

APPROVAL OF RESEARCH

The ETSU and ETSU/VA IRB are required to make certain determinations before the IRB can approve any research. This includes **all** approval decisions, including initial full studies, initial expedited studies, changes to approved research, and continuing reviews, etc.

Those required determinations are found in the rules that govern research. Before the IRB can approve research, the IRB has to receive enough information to be able to determine if the study meets the criteria for approval.

§46.111 Criteria for IRB approval of research

(a) In order to approve research, the IRB has to determine that the following criteria are met.

(1) Risks to the subjects are minimized:

- (i) By using the procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and
- (ii) Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

This means the IRB needs to know the answers to these questions:

- How does this study use procedures which are consistent with sound research design and which do not unnecessarily expose participants to risks?
- Whenever appropriate, how does this study use procedures already being performed on the participant for diagnostic or treatment purposes?

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When evaluating whether risks to participants are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk, the IRB will consider:

- Can alternative procedures answer the scientific question and reduce the likelihood or magnitude of harm?
- Can fewer procedures answer the scientific question and reduce the likelihood or magnitude of harm?

When considering risks, the IRB will evaluate physical, psychological, social, legal, and economic risks.

When evaluating whether risks to participants are minimized whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes, the IRB will consider:

- Are procedures that will answer the scientific question being done anyway?
- If so, can the data from these procedures be used to reduce the likelihood or magnitude of harm?

Again, the IRB will evaluate physical, psychological, social, legal, and economic risks.

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(2) Risks to the subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.

That means the IRB needs to know the following information:

- What are the objectives of the study?
- What are the specific risks to participants?
- Description of the benefits to participants?
- Description of 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.

When evaluating whether risks are reasonable in relation to benefits, if any, to participants and the importance of the knowledge that may reasonably be expected to result, the IRB will consider:

- Is the importance of the aims clear?
- Is the research likely to achieve its proposed aims?

In making this determination, the IRB will consider:

- Physical, social, psychological, legal, and economic risks
- Direct potential benefits to participants, if any.

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(3) Selection of Subjects is Equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted. The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.

The IRB needs to know the following information:

- Identify the participants.
- Does the list of participants for this study include vulnerable populations (populations that are likely to be vulnerable to coercion or undue influence such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons) Yes No
If yes, describe the additional safeguards included in this study to protect the rights and welfare of the participants.
- Describe how the selection of participants is equitable in relation to the purpose of the research and the setting in which the research will be conducted.
- Describe the specific steps used to identify and/or contact prospective participants.
- If applicable, describe how you have access to lists of potential participants.
- Will you be using letters, scripts or advertisements? Yes No
- List the criteria for inclusion and exclusion below or attach a copy of the criteria to this narrative. Inclusion/exclusion criteria attached OR List:
- Explain the procedures that will be used to determine eligibility.

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(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116

(5) Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117.

The IRB needs the following information Related to the Informed Consent Process:

- Will non-English speaking participants be consented? Yes No
 - If yes, how will they be consented?
 - Who will be providing translation as needed?
 - Describe the translator's qualifications.
- Will a VA consent form be required? Yes No
 - If yes, attach to this narrative
- Is a waiver or alteration of the consent process or a waiver or alteration of the consent documentation being requested? Yes No
 - If yes, justify the request the waiver request.
- Are you requesting permission for consent by legally authorized representative? Yes No
 - If yes, what is the rationale for this request?
- Who will be obtaining informed consent?
- Does the person obtaining consent have an existing relationship with the participant? Yes No
 - If yes, describe the relationship and how you will protect against undue influence or coercion.
- Describe the timing of the consent process, and any waiting period between discussion and consent.
- Are there any anticipated circumstances under which the participant will be removed from the research by the investigator without the participant's consent?

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

The IRB needs to know the following information:

- Is the research more than minimal risk? Yes No
- Does it involve an intervention? Yes No
- If yes to both, is there a data safety monitoring committee or board to review the study for safety? Yes No
 - 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.

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(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data

The IRB needs to know the following information:

Subject Privacy

Describe how the privacy of participants will be protected. (Note: privacy is about the person and their rights as opposed to confidentiality, which is about data).

Participant Confidentiality

- How will research data be recorded and maintained?
- Who will have access to the research information? (Include DHHS and study personnel; FDA if this is FDA-regulated drug or device study or includes data being submitted to FDA; ETSU IRB if non-medical research; ETSU/VA IRB if medical research; VA Research and Development, ORO and GAO if VA study; and sponsor)
- If identifiable information is to be retained, explain why it is necessary to the research to retain this identifying information.
- Describe how the confidentiality of participants will be assured. Include a description of any issues specific to the study that might increase the risk 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.
- Where will records be stored for the required period of 6 years? (if appropriate, include department, building and room number)
- Does the study include the use of audio or video taping? Yes 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.

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Additional Protections

When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.