Transcript: Ethics of Research with Human Participants
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SLIDE 1:
If your research includes doing a survey or any other method that involves human subjects, you need to be aware of the ethical issues involved.

SLIDE 2:
- You are required to follow guidelines for conducting research when that research involves human participants. The guidelines include:
  - U.S. federal regulations and
  - DSU policies and procedures
- Research involving human subjects must be approved by Dakota State University’s Institutional Review Board (IRB). The IRB is a committee designated to review your research to ensure that human subjects are protected.
- So that you understand the reasons behind the regulations, policies, and procedures, DSU researchers – whether students, faculty, or staff – must go through web-based training called the CITI program before doing research on human subjects.

SLIDE 3:
- CITI training covers:
  - The history & background related to protecting human subjects – Why guidelines exist – and
  - Specific regulations and guidelines that guide your research practices and guide the work of the Institutional Review Board.

SLIDE 4:
- To ensure protection of human participants in research, universities (and other agencies sponsoring research) must have Institutional Review Boards (IRBs). An IRB:
  - Is an independent committee with minimum of 5 members
  - Serves as “human subjects advocate” – Its role is to protect human subjects
  - Reviews research projects submitted by student, faculty or staff researchers
  - Has authority to approve, require changes to study procedures, or disapprove research projects
  - Reviews projects for compliance with institutional policies, state/local/federal laws, and ethical principles of the Belmont Report.
At Dakota State University, the IRB review process protects rights and welfare of human subjects

- Your research involving human subjects *cannot* be conducted without the approval of the IRB at Dakota State University
- Approval by the DSU IRB requires submission of a Human Subjects Application
  - Which can be obtained by contacting irb@dsu.edu

I currently serve as chair of the IRB at DSU, so I am very familiar with the process of review and what is needed from you, the researcher. Here is my advice.

When preparing an application for IRB review:

- Fully describe your research protocol
- Be sure that your application adequately addresses the key issues that IRB will need to know that:
  - risk is minimized
  - risks are reasonable in relation to benefits
  - selection of subjects is equitable
  - informed consent will be sought and documented [include copy of consent form or other consent plan]
  - adequate provision for safety of subjects is ensured
  - adequate protection of privacy and confidentiality is provided
  - researcher is adequately trained and qualified.

Sloppy applications will delay approval.

- A poorly developed and described research protocol creates great concern for the IRB because it implies lack of preparation and competency for carrying out research with human participants.
- IRB reviewers will have to ask questions if key information is missing
- A literature review is not required in the application for review by the IRB. However, citing some of the key literature demonstrates that you know the literature and are not wasting the time of the research participants through ignorance and inadequate preparation.
IRB reviewers have full-time jobs and are busy be considerate by not wasting their time with a haphazard application.

SLIDE 8:
In summary, you must protect human subjects.

- To adequately project human subjects, you must understand what you are required to do and why.
- To gain that understanding, you need to complete the web-based CITI training program provided by DSU.
- If your research involves human participants, DSU policy requires you to complete CITI training.
- Contact irb@dsu.edu to learn requirements and to get application forms for review of your research by Dakota State University’s Institutional Review Board.