History of Research Ethics

- 1932-1972: Tuskegee Syphilis Study
  - 40 year study carried out by the U.S. Public Health Service
  - 400 low-income African-American males with syphilis
  - Free medical examinations, but subjects not told about their disease
  - Even though a proven cure (penicillin) became available in the 1940s, the study continued without the participants knowing about the effective treatment.
History of Research Ethics

- **1974: National Research Act**
  - National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research
  - Charged with identifying the basic ethical principles and to develop guidelines
  - Drafted the Belmont Report

- **1979: Belmont Report**
  - The foundational document - ethics of human subjects research in the US
  - Three basic ethical principles
    - Respect for Persons - Informed consent
    - Beneficence - Risks and Benefits
    - Justice - Selection of subjects

- **1981: 45 CFR 46**
  - CFR (Code of Federal Regulations)
  - DHHS (Department of Health and Human Services) and FDA (Food and Drug Administration) issued regulations based on the Belmont Report
  - Details out IRB membership, function, review
  - Includes criteria for approval
  - Review categories (exempt and expedited)
  - Informed Consent requirements and documentation
  - Vulnerable populations

What is an IRB?

- IRB (Institutional Review Board)
  - Protect rights and welfare of research subjects
  - Ensures research is conducted in accordance with all federal, state, and local law, institutional rules and ethical guidelines.
  - Reviews and approves research prior to initiation
What is an IRB?

- IRB (Institutional Review Board)
  - Independent committee
  - Weighs risks and benefits
  - Includes affiliated and non-affiliated members
  - Includes scientific and non-scientific members

Which review category?

- Which review category?
  - Excluded
  - Exempt
  - Expedited
  - Full Board

Do I need IRB Review?

- Must meet 2 definitions:
  1. Research -
     - “a systematic investigation...designed to develop or contribute to generalizable knowledge”
  2. Human Subject -
     - “a living individual about whom an investigator conducting research obtains:
       (1) data through intervention or interaction with the individual, or
       (2) Identifiable private information”
- If doesn’t meet both definitions, is deemed Excluded from IRB review
Exempt/Expedited

- Must meet “minimal risk” definition:
  - “The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests.”
- Fit specific categories
- Main difference
  - Exempt – no expiration date
  - Expedited - has an expiration date of no greater than 1 year

Full Board

- Decided by 1 or both IRB chairs
- Common research:
  - Vulnerable populations such as:
    - Children, pregnant women, prisoners, decisionally impaired
    - Greater than minimal risk
    - Sensitive issues, risky procedures or harmful effects
    - Deception

Full Board

- Review occurs monthly
- Due date is date of IRB meeting the month prior, typically 4-5 weeks
- Closed meetings, but researchers typically invited if there are questions about the protocol
- Response to PI within 1 week of the meeting
Previously Approved Protocols

- Modifications
  - Must be submitted for ANY change in the research
  - Submit Modification Form and revised version of all documents affected by the change
- Continuing Review
  - Submitted via Continuing Review form to extend the research approval

How long does review take?

- Depends on multiple factors
  - Level of review
  - Condition of proposal
  - All documents submitted
  - Current review time

UNLV IRB

- Two Institutional Review Boards (IRB)
  - Social/Behavioral
    - Education, Psychology, Social Work, Business, Hotel, Anthropology, Sociology
  - Biomedical
    - Allied Health Sciences, Kinesiology, Physical Therapy, Nursing, Community Health Sciences, Dental School, School of Medicine OR Studies that include biomedical procedures/devices
  - Meetings held monthly for each board – even during the summer
How and what to submit?

- **How?**
  - IRBNet
    - Web-based paperless system
    - Forms are downloaded from IRBNet
    - All protocol materials are uploaded
    - Reviews occur within the system
    - Students must submit with a faculty member as the Principal Investigator (PI)
    - PI must be registered in the IRBNet system in order for student to “share” the protocol

- **Protocol Proposal Form - Most comprehensive form**
- **Informed Consent**
  - Parent Permission and Child/Youth Assent for those under 18 YO (NV)
  - templates/samples in IRBNet
- **Recruitment materials**
  - flyers, email script, brochures, verbal script, etc.
- **Instruments**
  - survey, interview guide, focus group guide, data collection sheets
- **Facility Authorization Form (Facility Acknowledgment when CCSD research)**
  - When conducting research OFF of the UNLV campuses
- **Copies of CITI training are not required, unless it was taken at another institution**
- **Other documents as needed**

Common Pitfalls

- **Supporting documents not included**
- **Subject Selection**
  - Not equitable
- **Difficulty in Evaluating Study Design and Quality**
  - Unclear, not thorough
  - Should answer: who, what, where, when, and how
- **Consistency between documents**
  - protocol form, consent documents, and recruitment
References

- OHRP website:
  - www.hhs.gov/ohrp/
- FDA website:
  - www.fda.gov

Questions?

- Contact the Office of Research Integrity – Human Subjects:
  - 702-895-2794
  - IRB@unlv.edu