Shawnee State University Institutional Review Board

HUMANS ARE PEOPLE, TOO!

PRESENTED BY: DR. SHARON EAVES
Former CHAIR OF THE SSU IRB 2012
Updated by Dr. Tim Hamilton
Chair of the SSU IRB 2021

What is the job of the IRB?

- **Must approve all <u>research</u> with <u>human subjects</u>**

Research - A systematic investigation designed to contribute to generalizeable knowledge, when you obtain data through interactions

- *Will it be published?*

Human Subjects - A live individual or obtaining identifiable private information from a live individual

Why does the IRB exist?

- **1950—1970s Willowbrook**
  - **Mentally Disabled Kids infected with hepatitis, not treated**
- **1930—1970s Tuskegee Syphilis Experiment**
  - **Poor black men not treated for syphilis**
- **1971 Stanford Prison Experiment**
  - **Male college students assigned to be a guard or prisoner; guards quickly began to mentally abuse prisoners**

Seemingly Innocent Studies Can Be Dangerous

- Risks in exercising with elderly
- Unauthorized release of personal data
- Admitting criminal acts in a survey
- Asking children about experiences with potential abusers

What are the primary ethical principles that the IRB is examining?

1. Respect for persons
2. Beneficence
3. Justice

How to Find Information About the IRB

- Go to the Shawnee State University Page
- Then type in Institutional Review Board in the search box in the top right hand side (or type IRB)
- The first result will be our webpage (the next six will also get you there)
- There are several pages: submit an application, federal guidelines and Belmont report, and NIH human research training are particularly important

https://www.shawnee.edu/about-us/provost/institutional-review-board

Types of Review

- Exempt Review (no risk)-Takes 1 week
- Expedited Review (minimal risk)-Takes 2-3 weeks
- Full Review (greater risk or vulnerable pops)-Application must be submitted 7 days before a scheduled meeting (see webpage for dates)
- Continuing Review (every 12 months)

Types of Exempt Studies

- Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special education instructional strategies, or (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Types of Exempt Studies, Cont.

- Research involving the use of educational tests (e.g., cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (a) data obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (b) any disclosure of the human subjects' responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation. No videotaping or photography is allowed for data collection.

How do I apply?

- You need human subject training on web
  - These certificates must be submitted with the applications.
  - The certificate will be valid for 3 years and will be on file.
- Applications must be fully completed and either emailed (with attachments) to IRB@shawnee.edu or to dhowell@shawnee.edu in Provost's office.

  Exempt Application Form (on website)
  - Expedited and Full Review Application Form (on website)

How do I apply, Cont.

- All student researchers must have a faculty advisor
- Faculty members have the ultimate responsibility for the research being conducted ethically
- Researchers will be invited to attend the Full Review Meetings
- You must get approval from IRB before you can contact the potential research participants

Vulnerable Populations

- Children: Need parent consent form and child assent forms
- Mentally Impaired (can include older adults): Need consent of custodian and participants
- Prisoners: need full review and prisoner representative

Elements of Informed Consent

1. **Study Title**
2. **Performance Site**
3. **Investigators**
4. **Purpose of the Study**
5. **Subject Inclusion**
6. **Number of subjects**

Elements of Informed Consent, Cont.

7. **Study Procedures**
8. **Benefits**
9. **Risks**
10. **Right to Refuse**
11. **Privacy**
12. **Signatures**

Elements of an Assent Form

- Usually, assent forms are only used for children ages 5-17
- Assent forms should include only the most relevant parts of the consent form: purpose of study, procedures, right to refuse, direct benefits, and risks to child.
- These forms should be written to be easily understood by the children.

Questions or Comments?

THANK YOU FOR YOUR ATTENTION!