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Biorepository and Data Management: Key Considerations for Clinical Trials

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3:30-4:30pm

Session T501

INTRODUCTIONS

Today's Presenters

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Learning Objectives

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1. Explore diverse models and strategies for biorepository and data management in clinical trials.

2. Understand the regulatory frameworks that influence bio-specimen and data management in clinical research.

AGENDA

Agenda

- Overview/Definitions
- Biorepositories
  - Models
  - Management considerations
- Data and Data Sharing
- Institutional Considerations
- Regulatory Considerations

OVERVIEW & DEFINITIONS

Biorepository

- An entity that collects, processes, stores, and disseminates samples of biological material, such as urine, blood, tissue, cells, DNA, RNA, and protein, for research
- Materials often have corresponding clinical data
- Can also include samples from animals or plants
- Also called “biobanks” or “biospecimen resources”

Data Registry

- A record of information collected about people which can include:
  - Demographic information
  - Health information
  - Information completed by the person (e.g. survey/questionnaire results)
- Can be created for non-research and research purposes
- Can be voluntary or federal/state mandated
- Can be used for non-research and research purposes, regardless of original intent

Secondary Data Analysis

- Analysis of data that was collected by someone else for another primary purpose
- Examples include:
  - Analysis of Centers for Medicare and Medicaid Services (CMS) data
  - Analysis of data from a research registry
  - Analysis of data collected from another research study

BIOREPOSITORIES

REPOSITORY MODELS

Repository Models

Centralized vs. Decentralized vs. Federated

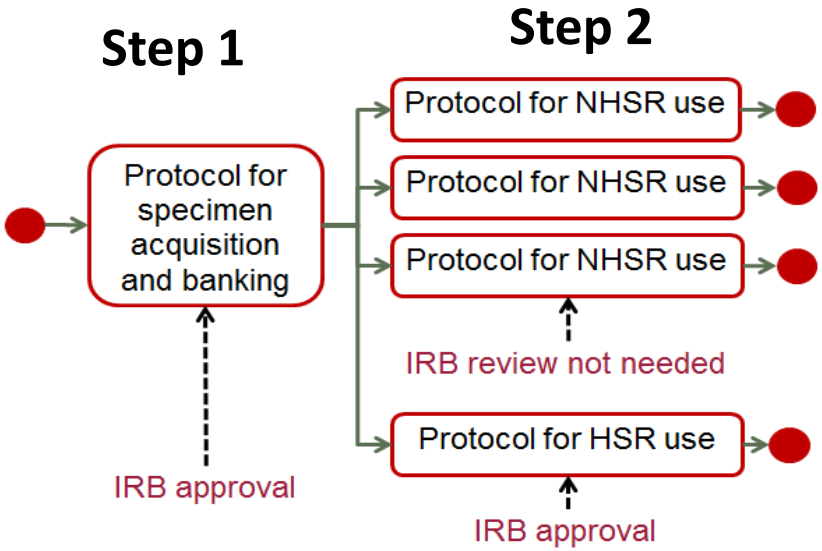
- **Centralized**: samples and data are submitted from multiple investigators/locations using standardized procedures (single and multi-institution)
- **Decentralized**: individual investigators/departments collect and store samples and data; procedures may vary (single institution)
- **Federated**: each location collects and stores samples and data using shared policies and procedures, but agrees to share with other sites (multi-institution)

Repository Models

Project-Driven vs. General

- **Project-Driven**: samples and data are collected and distributed to answer specific research questions
- **General**: samples and data are collected and available to respond to multiple requests for various research uses

