRB as detailed in this policy.

E. Policy 11 Continuing Review, revised 10.18.2019

Change Summary: Incorporated information about the administrative check-in for studies that do not require continuing review and simplified the continuing review language for old and new common rule

Change Rationale: Our institution has decided to require an administrative check for studies that do not require continuing review to maintain oversight of all active research. For any study undergoing continuing review, the same criteria would be applied and the review process would be the same. No need for distinction of old or new common rule throughout.

Change Specifics:

1. Removed Not Less Than Once Per Year definition
2. Section I, Pertinent Definitions, Added Administrative Check-in definition: “Periodic administrative review of ongoing research activities that do not require continuing review.”
3. Rewrote the Summary Policy section to define which studies require continuing review and which do not
4. Section II, Summary Policy, Added “For each initial or continuing review, the IRB will document the approval period in the approval letter with an expiration date specified. If the study does not require continuing review, no expiration date will be assigned, and the approval letter will inform the investigator of the administrative check-in date.”
5. Renamed Section III to “Level of Review” and simplified the language throughout
6. Section III, B Expedited continuing review, Added “The IRB Chair or designated expedited reviewer(s) complete the Continuing Expedited Reviewer Form to determine whether the research meets the criteria allowing continuing review using the expedited procedure, and if so, whether the research continues to meet the regulatory criteria for approval.”
7. Section III, C Exempt Studies, Added “Studies that have been granted exempt status may be required to undergo an administrative check-in by IRB staff to ensure that IRB records are current. Investigators will be informed of the administrative check-in date in their exempt status letter.”
8. Section V, A. Approval Criteria
    - Deleted “For studies under the 1991 Common Rule and FDA studies:”
    - Added “and (as applicable) FDA regulations at 21 CFR 56.111
    - Deleted regulatory criteria for approval and replaced with simplified list
9. Section VI, A. Written Progress Report, Deleted “For studies under the 1991 Common Rule and FDA studies:”
10. Section VII, Study Closure, now reads: “The IRB requires that all investigators notify the IRB when a study is completed by using either the IRB xForm 107 or Administrative Check-in xForm, as appropriate, when a study is completed.”