Navigating the IRB Review Process for Human Subjects Research

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Resources:

Definitions:
- Human Research: Research undertaken to extend knowledge about human beings and is reviewed by the IRB.
- Research: The systematic investigation through observation or experiments.

Objectives:
- To familiarize researchers with the IRB process.
- To provide guidelines for navigating the review process.

More information available online at:
- [IRB Website]
- [UConn Human Subjects Program]

IRB Manual:
- [Download IRB Manual]

Note: This diagram is an outline of the IRB review process for human subjects research.
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Definitions

Objectives

Resources
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Objectives

- Definitions
- Ethical Principles and Regulatory Requirements
- Criteria for approval
- IRB review process
- Flexibility and Exceptions
- Research off-campus/outside the U.S.
- Resources- Help is available!
Definitions

• **Research** – A systematic investigation, including research development, testing and evaluation, designed to contribute to generalizable knowledge

• **Human Subject** – A living individual about whom an investigator obtains data:
  › Data through intervention or interaction
  › Identifiable private information
What Is Not Research?

1. Case Report
2. Implementation of a proven intervention in a clinic
3. Assessment of health needs in a specific population
4. Quality Improvement/Quality Assurance projects
5. Literature Review
What/Who is Not a Human Subject?

1. Deceased persons/cadavers

2. De-identified data or samples, provided by others

3. Persons who provide information about business operations and/or environmental data
More Definitions

- **Intervention** – physical procedures for collection of data and manipulations of the subject or their environment that are performed for research purposes

- **Interaction** – communication or interpersonal contact between researcher and subject
Ethical Principles and Regulatory Requirements

- Belmont Report (1979)
  - Respect for Persons-
    - Individuals as autonomous agents
    - Diminished autonomy- entitled to extra protections
  - Beneficence- Maximize benefits and minimize possible harms
  - Justice- Equitable subject selection and burden of participation
Respect for Persons

Autonomous agents
  • No coercion/undue influence

Coercion- overt or implicit threat of harm

Undue Influence- excessive or inappropriate award or other overture

Diminished autonomy
  • "Vulnerable Populations"
Application

Informed Consent

- Information
- Comprehension
- Voluntariness
Ethical Principles and Regulatory Requirements

- Belmont Report (1979)
  - **Respect for Persons**:
    - Individuals as autonomous agents
    - Diminished autonomy - entitled to extra protections
  - **Beneficence**: Maximize benefits and minimize possible harms
  - **Justice**: Equitable subject selection and burden of participation
Beneficence

• "Do No Harm" vs. maximizing possible benefits and minimizing possible harms

• 5 common types of risk:
  • Physical
  • Psychological
  • Financial
  • Social
  • Legal
Application

- Identifying/anticipating risk
- Minimizing risk
- Examples?
Ethical Principles and Regulatory Requirements

- Belmont Report (1979)
  - Respect for Persons-
    - Individuals as autonomous agents
    - Diminished autonomy - entitled to extra protections
  - Beneficence - Maximize benefits and minimize possible harms
  - Justice - Equitable subject selection and burden of participation
Justice

- Fairness in distribution
- Burden/benefits not placed on one specific group

Application

- Equitable subject selection
Ethical Principles and Regulatory Requirements

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  - Respect for Persons-
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  - Beneficence- Maximize benefits and minimize possible harms
  - Justice- Equitable subject selection and burden of participation
Criteria for IRB Approval

- Risks to subjects are minimized
- Risks are reasonable in relation to anticipated benefits
- Selection of subjects is equitable
- Informed consent will be sought from each prospective subject
- Informed consent will be appropriately documented
Criteria for Approval (Continued)

- When appropriate the research plan makes adequate provision for monitoring the data collected
- The privacy of subjects is protected and confidentiality of the data is maintained
- Additional safeguards for vulnerable subject populations
Human Research Protection Program (HRPP)

- Institutional Review Board (IRB)
  - IRB-01 (Biomedical)
  - IRB-02 (Social/Behavioral/Educational)
  - IRB-03 (Veterans Administration)
- Human Subjects Office (HSO)
- Under the Office of the Vice President for Research and Economic Development (OVPRED)
Requirements to Conduct Human Subjects Research

- Collaborative Institutional Training Initiative (CITI)

- Know about federal regulations and UI policies and procedures

- ClinicalTrials.gov

- ICH-GCP

- IRB Approval!
Human Subjects Research Determination (HSRD) Form

- CITI training not necessary
- IRB Chair Review- 2 business days
- If not HSR- determination memo
- If HSR- draft HawkIRB New Project form
- 620 HSRD forms were submitted in 2016
IRB Forms & Review Process

- HawkIRB Forms
  - New Project Application
  - Modification
  - Continuing Review
  - Reportable Event Forms (REFs)

- Delegate System

- Time frame for IRB approval (4-6 weeks)

- IRB Review Process
  - Administrative Screen
  - Staff Review / Application Analysis
  - IRB Chair or Full Board
Types of IRB Review

- **Full Board** – greater than minimal risk

- **Expedited Review** – not more than minimal risk
  - **Exempt Status** - 6 categories of research
Resources

- Human Subjects Office Web Site
- Policies & Guidance
  › Investigator's Guide
- HawkIRB Training Sessions & Presentations
- IRB ICON Course
- IRB Connection Newsletter
- IRB Office Hours
Questions?

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Resources
- IRB online
- Human Subjects Office website
- University of Iowa institutional guidelines

Definitions

Objectives
- IRB processes and requirements
- Commonly asked questions
- Responsibilities and obligations
- Community engagement and involvement
- Potential benefits and risks
- Informed consent and confidentiality

Next Steps
- IRB application submission
- Protocol review and approval
- Participant recruitment and enrollment
- Data collection and analysis
- Follow-up and regulatory compliance

Conclusion
- Navigating the IRB review process
- Continuous education and training
- Compliance and ethical considerations