
THE IRB REVIEW

THE Office for the Protection of Human Research Subjects

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Project Narrative

The Project Narrative is one of the main forms submitted to the IRB for a study to be reviewed. The federal regulations require that the board members consider several approval criteria in order for a study to be approved. The narrative contains questions that help the board members make the appropriate determinations needed to approve a study. The following is an explanation of what the IRB is looking for when answering the questions on the narrative. The newsletter will start with question 2 since the response to question one is self-explanatory.

Message from the Director, Ms. Janine Richardson

Of all the forms submitted to the IRB for review, the project narrative contains the majority of the information needed to review a project. The regulations that govern research establish specific criteria that projects must meet in order to be granted approval by an IRB. This narrative is designed to facilitate clear communication of information relevant to these criteria to the IRB.

Some of the questions may be challenging, particularly to those new to the research process. It is our hope that this newsletter, written by the IRB Campus Coordinator, Aracelis Vasquez, will provide helpful explanatory information. In addition, the IRB staff is available to answer questions related to IRB submission of this and other forms.



Question 2

Project Title:

Hint: If any box is checked other than “Not Funded” on question 5 of the Form 103, the information below must be considered.

NOTE: If funded or submitted for funding, the title on grant application must match on all documents submitted.

NOTE: If funded or submitted for funding, the Principal Investigator on grant application must match the Principal Investigator on the Form 103.

Question 3a

Where will the study be conducted?

- ⇒ If studies are being conducted at ETSU, MSHA and/or the VA, then list department(s) if at ETSU, which institution if at MSHA or VA if at the VA.
- ⇒ If conducting research outside of ETSU, MSHA, and/or the VA (external sites), then complete the table provided on the form with the following information:

List each External Site	Permission Granted	Contact info for site	Is site engaged?	Does site have IRB?	If yes, had the site IRB approved research or does it plan to defer review to ETSU IRB or ETSU/VA IRB
List each external site being use	*If permission was granted, submit a permission letter from each site	Include a contact person in case the IRB has questions	Indicate whether the external site is “engaged” or not engaged. ** See below for definition of “engaged”	Indicate if external site has an IRB.	If external site has an IRB,, submit the IRB approval letter obtained from that IRB or IRBs If external site plans to defer review to ETSU or ETSU/VA IRB, submit a letter from that IRB

*If conducting the research in multiple schools from one school system, a permission letter from that particular superintendent is sufficient. Otherwise a permission letter from each site is necessary. These can be emailed, faxed or mailed to the IRB if not available at the time of submission.

**An institution becomes engaged in human subjects research when its employees or agents (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.

Question 3b

Is this a multi-site study?

A multi-centered study is one where different PIs at different institutions are conducting the same study.

For example: multi site clinical trial or a project performed jointly with another institution.

If the answer is “yes”, then complete the following questions:

1. **Are you the lead investigator?** This is asking if you are the lead person running the studies in the different locations.
2. **Which organization is the lead site?** This is asking which site is the lead site.
3. **If you are the lead investigator or the organization is the lead site, describe the management of information obtained in this multi-site research that might be relevant to the protection of research participants, such as unanticipated problems, interim results and protocol modifications.**

Question 4

List all study staff.

All study staff must be listed here by name and their role in the study. The IRB staff will complete the third column. Note that every study staff member **must** have current IRB training in human subject protection (training instructions and link available on the IRB website). Approval **will not** be issued until this requirement is met. If this is a VA study, answer the following question which is located below the chart:

If this is a VA study, indicate who will be conducting the consent interview or obtaining consent and explain the training provided.

The VA has the following requirement: “if someone other than the investigator will conduct the interview or obtain consent, the investigator must formally delegate this responsibility and the person so delegated must have received appropriate training to perform this activity.” Training must include current IRB certification and protocol-specific training.

Note to VA researchers

The VA requires that you complete training every year. For more information, contact the VA Administrative Office.



Study staff including the Principal Investigator must have IRB education completed before approval can be granted.

Question 5 and 6

The Objectives of the study are: Describe the purpose(s) of the study. Why are you conducting the research?

Summarize the study: Provide a brief description of the study. What is the study about? This does not need to contain a summary of background literature. It should just summarize the study itself.