Common Biorepository Model

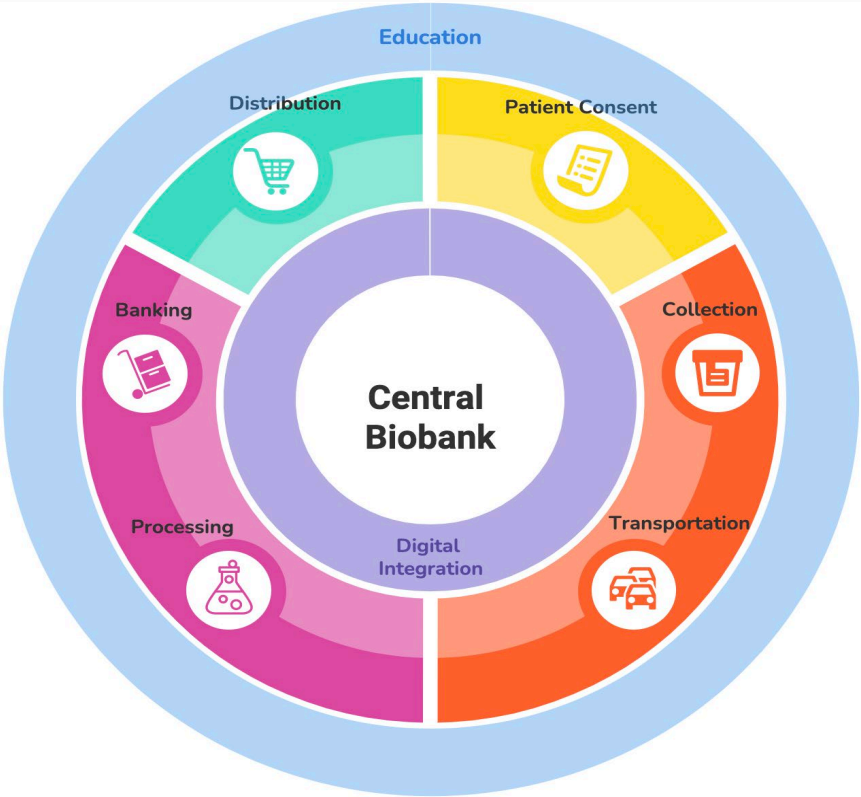


Step 1: Procedures for collection and banking of specimens
Step 2: Procedures for use of specimens

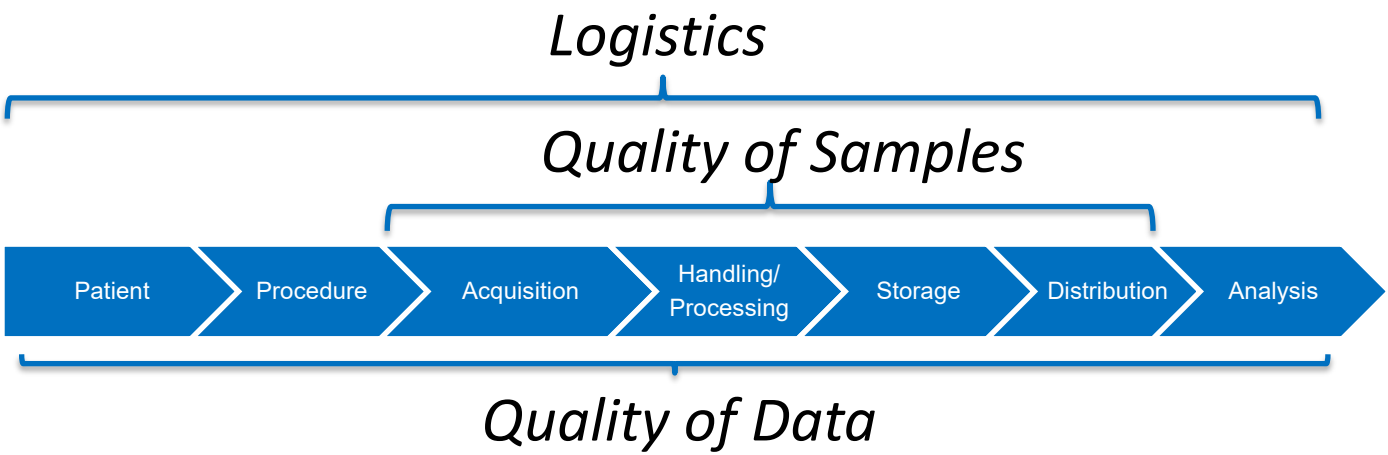
Note: NHSR=Non-Human Subject Research

REPOSITORY MANAGEMENT CONSIDERATIONS

Biobank Management



Lifecycle of Biospecimens*



*From NCI's OBBR Biospecimen Research Network

DATA AND DATA SHARING CONSIDERATIONS

Practical Applications

- Research databases
  - Current HHS interpretation: creating research database/repository and future unknown use of data are separate research activities
  - Challenge for clinical trials that also include creation of biospecimen storage
- Data mining for potential research projects
  - Requires prior patient authorization or IRB approval or waiver

Practical Applications

- Request for data mining as a pre-study process
  - Submit form with protocol submission detailing what data is needed
  - Follow approved protocol defined data collection plan
  - No use or disclosure of data outside IRB-approved study team
- Contracting with third parties to provide data hosting or analysis
  - May not provide identifiable data without prior written approval from the institution and business associate agreement or data use agreement

Information Security in Data Sharing

- Institutional restricted access in order to provide secure access to PHI for research
- Investigator's responsibility to safeguard patient/research data
  - Register with institution IT department
- Key components:
  - Encryption for mobile devices
  - Secure access to hospital network
  - Secure transfer of PHI for research

