



IRB Policies and Procedures



This newsletter focuses on the most recent policy revisions. The revised Policies and Summary of Changes are posted on our website <http://www.etsu.edu/irb/irb.html>. Please refer to them for more detailed information.

Introduction

This policy revision clarifies the language concerning when research involving human subjects is subject to the ETSU or ETSU/VA IRB. It reads as follows:

“All individuals engaged in research that is sponsored by East Tennessee State University, conducted by or under the direction of any faculty, staff, or student or agent of ETSU in connection with his or her institutional responsibilities; conducted by or under the direction of any employee or agent of ETSU using any property or facility of ETSU; on involves the use of ETSU’s non–public information to identify or contact human research participants or prospective participants must obtain ETSU or ETSU/VA IRB approval before beginning any research activities.

The IRB must review all human subject research if one or more of the following apply:

- ⇒ The research is sponsored by ETSU
- ⇒ The research is conducted by or under the direction of any employee, faculty, staff, student, or agent of ETSU in connection with his or her institutional responsibilities
- ⇒ The research is conducted by or under the direction of any employee or agent of ETSU using any of ETSU’s property or facilities
- ⇒ The research involves the use of non-public information maintained by ETSU to identify or contact prospective participants or participants
- ⇒ ETSU is the recipient of a direct federal award to conduct human subject research, even where all activities involving humans are carried out by a subcontractor or collaborator

IRB Policy Revision: Board (Policy 2)

The composition of the ETSU IRB has been changed to ensure accurate representation. The requirement to have ETSU IRB members from eight colleges was changed from eight to nine. The College of Applied Science and Technology was changed to the College of Business and Technology. The College of Public and Allied Health was changed to the College of Public Health and the College of Clinical and Rehabilitative Health Sciences. In addition, a member representing the Faculty Senate was designated as part of this policy revision.



IRB Policy Revision: Exempt Review (Policy 7)

In addition to other criteria, studies submitted requesting exempt review status will be reviewed by the Chair or Vice Chair to determine whether the research fulfills the organization's ethical standards. The standards are as follows:

- * The research holds out no more than minimal risk to the participants.
- * The selection of participants is equitable.
- * If the study includes recording of identifiable information, there are adequate provisions to maintain the confidentiality of the data.
- * If the study includes interactions with participants, there is a consent process that discloses such information as:
 - ◇ that the activity involves research
 - ◇ a description of the procedures
 - ◇ that participation is voluntary
 - ◇ the name and contact information for the investigator
- * The research has adequate provisions to maintain the privacy interests of participants.

IRB Policy Revision: IRB Committee Responsibilities (Policy 4) Expedited Review (Policy 8) and Full Review (Policy 9)

When a research is being reviewed, one of the approval criteria is:

- ◇ When appropriate*, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects).

The phrase "and involves an intervention" was added to the definition of "when appropriate" so that it now reads: *When research is more than minimal risk and involves an intervention

IRB Policy Revision: Continuing Review (Policy 11)

The following language was added for clarification:

“Continuing review occurs as long as

- * the research remains active for long-term follow-up of participants, even when the research is permanently closed to the enrollment of new participants and all participants have completed all research-related activities
- * the remaining research activities include collection or analysis of private identifiable information”



IRB Policy Revision: Informed Consent (Policy 13)

The following language was added under the Waiver of Informed Consent Section:

A waiver of parental permission (or student consent if the student is an adult) may not be granted if the study involves funding from the Department of Education and the study involves a survey, analysis, or evaluation that reveals information concerning the following categories:

- (1) political affiliations or beliefs of the student or the student’s parent;
- (2) mental or psychological problems of the student or the student’s family;
- (3) sex behavior or attitudes;
- (4) illegal, anti-social, self-incriminating, or demeaning behavior;
- (5) critical appraisals of other individuals with whom respondents have close family relationships;
- (6) legally recognized privileged or analogous relationships, such as those of lawyers, physicians, and ministers;
- (7) religious practices, affiliations, or beliefs of the student or student’s parent; or
- (8) income (other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under such program),

In addition, all instructional materials, including teacher’s manuals, films, tapes, or other supplementary material which will be used in connection with any survey, analysis, or evaluation as part of any applicable program shall be available for inspection by the parents or guardians of the children.”



