WHAT’S DIFFERENT ABOUT CLINICAL DATA?

AN RDAP TOWN HALL PANEL PRESENTATION

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- Research data librarian
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- Serving data needs at both the medical and core campuses

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- Helps students, faculty and staff navigate the research data lifecycle, health data resources, and software tools for research and beyond

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- Supports Health Sciences faculty, staff and students with research data management.
OUTLINE

- Nina: Terminology and overview of clinical data concepts
- Christy: Processes in clinical data
- Christy: Resources for working with clinical data
- Lori: Key infrastructure - REDCap
Terminology and Key Concepts in Clinical Research Data

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Just an overview

• Clinical data is its own complicated specialty
• The whole clinical research setting is very different than the nonclinical setting
  – Particularly at institutions with hospitals
• We’re just giving a sense of what your roles might be and how to work with clinical research teams
What do we mean by “clinical” data?

• Clinical data is data that is collected mainly in clinical treatment settings
  – Clinical trials
  – Patient treatment (doctor’s offices are “the clinic”)
  – Health surveillance data from clinics and hospitals
  – Health studies collecting biobehavioral data on medical conditions
Clinical Trials

• NIH definition is about health interventions
  - Human participants
  - Prospectively assigned to a study arm
  - To evaluate the effect of the intervention on the participants
  - Evaluating a health-related biomedical or behavioral outcome

• FDA definition focuses on their regulatory roles
  - Drugs, pharmaceuticals, and biologic agents
  - Medical devices
Key role of regulation

• Highly regulated
  – Most clinical research is subject to at least human protections, HIPPA, and clinical trial regulations
  – Follow the money:
    • Additional regulations come into it if it is government funded
    • Alternatively, industry sponsors may fund clinical research at academic medical centers. These come with contracts about data.

• Highly private, often sensitive data
Privacy scrutiny

• Just because PIs have access to data, doesn’t mean they can do research on it
• Typically expedited or full board IRB review
• Safe harbor de-identification by removing the HIPPA identifiers is a minimum expectation
  – Deidentified is not anonymized or anonymous
  – If deductive disclosure is likely, Safe Harbor probably isn’t enough without a very clear consent for the risks
What do you mean I can’t research it? I have it right here!
Team-based plus “core” supports

• PIs frequently are not solo researchers
  – Separate data collectors, or mediated data extraction
  – Clinical Research Administrators in their department
  – Biostatisticians, statisticians, or other analysts

• If they are funded, they also often chargeback (or recharge) parts of the study process to core services

• If the institution is too small for these services, the researcher probably trained somewhere larger
Make it so, number one!
Example

A nursing faculty member is studying diabetes disparities and wellness care across the lifespan. Clinical data might include:

• Records from a hospital or community care center
• Pretest/posttest on attitudes or nutrition affected by health education sessions
• Samples, especially any collected in medical offices
Different culture of data

• Clinical setting has a totally different vibe
• Data management, data services, and data curation may all emphasize some things much more and skip other things compared to core campus data librarians
• Why should you care?
  – Talking to faculty with clinical or semi-clinical backgrounds
  – Working with groups (e.g. the NIH) that think clinically
TRANSITION TO CHRISTY