Question 7

a: Identify the Participants: Check all that apply

The following populations require submission of an additional supplemental form with this application available on the IRB website:

- ⇒ Children/Minors
- ⇒ Pregnant Women/Fetal Tissue/Placenta
- ⇒ Prisoners
- ⇒ Cognitively Impaired

b: ONLY ANSWER IF VA STUDY: If this is VA Study, will non-veterans be Participating?

If using non-veterans, what is the rationale for using non-veterans in this study.

VA regulations state that non-veterans may be entered into VA approved research studies ONLY when there are insufficient veterans available to complete the study. Substantiate why there are insufficient veterans to complete the research.

c: Does the list of participants for this study include vulnerable populations?

These are populations that are likely to be vulnerable to coercion or undue influence. **For example:** children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons

If yes, describe the additional safeguards included in this study to protect the rights and welfare of the participants.

Describe what extra safeguards you will do to make sure these participants considered to be part of a vulnerable population are protected.

d: Describe how the selection of participants is equitable in relation to purpose of the research and the setting in which the research will be conducted.

Explain the scientific justification for the selection of participants. If participants of certain gender, age, groups, ethnic groups, socio-economic groups will be excluded, explain the scientific basis for the exclusion. The requirement for an equitable selection of subjects helps ensure that the burdens and

benefits of research will be fairly distributed. IRBs should consider the extent to which a proposed subject population is already burdened by poverty, illness, poor education, or chronic disabilities in deciding whether they are a suitable subject population. One group of subjects should not be asked always to bear the risks of research for the benefit of others.

Ex: conducting a survey of only 2nd grade boys, explain why other grades and girls will be excluded

e: Describe the specific steps used to identify and/or contact prospective participants.

Include who will make the initial contact and how will the contact be made. **For example:** will a list be provided?, will participants be called by phone?, etc. If there is contact with participants, but data about living participants is to be used, state this clearly and indicate there will be no actual contact.

f: If applicable, describe how you have access to lists of potential participants

Indicate who will give you access to the lists. If not applicable, indicate “not applicable”.

g: Will you be using letters, scripts, or advertisements?

This includes letters that will be sent to anyone who is to be considered to be a potential participant in the study, scripts of any kind and advertisements used to advertise the research to potential participants.

Provide a copy of any material with this application. In addition, the IRB must review and approve final copies of all audio and videotapes prior to use. The IRB will review the final copy of all advertisements, including print advertisements and audio/video tape for broadcast. If an advertisement is to be broadcast, the IRB may review and approve the wording prior to taping. The approval of the final taped message prepared from the IRB-approved text can be given through expedited review.

h: List criteria for inclusion and exclusion below or attach a copy of the criteria to this narrative. Include populations that will be excluded and included in the research.

Ex: Exclusion: Minors under the age of 18, **Inclusion:** Adults over the age of 18

i: Explain the procedures that will be used to determine eligibility

How will you determine who is eligible to participate in the study? How will you know who can participate in the study? How will you know who can participate in the study?

Question 8

a: Will non-English speaking participants be consented?

If enrolling populations whose first language is not English, provide a copy of the consent in both English and the appropriate language.

Department of Health and Human Services regulations for the protection of human subjects require that informed consent information be presented “in language understandable to the subject” (45 CFR §46.116 and §46.117).

If yes, how will they be consented? Describe how the Non-English speaking participants will be consented.

⇒ **Who will be providing translation as needed?** Indicate the name of the person providing translation services. This person is considered study staff.

⇒ **Describe the translator’s qualifications**
Indicate how this person is qualified to be a translator for the population chosen.

b: ONLY ANSWER IF VA STUDY: Will a VA consent form be required?

The only informed consent form the VA can recognize is the VA 10-1086 form. **If yes,** attach the completed VA 10-1086 form to this narrative.



c: Is a waiver or alteration of consent process or a waiver or alteration of consent documentation being requested? This is asking if you are requesting a **Waiver or Alteration of Requirement to Obtain Informed Consent** (which means no informed consent will be obtained from participants) or a **Waiver of Requirement for Written Documentation of informed Consent** (which means you are required to obtain consent, but not required to obtain the participants' signature)

If the answer to this question is "Yes", then a justification must be provided. The samples 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.

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 this determination is made, the PI 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 the research involves no procedures from which written consent is normally required outside of the research context because (**state your reason here**). **TIP:** Sample Plan located at www.etsu.edu/irb. Scroll down to "Waivers" and click on "Click here for sample plan". If using this sample letter, make sure to write it specifically for your research.

d: Are you requesting permission for consent by legally authorized representative? This question is asking if you are proposing to obtain permission from the legally authorize representative of the participants you are enrolling.