IRB Policy Revision: Performance Site (Policy 36)

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 appropriate approvals for “engaged” and “non-engaged” performance sites are obtained and documented.

Definition:

Engaged: An institution becomes "engaged" in human subjects research when its employees or agents¹ **(i)** intervene or interact with living individuals for research purposes; **or (ii)** obtain individually identifiable private information for research purposes [\[45 CFR 46.102\(d\),\(f\)\]](#).

An institution is automatically considered to be "engaged" in human subjects research whenever it receives a direct HHS award to support such research. In such cases, the awardee institution bears ultimate responsibility for protecting human subjects under the award.

The following are requirements that may be followed when conducting research outside of ETSU, VA or MSHA:

Performance Site Category	Description	FWA required?	Required approval
Category 1	<ul style="list-style-type: none"> * engaged in research * with federal research support or direct award for study 	Yes	Submit copy of site IRB approval or request that ETSU IRB be IRB of Record.
Category 2	<ul style="list-style-type: none"> * engaged in research * with no federal research support or direct award for study 	No	Submit copy of site IRB approval or request that ETSU IRB be IRB of Record.
Category 3	<ul style="list-style-type: none"> * Performance site not engaged in research * with established IRB 	No	Submit copy of site IRB approval or request that ETSU IRB be IRB of Record.
Category 4	<ul style="list-style-type: none"> * Performance site not engaged in research * without established IRB 	No	Submit letter of permission from the appropriate institutional official stating that the research may be conducted at site.

IRB Policy Revisions: VA Researchers ONLY

Policy 15– Vulnerable Population

- * **For research involving Pregnant Women, Fetuses and Neonates, the following language was added:**
 - ◇ Research in which the subject is a fetus, in-utero or ex-utero (including human fetal tissue), must not be conducted by VA investigators, while on official duty, or at VA facilities, or at approved off-site facilities.
 - ◇ Research related to in-vitro fertilization must not be conducted by VA investigators, while on official duty, or at VA facilities, or at approved off-site facilities.

Policy 30– Record Keeping

- * **Reference to VAMC records being kept in accordance with RCS 10-1 was deleted.**

Policy 31– Investigational Drug

- * **The following language was added:**
 - ◇ VA investigators must inform the Pharmacy Service through the use of VA Form 10-1223 that the IRB and Research and Development Committee approvals have been obtained. In addition, VA investigators must provide the Pharmacy Service with a signed copy of the VA Form 10-1086 to document each participant's consent to participate in the study. VA investigators are also responsible for informing the Chief, Pharmacy Service, and the Research and Development Committee when a study involving investigational drugs has been terminated .

Policy 32– Planned Emergency Waiver

- * **The following language was added:**
 - ◇ The IRB can not approve a waiver of informed consent for planned emergency research that is subject to VA regulations.

Policy 34– Reporting

- * **The following language was clarify:**
 - ◇ when the report involves unauthorized use, loss, or disclosure of individually identifiable patient information, the notification will be sent to the VA Privacy Officer. When the report involves violations of VA information security requirements, the report will be sent to the VHA Information Security Officer. (Refer to Policy 18, Section III and IV for immediate reporting requirements).

For information on all policy changes, go to <http://www.etsu.edu/irb/irb.html>



We're on the Web
www.etsu.edu/irb

ETSU
THE OFFICE FOR THE PROTECTION
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June 2008

Sun	Mon	Tue	Wed	Thu	Fri	Sat
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30					

- 3**-Medical Meeting
- 5**- Campus Meeting
- 9**- Deadline to submit initial full studies for the July 2008 meeting

July 2008

Sun	Mon	Tue	Wed	Thu	Fri	Sat
		1	2	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30	31		

- 1**-Campus Meeting
- 3**- Medical Meeting
- 4**- ETSU Closed
- 14**- Deadline to submit initial full studies for the Aug. 2008 meeting



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