

The Institutional Review Board

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Background¹

Federal law requires that researchers get approval from an Institutional Review Board (IRB) before conducting any research that involves human subjects. The law applies only to research that is funded or regulated by the federal government but even most privately funded institutions, professional associations, and industry journals rely on some type of IRB approval process.

An IRB is a standing committee established by the “institution” sponsoring the research. Thus, every major university, government agency and private corporation that engages in human subject research will have its own IRB. Each institution’s IRB reviews all research proposals involving human subjects in order to ensure that the “protocol,” or procedures of the research, adequately protects the subjects.

The Board is required to have at least five members, both men and women from varied professions with at least one member who is not a scientist, one who is, and one person who is not affiliated with the institution at all. They should have diverse backgrounds with some experience in the types of research being reviewed and be sensitive to community attitudes and vulnerable populations.

IRBs are quite powerful. They have the authority to approve research, reject it, require modifications, require ongoing monitoring, and to terminate research already in progress. Typically, any decision by an IRB is accompanied by a justification or a list of reasons why the Board decided as it did. Researchers use this feedback to modify or create new research proposals.

Decision Criteria

Review Boards must consider several aspects of the research when deciding whether or not to permit it, including:

- **Risk vs. Reward**
 - Does the proposal identify all the potential risks?
 - Does the protocol minimize the risks?
 - Are the potential benefits worth the risks?
- **Selection of Subjects**
 - No discrimination by gender, race or ethnicity.
 - Safeguards for vulnerable populations.
 - Benefits distributed fairly (i.e. not testing a population that couldn’t benefit from the results)
 - Privacy of subjects adequately protected.
- **Informed Consent**
 - Do subjects agree to participate?
 - How is assent documented?
 - If deception is required, is it warranted?
- **Research Design**
 - Are the methods scientifically valid enough to warrant the risks?
 - Is the primary investigator (PI) qualified for this kind of research?

- How will the data be collected and stored?

Research Exempt from Review

A representative of the IRB, usually the chairperson, will review each proposal submitted to the IRB and decide if the proposal should be reviewed by the full committee, get an expedited review or if it is exempt from IRB review altogether.

If a research proposal meets certain criteria, it can be exempted from IRB review but only the IRB can make this determination so *all relevant research proposals still need to be submitted to the IRB*. Proposals that involve little risk may receive an expedited review by just two or three board members. Research that involves vulnerable populations or some other increased risk factor will be reviewed by the full IRB.²

The criteria for exempting research include:

1. When “conducted in established or commonly accepted educational settings, involving normal **education practices** such as research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.”³
2. When using **existing data**, records, documents or pathological or diagnostic specimens.
3. Research conducted or approved by government department or agency heads that examines **public benefit or service programs**.
4. Educational tests, surveys, interviews, or observation of **public behavior** when:
 - a. Subjects cannot be identified or linked to their response.
 - b. Subject participation does not expose them to criminal or civil liability, damages their financial standing, employability or reputation.
5. Research that is not exempt under #4 above may still be exempt if the subjects are elected or appointed public officials or candidates running for **public office**.

Research involving vulnerable populations such as pregnant women, fetuses, prisoners, children and anyone who is unable to understand the risks involved and therefore cannot provide *informed* consent cannot be exempted from IRB review.

Deceptive Research

Researchers may submit proposals in which the subjects are not told the true nature of the research. Usually, subjects are misled in some way and their response to an unexpected event is what is being studied. While this seems to violate the principle of informed consent, it is not sufficient grounds for rejecting a proposal. In cases where deception is involved, IRBs will look closely at several other factors:

- Are sufficient steps taken to inform subjects that they can **withdraw** from the experiment at any time? If so, this can satisfy the informed consent requirement because the participant knows they can stop at any time.
- Are the subjects properly **debriefed**? At the conclusion of the study, researchers should explain the deception, why it was necessary, and the true objective of the study.
- Could the deception inflict **harm** on subjects? In this case, the deception itself is added to the risk side when weighing the risks and benefits of the research. Do researchers take proper steps to counter any ill effects the deception may have on the subjects?

Again, the IRB weighs the potential risks versus the benefits of the research to make a decision on whether to allow the research to proceed and under what conditions. Except in this case, the deception itself is treated as an additional risk factor.

Responsibilities of the Primary Investigator (PI)

The person responsible for the research must protect the rights and welfare of the subjects at all times. The PI is also responsible for understanding the ethical standards and regulations governing research, including the role of the IRB, and for educating his/her research staff on these matters as well.

The role of the IRB does not end with a rejection or approval of research. Indeed, it is the responsibility of the PI to inform the IRB of any deviations from the approved protocol or of any unanticipated results. Once research has begun, early results may necessitate a change in protocol. Any changes must have IRB approval before being implemented. Likewise, any unexpected results that may have adverse physical or psychological effects on subjects must be reported to the IRB.

Consequences

If the IRB procedures are not followed properly, the results could include:

- Suspension of the research.
- Suspension of all the PI's research projects.
- Inability of publish or use results.
- Debarment from federal grant process.
- Termination of employment.
- Loss of licenses.
- Shut down of all research at the institution.

¹ Much of the information contained in this summary was derived from an excellent online course found at www.citiprogram.org. By submitting an email address users can step through a demo of the class with details about IRBs and human subject research in general.

² At NCSU an expedited review usually takes 2 to 4 weeks and a full review up to 6 weeks. For details on the NCSU IRB process, see www.ncsu.edu/sparcs/policy/policies.html

³ Quoted from citiprogram website.