IRB Policy 4: IRB Committee Responsibilities
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I. Summary Policy

It is the policy of both the ETSU IRB and the ETSU/VA IRB to protect the rights and welfare of human research participants through research review complying with all applicable regulations, monitoring of research activities, and educating the research community.

The IRB is responsible for reviewing research projects involving human subjects proposed by students at, or employees of, East Tennessee State University and employees or medical staff of the James H. Quillen Veterans Affairs Medical Center and for any institution for whom these services are provided by contractual agreement.

Committee members must:

1. Have an understanding of the basic ethical principles, regulatory requirements, and IRB policy and procedures.
2. Conduct all review, including prospective and continuing review, according to all applicable regulations, including DHHS regulations at 45 CFR 46; FDA regulations at 21 CFR 50 and 56; federal, state, and local laws; institutional policies and procedures; and when applicable, VA regulations including 38 CFR 16.
3. Evaluate research for both scientific and scholarly merit (refer to scientific review policy)
4. Identify any conflict of interests prior to review of research (refer to conflict of interest policy)
5. Obtain guidance/expertise as needed to conduct a complete review

Institutional Review Board responsibilities include:

1. Assures compliance with the FWA.
2. Assures ETSU policies and procedures are effectively applied in compliance with State and Federal laws and regulations, the FWA, OHRP, FDA, NIH, OCR, and any other applicable Federal agencies (including ORO for ETSU/VA IRB).

3. Provides interpretation and application of Federal regulations.
4. Develops, implements, and interprets IRB policies and procedures.
5. Takes action on non-compliance according to IRB policies and procedures, as necessary.
6. Supports and facilitates the IRB process.
7. Participates in mandatory training as well as other ongoing educational activities to keep abreast of current events.

II. Approvals of Research

The duties and responsibilities of the members of the IRB are best described by reproducing the statement published in 45 CFR 46.111.

The IRB will review and has authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy.

§46.111 Criteria for IRB approval of research.

(a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

For research subject to the 1991 Common Rule and FDA research:

(1) Risks to subjects are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the

research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116.

(5) Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117.

(6) When appropriate*, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

*When research is more than minimal risk and involves an intervention

(b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

For non-FDA research subject to the 2018 Common Rule:

The IRB will review and has authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy. For studies subject to the 2018 Common Rule, this will include exempt research activities under § __.104 for which limited IRB review is a condition of exemption (under § __.104(d)(2)(iii), (d)(3)(i)(C), and (d)(7), and (8)).

In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

> (1) Risks to subjects are minimized: (i) by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted. The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116.

(5) Informed consent will be appropriately documented, or appropriately waived in accordance with § __.117.

(6) When appropriate*, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

*When research is more than minimal risk and involves an intervention

At the time of this policy revision, ETSU is not allowing exemption under exempt categories 7 and 8. However, the information regarding limited review is included below.

(8) For purposes of conducting the limited IRB review required by § __.104(d)(7)), the IRB need not make the determinations at paragraphs (a)(1) through (7) of this section, and will make the following determinations:

(i) Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained in accordance with the requirements of § __.116(a)(1)-(4), (a)(6), and (d);

(ii) Broad consent is appropriately documented or waiver of documentation is appropriate, in accordance with § __.117; and

(iii) If there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(b) when some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

III. Consultants

If an IRB member with sufficient expertise adequate to the scope and complexity of the research proposal is not available, the Chair will ask a consultant with such expertise to review the study and provide written recommendations. Consultants may evaluate research for any issues requested by the IRB. A conflict of interest form must be completed by the consultant prior to review, and a consultant may not review research if any conflict of interest is identified. In addition, consultants must agree to confidentiality prior to review.

For full studies, IRB Coordinator ensures that the consultant's written report is posted in IRBManager for IRB members prior to the board meeting.

If the consultant is unable to attend the IRB meeting, the Chair will present his/her written report to the convened board.

For expedited studies, IRB Coordinator will obtain consultant's written report and include this report when proposal is forwarded to expedited reviewers for review. Consultants will be asked to provide written report within 3 days.

Consultants may attend the IRB meeting but will not count toward quorum or vote.

IV. IRB Committee Determinations

After review, the possible actions which may be taken by the IRB are:

- Approval of the proposal
- Approval with stipulations
- Defer pending receipt of additional information
- Disapproval

A. Approved: An approval is granted if the research activity meets the criteria for approval as defined in 45 CFR 46.111 (see Section II above) and no changes are recommended to the proposal.

B. Approval with stipulations: An approved pending status is given if the research meets the 45 CFR 46.111 criteria for research approval and any modifications required by the IRB require simple concurrence by the Investigator. When the modifications requiring simple concurrence are received from the investigator, the Chair or his/her designee may then review and confirm the modifications through an expedited procedure. The proposal may be referred back to the full committee if deemed necessary by the Chair or his/her designee.

C. Defer pending receipt of additional information: When the convened board requests substantive modifications or clarifications directly relevant to the determinations required at 45 CFR 46.111, IRB approval of the proposed research is deferred, pending subsequent review by the convened board of responsive material. The investigator will receive a written request for specific or additional information required.

D. Disapproval: Disapproval is given if the proposal does not meet the criteria for approval as defined in 45 CFR 46.111 (refer to section II above). If the IRB

decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

When the IRB requires changes in research, the basis for requiring those changes will be noted in the minutes.

V. Confidentiality

The IRB membership must be diligent to maintain confidentiality. The Board must be free to deliberate in private without fear of coercion. With the exception of the IRB Chair or Vice-Chair, at no time may a member discuss deliberation content or outcomes with investigators post-review. The IRB policy is to notify the investigator in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. The OPHRS staff will be responsible for dispatching written notifications (post-deliberation), to the appropriate investigator.

Designated IRB members tasked with conducting primary reviews of initial submissions, continuing reviews, or reviews of unanticipated events are authorized by the convened Board to contact the Principal Investigator to discuss issues related to clarity, risk, benefits, etc.