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Institutional Review Board

Damon Michaels, CCRP
Gail Mayo, RN

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Objectives

- Overview of the IRB web site
- Review the different types of IRB submissions
- Apply regulatory knowledge to specific research senerios

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http://www.mc.vanderbilt.edu/irb/

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Financial Accountability and Compliance Tracking for Research (FACT^{R})

https://webapp.mis.vanderbilt.edu/factr/index.jsp

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Important Research Web Sites

ICMJE INTERNATIONAL COMMITTEE of MEDICAL JOURNAL EDITORS

http://www.icmje.org

ClinicalTrials.gov
A service of the U.S. National Institutes of Health

http://clinicaltrials.gov/

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Types of Study Reviews

- Non-Human/Non-Research
- Exempt Review
- Expedited Review
  - With a waiver of consent
  - Without a waiver of consent
- Full Committee
- Behavioral/Social Sciences

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Types of Study Reviews

- Amendments
- Continuing Reviews
- Deviations / Violations
- Adverse Events

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Non-Human/Non-Research

What is "Research" as defined by 45 CFR 46.102(d):
Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

If your study does not fit this definition, then you are not conducting "research".

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Quality Improvement initiatives

A matter of Intent

- Implementation of a practice to improve the quality of patient care. **Not** for generalizable knowledge.
- Collect patient or provider data about the implementation of the practice for clinical, practical, or administrative purposes (e.g., measuring or reporting provider performance data)

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Non-Human/Non-Research

What is a "Human Subject" as defined by 45 CFR 46.102(f):

A ***living*** individual about whom an investigator (whether professional or student) conducting research obtains:

- Data through intervention or interaction with the individual
- Identifiable private information

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Non-Human/Non-Research

- Does the study involve intervention or interaction with a "human subject"?
- Does the study involve access to identifiable private information?
- Are data/specimens <u>received</u> by the Investigator with identifiable private information?

- ***All three questions above <u>must</u> be "no" in order to qualify as a non-human subject.***

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Exempt Reviews

45 CFR 46.101(b)(2)

EDUCATIONAL TESTS, SURVEYS, INTERVIEWS, OR OBSERVATIONS

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior

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Exempt Reviews

45 CFR 46.101(b)(4)

COLLECTION OR STUDY OF EXISTING DATA

Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

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Exempt Reviews

- Fast Approval
- “Once and Done” approval
- Must de-Identify the data set when it’s complete and before you send it to the statisticians for analysis
- Only approved for 1 year
- Can only be amended prior to data collection

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Exempt Reviews

Subject Identifiers

- Names;
- Any geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code;
- All elements of dates (except year) for dates directly related to an individual (e.g., date of birth, admission);
- Telephone numbers;
- Fax numbers;
- Electronic mail addresses;
- Social security numbers;
- Medical record numbers;
- Health plan beneficiary numbers;

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Exempt Reviews
Subject Identifiers

- Account numbers;
- Certificate/license numbers;
- Vehicle identifiers and serial numbers, including license plate numbers;
- Device identifiers and serial numbers;
- Web Universal Resource Locators (URLs);
- Internet Protocol (IP) address numbers;
- Biometric identifiers, including finger and voiceprints;
- Full-face photographic images and any comparable images; and
- Any other unique identifying number, characteristic, or code.

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Limited data set

The limited data set is protected health information that **excludes** all 18 data elements with the exception of elements of dates, geographic information (not as specific as street address), and any other unique identifying element not explicitly excluded in the list above.

To qualify for exempt status, the limited data set cannot have the entire date (as otherwise allowed) but must have only year/month, or year only.

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Expedited Review

- Minimal Risk Studies
  - Collection of biological specimens by noninvasive means
  - Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture
- Reviewed by the IRB at least once per year
- Standard requirements for informed consent (or its waiver, alteration, or exception)
- FDA approved devices that are used according to its approved labeling
- Research on drugs that don't require an Investigational New Drug (IND) application and don't increase risk to study subjects

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Full Committee Review

- Greater than minimal risk to patients
- Requires patient consent unless the IRB has approved an alteration
- Reviewed at least once per year
- A full IRB Committee must review studies
- The IRB has the authority to approve, require modification in, or disapprove all research activities that fall within its jurisdiction

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Behavioral/Social Sciences

- Reviewed by the IRB at least once per year
- Standard requirements for informed consent (or its waiver, alteration, or exception)
- Protocol can be incorporated into the study application

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Scenario #1

A Principal Investigator designs a prospective study to recruit 100 subjects. He obtained IRB approval and registered his study with Clinicaltrials.gov. After 70 patients were recruited, he decideed to perform an interim analysis to see if he has sufficient power to publish his results.

Ultimately, his manuscript is rejected……. WHY?

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Scenario #2

An attending Anesthesiologist noticed that patients receiving medication “A” seem to have less nausea than medication “B” after surgery. She would like to start documenting these differences and publish a manuscript on her results.

What type of IRB review will this require?

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Scenario #3

A year ago, Dr. Jones started offering preoperative psychological counseling to his patients that are facing major surgery. He believed it reduced PTSD and POCD. He's provided this service to 83 patients and would like to compare their recovery to patients that have not received counseling.

What regulatory concerns will he have?

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Scenario #4

The Principal Investigator for a large prospective study is near the end of patient recruitment. He's been very busy and missed the study's Continuing Review.

What are the regulatory issues that he will need to address?

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Scenario #5

A Principal Investigator has completed a retrospective chart review and sent the data to a statistician for analysis. During the analysis, the statistician realized that 3 key elements were not included in the data set.

What are the PI's options?

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Scenario #6

- A Principal Investigator was reviewing his data on a study using a drug that could potentially cause liver damage. During his review, he discovered 10 patients that did not have safety labs drawn before they were discharged from the hospital.

- What regulatory issues will he need to address?

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Scenario #7

A Principal Investigator is conducting a prospective study using a new Investigational Drug. He has noticed that 11% of the patients are experiencing a rash that required treatment, including steroids.

What regulatory issues will the Investigator need to address?

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Conclusion

- Use the IRB website and other resources for assistance in fulfilling Investigator obligations.
- Ultimately it is the Principal Investigator's responsibility to comply with current IRB policy.

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Questions?