If yes, what is the rationale for this request?

If "yes", the IRB must approve enrollment of participants based on the permission of a legally authorized representative (LAR) before enrollment of participants using LAR can begin.

e: Who will be obtaining informed consent? This question is asking which members of the study staff will be going through the consent process with the participants. If a waiver is being requested, state that here.



Note: This person must be a member of study staff listed in question 4 and must have completed IRB education requirements.

f: Will the person obtaining consent have an existing relationship with the participant? This question is asking if the person or persons mentioned in question 8e have an existing relationship with the participants they are enrolling.

If yes, describe the relationship and how you will protect against undue influence or coercion.

This can include but not limited to: physician/patient, teacher/student, coach/athlete, lawyer/defendant, etc. This is to make sure undue influence or coercion are not present.

g: Describe the timing of the consent process and any waiting period between discussion and consent. Explain the timing between the time you discuss the study with the participant and the time they make their decision to participate or not participate.

The participants should be given sufficient time to make a decision on whether they want to participate or not. The participants should never feel coerced to participate because of lack of time in the process. However, there are times when situations warrant that a decision be made quickly. **Ex:** Cancer study.

h: Are there any anticipated circumstances under which the participant will be removed from the research by the investigator without the participant's consent?

Do you anticipate removing the participant for any reason without their consent?



If yes, list those circumstances

Note: The participants must be notified about the possibility of them being removed from the study for any reason by adding this information to the letter to participants or the informed consent document that will be given to participants.

Ex: no longer in the best interest of the participant; fails to follow protocol, etc.

Question 9

Describe what procedures the participant will be required to do. Describe what the participants are expected to do once enrolled in the study. **Examples:** complete a survey/questionnaire, attend an interview, attend a conference/workshop, etc.

Question 10

Specific risks to participants This is asking you to describe any risks to participants if they are enrolled in the research. Be sure to consider physical, psychological, economical, social and legal risks. If there are none, then say so. **Do not indicate NA.**



VS.



Question 11

a: How does this study use procedures which are consistent with sound research design and which do not unnecessarily expose participants to risks?

This is asking how the procedures and design of your study are minimizing the potential risks to participants. Be sure to consider physical, psychological, economical, social and legal risks. Can alternative or fewer procedures answer the scientific question and reduce the likelihood or magnitude of harm?

b: When appropriate, how does this study use procedures already being performed on the participant for diagnostic or treatment purposes?

Are procedures that can answer the scientific question being done anyway? If so, can the data from those procedures be used to reduce the likelihood or magnitude of harm? If none are being done, then state that.

Example: analyzing blood samples. Have participants had blood samples already taken from another procedure that can be used in the research?

c: Is the research more than minimal risk? If yes, does the research involve an intervention?

If yes to both questions above, is there a data safety monitoring committee or board to review the study for safety?



If yes, describe the timing of reviews and reports and planned interim analysis.

If no, provide a general description of the data and safety monitoring plan.

Definition of Minimal Risk: Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Note: Sample Plan located at www.etsu.edu/irb. Scroll down to “Data and Safety Monitoring Plans” and click on “Click here for sample plan”. You can make the initial evaluation but the IRB makes the final determination of risk level.



Question 12

a: Describe the benefits to participants.

What are the potential benefits to participants or society as a whole if this study is conducted?



Note: Include information about payment to participants or extra credit in question #13

b: 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. 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

Question 13

Describe any payments being offered, including method and timing.

Mention any payments being offered, and the method and timing in which the participants will be paid.



 **Note:** When participants must provide their name, address and social security number in order for them to get paid by check, this information must be disclosed in the informed consent document or letter to participants. This is always the case when issued by ETSU.

Describe how the payments are considered reasonable and commensurate with the expected contributions of the participant, and how the payments do not constitute undue influence or pressure.

This question is asking how the payment is considered appropriate to the expected contributions of the participants in the research. This question is also asking how the payment you are offering will not pressure the participants to get involved in the research.

Examples:

- ⇒ Economically disadvantaged participants might be pressured to participate if offered a considerable amount because they see it as a means of feeding their family or paying off bills.

If extra class credit is being offered, an alternative to participating in the research must be offered.

Describe the alternatives available for earning extra class credit.

Question 14

Will there be any additional costs to the participant that may result from participation in this research? If yes, describe those costs. If no, then move on to question 15.

