



THE IRB REVIEW

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THE OFFICE FOR THE PROTECTION OF HUMAN RESEARCH SUBJECTS (OPHRS)



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Initial Review Process for Expedited and Full Studies

It is the policy of the ETSU IRB and the ETSU/VA IRB to review human subjects research activities under their jurisdiction to determine which level of review is required. The studies determined to be human subject research under the DHHS or FDA definition can fall into one of the following reviews:

Exempt: It has to meet criteria set forth by 45 CFR 46.111 for approval and be less than minimal risk. This review only requires the Chair’s approval to be processed. Exempt reviews do not require continuation unless a modification changes the status to expedited or full review.

Expedited: It has to meet criteria set forth by 45 CFR 46.111 and if applicable, 21 CFR 56.111 or 38 CFR 16.111 for approval and be minimal risk. This review requires review from individual board members who serve as reviewers.

Full: It has to meet criteria set forth by 45 CFR 46.111 and if applicable, 21 CFR 56.111 or 38 CFR 16.111 for approval and more than minimal risk. This review requires review and approval from the full convened board.

Continuation Review Process for Expedited and Full Studies

The Department of Health and Human Services (DHHS), the Food and Drug Administration, East Tennessee State University and the James H. Quillen Veterans Affairs Medical Center, under the DHHS Regulations, Title 45 Code of Federal Regulations Part 46 (45 CFR 46), require at 46.109(e), that “an IRB shall conduct continuing review covered by this policy at intervals appropriate to the degree of risk, but not less than once per year...” of all projects involving human subjects. 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) is to conduct continuing review of all research proposals at intervals appropriate to the degree of risk, but not less than once per year [21 CFR 56.108(a)(1) and 56.109(f)]. Continuing review is substantive and meaningful, and of sufficient depth and frequency to ensure the continued protection of the rights and welfare of research participants.

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Both Initial and Continuations

Check for Completeness for Chair Review

The proposed project will be reviewed for completeness, including attachments of any pertinent documents. If any necessary documents are not present or proposed documents are incomplete, the IRB Coordinator will contact the study staff and request missing items or completion of documents. The IRB Coordinator will attach the appropriate forms for the Chair to indicate his/her review of the proposed project.



Chair Review

If the Chair or Vice Chair determines that the study can be approved through the expedited process, the proposal is forwarded within 7 days of receipt to one or more members of the Expedited Review Committee, and to additional reviewers as indicated by the Chair or Vice Chair. Full studies are sent to all members, including designated primary reviewers.

If the IRB Chair determines that an external consultant is necessary, the Chair or Director is responsible for contacting the designated consultant to determine his/her availability and lack of conflict of interest, and to ensure consultant agrees to confidentiality per policies.

If the study involves the VA, the VA Checklist is forwarded to the VA Administrative Officer who serves as consultant for VA studies.



Send to Reviewers

The appropriate materials are forwarded to the reviewers chosen by the Chair. The reviewers have 10-15 days to return their packets with their determination.



Full Studies go to Full Board

A letter of invitation is forwarded to the PI notifying him or her of the scheduled presentation date, time and location. This invitation will require the PI or knowledgeable representative to attend the meeting in which his/her proposal will be discussed. If the PI is a student, the student's advisor must be present at the meeting. The PI is to give a synopsis of the research and to explain or clarify points that bear on the risk/benefit ratio or to supply missing materials. The board is then informed of the primary reviewers' findings at the meeting. After discussion, the board will vote on the study.

IRB Determinations

There are four possible determinations:

- ⇒ **Approved:** an approval is granted if the research activity meets the criteria for approval as defined in 45 CFR 46.111 and no changes are recommended to the proposal.
- ⇒ **Approval with stipulations:** An approved pending status is given if the research meets the 45 CFR 46.111 criteria for research approval and any modifications required by the IRB require simply concurrence by the Investigator.
- ⇒ **Defer pending receipt of additional information:** When substantive modifications or clarifications directly relevant to the determinations required at 45 CFR 46.111 are required, IRB approval of the proposed research is deferred, pending subsequent review of responsive material. The investigator will receive a written request for specific or additional information required.
- ⇒ **Disapproval:** Disapproval is given if the proposal does not meet the criteria for approval as defined in 45 CFR 46.111 (refer to section II above). If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing. Expedited studies cannot be disapproved by the reviewers. They are deferred to the full committee.

Modification Submitted with Continuations

A modification received during a continuation review will be processed in accordance to IRB Policy # 10.

