Northeastern University
Human Research

Guidance: Designing human subject research

Note: Regardless of whether research study meets the federal definitions of research and human subjects, measures must be taken to ensure research participants are treated with respect and that their rights and welfare are considered during every stage of the research. The Belmont Report identifies three principals that are to be considered. Individuals should have the choice to participate in the research after being full informed of all study components (respect for persons), that the benefits of the research out-weigh the risks associated with the research (beneficence), and that the selection is equitable (justice).

There are lots of areas to consider when developing a research study and this document can be used as a guide of items to consider when planning your project. The information provided on the completed form will be reviewed to ensure the rights and welfare of participants are protected, study benefits outweigh study risks, and there are plans to protect the privacy of participants and confidentiality of their data.

Study Purpose

Consider what it is you intend to study:

- What are your research questions and study aims?
- What information do you need to help answer these questions?
- What are the ways in which you can collect this information? What resources do you need?

Training & Experience

Investigators, including student researchers, should have the experience to complete the research and collect data.

- Have you completed the required human subject research training?
- Do you need to complete additional CITI modules due to the nature of your research? For example, international research, internet-based research, vulnerable populations.

Subject Population

Consider participant number and characteristics:

- Approximately how many participants do you anticipate enrolling in the study?
- Will all participants be adults? If not, how will you obtain both child assent and parent permission?
- Are there any specific selection criteria based on age, sex/gender, race/ethnicity, participation in a program, etc.?
- Will you need to utilize or be helped by other institutions – school, hospital, corporation, or other relevant organization?

Recruitment & Voluntary Participation

Researchers should design their studies to minimize the risk of coercion or undue influence and always emphasize to potential participants that taking part in the project is voluntary.

- What methods will be used to recruit participants: posted flyer; script read by a researcher in person; email invitation; social media?
- Is there a possibility of *real or perceived* coercion, and if so, what measures will be put in place to minimize this?
- Will participants be recruited by someone who might unduly influence them to participate? And if so, can this be avoided?
- How can prospective participants be protected from feeling influenced or compelled to participate when they might not want to?

Vulnerable Populations

Vulnerable participants are individuals who are likely to be susceptible to coercion or undue influence (e.g., students, subordinates, patients). Vulnerable populations also include individuals whose autonomy is limited (e.g., children, cognitively impaired people, prisoners).

Restrictions and/or special considerations may apply where certain characteristics render populations vulnerable:

- Children: When recruiting children, both parents and their children must be involved in the recruitment process. Minors are not eligible to participate in research without a parent's permission (unless waived by the IRB). In some cases, both parents/guardians need to give permission.
- Adults living in potentially coercive conditions – e.g., nursing home residents, half-way house residents.
- People who have experienced or now have: major injuries or acute or chronic disease; disabilities that interfere with the quality of their lives; homelessness; undocumented status; or stigmatized identity.

Procedures & Data Collection

Consider what participants will be asked to do, what will be done to them, or what information will be gathered:

- How frequently and over what time period will interviews, tests, etc., be conducted? Will there be breaks?
- Where will research be conducted? If interviews will be conducted, how will interviewees be made comfortable? What privacy (if any) will be available?
- Are interviews to be audio and/or video recorded? This should be disclosed ahead of time to participants and their agreement obtained as part of the consent process.

- If recordings will be made, where will these recordings be stored? Do you have plans for transcription? If you wish to have the option to use recordings in the future, you should tell participants this and obtain their consent.

Informed Consent

Participants must be fully informed of all aspects of the research so they may understand what they are consenting to and know their decision is voluntary with no (perceived or actual) coercion or undue influence.

- How will you inform participants about your research and then obtain their consent (e.g., orally, in writing, in person, by phone, by email)?
- Will you ask participants to sign a written document – a consent form? (A valid signature is required unless waived by the IRB.)
    - Whether the consent process includes a signed consent form or not, you should give participants a document that repeats the explanation of the research, identifies you, and provides contact information.
- If children are recruited, they may also have to agree to participate via an *assent* form and process.
    - In addition, one or both parents must provide consent to their child's participation (unless waived by the IRB), even if the parents themselves are not recruited to be study participants.
- Consent language should be as simple and straightforward as possible, and appropriate for the level of literacy, education, etc. of the participants.
- Will language translation/interpretation be needed? Is there any language barrier that could affect the consent process? If so, be sure to address this and, if needed, make plans for use of translators and translated documents.
    - Complete a Certificate of Translation form, as applicable.

Deception

Consider whether the study will involve either active deception or incomplete disclosure that is likely to significantly mislead participants.

- What is the nature of the deception or incomplete disclosure?
- Is it likely to be significant to participants? If yes, is there another way to conduct the research that would not involve deception or incomplete disclosure, and, if so, why have you not chosen that alternative?
- Will participants be "debriefed" or receive information about the research project following its conclusion?

What explanation for the deception or incomplete disclosure do you give to participants following their participation?

Study Sites

- Will approval from other universities, organizations, international sites, K-12 schools, etc. be needed? Will they need to provide a letter of support?
- Are there any local laws that could impact your ability to complete the research, e.g., are there any special governmental permissions that are needed?

International Sites

- Is any of the research conducted outside the United States? If yes, complete an International Research Form.
- Describe your knowledge and familiarity of the local context, including cultural norms.
- Is there a local ethics committee or equivalent IRB that must also review the proposed research?
- Is a local contact identified and shared with the research subjects (e.g., on the consent form?
- Are there any local laws that could impact the research, (e.g., PIPL, GDPR)?

Confidentiality

- Will you use a key or code to identify participants? How will you securely store the information that links codes to identifying information (names, addresses, SSNs)?
- Will the research data be collected and stored in a manner to keep it separate from the information (names, etc.) that uniquely identify participants?
- For online studies, will IP addresses or other potentially identifying information be collected? What host site will be used (e.g., SurveyMonkey, Qualtrics, iCommons, etc.)? Will those identifiers be removed from the data? If so, at what point, and if not, why must identifiers be retained?
- Where will data be stored, who has access, and how will it be secured?
- Will research data be destroyed at the end of the study? If not, where and in what format and for how long will the data be stored? To what uses – research, public performance, archiving – might the data be put in future?
    - Note: Refer to the investigator manual for guidance on which research data must be retained past the end of the study.
    - Note: You should obtain participants' permission for possible future use of their data, even if de-identified.
- If there is a key code connecting participants' data to their identity, when will the link be destroyed? Include this information during consent process.

Compensation

It is acceptable to provide compensation to participants, but you will want to eliminate any perception of coercion.

- Are participants offered any material inducement to participate? (This includes rewards and gifts, not just money.)
- If participants are paid, what amount, when are they paid, and what is the payment method (gift cards, cash, etc.)?
- Is there partial payment for partial completion? Are payments pro-rated?
- If recruitment material mentions compensation, is it over-emphasized?
- Is there a risk that the compensation might be large enough to induce someone to participate when participation might be against their own best interests?

Data Security & Management

Whether your project needs IRB review or not, breach of confidentiality is a serious risk posed to participants. Rigorous data security is a key element of protecting subject data from an accidental or malicious breach. Data security includes:

- A plan to manage the physical and electronic documentation associated with the project, such as paper surveys, signed consent forms, or documents that contain contact information for subjects and
- Steps to ensure that those materials are not lost or accessed inadvertently by an unauthorized person.

The management of electronic data (on desktops or servers as well as on mobile devices such as laptops and flash drives) is increasingly important. See the Data Classification site for information on how to protect your data, links to University resources, and more on your responsibilities as a researcher.