



THE IRB REVIEW

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



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Definition of Research According to DHHS

Research is defined in the DHHS Federal regulations (45 CFR 46) as a “systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.”

Human Subjects are defined in the “Common Rule” as “living individuals about whom an investigator (whether professional or student) conducting research obtains either (1) data through intervention or interaction with the individual or (2) identifiable private information.”

Definition of Research According to FDA

Research is defined in the FDA federal regulations as any experiment that involves a test article and one or more human participants and that either is subject to requirements for prior submission to the Food and Drug Administration under Section 505(i), 507(d) or 520 (g) of the act, or is not subject to requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. Under FDA regulations the terms “research” and clinical investigation are synonymous.

FDA regulations define **subjects** as an individual who is or becomes a participant in research, either as a recipient of the test article or control. Subjects may be either a patient or a healthy human.

Jurisdiction of the IRB

Activities that meet the definition of “research” and “human subjects” as defined in DHHS regulations, or meet the definition of “research” and involve “human subjects” as defined in FDA regulations are subject to the ETSU or ETSU/VA IRB’s jurisdiction. Activities that constitute human subject research are determined by the ETSU and ETSU/VA IRB.

The IRB has the sole authority to make a final determination of whether a proposed activity is human research according to DHHS or FDA regulatory definitions. Unless you are familiar enough with these regulations to be certain that the activity does not represent human research, the activity should be brought forward to the IRB for a determination.

Janine Richardson
HRPP Director
(423) 439-6054
richardf@etsu.edu

Kasey Boyd-Smith
IRB Secretary
(423) 439-6053
boydsmit@etsu.edu

Becky Haas
IRB Coordinator
Medical Board
(423) 439- 6055
haasr@etsu.edu

Aracelis Vasquez
IRB Coordinator
Campus Board
(423) 439-6002
vasqueza@etsu.edu
Editor-in-Chief

Is My Proposal Research or Not?

Form 129

Any project meeting the definition of “research” and Human Subjects” according to DHHS or the FDA must undergo IRB review and approval before implementation. An initial IRB submission requires the researcher to complete several forms before the IRB can review and approve the proposal. However, when the researcher is not sure whether the particular project must undergo IRB review and approval, then a Form 129 can be completed and faxed to the IRB office instead of the required submission documents. This can avoid having to complete unnecessary documents should the proposal not meet the definitions stated earlier in this newsletter. After receipt of the form, the Chair will decide whether the particular proposal constitutes research involving human subjects. If the Chair determines that the proposal does not constitute human subjects research, then a letter will be mailed stating that the project does not meet the definition of human subjects research and therefore not under the purview of the IRB. However, should the Chair determine that the proposal is human subjects research, the PI will be mailed a letter stating that the activity meets the definition of human subjects research and must be submitted to the IRB for review. The proposed research cannot be initiated until IRB approval is received.



Did You Know???

when submitting a proposal that is either funded or submitted for funding, the title on the grant application must match all the forms submitted to the IRB.



Narrative Question of the month.....



Question 12b: Describe how the risks to participants are reasonable in relationship to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result.

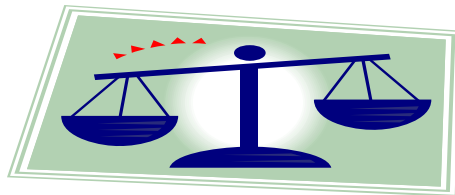
In evaluating this information, the IRB will consider if the importance of the research aims is clear and if the research is likely to achieve its proposed aims. Physical, psychological, social, economic and legal risks must be considered.

A. This question is looking for the validity of the study. The IRB must determine the following:

- ⇒ The likelihood and magnitude of the risks and potential benefits, and understand the importance of the knowledge reasonably expected to result.
- ⇒ the range of harm, including physical, social, economic, psychological, and legal harm.
- ⇒ the range of benefit. Benefit can take the form of therapy, education, information, resources or empowerment. The benefits can be directed at participants or their community as a whole.
- ⇒ The validity of research design must be taken into consideration in determining the risk benefit ratio.
- ⇒ What is the importance of the knowledge expected to result from the research?

B. When answering this question, consider the following:

- ⇒ Risks to participants; Narrative question # 10
- ⇒ Benefits to participants; Narrative question # 12
- ⇒ The importance of the knowledge that may be expected to result; Narrative question #5



Resource Available

Did you know that the IRB Office has provided graduate students and their Faculty Advisor with an **Graduate Brochure**? This provides all the information graduate students and their advisors needs to know about thesis and dissertation research involving Human Subjects. You can access the handbook through the IRB website under "Resource" or by going to <http://www.etsu.edu/irb/Graduate%20Brochure1%20updated%2062606.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).

Initial Submission Checklist

Forms Required for All IRB Reviews



- Form 103 with original signatures
- Project Narrative
- Conflict of Interest Form
- Copy of the Principal Investigator's CV/Resume
- Informed Consent Document (unless requesting a Waiver or Alteration of Requirement to Obtain Informed Consent) **Note:** The Chair makes the final determination of whether the request for a waiver can be granted. If request for a Waiver or Alteration of Requirement to Obtain Informed Consent is not granted, then an Informed Consent Document or Letter to Participants will be requested by the IRB Office.
- Advertisements intended for subject recruitment
- Final copy of Photo or video release, if applicable
- Any questionnaires, surveys, testing forms, data collection sheet, or introductory letters associated with this study and intended for subject use
- Grant Application (if any box other than the "Not Funded" box is marked on Form 103) *(if funded or submitted for funding, the title on the grant application must match all the IRB forms)*
- If the study is being conducted outside of ETSU, then permission letters from the institution(s) are needed

Additional Required Forms

Submit only if any of the following documents pertain to your research

- VA 10-1086 (for VA studies only)
- Complete Protocol, if applicable
- Investigator's Brochure (required if question # 7 on Form 103 is "yes")
- Unaffiliated Investigator Agreement Form (if any investigator not affiliated with ETSU, VA or MSHA)
- MSHA Research Request Form (MSHA Study Only)
- For 1572 (for Investigational Drug Studies)

Required for Studies Accessing or Disclosing Protected Health Information

- HIPAA Authorization to Use or Disclose PHI **OR** HIPAA Waiver



Initial Submission Checklist Continuation



Supplemental Forms

Submit appropriate supplemental form if the research involves any of the following Vulnerable Populations as participants

- Studies with Prisoner Participants
- Studies with Pregnant Women/Fetuses Participants
- Studies with Cognitively Impaired Participants
- Studies with Neonate Participants

Submit appropriate supplemental form if your research involves Drugs or Devices

- Studies involving Drugs
- Studies involving Device

Forms for Studies involving Children

Submit if your study involves Children as Participants

- Child Assent
- Supplemental Form for Studies involving Children

Once submission of forms is complete, the process stated in the July Newsletter will be followed.



Note

IRB training must be completed for ALL study personnel before final approval can be granted.

The Office for the Protection of Human
Research Subjects

PO Box 70565
Johnson City, TN 37614

Phone: (423) 439-6053
Fax: (423) 439-6060

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

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September 2006

Sun	Mon	Tue	Wed	Thu	Fri	Sat
					1	2
3	4 <i>Labor Day</i> <i>Office closed</i>	5 <i>Medical Meeting</i>	6	7 <i>Campus Meeting</i>	8	9
10	11 <i>Deadline for Full submission for October meeting</i>	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30

Coming Up Next Month

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

Coming Up in October

- TBA

Did you Know ????

that you can call or visit the IRB Office for help with completing any documents for submission. The IRB coordinator will be happy to assist you in any way to make the submission process easier.

