Considerations for Social-Behavioral Research

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Objectives

- Learn about how the IRB reviews:
  - Common research designs including surveys, interviews, ethnography, implementation science
  - Consent and waivers
  - Vulnerable populations

Surveys and Interviews

Confidential vs. Anonymous

Confidential: Identifiable information collected and known to the researcher.

- Example: An online survey that collects email for follow-up or compensation.

Anonymous: Data is often considered anonymous (in regulatory or IRB contexts) if the identity of the subject cannot be readily ascertained by the investigator or linked with the data, either directly or indirectly (e.g., through codes or identifiers).

- Example: Online survey that doesn't collect IP addresses or identifiers.

IRB Considerations

Ask if the participant could be re-identified with this data point--Think through the entire data lifecycle.

Make sure the consent form aligns with actual data collection procedures when claiming anonymity or confidentiality.

Technical Cautions

- Be cautious about indirect identifiers that can still reveal a person's identity.
- Check if online survey platforms collect IP addresses.
- Audio, video, and photo data is always identifiable.

Ethical responsibility. Affects consent, risk level, and review category.

Waiver of Documentation of Consent

A **Waiver of Documentation of Consent** is when a participant will not provide a consent via a written signature or electronic signature. Consent will be obtained online, verbally, etc.

Explain why a waiver of documentation of consent is needed on the protocol (signature may be cumbersome but still feasible).

Use the appropriate consent block on the consent doc.

Waivers and Alterations of Consent

Waivers and **Alterations** of Consent is when omitting certain information in the consent process is necessary to render the research feasible and to produce valid data by using Deception or Incomplete Disclosure.

- Deception: Purposely misleading participants
- Incomplete Disclosure: Withholding some aspect of the research

To request an Alteration of Consent, answer all five questions in protocol section 14.0 justifying why it is needed.

- Include additional language in the consent that is specific for deception or incomplete disclosure.
- Submit Debrief form (HRP-1726) to eIRB.

Audio/Video Recording

Protocols should describe the type of recording planning to use, why the type of recording is necessary to the research, device used to record, and whether the recording is mandatory or optional to participate in the research.

How the recordings are going to be used, public presentations or publications—consent needed, storage, access, and how long they'll be kept.

Consent should include the type(s) of recording, how it will be used, and if mandatory/optional to participate.

Transcription Services

When using a transcription service, name the service that will be used and describe how it will be used in protocol and consent.

- When using a transcription service or tool, you may need to consult with Data Services to confirm if the tool/service is approved.
- Add a summary from DS in the protocol and consent form.
- Include a link to the transcription service's terms & conditions in the consent.

Ethnography

Ethnography

- When do you need consent?
  - Defining human research
    - Generalizable and Systematic?

    - Interacting or intervening with participants?
    - Collecting data about people that is private AND identifiable?

Ethnography

- When do you need consent?
  - Defining human research
    - Generalizable and Systematic?
    - Interacting or intervening with participants?
    - Collecting data about people that is private AND identifiable?
- But what counts as public?

Ethnography

- When you do need consent

Ethnography

- When you do need consent
  - Exempt Research
    1. An explanation that they are being asked to participate in a research study.
    2. The identity and affiliation of the researcher.
    3. A clear description of the study procedures and how data will be used in the future.
    4. A statement that participation in the research is voluntary.
    5. Contact information for questions and concerns about the research.

Ethnography

- When you do need consent
  - Secondary participants

Implementation Science

Implementation Science

- Implementation science is the scientific study of methods and strategies that facilitate the uptake of evidence-based practice and research into regular use by practitioners and policymakers.
- This means that we take strategies that we think will work and bring them into real-world settings to see how they operate on a practical level.
- At Northwestern, we do this in a variety of settings, particularly in hospital/clinic setting as well as classrooms.

https://impsciuw.org/implementation-science/learn/implementation-science-overview/

Implementation and the IRB

- When bringing implementation science projects to the IRB, we have some considerations we need clarified
  - Which procedures are Human Subjects Research?
  - Who are the participants?
  - What is the current standard practice?
  - Is the new procedure a research procedure or a new initiative that is becoming the new standard practice?

Human Subjects Research?

- A lot of implementation ends up being what we call Quality Improvement/ Quality Assurance.
  - https://irb.northwestern.edu/docs/hrp-1906-guidance-qi-pe-and-research.pdf
- What this looks like is that a new evidence-based practice is being rolled out with administrative support that will affect all people in the setting such as clinicians/patients or teachers/students
- For something to be called QI/QA, we need to make sure that the purpose of the initiative is not to be generalizable, but instead, to improve the practices by the initiating institution.

Who are the participants?

- If the reason for initiating a new process is generalizability, we need to look at who is the participant or subject.
  - Ex: a new mandatory class for doctors that improves patient care would mean that doctors and patients are considered participants because we're looking at outcomes for both
  - Look at the data you're hoping to collect. That should determine who the participants are

Obtaining Consent

- Some implementation measures seek consent from all participants. Some require waivers.
- If the team believes it is impracticable to obtain consent from a specific population, a waiver can be requested.
  - This is likely the case if all employees now have to take a class as part of their job requirements or if the implementation is environment-based and would not be possible to avoid.

What if a project is both QI/QA and research?

- Sometimes, the actual processes are not HSR because they are being rolled out as new policy or as new practice, but we still want to make generalizable conclusions about how certain populations have been affected.
- It's important in these cases to explain to the IRB what is considered research and what is not.
  - Refer to the HSR Determination form and the QI vs Research guidance

Vulnerable Populations

Vulnerable Populations

- Federally protected categories
  - Children
  - Prisoners
  - Pregnant People
  - Situationally vulnerable persons
    - Students and Employees

- Broader considerations of vulnerability
  - Legal status

Vulnerable Populations

- Children
  - Additional federal regulations apply
  - Excluded from most exemption categories
  - Requires review by a children's reviewer
  - Parental Consent/Child Assent
  - When does it go to Panel?

Vulnerable Populations

- Prisoners
  - Additional federal regulations apply
    - Must be research is seeking to answer a question about prisoners
  - Cannot be exempt
  - Requires review by a prisoner's reviewer
  - Will be reviewed by the Panel

Vulnerable Populations

- Students and Employees

Vulnerable Populations

- Collecting information on illegal behavior

Vulnerable Populations

- Collecting information on illegal behavior
- Immigration status

Questions?