

East Tennessee State University

Policy Title: Policy on Sponsored Human Subject Research

Issued: 7/13/15

Responsible Official: Vice Provost for Research and Sponsored Programs

Responsible Office: Office of Research and Sponsored Programs

Policy Statement

All human subject research at East Tennessee State University (ETSU), conducted by agents of the University, or involving non-public information held by ETSU will be reviewed and approved by the applicable Institutional Review Board (IRB) and follow the requirements set forth in Title 45, Part 46 of the Code of Federal Regulations regardless of sponsorship. For Federal sponsors that have adopted the Common Rule, ETSU will accept grant award terms and conditions as provided by the sponsor. For all other sponsors, ETSU will insist in writing that the sponsor will comply with the Health Insurance Portability and Accountability Act of 1996, as codified at 42 U.S.C. Section 1320d ("HIPAA") and follow procedures that protect human research participants as provided in the ETSU Human Research Protection Program Policies and Procedures.

Purpose

This policy addresses sponsored human subject research and the procedures employed by ETSU to ensure its compliance with federal regulations and the standards set forth by its accrediting body, the Association for the Accreditation of Human Research Protection Programs (AAHRPP).

Definitions

Sponsored Human Subject Research

Any research or clinical investigation that is funded by an outside agency either through a grant or contract and involves human subjects

Procedures

Protection of human research subjects in sponsored agreements awarded to ETSU [AAHRPP Standard I.8]

Per AAHRPP Standard I.8, all sponsored agreements awarded to ETSU in support of human subject research will include language that addresses the following 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 (Element I.8.A.).

Note: For those studies in which ETSU is a named party in the sponsored agreement, 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.

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

	<p>study, or alter the IRB’s approval to continue the study (Element I.8.B.).</p> <p><i>Note: It is the Principal Investigator’s responsibility according to IRB Policy 18 to assess any such findings and report accordingly to the IRB.</i></p> <ol style="list-style-type: none"> 3. In studies where the sponsor has the responsibility to conduct data and safety monitoring, ETSU 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 (Element I.8.C.). 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 Principal Investigator and sponsor will play in publication or disclosure of results are addressed (Element I.8.D.). 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 (Element I.8.E.). <p>Inclusion of these required elements will be documented by ORSPA by way of the completion of the “Sponsored Research Review for Human Subjects Provisions” checklist (Doc 23), signed by the Associate Director for Contract Management (as contract negotiator) and the Vice Provost for Research and Sponsored Programs, attesting that the required human subjects related provisions are present in the final agreement between the organization and the sponsor.</p> <p>The ETSU IRB may determine that there is minimal risk for research-related injury, for example, if the study does not involve investigational drugs or devices or other types of medical interventions. In those cases, Element I.8.A under AAHRPP Standard I-8 might not apply. The Vice Provost for Research and ORSPA may exempt the sponsored agreement from having to comply with this Element by indicating on the “Sponsored Research Review for Human Subjects Provisions” checklist (Doc 23) that the protocol associated with the agreement poses minimal risk for research-related injury.</p>
<p>Protection of human research subjects in sponsored agreements issued by ETSU</p>	<p>Any sponsored agreement issued by ETSU that supports human subject research will require that the receiving party (<i>recipient/subrecipient</i>) complies with procedures that protect human subjects and will include the following human subjects related provisions:</p>

	<ol style="list-style-type: none"> 1. The <i>(recipient/subrecipient)</i> will protect the rights and welfare of human subjects in accordance with the principles of the Belmont Report and applicable policies set forth in 45 CFR 46 and 21 CFR 50 and 56. 2. The <i>(recipient/subrecipient)</i> Principal Investigator will apply for approval to conduct the study with the Institutional Review Board and will not initiate the study until approval is obtained. 3. The <i>(recipient/subrecipient)</i> will comply with the Health Insurance Portability and Accountability Act of 1996, as codified at 42 U.S.C. Section 1320d ("HIPAA").
<p>Protection of human research subjects in sponsored agreements in which ETSU is not a named party</p>	<p>For those studies in which ETSU is not a named party in the sponsored agreement, the research organization must submit, along with the protocol and informed consent documents, a "Sponsored Research Review for Human Subjects Provisions" checklist (Doc 22), signed by an authorized representative of the organization, attesting that the human subjects related provisions required under AAHRPP Standard I-8 are present in the final agreement between the organization and the sponsor.</p> <p>For any studies for which the ETSU IRB is the IRB of record, the IRB may determine that there is minimal risk for research-related injury, for example, if the study does not involve investigational drugs or devices or other types of medical interventions. In those cases, Element I.8.A under AAHRPP Standard I-8 might not apply. The Vice Provost for Research and Sponsored Programs may exempt the sponsored agreement from having to comply with this Element by indicating on the "Sponsored Research Review for Human Subjects Provisions" checklist (Doc 22) that the protocol associated with the agreement poses minimal risk for research-related injury.</p>
<p>Roles and Responsibilities</p>	
<p>Vice Provost for Research and Sponsored Programs</p>	<p>The Vice Provost for Research and Sponsored Programs is the institution's chief research officer and is ultimately responsible for providing oversight and resources in support of the institutional policies and procedures that ensure that human subjects research conducted by agents of the University or by research organizations that contract with the ETSU for IRB services is compliant with federal regulations and the standards set forth by its accrediting body, the Association for the Accreditation of Human Research Protection Programs (AAHRPP).</p>
<p>Human Research Protection Program (HRPP)</p>	<p>The ETSU Human Research Protection Program (HSRPP) reports to the Office of the Vice Provost for Research and Sponsored Programs. Its staff provides guidance to ETSU faculty and staff and administrative support to the function of the institution's two IRB's – 1) the ETSU Medical/VA IRB, and 2) the ETSU Campus IRB.</p>

<p>Institutional Review Board</p>	<p>It is the policy of both the ETSU Campus 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, ETSU 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.</p>		
<p>Office of Research and Sponsored Programs Administration (ORSPA)</p>	<p>The Office of Research and Sponsored Programs Administration (ORSPA) reports to the Office of the Vice Provost for Research and Sponsored Programs and is the organizational unit responsible for negotiating and accepting sponsored agreements (grants and contracts), identifying which sponsored agreements require IRB approval, and for certifying that each grant and contract accepted by ETSU that includes human subject research is reviewed and approved by the IRB before a grant account is established and spending is allowed to occur. ORSPA staff coordinate with the HRPP staff and the Vice Provost for Research and Sponsored Programs to ensure consistency between the content of the sponsored agreement and the study protocol.</p>		
<p>Related Forms</p>			
<p>Independent Human Subjects Contract Review Checklist (Doc 22; revised 1/11/16)</p>			
<p>ETSU Human Subjects Contract Review Checklist (Doc 23; revised 1/11/16)</p>			
<p>Links</p>			
<p>45 CFR 46: Protection of Human Subjects</p>			
<p>AAHRPP Evaluation Instrument for Accreditation (January 1, 2015); Standard I-8 (pg 48-52)</p>			
<p>Revision Dates</p>			
<p>1/13/16; 5/26/16</p>			
<p>Subject Areas</p>			
<p>Academic</p>	<p>Research</p>	<p>Finance</p>	<p>Human Resources</p>
<p>✓</p>	<p>✓</p>	<p>✓</p>	