East Tennessee State University

Policy Title: Policy on Sponsored Human Subject Research
Issued: 7/13/15; Revised: 12/01/20
Responsible Official: Vice Provost for Research and Sponsored Programs (VPR)
Responsible Office: Office of Research and Sponsored Programs (ORSPA)

Policy Statement

All human subjects research funded by any Federal agency that has adopted the Common Rule, 45 CFR 46, revised August 2020, in which East Tennessee State University (ETSU) is engaged as defined by OHRP guidance, will be reviewed and approved by the applicable Institutional Review Board (IRB) and follow the requirements set forth in the regulations.

For all other sponsored human subjects research, such projects shall be reviewed, as appropriate and required, to ensure the protection of human subjects.

For Federal sponsors that have adopted the Common Rule, ETSU will, when appropriate, without further negotiation accept grant award terms and conditions as provided by the sponsor.

For all other sponsors, ETSU will, as appropriate, negotiate terms consistent with applicable laws, rules, and regulations regarding the research; this may include but is not limited to those regarding the Health Insurance Portability and Accountability Act of 1996, as codified at 42 U.S.C. Section 1320d ("HIPAA") and Association for the Accreditation of Human Research Protection Programs (AAHRPP) Standard I-8.

Any subaward or subcontract issued by ETSU that supports human subject research will require the subawardee or subcontractor to comply with all applicable laws, rules, and regulations regarding the research; this may include those regarding HIPAA and AAHRPP Standard I-8.

Purpose

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

Definitions

Sponsored Human Subject Research	Any research, including clinical investigation, that is funded by an outside entity through a grant or contract and that involves human subjects.
Research	A systematic study directed toward fuller scientific knowledge or understanding of the subject studied.

Human Subject	A living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual or obtains identifiable biospecimens or private information.
Investigator	An Investigator is an individual, regardless of title or position, who contributes to the scientific development or execution of a research project or program in a substantive, measurable way, whether or not they request salaries or compensation, this may include, but is not limited to, physicians, research nurses, coordinators, data managers, or others.
Principal Investigator	A Principal Investigator (PI) is an individual who has primary responsibility for the scientific and technical design, conduct, reporting, and fiscal and programmatic administration of a sponsored research project or program.
Clinical Trial	A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.
Multi-site Clinical Trial	A Clinical Trial for which a Sponsor manages, by way of the collection of data and organization and monitoring of the research at multiple sites, the Trial from a single location.
Review of Grants and Contracts in Support of Clinical Trials for Consistency with AAHRPP Standard I-8	
In General	For sponsored agreements in support of Clinical Trials, ORSPA will, in conjunction with the VPR, complete a "Sponsored Research Review for Human Subjects Provisions" checklist indicating whether the elements of Standard I-8 are applicable and required and, if applicable and required, are present in the final agreement between ETSU and the sponsor. The VPR makes the final determination as to whether any or all elements of Standard I-8 are applicable and required. The VPR is responsible for any review to determine congruency between any protocol, consent plan or similar document and the sponsored grant or contract. The VPR and IRB will coordinate to make any necessary changes to any protocol, consent, plan or similar document, as applicable. If the IRB believes that Standard I-8 necessitates any change or amendment to the sponsored agreement, it shall so inform ORSPA, and ORSPA shall work with the IRB to determine what, if any, changes or amendments are appropriate to the sponsored agreement. If the IRB and ORSPA agree that any change or amendment is appropriate and necessary, ORSPA shall negotiate such changes or amendments with the sponsor. Final say as to whether any changes or amendments are necessary belongs to the VPR.

