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Navigating the IRB

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NAVIGATING THE IRB

2010

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Process of Review

Human Subjects Research (No)	No Regulations
Exempt	Minimal/No Regulation
Expedited Review	All Regulations
Full Board Review	All Regulations

Does the IRB Have Oversight? (Is it Human Subjects Research?)

- Two parts (HHS regulations):
 - Research: A **systematic investigation**, including research development, testing, and evaluation, designed to develop or contribute to **generalizable knowledge**.
 - Human Subject: a **living** individual **about whom** an investigator conducting research obtains
 - Data through intervention or interaction OR
 - Identifiable private information

Does the IRB Have Oversight?

(Is it Human Subjects Research?)

- FDA:
 - Device:
 - Subject means a human who participates in an investigation, either as an individual on whom **or on whose specimen an investigational device is used** or as a control. ****Can be de-identified****
 - Safety or effectiveness of a device
 - Drug:
 - Clinical investigation: any experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects...any use of a drug except for the use of a marketed drug in the course of medical practice

Exempt Research

- Must fit one of 6 categories
 - Normal educational practices, anonymous surveys, existing data– publicly available, taste/food quality evaluations
 - Determined by HRPO
 - Submit application to HRPO
 - Must await “approval” before initiation

Expedited Research

- Minimal risk AND fits 1 of 7 categories
- Blood collection (limited amounts), noninvasive specimen collection, MRI, ECG, moderate exercise, medical record reviews, surveys/interviews
- Submit application to HRPO
 - Screened/reviewed by “designated” reviewer
 - SAME review criteria as Full Board, only review is by single reviewer.

Full Board Review



- More than minimal risk OR does not fit Expedited categories
- Process for this at HRPO currently under revision

Criteria for approval

- Risks to subjects are minimized
- Risks to subjects are reasonable in relation to anticipated benefits
- Selection of subjects is equitable
- Obtain informed consent
- Document informed consent
- Monitoring plan
- Protect privacy & maintain confidentiality
- Protect vulnerable populations

“Special” Reviews

- Treatment Use
 - Obtain IND/IDE
 - Full Board review/approval
- Humanitarian Use Device
 - HDE
 - Full Board review/approval
- Emergency Use
 - Life-threatening/no standard treatment
 - No time for full board review
 - IRB Chair provides letter acknowledging notification
- Planned Emergency Research

Grants

- We follow JIT procedures
 - Do NOT submit to IRB until you have been notified that you have award
 - Include full copy of grant (black out salaries) on budget pages
 - IRB application must be consistent with grant
 - Multi-phase
 - Overall/Concept

Recruiting patients

- Who are you recruiting
 - Your patients
 - Patients of others
- HIPAA
 - Do you need a waiver of authorization?
 - Clinical vs. research – DIFFERENT!
- IRB approval first

Chart reviews

- Retrospective – all data currently exist
- Waiver of consent/HIPAA authorization
- CIDER
- Exempt 4 vs Expedited 5

Biomedical vs Behavioral

- Biomedical Research Studies designed to increase the scientific base of information involving human biological function, pathology, or clinical issues, diagnosis or treatment.
- Social-Behavioral Research Research is defined by topic areas, not methodology, and includes studies designed to increase the scientific base of information about human behavior, social functioning, and the social and biological contexts of behavior. Disciplines included in this research type are: psychology, anthropology, human ecology, history, communications, organizational behavior, strategy, and management.

Contact HRPO

- <http://hrpohome.wustl.edu/>
- “Contact Us” link