

Requirements for Research on Human Subjects

QEM Network

CAREER Workshop

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Ethics issues may arise in the practice of STEM (research and education) as well as in the many relationships and interactions among STEM professionals and the general public.

Overview

- Basic Principles of Human Subjects Protection
 - Persons should not be subjects of research without their **informed consent**
 - Subjects should **not incur increased risk of harm** from their research involvement, beyond the normal risks inherent in everyday life
- **What are the regulations** regarding research involving human subjects?
- **Who decides** what is appropriate?

NSF PROPOSAL REQUIREMENTS

If the proposal includes use of Human Subjects, supplemental information is required.

<http://www.nsf.gov/bfa/dias/policy/human.jsp>

Human Subjects/IRB: NSF Guidelines

Proposal submitters will want to review the NSF guidance on research that includes Human Subjects <http://www.nsf.gov/bfa/dias/policy/human.jsp> and the requirements that need to be addressed for award consideration

- compliance with the regulations regarding human subjects' research - NSF Proposal & Award Policies & Procedures Guide (PAPP),

NSF 10-1, GPG Chapter II, Section D.7

http://www.nsf.gov/pubs/policydocs/pappguide/nsf10_1/gpg_2.jsp#IID7

and AAG Chapter VI, Section B.1

http://www.nsf.gov/pubs/policydocs/pappguide/nsf10_1/aag_6.jsp#VIB1

WHAT ARE THE REGULATIONS?

Projects involving research with human subjects must ensure that subjects are protected from research risks in conformance with the relevant federal policy known as the Common Rule (Federal Policy for the Protection of Human Subjects, 45 CFR 690)

http://www.access.gpo.gov/nara/cfr/waisidx_99/45cfr690_99.html

WHO DECIDES?

All projects involving human subjects must either (1) have approval from the organization's Institutional Review Board (IRB) before issuance of an NSF award or, (2) must affirm that the IRB or an appropriate knowledgeable authority previously designated by the organization (not the Principal Investigator) has declared the research exempt from IRB review, in accordance with the applicable subsection, as established in section 101(b) of the Common Rule.

What are the regulations around research involving human subjects?

- “The Common Rule” is used by 18 US federal agencies to govern research involving human subjects
- The Common Rule has 4 subparts
 - Subpart A – all research governing human subjects
 - Subpart B – research on fetuses, neonates, and pregnant women
 - Subpart C – research with prisoners
 - Subpart D – research with children
- Your institution may adhere to subpart A or all of the other subparts

Goals of the Common Rule

- RESPECT FOR PERSONS' AUTONOMY
 - adequate and comprehensive information about the research and any risks likely to occur, understandable to the participant, and allows them to voluntarily decide whether to participate.
- BENEFICENCE
 - the research is designed to maximize benefits and minimize risks to subjects and society.
- JUSTICE
 - the research is fair to individual subjects and does not exploit or ignore one group (e.g., the poor) to benefit another group (e.g., the wealthy).

Purpose of Regulations

- The regulations balance the risks of harm to individuals with the possible benefits from the research results.
- Level of risk is determined not by how likely the risk is to occur, but the amount of harm likely from the risk
 - Minimal Risk - “The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.” (§ 690.102 (i))

Types of Harm

- There are several types of “harm” that are more than minimal that can occur in social science and education research.
 - ***Emotional or psychological harm***, for example when a research interaction causes upset, or worry about breach of confidentiality.
 - ***Social harm*** due to stigma or other negative social outcomes of breach of confidentiality.
 - ***Physical harm*** if revelations about others get back to those persons, particularly when researchers study domestic violence, gang activity, political activity in a conflict zone, or other phenomena concerning violence-prone individuals.

(NSF FAQ)

Types of Harm (CONTINUED)

- ***Financial harm*** if revelations result in loss of employment or insurance coverage.
- ***Legal harm*** when illegal activities are disclosed.
- ***Moral harm*** when participation in research strengthens subjects' inclinations to behave unethically.

(NSF FAQ)

What types of research are exempt?

- Research in educational settings involving educational practices. (§ 101 (b) (1))
- Research involving educational tests (cognitive, diagnostic, aptitude, achievement), surveys, interviews, or observations of public behavior, unless subjects are identified and disclosure of responses would involve more than reasonable risk. (§ 101 (b) (2))
- Research involving educational tests (cognitive, diagnostic, aptitude, achievement), surveys, interviews, or observations of public behavior not exempt under preceding exemption if human subjects are elected public officials, and if federal statutes require confidentiality of identifiable information. ((§ 101 (b) (3))

What types of research are exempt?

- Research involving the collection or study of existing data if publicly available or unidentifiable. ((§ 101 (b) (4))
- Research and demonstration projects designed to study public benefit or service programs. ((§ 101 (b) (5))
- Taste and food quality evaluation and consumer acceptance studies. ((§ 101 (b) (6))

YOU DO NOT DECIDE IF YOUR RESEARCH IS EXEMPT!!!!