AAHRPP Standard I.8.A	All sponsored agreements awarded to ETSU in support of Multi-site Clinical Trials, and those sponsored agreements with the potential for research-related injury as determined by the VPR, will address whether care will be provided and, if so, who will provide such care and who is responsible to pay for such care in the event of a research-related injury.
AAHRPP Standard 1.8.B	For Multi-site Clinical Trials where the sponsor monitors the conduct of the research, the sponsored agreement will require the sponsor to promptly (within 30 days) report to the Principal Investigator any findings that could affect the safety of study participants or which could influence the conduct of the study. The agreement may also require the prompt reporting of any findings that could impact participants' willingness to continue to participate in the study or that could alter the IRB's approval to continue the study. It is the Principal Investigator's responsibility to report any such findings as soon as possible to the IRB and to assess any such findings.
AAHRPP Standard 1.8.C	For Multi-site Clinical Trials where the sponsor has the responsibility to conduct data and safety monitoring, the grant or contract shall require the sponsor to provide data and safety monitoring plans and reports to the Principal Investigator. The grant or contract will require that data and safety monitoring reports be sent at least on an annual basis. The agreement may require the sponsor also to provide routine and urgent reports more frequently than annually. It is the Principal Investigator's responsibility to provide copies of any data and safety monitoring plan and revisions thereto, and any data and safety monitoring reports to the IRB as soon as possible, unless otherwise directed by the IRB.
AAHRPP Standard 1.8.D	For sponsored agreements in support of Clinical Trials, the sponsored agreement shall not limit ETSU's ability to publish consistent with its principals and policies. It is ETSU's position that, in support of fundamental research, no sponsored agreement should restrict ETSU from publishing or otherwise disseminating study results. Though ETSU may allow sponsors to review publications to protect the sponsor's confidential information, ETSU shall be otherwise free to publish the results of any study.

AAHRPP Standard 1.8.E	For Multi-site Clinical Trials, the funding agreement will require the sponsor to communicate findings after a study has closed to the Principal Investigator when those findings directly affect participant safety. The sponsor shall be required to communicate such findings for a period after the end of the study consistent with the sponsor's experience and expertise; two years may be considered an appropriate default window of time. It is the Principal Investigator's responsibility to inform the IRB of any such findings as soon as possible.

Roles and Responsibilities	
Vice Provost for Research and Sponsored Programs	The Vice Provost for Research and Sponsored Programs is ETSU's chief research officer and is ultimately responsible for providing oversight and resources in support of the institutional policies and procedures that ensure that research conducted at and by ETSU provides necessary and appropriate protections for human subjects. The VPR is the final authority on whether research conducted at and by ETSU 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).
Human Research Protection Program (HRPP)	The ETSU Human Research Protection Program (HRPP) reports to 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.
Institutional Review Board (IRB)	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 by reviewing research protocols for compliance with all applicable laws and regulations, monitoring of research activities, and educating the research community.
Office of Research and Sponsored Programs Administration (ORSPA)	The Office of Research and Sponsored Programs Administration (ORSPA) reports to the Vice Provost for Research and Sponsored Programs and is ETSU's organizational unit responsible for, among other tasks not enumerated here, negotiating and accepting sponsored agreements (e.g., grants and contracts).

Coordination between Principal Investigator, HRPP, IRB, and ORSPA for monitoring and review of IRB submissions related to Sponsored Projects	Each Investigator will reference any proposed or funded sponsored project in any relevant submission they make to the IRB. When an Investigator makes a submission to the IRB while a sponsored project is in the proposal phase, the Investigator's initial correspondence to the IRB, must include the ORSPA number that has been assigned to their proposal. If that project is later funded, the Investigator will update their IRB submission by informing the IRB as soon as possible that the relevant project has been funded. If the Investigator does not make a submission to the IRB until after the project has been funded, the Investigator will provide the ORSPA number and an acknowledgment that the project has been funded in their initial submission to the IRB. When the ORSPA Internal Routing Form indicates Human Subjects Research, as soon as practicable after notice of award, ORSPA will provide a copy of the award document to the VPR for their congruency review. Thereafter, ORSPA will continue with its standard internal processes for award documents. The VPR's signature on the award document and Internal Routing Form will serve as confirmation that the congruency review has satisfactorily concluded. For each sponsored project with an approved protocol, IRB will send ORSPA a copy of the approved protocol to store in the sponsored project file.

Subject Areas			
Academic	Research	Finance	Human Resources
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