Topics

• Research Compliance Services at UNL

• CITI Training

• Basics of the IRB Process

• Approvals/permissions from multiple sources

• Examples

• Websites
Research Compliance Services

- Conflict of Interest
- Export Control
- Responsible Conduct of Research
- Research Misconduct
- IRB
Research Compliance Services at UNL

- Human Research Protections Program (HRPP)
  - Institutional Review Board (IRB)

- Conflict of Interest (COI)
  - Conflict of Interest in Research Committee (CIRC)

- Export Control

- Responsible Conduct of Research (RCR)

- Research Misconduct
CITI Training

• Human subjects research:
  – Group 1 (Biomedical) or Group 2 (Social/Behavioral) completion depending on the nature of the person’s research

• Conflict of Interest

• Responsible Conduct of Research
  – Course is labeled Biomedical

http://www.citiprogram.org
Basics of IRB Review Process

1. General Project Information

1. Project Title:

2. Principal Investigator and 3. Secondary Investigator:

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<tr>
<th>Principal Investigator:</th>
<th>Decky Freeman</th>
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<tr>
<td></td>
<td><a href="mailto:ofeeman@uni.edu">ofeeman@uni.edu</a></td>
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<td>402 472 0127</td>
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<th>Secondary Investigator:</th>
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4. Type of Project:

5. Does the research involve an outside institution or agency other than UNL?

   Yes

6. Where will participation take place (e.g., UNL, at home, in a community building, schools, hospitals, stores, phone, union, etc.)? Please specify and give location if not already listed above.

7. Briefly describe the facilities available for the research (e.g., there will be a quiet room in the school to conduct interviews, a secure lab space is available, etc.)
Definition: Research

• As defined in 45 CFR 46.102(d):
  A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.
Definition: Human Subject

• As defined in 45 CFR 46.102(f):

A living individual about whom an investigator (whether professional or student) conducting research obtains

– Data through intervention or interaction with the individual, or

– Identifiable private information
Categories of Review

- Not Human Subjects
- Exempt
- Expedited
- Full Board
Participant Population Characteristics

• Children

• Prisoners

• Targeting certain ethnic or racial groups
  – Targeting other groups of people

• Pregnant Women, Fetuses, Neonates

• Vulnerable Populations

• Others
Informed Consent
Approvals/Permissions from Multiple Sites

- Organization Permissions
- School District Permissions
Example

A professor in the engineering department has developed a new device for cell phones which can track if the person is texting while driving. She needs people to test the device and has decided to make it a class requirement for students in her class. The students are asked to plug the device into their phone and test it while they are driving around town.
Useful Websites

- Office of Research:
  http://research.unl.edu

- UNL IRB:
  http://research.unl.edu/researchresponsibility/the-institutional-review-board-at-unl/

- Office for Human Research Protections (OHRP):
  http://www.hhs.gov/ohrp/index.html
Research Compliance Services
Human Research Protection Program
402-472-6965
irb@unl.edu