IRB Overview

An Introduction to our HSPP

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Objectives

• Help you succeed by exploring the IRB
  – Basic Review Criteria
  – Historical Context
  – Submission Forms
  – Internal Processes
HUMAN SUBJECTS PROTECTION PROGRAM

SPONSOR

RESEARCH STAFF

RESEARCHER

UT

IRB

GRANTS AND CONTRACTS

RESEARCH SUBJECT
A closer look at two diverging needs

**HSPP**
- Ensure submissions are complete and coherent
- Ensure federal and UT rules/policies are upheld
- Ensure submitted protocols and research materials receive appropriate review
- Ensure informed consent document and procedures are appropriate

**Research Investigators/Teams**
- Develop and conduct relevant research
- Develop and perform sound research methods
- Maintain proper documentation and approvals
- Interact with subjects in an ethical manner
- Analyze and report data
Unified Goals and Jurisdiction

- **IRB Primary Goal:** To protect the rights and welfare of human research participants.
- **HSPP Primary Goal:** serve as regulatory specialist to enhance and facilitate the review of human subjects research.
- **Human Subject:** Individual from which an investigator conducting research obtains data through intervention/interaction or private information from some other source.
- **Basic Ethical Principles:** 1) Respect for persons, 2) Beneficence, and 3) Justice
- **Jurisdiction:** Research being conducted by an employee of the university, on our facilities, or with our UT student/employee population.
- **Submissions that Require Review:** 1) Initial Reviews, 2) Change Requests, 3) Continuing Reviews, 4) Protocol Deviations, 5) Data and Safety Monitoring Reports, 6) Adverse Events, 7) Miscellaneous Submissions, and 8) Study Closures.
SUBMISSION DEVELOPMENT
The Ultimate Study Submission Balance

- Is the study scientifically sound?
- Are all of the activities ethical and meet regulatory requirements?
- Are all of the logistics explicit?
Scientific Assessment Criteria

• Rationale is clear and scientifically sound.
• Study design is adequate & aims are measurable.
• Research relies on the least risky procedures that are clinically/scientifically sound.
• Literature review is adequate.
• Statistical considerations (sample size, accrual, analysis) are adequate for objectives.
• Investigators are qualified to conduct the study.
• Proposed subject population is appropriate.
• Data collected is needed to meet study objectives.
Protocol Elements

- Literature review/current state of knowledge
- Justification for the study
- Potential use of study findings
- Study design and locations
- Hypothesis
- Methodology
- Description and source of study population
- Inclusion and exclusion criteria
- Number of participants
- Sampling and participant selection
Protocol Elements (2)

- Recruitment/enrollment activities
- Consenting process
- Confidentiality/privacy
- Data monitoring
- Explanation of study instruments
- Data analysis plan
Recruitment/Screening

• Recruitment:
  – Process that is implemented to identify or inform prospective individuals about the research study.
    • Direct contact in a medical or non-medical setting; solicitation letters; flyers/brochures; media outlets; etc.

• Screening:
  – To select, reject, or consider persons by examining either their desire and/or the appropriateness for inclusion into a study.
    • This can occur before or after obtaining informed consent with the proper IRB approval.
Enrollment/Consent

• Enrollment:
  – Point at which research data is collected on individuals
    • Can be retrospective or prospective
    • If prospective, informed consent is obtained (unless otherwise waived by the IRB)

• Informed Consent:
  – The process by which a study participant provides prospective agreement to participate in a research study once he/she has gathered enough essential information to independently make that decision.
Subject Recruitment

- Recruiting subjects from the general public
  - Use of patient brochures
  - Use of recruitment flyers
  - Use of media outlets, including the internet, radio, etc.
    - Basic guidelines include: research indicating, eligibility, title, purpose, contact information, and institution.
    - What should not be stated:
      - emphasize on monetary compensation;
      - amount of compensation;
      - catchy words such as “exciting”, “cutting-edge”, etc.;
      - statements that recruit children directly;
      - or misstatements of information contained within the protocol.
Informed Consent Overview

• All modern codes of ethics concerning research with human subjects affirm the moral importance of a principle of informed consent.
• “The voluntary consent of the human subject is absolutely essential”
• Obtaining consent is an ongoing process of communication and mutual understanding
• The process is misrepresented as:
  • A piece of paper
  • A moment in time
  • A legal contract
Informed Consent Overview (2)

- Must be obtained for each research subject
- Must be obtained prior to initiation of screening procedures or receipt of personal information
- Must be tailored to the level of understanding
- If a medical term is used, a lay definition is needed
- Sufficient opportunity must be given for consideration, without coercion
Four Tenets for Effective Consentong

1. Accurate Information
2. Understanding
3. Voluntariness
4. Decision Making Capacity
IRB Overview

• Mission:
  – To protect the rights and welfare of human research participants.

• Definition of Research:
  – Systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
Key Features Of Research

• **Intent**: generate new knowledge, principles, or theories that revises or improves existing knowledge, programs or processes.

• **Systematic** collection and/or analysis of data.

• **Anticipated results** that are valid
HUMAN SUBJECTS

• Individuals from which an investigator, whether professional or student, conducting research obtains:
  – data through intervention or interaction with the individual, or
  – identifiable private information
Assessment Criteria

• Reviewing research to ensure:
  – Risks are minimized
  – Risks are reasonable vs. benefits
  – Selection is equitable
  – Informed Consent is obtained
  – Data and Safety are protected/monitored
  – Privacy and confidentiality are upheld
  – Vulnerable population protections are enhanced
TYPES OF RISKS

- Harm
- Discomfort
- Inconvenience

Physical
Psychological
Social
Economic
Legal
<table>
<thead>
<tr>
<th>EXEMPT</th>
<th>EXPEDITED</th>
<th>FULL BOARD</th>
</tr>
</thead>
<tbody>
<tr>
<td>No risk</td>
<td>Minimal risk</td>
<td>Greater than minimal risk</td>
</tr>
<tr>
<td>Case Study</td>
<td>Prospective data</td>
<td></td>
</tr>
<tr>
<td>Existing data</td>
<td>MRI, blood, Ultrasound</td>
<td></td>
</tr>
</tbody>
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Recent Changes

- IRB leadership
- IRB Membership
- IRB Compliance Officer
- iMedRIS implementation
- Process enhancements
  - Continuing Review Cycle
  - Link to Sponsored Programs
  - Oversight through data analysis