What Happens Once the Study is Reviewed

- ⇒ If the study is approved by the reviewers or the IRB an approval letter is forwarded to the PI in a timely manner along with any stamped approved documents.
- ⇒ If the study is approved pending stipulations, the PI is notified of the changes needed. When the modifications requiring simple concurrence are received from the investigator, the Chair or his/her designee may then review and confirm the modifications through an expedited procedure. The proposal may be referred back to the full committee if deemed necessary by the Chair or his/her designee. Once the changes are approved, a final approval letter is forwarded to the PI along with any stamped approved documents.
- ⇒ If the study is deferred pending receipt of additional information, the PI will be notified of the necessary documents needed.
 - If the study was originally determined to be expedited, then documents are sent to the reviewers.
 - If the study was originally determined to be full, the documents received will be sent the board members to be reviewed at the next convened meeting.
- ⇒ If the study is disapproved or deferred to the full board, the PI is notified of the decision.
 - If an expedited study is deferred to the full board by the reviewers, the PI will be notified and the proposal will be schedule for review by the convened IRB at the next meeting
 - If a full study is denied, the PI is notified in writing of the Board's disposition along with an invitation to respond in person or in writing. The appeal process will additionally be made available. The PI may alternately choose to represent the protocol rather than appeal.

Narrative Question of the month.....

Question 8c: Is a waiver or alteration of the consent process or a waiver or alteration of the consent documentation being requested?

If the answer to this question is “Yes”, then a justification must be provided. This question will be “yes” if you requested a waiver on question #6. The sample provided below are guides for you to use. Keep in mind that the answers given will be protocol specific. Your request for a waiver does not guarantee you will be granted the waiver because the IRB makes the final determination.

SAMPLES

Approval for a [Waiver or Alteration of Requirement to Obtain Informed Consent](#) could be granted under [45 CFR 46. 116(c)] or [45 CFR 46. 116(d)] .

◇ [A sample for category \[45 CFR 46. 116\(d\)\] is provided:](#)

The research involves no more than minimal risk to the participants because (**state your reason here**). The waiver or alteration will not adversely affect the rights and welfare of the subjects because (**state your reason here**). The research could not practicably be carried out without a waiver or alteration because (**state your reason here**) and providing participants additional pertinent information after participation is not appropriate because (**state your reason here**).

Approval for a [Waiver of Requirement for Written Documentation of informed Consent](#) could be granted under [45 CFR 46. 117(c)(1)] or [45 CFR 46. 117(c)(2)]

◇ [A sample for category \[45 CFR 46. 117\(c\)\(1\)\] is provided:](#)

The only record linking the participants and the research would be the consent document because (**state your reason here**). The principal risk would be potential harm resulting from breach of confidentiality because (**state your reason here**). Each participant will be asked whether he or she wants documentation linking the participant with the research, and the participant’s wishes will govern (**If you choose this determination, you must submit an Informed Consent Document to be used for this purpose**)

◇ [A sample for category \[45 CFR 46. 117\(c\)\(2\)\] is provided:](#)

The research involves no more than minimal risk to the participants because (**state your reason here**) and that the research involves no procedures from which written consent is normally required outside of the research context because (**state your reason here**).

Resource Available

Did you know that the IRB Office has provided investigators and their study staff with an **INVESTIGATOR HANDBOOK**? This provides all the information an investigator needs to know about conducting research. You can access the handbook through the IRB website under “IRB” or by going to <http://www.etsu.edu/irb/Investigator's%20Handbook1.pdf> You can copy and paste this website in blue to the address bar, then click enter. It will take you directly to the handbook. Hard copies will be provided upon request (one per PI or office).

Checklist

Required Elements

Does my Informed Consent Document or 10-1086 include....

- Disclosure that the study involves **research** (the word “research” must be present in the sentence)
- An explanation of the **purposes** of the research
- An explanation of the expected **duration** of the participant’s participation
- A description of the **procedures** to be followed
- Identification of any procedures that are **experimental**
- Description of any reasonably foreseeable **risks or discomforts** to the participants,
- Description of any **benefits** to the participants or to others which may reasonably be expected from the research
- disclosure of appropriate **alternative procedures or courses of treatment**, if any, that might be advantageous to the participant
- disclosure to which **confidentiality of records** identifying the participant will be maintained
- For ETSU studies deemed more than minimal risk: Include ETSU **compensation paragraph**, the second sentence must state, “**ETSU makes no commitment to pay for any other medical treatment**” instead of “ETSU will not pay for any other medical treatment”,
- Contact information** for answers to questions about the research,
- Contact information** for answers to pertinent questions about the participants’ rights,
- Contact information** in the event of a research-related injury to the participant,
- In **contact information** section, the following sentence is included, “**If you have any questions or concerns about the research and want to talk to someone independent of the research team or you can’t reach the study staff, you may call an IRB Coordinator at 423/439-6055 or 423/439/6002.**”
- disclosure that participation is **voluntary**,
- disclosure that **refusal to participate will involve no penalty or loss of benefits** to which the participant is otherwise entitled,
- disclosure that the participant **may discontinue participation at any time without penalty or loss of benefits** to which the participant is otherwise entitled.