This information must be added in the informed consent document or letter to participants.



Question 15

This is different than Confidentiality

Describe how the privacy of participants will be protected.

Privacy refers to the person rather than the data. Consider issues such as whether the participants will be comfortable in the research setting when completing a survey, questionnaire or being interviewed and whether the participants will think the information being sought is any of the investigator's business. **Examples:**

- ⇒ when participants are completing a paper survey or questionnaire or undergoing a physical exam, will the participants be in a private room? If not, how is their privacy maintained while completing the survey or questionnaire?
- ⇒ When participants are completing online surveys or questionnaires, will they be completing them in a place of their choice?

Question 16

This is different than Privacy

a:How will research data be recorded and maintained?

Are you recording identifiable information? How will you be maintaining the data collected during the course of the research?



What safeguards are in place to ensure confidentiality?

E.g. locking computer, logging off the computer after use, password protected computer access, locked office or storage cabinet)



b: Who will have access to the research information? List any person or persons, organizations, study staff that will have or may have access to the research information.

Always add:

- ⇒ DHHS- Department of Health and Human Services
- ⇒ Study Personnel (list of people from question 4)

Choose one of the following boards:

- ⇒ ETSU/VA IRB– for medical research
- ⇒ ETSU IRB for non-medical research

Include the following if conducting a VA study:

- ⇒ VA Research and Development, if VA study
- ⇒ GAO, - Government Accounting Office, if VA study
- ⇒ ORO– Office of Research Oversight, if VA Study

Include the following if conducting a study involving an investigational drug or device or if data from this study will be reported to the FDA:

- ⇒ FDA– Food and Drug Administration, if FDA regulated drug or device study or includes data being submitted to the FDA
- ⇒ **Add, if applicable:** Sponsor, if any

c: If identifiable information is to be retained, explain why it is necessary to the research to retain this identifying information.

If the research requires that you retain identifiable information (information that can possibly identify who the participants are), then an explanation must be given as to why this is important to the research.

d: Describe how the confidentiality of participants will be assured

How will the information obtained from the participants be protected?

⇒ **Include a description of any issues specific to the study that might increase the risk of loss of confidentiality** Is there anything specific that might increase the possibility of loss of confidentiality?

⇒ **If codes will be used to protect identities, describe how codes will be generated and who will have access to the codes.** What kind of code system will you be using to protect identities of the participants.



e: Will the data be electronically or physically sent to another location?

If yes, describe the provisions for transporting the data securely. How is the data going to be transported securely from one place to the other.



f: Does the protocol involve the use of identifiable data?

If yes, describe the provisions to destroy the identifiable data once it is no longer needed. Once the data is no longer needed , how is this data going to be destroyed?

Include provisions for secure destruction of electronic files. If you have electronic files, how are those files going to be destroyed?

g: Where will records be stored for the required period of 5 years?

Indicate where all the records will be stored after study is completed for the required number of years. Indicate a physical address.

h: Does this study include the use of audio or video taping? Yes or No

If yes, answer the following questions:

- ⇒ **Describe how the audio/videotapes will be stored.**
- ⇒ **Describe how the tapes will be disposed of when the research is complete.**



Question 17

Provide a bibliographic listing of pertinent literature.

This shows what you are basing the proposed study on and provides references for the IRB members when reviewing the study.



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April 2007

Calendar grid for April 2007 with days of the week and dates.

- 3- Medical Board Meeting
5- Campus Board meeting
6- ETSU Closed
9- Deadline to submit initial full reviews and continuation review for studies that expire in June 2007



May 2007

Calendar grid for May 2007 with days of the week and dates.

- 1- Medical Board Meeting
3- Campus Board meeting
14- Deadline to submit initial full reviews and continuation review for studies that expire in June 2007
28- ETSU CLOSED

Other Issues available on the IRB website for your information

- => November 2005: Who is AAHRPP?
=> December 2005: approval Criteria/New Narrative template
=> January 2006: Informed Consent Process
=> February 2006: Vulnerable Populations
=> March 2006: VA Submission
=> April 2006: Conflict of Interest
=> May 2006: Investigational Drug/Device
=> June 2006: After Approval Overview?
=> July 2006: Approval Process, Narrative Question of the Month, Required Elements for ICD, Additional Required Elements, and Additional Required Elements from the VA
=> August 2006: Definition of Research according to DHHS and FDA, Form 129, Narrative Question of the Month

