

INSTITUTIONAL REVIEW BOARD
Research Proposal Review Criteria

The following are the criteria that will be considered during the review of your human subject research proposal.

Research Design:

The hypothesis is clear, and clearly stated.

The study design is appropriate to prove the hypothesis.

The research will contribute to generalizable knowledge and is worth exposing subjects to risk.

Risk:

Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects.

Risks to subjects are reasonable in relation to the importance of knowledge that may reasonably be expected to result.

Subject Selection:

The subjects are appropriate for the protocol.

The subjects are a vulnerable population that might be susceptible to undue influence or coercion.

Safeguards are in place to minimize the possibility of coercion.

Privacy and Confidentiality:

Personally identifiable research data will be protected to the extent possible from access or use.

Special privacy or confidentiality issues are properly addressed.

Informed Consent contains the following statements or explanations:

The study involves research.

The purpose of the research and the expected duration of the subject's participation.

The procedures to be followed and identification of any procedures that are experimental.

Any foreseeable risks or discomforts, their likelihood, and steps to prevent or minimize them.

Any benefits that may be expected from the research. (Compensation is not a benefit.)

A statement describing to what extent records will be kept confidential, including who may have access to records.

For research with more than minimal risk, what treatments and/or compensation are available, and from whom.

PI and IRB contact information for questions about the study or about the rights of the research subject.

Participation is voluntary, and refusal to participate or discontinuing participation at any time will involve no penalty.

Remuneration, and how it will be paid, if applicable.

There is a request to waive or alter a consent requirement.

There is a children's assent form if the subjects are minors; and a consent form for their guardian.

The consent and/or assent form is written in age-appropriate language and is understandable.