You must still submit an application to your Institutional Review Board (IRB)* claiming it is exempt. The IRB makes the final determination. Having your research classified as exempt relieves you of further oversight from the IRB.

*IRBs review research protocols and designs and ensure the protection of the rights of human subjects

Institutional Review Board

- Each institution is responsible for convening a committee that will execute the Common Rule for that institution
- The application and review procedure is different at each institution but includes common elements
- NSF will not release funding to your institution without confirmation of IRB approval of the research/evaluation

Expedited Review

- Many IRBs offer expedited review, particularly for social science and non-medical research with less risk of physical harm.
- Contact your IRB to determine if there are different requirements for expedited review

IRB Requirements

- An application describing the general process for data collection and analysis
 - How participants will be recruited, including compensation
 - How informed consent will be obtained from adults and children, including the level of risk to participants and potential benefits to participants and society
 - A copy of all data collection instruments (tests, surveys, interview questions, observation instruments, etc.) and description of procedures
 - How data will be stored and who will have access to it
 - Anonymity in data collection
 - Confidentiality of identifiable data

Recruitment and Compensation

- How will you get participants to participate in your research?
 - Advertising, direct invitation
 - Many IRBs discourage use of your own students
- Who will be included and who will be excluded? Is this process fair?
 - Will particular groups be excluded and why?
 - Will this research include protected populations (including children)?
- Will there be any compensation for participation?
 - If so, is the amount offered coercive?
 - If a person drops out during the study, will they still be compensated?

Risks and Benefits

- What are the risks to the participant and how will they be mitigated?
 - Minimal risk or greater than minimal risk?
 - If greater than minimal risk, how is the investigator going to attempt to prevent any risk?
- What are the benefits of this research?
 - To the participant, if any?
 - To society in general?

Informed Consent

- How will you inform the participants and obtain consent for their participation?
 - Notify them of their commitments
 - Notify them of any risks and how you will address them
 - Notify them of any benefits
 - Describe any compensation and what is necessary to receive compensation
 - Who to contact if they have any questions, including contact information for the IRB
- **NOTIFY THEM THAT THEY MAY STOP AT ANY TIME WITHOUT REPERCUSSIONS**

Data Collection and Analysis

- What data are you collecting?
 - Copies of all tests, surveys, interview questions, observation instruments, and other data collection tools
- Who will be collecting the data?
- Where are you collecting data? How are you collecting data?
- How are these procedures going to ensure confidentiality or anonymity?
- How will compensation be made?

Data Storage and Access

- Where will the data be stored? How will confidentiality be ensured?
- How long will the data be kept?
- Who will have access to the data?
- How will the data be disposed of when the study is complete?
 - Note: Federal funding agencies have requirements that data be kept for a period of time after the end of funding (currently 3 years)

Other Information the IRB May Request

- Approval from cooperating institutions:
 - School districts
 - Other universities
- Evidence that the investigators have had training in the ethics of research involving human subjects
 - Many institutions have online examinations or courses

Human Subjects Certification Training

- National Institute of Health Office of Extramural Research
<http://phrp.nihtraining.com/users/login.php>
- New York University
www.nyu.edu/ucaihhs/tutorial
- University of Washington
www.washington.edu/research/hsd/training_citi.html

The Collaborative Institutional Training Initiative (CITI) offers a web-based training program in research ethics education, including the protection of human research subjects.

“CITI is a volunteer organization whose goal is to develop and distribute high quality, peer reviewed educational resources designed to raise awareness to the Responsible Conduct of Research for all members of the research team. CITI maintains an educational website where participating organizations can design and roll out a customized curriculum for their investigators, students staff and administrators.”

<https://www.citiprogram.org/aboutus.asp?language=english>

Other Issues that Arise

- International Research
 - Many other countries do not have IRBs and review procedures. Consult with your IRB about how to handle international research.
- Deception
 - There are situations in which you may wish to tell the participants untruths in the course of the research (e.g., stereotype threat research). How will you handle debriefing of the participants once the research is complete?

**For more information on the
Common Rule and the IRB, see
NSF's Frequently Asked
Questions (FAQs) and Vignettes:**

<http://www.nsf.gov/bfa/dias/policy/hsfaqs.jsp>



NO QUESTIONS, RIGHT?

THANK YOU!

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Human Subjects/IRB Sec. 690.107

IRB Membership

(a) Each IRB shall have at least **five members**, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.

Human Subjects/IRB Sec. 690.107 IRB Membership (continued)

- (b) Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. No IRB may consist entirely of members of one profession.
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- (c) Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.
- (d) Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.
- (e) No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.
- (f) An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.