Research Ethics & Tips for Successful IRB Review

Quick Guide for Researchers

UNLV Office of Research Integrity – Human Subjects

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Objectives

- History of Research Ethics
- What is an IRB?
- IRB Review Categories
- UNLV IRB
- How and what to Submit
- Common Pitfalls

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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 1940's, the study continued without the participants knowing about the effective treatment.

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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

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History of Research Ethics

- **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
- **45 CFR 46**
  - Details out IRB membership, function, review
  - Includes criteria for approval
  - Review categories (exempt and expedited)
  - Informed Consent requirements and documentation
  - Vulnerable populations

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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

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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

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Which review category?

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

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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

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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

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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

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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

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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

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How long does review take?

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

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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

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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

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How and what to submit?

- **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**

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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

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References

- Bankert, E.A., & Amdur, R.J. (2006). Institutional Review Board: Management and Function (2nd ed.). Sudbury, AMA: Jones and Bartlett Publishers.
- OHRP website:
  - www.hhs.gov/ohrp/
- FDA website:
  - www.fda.gov

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Questions?

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

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