

IRB Policy 6: Scientific Review

Revision Date: October 6, 2008, revised April 2, 2012

I. Summary Policy

It is the policy of both the ETSU IRB and the 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, if any to participants, and the importance of the knowledge that may reasonably be expected to result from the study.

II. Departmental Scientific Review

The comprehensive review of ETSU and ETSU/VA 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 Head, Dean, or VA Service Chief, attesting that the proposal has been reviewed for scientific merit, is required on initial submission for all ETSU/VAMC applications 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 will be accepted.
- Initial submissions for investigators unaffiliated with ETSU or the VA who are proposing to utilize Mountain States Health Alliance facilities or patients require the approval signature of the Vice Provost for Research. This signature attests that the proposal has been reviewed for scientific merit. This policy applies to all Full, Expedited, and Exempt Review Submissions.

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 guidance of additional information in order to conduct a thorough review of the proposal.

References:

45 CFR § 46.111(a)(1)(i)
45 CFR § 46.111(a)(2)
21 CFR § 56.111(a)(1)(i)
21 CFR § 56.111(a)(2)