Contracts and the IRB (1/11/16)

East Tennessee State University is committed to the following standard established by our accrediting body, the Association for the Accreditation of Human Research Protection Program.

Standard I-8: The Organization works with public, industry, and private Sponsors to apply the requirements of the Human Research Protection Program to all participants.

As part of this standard, ETSU reviews ETSU sponsored agreements to ensure that these documents have the necessary elements to ensure the protection of participants.

For example, the contract must indicate that the sponsor will promptly report findings of study monitors that could affect the safety of participants or influence the conduct of the study. (when appropriate to the type of research).

The ETSU/VA IRB reviews studies submitted by researchers who work at ETSU, or other institutions like the James H. Quillen VAMC or Mountain States Health Alliance.

For ETSU researchers whose contract is negotiated through ETSU’s Office of Sponsored Programs Administration (ORSPA):

1. ORSPA will review your contract and negotiate with the sponsor to make sure the required language is included in the document.
2. A contract checklist will be completed by ORSPA and submitted to the IRB.
3. Final IRB approval can not be issued until the IRB receives a contract checklist documenting the inclusion of all required language. Your study can still go through the review process, but it would be held in an “approval pending” status until this checklist is received and a final approval is issued (if study is approved otherwise).

For researchers whose contract and funding is processed through an entity other than ORSPA (e.g., ETSU Research Foundation, VA Research Foundation, Mountain States Health Alliance)

1. The appropriate representative (usually the person negotiating the contract) ensure, by completing and signing the contract checklist, that AAHRPP-required language is included in the agreement.

2. Final IRB approval can not be issued until the IRB receives a contract checklist documenting the inclusion of all required language. Your study can still go through the review process, but it would be held in an “approval pending” status until this checklist is received and a final approval is issued (if study is approved otherwise).

All sponsored agreements supporting human subjects research reviewed and monitored by the ETSU IRB must contain the following 5 elements:

1. Arrangements for the provision of medical care for research-related injury is addressed prior to the commencement of the research and clearly outlined in the sponsored agreement. For ETSU studies, ETSU may pay the cost of emergency first aid for any study-related injury. ETSU makes no commitment to pay for any other medical treatment. All attempts will be made to obtain a commitment from the sponsor to pay for all reasonable and necessary costs of diagnostic, therapeutic and medical treatment including hospitalization costs for study-related injuries. In all cases the roles and responsibilities of the sponsor and ETSU in the coverage of research-related treatment costs are clearly defined in each sponsored agreement. Any claims against ETSU or any of its agents or employees are to be submitted to the Tennessee Claims Commission. These claims will be settled to the extent allowable as provided under TCA Section 9-8-307.

2. In studies where the sponsor monitors the conduct of the research, the sponsored agreement will require the sponsor to promptly (no longer than within 30 days) report to the Principal Investigator any findings that could affect the safety of participants or their willingness to continue participation, influence the conduct of the study, or alter the IRB’s approval to continue the study. It is the Principal Investigator’s responsibility according to IRB Policy 18 to assess any such findings and report accordingly to the IRB.

3. In studies where the sponsor has the responsibility to conduct data and safety monitoring, the University will require the sponsor to provide the data and safety monitoring plans to the Principal Investigator and the IRB. The sponsor will also provide routine and urgent reports from data and safety monitoring to the Principal Investigator who will provide them to the IRB. The time frame for providing routine and urgent data and safety monitoring reports to the organization will be indicated, consistent with what is stated in the data and safety monitoring plan approved by the IRB.

4. Plans for disseminating study results and the roles that Investigator and sponsor will play in publication or disclosure of results.

5. The sponsor will communicate findings from a closed study to the IRB or to the Principal Investigator who will provide them to the IRB within a specified time frame (e.g. two years) when those findings directly affect participant safety.