The Ethical Conduct of Research/IRB

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Ethics

Every academic discipline involved in the study of human behavior has a code of ethics.

- Ensure that participation is voluntary, confidential, and harmless.
- Ensure that participants understand the research procedures and any risks involved.
- Promote research accuracy, honesty, and truthfulness.
- Study and report data on many issues that are crucial for the optimal development of all people.

Feldman, 2009
Protecting human participants is critical for ethical reasons, but also for ensuring good science.
Belmont Report (1979)

- Released by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, this document provides the ethical framework for human participant protection.

NSF Requirements

“All projects involving human subjects must either:

1) have approval from an Institutional Review Board (IRB) before issuance of an NSF award;

OR

2) must affirm that the IRB has declared the research exempt from IRB review, in accordance with the applicable subsection, as established in section 101(b) of the Common Rule.”

National Science Foundation, 2016
Common Rule for Protection of Human Subjects

- There are six categories of research that qualify for exemption (summarized below):

**Category 1:** Research conducted in established or commonly accepted educational settings, involving normal educational practices

**Category 2:** Research involving the use of educational tests, surveys, interviews procedures, or observations of public behavior unless data is identifiable, could make participants liable, includes minors and entails interaction with the investigator

**Category 3:** Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observations of public behavior that is not exempt under #2 of this section, if: (i) the human participants are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

**Category 4:** Research involving the collection or study of existing data, documents, records, etc if sources are publicly available or if participants are non-identifiable

**Category 5:** Research and demonstration projects conducted/approved by dept or agency heads, and are designed to study, evaluate, or examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services; (iii) possible changes/alternatives to those programs/procedures; (iv) possible changes in methods or levels of payment for services
Informed Consent

• APA's Ethics Code mandates that psychologists who conduct research should inform participants about:
  ✓ The purpose of the research, expected duration and procedures.
  ✓ Participants' rights to decline to participate and to withdraw from the research once it has started, as well as the anticipated consequences of doing so.
  ✓ Reasonably foreseeable factors that may influence their willingness to participate, such as potential risks, discomfort or adverse effects.
  ✓ Any prospective research benefits.
  ✓ Limits of confidentiality, such as data coding, disposal, sharing and archiving, and when confidentiality must be broken.
  ✓ Incentives for participation.
  ✓ Who participants can contact with questions.

APA, 2011
Important considerations regarding consent

K-12

• The regulation is Title 34, Code of Federal Regulations, Part 97, Protection of Human Subjects, which includes Subpart A, Basic Policy, and Subpart D, lists Additional Protections for Children.
  • Assent procedures
  • State-Mandated reporting

Higher Education

• Participants under 18 require parental consent
• Consider allowing participants to opt in or out of specific aspects of data collection
• FIRPA
• Withdrawal from participation
Successfully navigating the IRB process

1. Determining Human Subjects Research
2. Completing Required Training for Conducting Research
3. Determining Exempt, Expedited or Full Board Review
4. Understanding the Submission Process
5. Post-Approval Reporting
1. Determining Human Subjects Research

Office for Human Research Protections (OHRP) provides charts to guide investigators in determining if an activity is research involving human subjects that must be reviewed by an IRB under the requirements of the U.S. Department of Health and Human Services (HHS) regulations at 45 CFR part 46.
2. Completing Required Training for Conducting Research

Most institutions require that all research personnel complete the Collaborative IRB Training Initiative (CITI) Basic Human Subjects Protection course before beginning human subjects research. The CITI course and exam are web-based and can be accessed at www.citiprogram.org. All the modules listed for your institution must be completed. Most modules include a short quiz. An aggregate passing score of 80% is required.
3. Determining Exempt, Expedited or Full Board Review Status of a Study

The federal regulations (45 CFR 46) allow certain categories of minimal risk research to be reviewed as “Exempt” but the research must still undergo IRB review to ensure ethical standards are met. “Expedited” refers to the quicker IRB review process. Full board
4. Understanding the Submission Process

This will be specific to your institution. The IRB usually meets on a pre-specified schedule, and you are required to submit specific forms prior to review; including copies of your recruitment materials, consent forms, and measures. This is an example of the process at my institution:
5. Post-Approval Reporting

NSF will require Assurance of Compliance and institutions typically provide a letter that will meet the requirements. It is important to follow guidelines for storing consent forms, and maintaining data security. IRB requires reports of Adverse Events, and annual Continuing Review.

**adverse events:** things that have happened that pose unanticipated problems that may confer risk to participants or others

NOTE: Typically, “Exempt” research does NOT require continuing review
Ethical considerations are imbedded in NSF’s required data management plan

• The plan must include:
  - the types of data, samples, physical collections, software, curriculum materials, and other materials to be produced in the course of the project;
  - the standards to be used for data and metadata format and content
  - policies for access and sharing including provisions for appropriate protection of privacy, confidentiality, security, intellectual property, or other rights or requirements;
  - policies and provisions for re-use, re-distribution, and the production of derivatives;
  - plans for archiving data, samples, and other research products, and for preservation of access to them.
Ethics and IRB concerns relevant to the new requirement that data be shared

• **Data Management for NSF EHR Directorate**

“Data on EHR projects involving human subjects should be made available to the public subject to constraints imposed by IRB decisions. Other data, such as software, publications, and curricula, should be made available subject to intellectual property rights. Any data collection required by the program announcement should be incorporated into the proposal’s DMP. For example, the management of assessment, evaluation, or monitoring data required for all projects within a given program should be addressed in the data management plan. “

• **Example of reviewer feedback on a recent submission:** “The team plans to archive data privately and share data on request. While acceptable, the panel would like the data to be more accessible.”
Challenges to Meeting NSF and IES’ data sharing requirements
Resources

• Belmont Report

• Office for Human Research Protections
  • https://www.hhs.gov/ohrp/

• National Science Foundation
  • https://www.nsf.gov/bfa/dias/policy/human.jsp