Additional elements may apply, see page 6 for more information

Checklist

Additional Elements that might be Required

Does my Informed Consent Document or 10-1086 include these elements, if applicable

- disclosure that the particular treatment or procedure may involve risks to the participant which are currently unforeseeable **if**
 - ⇒ the risk profile of all research-related interventions is not well-known and the research involves investigational drug or device.
- disclosures that the particular treatment or procedure may involve risks to the embryo or fetus, if the participant is or may become pregnant, which are currently unforeseeable **if**
 - ⇒ the research does not exclude women of child bearing potential and pregnant women or the risk profile of all research-related interventions or interactions on embryos and fetuses is not well known or there is reasonable expectation that this research causes risks to fetuses or embryos. (revised 2007)
- disclosures of anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's consent **if**
 - ⇒ **Narrative question # 8g Is "yes"**: there are anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's consent
- disclosures additional costs to the participant that may result from participation in the research **if**
 - ⇒ **Narrative question # 14 is "yes"**: there are costs to the participant that may result from participation in the research
- disclosure of consequences of a participant's decision to withdraw from the research **and** disclosure of procedures for orderly termination of participation by the participant **if**
 - ⇒ there are adverse consequences (physical, social, economic, legal, or psychological) of a participant's decision to withdraw from the research
- disclosure that significant new findings developed during the course of the research which may relate to the participant's willingness to continue participation will be provided to the participant **if**
 - ⇒ significant new finding during the course of the research which may relate to the participant's willingness to continue participation are likely to develop
- disclosure of approximate number of participants (locally or in total) involved in the study **if**
 - ⇒ the approximate number of participants involved in the study (locally and in total) is important to a decision to take part in the research.

Is your study VA? If yes, see next page for additional elements for the 10-1086.

Checklist

VA STUDIES ONLY

In addition to the elements on page 5-6, does my 10-1086 Informed Consent Document also include:

- Financial Costs** paragraph "You will not be charged for any treatments or procedures that are part of this study. However, if you are required to make co-payments for services provided by the VA, or if you receive treatment that is part of your usual medical care, you or your third-party payer (e.g., insurance company) may be billed."
- Contact for Questions** paragraph "See Contact for Questions sections on page 5"
- Injury/Complications** paragraph "According to VA Regulations [38CFR17.85(a)] the medical facility shall provide necessary medical care to a research subject injured as a result of participation in a research project. However, no additional compensation has been set aside. You have not waived any legal rights or released the VA or its agents from liability for negligence by signing this form"
- Statement required for veteran subjects** "If you are a veteran taking part in a research study at the James H. Quillen VAMC, a copy of your signed/dated consent form will be placed in your medical record"
- Statement required if the study involves an investigational drug with an IND** "I have been told that because this study involves articles regulated by the Food and Drug Administration (FDA), the FDA may inspect research identifying me as a subject in this investigation"
- Statement required if the researcher believes that bodily fluids, substances or tissues of a research subject could lead to the development of a commercially valuable product** "I authorize the use of my bodily fluids, substances or tissues for research purposes."
- Confidentiality of Records** Add "ETSU/VA IRB, VA Research and Development Committee, Office of Research oversight (ORO) and Government Accounting Office (GAO), FDA, OHRP-specify drug company or sponsor, if any and specify who in study personnel" to the list of people who will have access to the records.
- Check payment through Austin** Include a statement that the subject's social security number will be required to process the check and that payments will be reported to the IRS and may be counted as income.

The Office for the Protection of Human
Research Subjects

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

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August 2006

Sun	Mon	Tue	Wed	Thu	Fri	Sat
		1 <i>Medical Board meeting</i>	2	3 <i>Campus Board meeting</i>	4	5
6	7	8	9	10	11	12
13	14 <i>Deadline for Full submission for Sept meeting</i>	15	16	17	18 <i>mail campus packets</i>	19
20	21	22	23	24	25	26
27	28 <i>classes start at ETSU</i>	29	30	31		

Coming Up Next Month

- Recruitment/Ads/Payments
 - Examples of what can be said or not
- Narrative Question of the Month
- Available Resource

Coming Up in September

- Children Involved in Studies
 - Supplemental Forms
 - How to complete a Child Assent, etc
- Narrative Question of the Month
- Available Resource

More Information

For more detailed information about the IRB process, see IRB Policies #7-10 and IRB Procedures 7a-10a available on the IRB website.

IMPORTANT NOTE

As of May 1, 2006, the ETSU and ETSU/VA Institutional Review Board no longer accepts any old forms. When submitting an initial proposal or a proposal for continuation review, please check the IRB website for new Forms. Always obtain forms from the IRB website. Do not use older forms that you or someone else have previously saved.

