# IRB Policy 9: Full Board Review
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## I. Summary Policy

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) is to receive and review sufficient information to make the determinations required for approval of research consistent with HHS regulations at 45 CFR 46.111. This includes sufficient information about recruitment and enrollment procedures, the equitable selection of subjects, provisions to protect the privacy of subjects and maintain the confidentiality of data, and additional safeguards to protect the rights and welfare of subjects who are likely to be vulnerable.

## II. Pertinent Definitions:

A. **Continuing Review:** Periodic IRB review of ongoing research activities to ensure that the rights and welfare of human subjects are protected. Includes analysis of risk/benefit ratio, with special attention to 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.
B. **Exempt Review:** Studies determined by the IRB Chair to be minimal risk and meet the exempt criteria as defined by IRB Policy 7.
C. **Expedited Review:** Studies determined by the IRB to meet the expedited criteria whereby research is reviewed by one or more IRB members rather than the convened IRB.
D. **Initial Review:** Studies presented for review prior to project initiation.
E. **Full Board Review:** Research that does not qualify for exempt or expedited review requires review by convened IRB.

## III. Convened IRB Meetings

Studies not qualifying for exempt or expedited review procedures must be reviewed by the convened IRB where a quorum of members are present. Approval of research is by a majority vote of this quorum. In general, each panel meets monthly on a regular basis throughout the year. Refer to Policy 2 for structure and composition of the ETSU and ETSU/VA IRBs. Members with a

conflict of interest with any protocol may not participate in the deliberation and voting process, although these members may participate in the discussion of such proposals to provide information requested by the IRB. Deliberations and voting decisions of the convened IRB are recorded in the minutes by the IRB Coordinator.

Convened IRB review usually involves research that is greater than minimal risk but also includes research not eligible for exempt or expedited categories. At their discretion, the IRB director, chairs, or members may also refer research to the convened IRB for review. The convened IRB must conduct annual continuing review and review non-minor amendments to previously approved research that was determined by the IRB to be greater than minimal risk. In addition, the convened IRB reviews events that represent possible unanticipated problems to subjects or others (UPIRTSOs) or serious or continuing noncompliance and determines appropriate actions to ensure the safety and welfare of research subjects.

Submissions for consideration at the convened meeting of the IRB shall be made available to the assigned reviewers and the members of the IRB approximately 10-14 days prior to the convened meeting. IRB members receive the materials sufficiently in advance of the meeting date to allow review of the material. All full board proposals will be individually presented and discussed by the IRB as a group. Approval will only be granted after substantive review and careful consideration of the approval criteria described in this policy. Any controverted issues and their resolution will be documented in the minutes.

## IV. Initial Full Board Reviews

In conducting the initial review of proposed research, the IRB will obtain information in sufficient detail to evaluate the risk of the research and to document determinations that the proposal meets the applicable approval criteria. New submissions are screened by the IRB Coordinator for completeness and may be returned to the Principal Investigator to obtain missing documentation or clarification prior to being scheduled for IRB review.

The Principal Investigator will be asked to attend the meeting in which his/her proposal will be discussed. If the investigator cannot attend the meeting, a qualified, knowledgeable representative may attend on his/her behalf. In the event of a study being presented by a graduate student, the student's knowledgeable advisor or faculty co-investigator should attend the meeting to support the presentation of the protocol alongside his/her student. The Principal Investigator provides a synopsis of the research and is given the opportunity to clarify points as requested by the IRB or to supply missing/supplemental materials to facilitate the review.

# V. Primary Reviews

To improve the quality and efficiency of IRB review, the Primary Reviewer system will be used to conduct initial and continuing review of proposals considered by the convened IRB. Primary Reviewers shall be IRB members who are selected by the IRB Chair based on consideration of the protocol and reviewer's area of expertise, dedication to continuing education, and availability to accept review assignments. The IRB Chair completes the Chair Determinations xform documenting reviewer assignments, including designation of any consultants as deemed necessary.

A minimum of two members will be assigned to each protocol to be reviewed at the convened meeting. Each initial full board review is assigned a Primary Scientific Reviewer and a Secondary Informed Consent Document (ICD) Reviewer. The assigned Primary Reviewer will have scientific or scholarly expertise in the area of the research adequate to the complexity and scope of the research.

