UCLA IRB Review: Tips for Conducting Risk Assessments and Determining Level of Review

UCLA K30 Training Program
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Learning Objectives

- Define human subject (HS) research and explain the role of IRB
- Define “risk” in the context of HS research
- Discuss how to conduct a risk assessment
- Determine the level of IRB review based upon performing a risk assessment
Human Research Is... any research or clinical investigation that involves people or identifiable data from people.
Research” is a **systematic investigation**, including research development, testing and evaluation, designed to develop or contribute to **generalizable knowledge**.

- **Systematic Investigation**: a proposed research plan that incorporates data collection & analysis

- **Generalizable Knowledge**: designed *with intent* to draw general conclusions (beyond population(s) studied), inform policy, and/or disseminate findings.
What is a Human Subject?

A **living individual** about whom an investigator conducting research obtains data:

- Through an *intervention* or *interaction* with the individual, or
- Access to identifiable, *private information*.

45 CFR 46.102(f)
Guidance Documents

Guidance and procedures website:
http://ohrpp.research.ucla.edu/pages/policies-guidance

- Determining Which Activities Require UCLA IRB Review
- Determining When Use of Data and Specimens Requires IRB Review

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Institutional Review Board (IRB)?

An independent internal review committee

- **Composed of**
  - institutional members (UCLA faculty) with relevant expertise and
  - at least one nonaffiliated member and
  - at least one nonscientific member

- **Reviews proposed human subjects research**
  - conducted by UCLA faculty and students
  - regardless of funding source and
  - usually regardless of performance site

- **Based on federal criteria, IRB has the authority**
  - to approve,
  - require changes
  - or disapprove human research.
Role of the IRB

Promote the rights and welfare of human subjects in research & support and facilitate the conduct of human research at UCLA by:

- Applying ethical principles to the conduct of research
- Assuring federal criteria for approval of human subjects research are met
Belmont Ethical Principles

- **Beneficence** (*be nice*)
  - Do no harm
  - Minimize risk/maximize benefits

- **Respect for Persons** (*be respectful*)
  - Individuals should be treated as autonomous agents (choice)
  - Individuals with diminished capacity are entitled to additional protections

- **Justice** (*be fair*)
  - Fair distribution of risks and benefits of research
IRB Criteria for Approval: Assessing Risks & Benefits

- **Focus on risks associated with the research**, as distinguished from the risks of procedures the subjects would receive even if not participating in research.

- Determine that the **risks are minimized** to the extent possible.

- **Maximize the probable benefits** to be derived from the research.

- Determine that the **risks are reasonable in relation to the benefits** to subjects, if any, and the importance of the knowledge to be gained.

- Assure that potential subjects are provided with an **accurate and fair description of the risks** or discomforts and the anticipated benefits (informed consent).
Identification of Risks

- **Risk**: The probability and magnitude of harm or injury occurring as a result of participation in research.

- **Consider all harms:**
  - **Physical harms**, e.g., pain, discomfort; side effects of drugs or procedures
  - **Psychological harms**, e.g., undesired changes in thought processes (depression, stress, guilt, loss of self esteem)
  - **Social/Economic harms**, e.g., breaches in confidentiality that could result in social embarrassment or stigma; risks to insurability or employability
Assess the type of harms associated with the research and the probability and magnitude of harm that could result from participation.

Attempt to minimize risks and maximize benefits:
- Consider changes to research design; inclusion & exclusion criteria; subject monitoring; stopping rules & endpoint criteria.
Conducting a Risk Assessment

in four easy steps…
Step 1: Identify and Assess Risks

Identify and distinguish risks associated with:

- Procedures performed solely for research
- Procedures or therapies subjects would receive even if not in research
- Procedures that are experimental or investigational

- Conventional (standard of care) procedures:
  - Are they performed solely for research purposes?
  - Will they occur even if a person is not participating in the study or are they required by the study protocol?

- When performed for the research study, they need to be considered a part of the risk assessment.
Step 2: Context in Which Research is Performed

- Are research procedures added to a conventional (standard) care event?
  - Examples: extra blood draw at routine draw; additional time in CT scanner for research imaging; additional biopsies; longer anesthesia time to measure O2 saturation levels
Step 3: Subject Population

Consider the subject population:

- Age, health status?
- Are they more sensitive or vulnerable to the risks posed by the research?
- How are they identified and recruited?
- Should additional protections be place to minimize risks and maximize benefits?
Step 4: Minimal Risk?

Minimal risk or greater than minimal risk?

- Do the risk(s) meet the federal definition of minimal risk?

- If yes, do the procedures fit into a expedited or exempt category of review?
“Minimal risk” means that

- 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**
  - of the **general population** or
  - during the performance of **routine** physical or psychological examinations or tests.
Levels of IRB Review

There are three levels of IRB Review, based upon on level of risk:

- **Expedited** review for minimal risk studies
- **Full Committee** review for more than minimal risk
- **Exempt** certification for studies that fall into one of six federal categories
Expedited Research

- No more than \textbf{minimal risk} to subjects, and
- The procedures fit into seven federally-defined expedited categories
- Expedited protocols typically are reviewed by an IRB subcommittee
Full Committee Research

- Greater than minimal risk to subjects
- Full committee protocols are reviewed at a convened IRB meeting
- Informed consent required in almost all cases
- Includes most clinical trials: studies involving non FDA-approved drugs and devices or medical interventions
Exempt Research

- “Virtually no risk to subjects”
- “Exempt” from the provisions stated in the Common Rule
- UCLA IRB reviews and certifies Exempt status
- Must fit into one of six federally-defined categories
- Oral consent or no consent appropriate in most circumstances
Guidance Document

Guidance and procedures website:
http://ohrpp.research.ucla.edu/pages/policies-guidance

- Conducting Risk-Benefit Assessments and Determining Level of Review
UCLA webIRB for Protocol Submission

- Online IRB protocol submission and IRB review (WebIRB)
- Efficient IRB review and approval process
- Ability to track your application status online
- Automatic reminders when continuing reviews and responses are due
- Centralized electronic storage of all protocol information, documents and correspondence

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We’re Here to Help

- UCLA OHRPP Website: www.research.ucla.edu/ohrpp

- Medical IRBs
  - Telephone: (310) 825-5344
  - E-mail: MIRB@RESEARCH.UCLA.EDU

- webIRB Help Desk
  - 310-267-1887
  - webIRBhelp@research.ucla.edu

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Questions & Discussion