



Institutional Review Board

IRB Approval Criteria Guidance for Initial Submissions

Overview

This guidance document is designed to provide investigators with an overview of the parameters that IRB members (and staff) will consider when reviewing your applications to the IRB to determine that appropriate approval criteria (as defined in the regulations) are met.

Criteria for approval FOR ALL APPLICATIONS TO THE IRB – regardless of minimal or greater than minimal risk (NOTE: appropriate supportive information must be provided in the application to the IRB from the Investigator to assure that all applicable criteria are met):

1. Risks to subjects are minimized:

- a. This criteria is determined to be met by the Investigator designing the research in a way that assures the following: By proposing only procedures which are **consistent with sound research design** and which **do not unnecessarily expose subjects to risk**

DO INCLUDE IN PROCEDURES	DO NOT INCLUDE IN PROCEDURES
<ul style="list-style-type: none">•An explanation for why all proposed procedures are necessary to answer the research question(s)•An overview of the expected risks, as well as a commentary on any unexpected risks•A plan for mitigation of any risks likely to result from study procedures	<ul style="list-style-type: none">•Procedures that appear unnecessary•Procedures that do not align with the research objectives

- b. Whenever appropriate, by using procedures already being performed on the subjects for clinical purposes

→ **RESULT: clearly distinguish between:**

- 1) Procedures that would occur **regardless of** the research;
- 2) Procedures that occur **specifically for / differently because of research** aims
(E.g. timing/frequency altered, procedure added, etc.)

2. Risks to 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.

→ **RESULT:** recognize that **every research study carries some risk** (however limited); therefore:

- 1) Be sure to **account for all risks**; and
- 2) Explain why **risks are appropriate** to incur from subjects based on how they balance **with the potential benefit**
(E.g. potential direct benefit to the subject; benefit of learning information for generalizable knowledge, etc.)

3. Selection of subjects is equitable.

→ **RESULT:** must **make an argument for who you need to include** in the study **and why** (i.e. how it aligns with the objectives); this also includes:

<p>1) Adequate rationale for who is being excluded, considering that those who may benefit without experiencing undue risks should be included; and</p> <p>2) Adequate rationale for the inclusion of any vulnerable populations (I.e. Both those defined in the regulations – that is, pregnant women, children, & prisoners – as well as those who are potentially uniquely vulnerable to coercion when consenting, like Penn affiliates, educationally/socially/monetarily disadvantaged persons, etc.)</p>
<p>4. Informed consent will be sought and properly documented (or determined to be appropriate to waive documentation) from each prospective subject or the subject's legally authorized representative.</p> <p>➔ RESULT: outline the clear plan for obtaining consent, including:</p> <p>1) The plan for re-consenting on an ongoing basis; and</p> <p>2) The plan & rationale for any waivers/alterations of consent (E.g. potential direct benefit to the subject; benefit of learning information for generalizable knowledge, etc.)</p>
<p>Additional approval criteria when research is likely to be assessed as greater than minimal risk:</p>
<p>5. The research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.</p> <p>➔ RESULT: outline plan for how to collect, assess, document, & share information from subjects in real-time to mitigate risk (as well as a plan for taking action in the event of consequential findings indicate changes are needed)</p>
<p>6. There are adequate provisions to protect the privacy of subjects AND to maintain the confidentiality of data.</p> <p>➔ RESULT: differentiate the plans for both privacy and confidentiality in the application (including considerations of appropriate locations for consent, information-sharing, procedures, etc.)</p>
<p>Potential IRB member/staff assessments regarding meeting approval criteria after review of your application:</p>