The Primary Reviewer conducts an in-depth review of the protocol and other pertinent documentation prior to the IRB meeting. Issues to be analyzed include, but are not limited to, scientific merit, risk/benefit ratio, ethical standards, and approval criteria. The Primary Reviewer presents a summary of the study to the IRB with any recommended modifications and offers approval recommendation. The Primary Reviewer may present findings and recommendations regarding initial or continuing review in the presence of the PI or once the investigator has been excused from the meeting (along with any IRB member(s) declaring association or other conflict of interest).

The ICD Reviewer conducts an in-depth review of the Informed Consent Document and associated documents (i.e., Child Assent, HIPAA authorization). Issues to be considered will be the adequacy of the Consent Forms in conveying the procedures, implications, and full intent of each study. The reviewer then presents his/her ICD assessment and any recommended modifications to the IRB.

Both the Primary Reviewer and ICD Reviewer may contact the Principal Investigator prior to the IRB meeting to request additional information if necessary. The IRB members will have access to any additional information provided to assigned reviewers.

## A. Materials to be reviewed by the Primary Reviewer

The Primary Reviewer is expected to review these materials prior to the meeting:

a. New protocol submission xform, which includes the study summary and objectives, and any attached documents
b. Proposed informed consent, assent, and/or parental permission document
c. Recruitment materials
d. Data collection tools such as questionnaires, surveys, or testing forms
e. HIPAA Authorization, as applicable
f. Principal Investigator's CV/resume (to confirm the qualifications of the investigator and confirm research experience)
g. Investigator's Brochure, if there is one
h. Conflict of Interest Management Plan, if there is one
i. Data Safety and Monitoring Plan
j. Any consultant's report

For HHS supported multicenter clinical trials, a copy of the HHS approved sample informed consent document and complete HHS approved protocol (if there is one) should be reviewed as well.

The ICD Reviewer is responsible for reviewing the above documents with the exception of the investigator's brochure.

The Primary Reviewer performs an in-depth review of all documentation and completes the Initial Full Board Reviewer xform 111 to provide documentation of consideration of approval criteria. The Primary ICD reviewer also completes the required sections of the reviewer xform.

**B. Materials to be reviewed by all other IRB members:**

All other IRB members are provided access to and are expected to review the above documents with the exception of the investigator's brochure.

Upon request, any IRB member has access to the complete IRB protocol file and relevant IRB minutes prior to or during the convened IRB meeting. In addition, any IRB member has access to additional information provided to assigned reviewers.

## VI. Committee Responsibilities

The full committee is informed of the Primary Reviewer's findings during the convened meeting. At the meeting, following the investigator's presentation, the assigned reviewers will initiate discussion by presenting their review. Problems identified by the assigned reviewers or by other IRB members will be discussed and suggestions for any necessary changes will be voted on by the IRB. The IRB is responsible for substantively reviewing all proposals and ensuring that the approval criteria are met.

In instances where the IRB determines their expertise is not sufficient to adequately review the technical aspects of the study, outside consultants may be utilized. Consultants may be present for the discussion of the study but will be excused during the deliberation and voting process.

In conducting the full committee review, the majority of the members must agree that sufficient materials are present to determine that the study meets the following criteria for approval:

1. Risks to subjects are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, and 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/educationally disadvantaged persons.
4. Informed consent will be sought from each prospective subject, or the subject's legally authorized representative, in accordance with applicable regulations and ETSU IRB Policy.
5. Informed consent will be appropriately documented or appropriately waived in accordance with relevant regulations and ETSU IRB Policy.
6. When research is more than minimal risk and involves an intervention, 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.
8. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

For VA studies, the patient's medical record must be flagged if study is determined to be more than minimal risk. If the IRB determines and documents that the patient health record must be flagged in Computerized Patient Record System (CPRS) as participating in a research study, then the health record must identify the Researcher, as well as contact information for a member of the research team that would be available at all times, and contain information on the research study or identify where this information is available. The duration of flagging is the length of the duration of the individual's participation in the study.

The instructions above apply to studies that do not have a Certificate of Confidentiality. Refer to Policy 13 for more information.

