

IRB Policy 6: Scientific Review

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I. Summary Policy

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.

II. Departmental Scientific Review

The comprehensive review of human research protocols includes a departmental evaluation of the scientific or scholarly merit of the research. This review encompasses the merits of the research question; the feasibility of the methodology; the statistical analysis, if applicable to the type of research; the experience of the investigator; when involving drug studies, the pharmacology of the drug as it might relate to subject safety; and when involving devices, for example, as used medically or in exercise science, the engineering and design of the device as it might relate to subject safety. The approval signature of the ETSU Department Chair, Dean, or VA Service Chief, attesting that the proposal has been reviewed for scientific merit, is required for all new protocol submission xforms with the following exceptions:

- IRB submissions originating from students and having been approved by the student's research director and supervisory committee do not require the signature of the Department Chair. In this situation, the signature of the thesis/dissertation Committee Chair is accepted.

III. IRB Scientific Review

The IRBs have full responsibility and authority to thoroughly review each protocol for scientific and scholarly merit of the research as part of the overall ethical review of the research. The expertise of consultants may be sought if the IRB Committee requires additional expertise in order to conduct a thorough review of the proposal.

References:

45 CFR § 46.111(a)