

IRB Policy #:	250
Policy Title:	<i>Full Board Review Research</i>
Date Approved:	
Date Reviewed:	

Purpose: To describe research that requires review by the full Board.

Policy:

The IRB may require full review of any research submitted or approved under expedited review and any research not approved by expedited review.

The primary criterion for full board review is the risk to subjects, including not only the procedures followed but the interaction between research procedures and the populations being studied.

Examples of research activities that must be reviewed by the full IRB include:

- a. Research in which potential subjects may not be given sufficient information to make decisions about whether to participate and accept potential risks. This may include research in which outright deception or incomplete disclosure of the purpose of the study might reasonably affect a person’s decision to participate in the study.
- b. Research involving more than minimal risk, where defined as “the probability and magnitude of harm or discomfort are not greater in and of themselves than those ordinarily encountered in the daily life or during the performance of routine physical or psychological examinations or tests”.
- c. Non-curricular, interactive research in primary and secondary schools.
- d. Research in which participation per se in the study constitutes a risk (e.g., identification as a subject in a drug-use survey). This would include research in which researchers have applied for a waiver of documentation of consent, which can be used as a method of reducing risks to subjects who may be placed at risk simply by being involved in the study.
- e. Some research involving special populations, e.g., children, pregnant women and mentally incompetent persons.
- f. Research involving potential risks to subject’s right to privacy and/or threats to confidentiality.

When IRB protocols are reviewed by the full board, related continuing review and amendment requests and safety event reports shall continue to be reviewed

by all members of the committee prior to the meeting.

A majority of the IRB constitutes a quorum and is required in order to convene a meeting for the review of research protocols. At least one non-scientist and one scientist must be present at the convened meeting before the IRB can conduct its review of research.

Before a research application can be approved, it must receive the approval of the majority of those voting members present at the convened meeting.

The IRB will make one of four determinations regarding an application:

Forward for approval without questions, concerns, or requests for modifications.

Provisional approval. The research activity may not be undertaken until the IRB's concerns are addressed and submitted to the designated IRB member for review and approval.

Postpone. This action is used if quorum is lost and therefore, review of the application cannot proceed. The application returns to administrator review and will be rescheduled for the next meeting.

Table. This indicates approval by the IRB has been withheld as substantive concerns or significant requests for clarification have been raised and/or the proposed research does not meet University or Federal guidelines for the protection of human subjects. The research activity may not be undertaken until the IRB's concerns are addressed and submitted to the full IRB for review and approval.

Disapprove. The IRB may disapprove a proposed activity with serious and substantive problems and/or that fails to meet University or Federal guidelines for the protection of human subjects.

Approval of the proposed research is usually granted for a period of one year commencing on the date of the convened meeting of the IRB at which the protocol was reviewed and approved. Based upon an assessment of the degree of risk to human subjects or of protocols with a high risk to potential benefit ratio, the IRB may specify special conditions whereby the investigator has a shorter approval period or must report research progress at specific intervals.

Investigators will be notified of the IRB's decisions in accordance with 45 CFR 46.109(d).

Criteria for IRB approval of research include the following:

Risks to subjects are minimized by using procedures that are consistent with sound research design and do not unnecessarily expose subjects to risk.

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 from the research.

Selection of subjects should be conducted in an equitable manner and recruitment procedures should be free of coercion.

The proposed research considers the privacy rights of subjects and protects their confidentiality. Privacy refers primarily to the methods used to obtain information about subjects; confidentiality to the methods used to ensure that information obtained by investigators is not improperly divulged.

The IRB must ensure that the researcher has made adequate provision to protect the privacy of subjects by considering:

- the private nature of any information sought
- the likelihood that subjects would consider the release of information as an invasion of privacy
- the importance of the research
- the availability of alternative ways to conduct the study

Because IRB approval must be secured when a researcher wishes to access existing records to identify subjects for participation in a study and will record subjects' names or use other methods of identification for follow-up, the Board must determine if subjects' consent must be secured by considering the following:

- the sensitivity of the information to be reviewed
- the vulnerability of the subject population
- the purpose for which the investigator wants access to the information

Special Populations. When some or all of the subjects are likely to be vulnerable to coercion or undue influence (such as children, pregnant women, handicapped or mentally disabled persons, or economically or educationally disadvantaged persons), additional safeguards must be included in the study to protect the rights and welfare of these subjects. (46 CFR 46(Subparts B, C, D))

The IRB must ensure that appropriate procedures are included to protect the confidentiality of the study data and subjects' identities. Researchers are encouraged to apply for "Certificates of Confidentiality", which protect investigators against compelled disclosure of identifying information about subjects, under the Public Health Service Act of 301(d), 42 USC 241(d) when research is especially sensitive and confidentiality cannot be guaranteed.

Review and approval of research requires that the investigator follow the procedures and policies laid out in this document.