## VII. IRB Voting Actions

The possible actions which may be taken by the IRB are:

- Approval
- Approval pending modifications
- Table requiring substantive changes
- Disapproval

Motions are made by voting IRB members, and votes taken on such motions, only in the absence of the investigator and those IRB members with a conflict of interest in the protocol. Voting is by voice or raised hands unless a secret ballot is requested by any IRB member. The IRB staff records all votes. The minutes will record those IRB members who are in attendance at the meeting but are absent from the room at the time of vote. The recording of votes will denote the number of votes for, opposed, abstained and recused.

### A. Approval:

The study is approved as submitted, or with administrative changes confirmed by IRB staff. Verification of completed education/training requirements, confirmation of receipt of standard letters (e.g., IAAs, external site permission, letters of support), and/or confirmation of receipt of contract checklist may be confirmed by IRB staff without required additional committee review. IRB staff may administratively change an Approval decision to Approval Pending in order to ensure completion of administrative changes as required by ETSU IRB Policy.

### B. Approval Pending Modification:

The study is approved pending modifications based on the committee's understanding of the research, in order to meet the criteria for approval and ensure adequate human research protections. Provided that the modifications

are made as requested, the committee finds that the research meets the approval criteria. If the proposal is approved with stipulations that require simple concurrence by the investigator, the IRB staff informs the investigators in writing of the stipulations and the actions required by the investigator to satisfy them. The IRB Chair or another IRB member designated by the Chair may subsequently approve the modifications on behalf of the IRB without further committee review. The final approval of research will be reported on the agenda of the next IRB meeting. If necessary, the investigator's response may be assigned to the full committee for reconsideration. Final approval of the proposal will not be granted until all deficiencies are addressed to the satisfaction of the IRB.

### C. Tabled Pending Receipt of Additional Information

Substantive modifications or clarification are required regarding the protocol and/or consent form. This action is taken when insufficient information is provided to the committee to determine the approval criteria are met, or when substantial concerns exist regarding the ethical standards or participant protections described in the proposal. The investigator will receive a written request for specific or additional information required. IRB approval of the proposal cannot occur until the requested information is considered at a subsequent convened meeting, and the IRB deliberation will be documented in the minutes of that meeting. Approval of the project will not be granted until all deficiencies are addressed to the satisfaction of the IRB.

### D. Disapproval

Concerns of such significance that the IRB determines that approval of the study is unwarranted. In the event that a proposal is disapproved by the IRB, the investigator will be notified in writing of the IRB's decision and rationale along with an invitation to respond either in person or in writing. The appeal process will additionally be made available. IRB review of a previously disapproved proposal requires a new protocol submission that is considered at a subsequent convened IRB meeting.

## VIII. Other Considerations

### A. Determination of Risk

At the time of initial review, the IRB will make a determination regarding the level of risk of the proposal. Risk will be defined as either "minimal risk" or "greater than minimal risk." The convened meeting minutes will document the risk determination. Proposals determined to be greater than minimal risk require subsequent convened IRB review no less than annually.

### B. Approval Period

If the proposal is approved or approved pending modifications, the IRB also determines the interval for continuing review of the study based on the degree of risk to human subjects. The criteria as specified in Policy 11 are considered when determining the review interval for full studies.

### C. Vulnerable Populations

When a proposal includes populations that might be vulnerable to undue influence or coercion, the IRB evaluates the protocol-specific information to determine that appropriate protections are in place. Additional risk determinations will be made to fulfill the obligations under Subparts B, C, or D as needed.

## IX. Approval Notification

Upon approval of protocols by the convened IRB, a letter informs the investigator of the determination of the IRB, including the determined period of approval. The IRB coordinator will release approvals for the protocol only after the any required modifications have been made, received by the IRB office, and approved as indicated above.

The approval letter instructs the PI that any changes in approved projects must be reviewed and approved before they are initiated; that any unanticipated problems, deaths or other adverse event must be reported to the IRB; and that monitoring will occur. The approval period will be determined by the IRB at the time of initial or continuing review (as noted above and in continuing review policy), and investigators will be informed of this period in the approval letter.

**References**:
45 CFR 46.111
OHRP Compliance Activities: Common Findings and Guidance
63 FR 60634-60637
4 CFR § 46.107(f)
21 CFR § 56.107(f)
VHA Directive 1200.05