



IRB Policies and Procedures



This newsletter focuses 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.

Policy 11

- ◆ In Section IV.B, clarifying information was added as follows: “If an investigator does not provide continuing review information to the IRB or the IRB has not approved a protocol by the expiration date, new enrollment of participants cannot occur”.
- ◆ In addition, the policy was clarified as follows regarding when a full study is eligible to undergo continuing review. “The research presents no more than minimal risk to subjects (not applicable for category (8)(b), The identification of the subjects or their responses will not reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks to invasion of privacy and breach of confidentiality are no greater than minimal (Not applicable for category (8)(b), The research is not classified, and the research falls into one of more of the following categories:
 - ⇒ **Category 8:** Continuing review of research previously approved by the convened IRB as follows:
 - * **a)** where **(i)** the research is permanently closed to the enrollment of new subjects,; **(ii)** all subjects have completed all research-related interventions,; **AND (iii)** the research remains active only for long-term follow-up of subjects; **OR**
 - * **(b)** Where no subjects have been enrolled and no additional risks have been identified; **OR**
 - * **(c)** Where the remaining research activities are limited to data analysis.
 - ⇒ **Category 9:** Continuing review of research, not conducted under an investigational new drug (IND) application or investigational device exemption (IDE) where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

IRB Policy Revision: Board (Policy 2)

In section II.N., to ensure consistency, conflict of interest criteria were deleted and replaced with a reference to Policy 17b.

In section III, clarification that meetings are not conducted by videoconference or teleconference was added.



IRB Policy Revision: IRB Emergency Use (Policy 20)

Section III, the following information was inserted: “The ETSU/VA IRB Chair will also determine if the research is (or was) not a systematic investigation designed to develop or contribute to generalizable knowledge. The Chair will also determine that unless the criteria for the exception to the requirement for consent are (were) met, consent will be (or was) sought from each prospective participant or the participant’s legally authorized representative, in accordance with and to the extent required by FDA regulations and will be appropriately documented, in accordance with and to the extent required by FDA regulation.”

IRB Policy Revision: Research Activities (Policy 5)

Section I, the following clarifying sentence was inserted regarding FDA definition of a subject:

“FDA regulations also define subjects as an individual on whose specimen a device is used.”

IRB Policy Revision: Modification (Policy 10)

Section I.C., clarification of minor modification was addressed by adding “does not add procedures involving more than minimal risk to participants, and does not add procedures that do not fall into categories (1)-(7) of research that can be reviewed using the expedited procedure” to the definition of minor mod.

IRB Policy Revision: UPIRTSOs (Policy 18)

The list of reportable events was amended to include: “Addition of a black box warning on any drug used in your research”.

IRB Policy Revision: Informed Consent (Policy 13)

In Section IV.G, additional instruction as follows was added regarding consent by a legally authorized representative outside of the state of Tennessee.

“In addition, if research involving adults who are unable to consent is being conducted outside of the state of Tennessee, the investigator must consult Legal Counsel about which individuals are “legally authorized representatives” when the research is conducted in that jurisdiction. Researchers must submit a copy of this legal opinion to the IRB.”



IRB Policy Revision: Non-Compliance (Policy 25)

In Section IV. J, a statement that IRB members will review the narrative description of the project and the currently approved consent document was added.

IRB Policy Revision: Record Keeping (Policy 30)

The IRB records requirement was amended to include “for each protocol’s review, the frequency for continuing review”. In addition, in Section I.B., the following statement was added: “If a protocol is cancelled without participant enrollment, IRB records have to be maintained for at least five years after cancellation” was approved.

IRB Policy Revision: Research Involving Deception (Policy 37)

This new policy was approved and added to existing policies. In addition, a new Supplemental Submission Form for Studies Involving Deception was added as a required form. This form will capture information specific to deception studies.



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

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August 2008

Sun	Mon	Tue	Wed	Thu	Fri	Sat
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- 5-Medical Meeting
- 7- Campus Meeting
- 11- Deadline to submit initial full studies for the September 2008 meeting

September 2008

Sun	Mon	Tue	Wed	Thu	Fri	Sat
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- 1- ETSU Closed
- 2- Medical Meeting
- 4-Campus Meeting
- 15- Deadline to submit initial full studies for the October 2008 meeting



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