NIH Data Management and Sharing (DMS) Policy

- Effective January 25, 2023
- Applies to NIH funded studies
- Promotes sharing of scientific data and data reuse for future research studies
- NIH expects investigators and institutions to:
  - Plan and budget for the managing and sharing of data
  - Submit a DMS plan for review when applying for funding
  - Comply with the approved DMS plan

Data Use Agreements (DUAs)

- A DUA is used for a Limited Data Set (LDS)
- A DUA establishes who is permitted to use and receive the LDS, and the permitted uses and disclosures of such information by the recipient, and provides that the recipient will:
  - not use or disclose the information other than as permitted by the DUA or as otherwise required by law,
  - use appropriate safeguards to prevent uses or disclosures of the information that are inconsistent with the DUA,
  - report to the covered entity uses or disclosures that are in violation of the DUA, of which it becomes aware
  - ensure that any agents to whom it provides the LDS agree to the same restrictions and conditions that apply to the LDS recipient, with respect to such information, and
  - not re-identify the information or contact the individual.

https://www.hhs.gov/hipaa/for-professionals/special-topics/emergency-preparedness/data-use-agreement/index.html

What About Material Transfer Agreements (MTAs)?

- A MTA is a contract that governs the transfer of tangible research materials between two organizations
- A MTA specifies the rights, obligations, and restrictions of both the providing and receiving parties with respect to issues such as ownership, publication, intellectual property and permitted use and liability
- Can be required when an organization sends or receives research materials; often originates with the sending organization
- There is often the misperception that execution of a MTA for human tissue requires IRB review and approval of an associated research protocol

Who Owns the Samples and Data?

Samples are owned by the institution

Contractual considerations if investigator leaves the institution

Participants should have the opportunity to withdraw samples

Exception: completely de-identified

REGULATORY CONSIDERATIONS

HHS and OHRP

- The Office of Human Research Protections (OHRP) is the oversight arm of the Department of Health and Human Services (DHHS) for federally funded human research
- OHRP considers the collection of specimens or data for research purposes to be research and guidance recommends that human tissue repositories supported by HHS should be subject to oversight by an Institutional Review Board (IRB)
- The IRB should determine if:
  - The activity is research as defined by the Common Rule
  - If so, whether the research involves human subjects as defined by the Common Rule

OPRR, ***Issues to Consider in the Research Use of Stored Data or Tissues****, November 7, 1997*
OHRP, ***Guidance on Research Involving Coded Private Information or Biological Specimens,*** *October 16, 2008*

HHS and OHRP

- If the repository involves human research, the IRB should review:
  - Conditions under which data & samples are collected/shared
  - Provisions to protect privacy
  - Provisions to maintain confidentiality of data
- OHRP has guidance as to when coded private information or samples are not identifiable so that research on that information does not involve human subjects.

OPRR, ***Issues to Consider in the Research Use of Stored Data or Tissues****, November 7, 1997*
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FDA

- FDA considers data regarding the use of a device on human specimens (identified or unidentified) to be a clinical investigation if it will be submitted to or held for inspection by FDA as part of an application for a research or marketing permit

- Subject to 21 CFR 50 and 56

- This means that testing of a device (e.g. development of an assay/lab test) using anonymous leftover specimens requires IRB review if seeking to market that device

HIPAA

- Samples & data are collected within or received by covered entity
- Most likely scenarios for repository data, sample labeling:
  - Identifiable
    - Authorization from the patient; OR
    - Waiver of authorization from IRB/Privacy Board
  - Limited Data Set
    - Data Use Agreement is in place
  - De-identified (all PHI removed)
    - If samples are coded to achieve de-identification, HIPAA requires coding not be derived from or related to information about the individual and is not otherwise capable of being translated to identify the individual.
    - For example, the code may not be derived from the individual's name (i.e., initials), social security number or medical record number.

De-identified vs. Limited Dataset

- De-identified data: all 18 identifiers removed
  - Safe harbor method
  - HHS creating new guidance on de-identification standard
- Limited data sets: remove all identifiers except
  - City, State, ZIP code
  - All elements of dates (DOB, admission/discharge date)
  - Any other unique identifying number, characteristic or code
- Limited data sets may be disclosed for research purposes with data use agreement

GINA and HIPAA

The Genetic Information Nondiscrimination Act (GINA) protects individuals against discrimination based on their genetic information in health coverage and in employment

GINA has two primary components: an employment component; and a health insurance component

Effective March 26, 2013, implemented the statutory prohibition on the use or disclosure of genetic information by a health plan for underwriting purposes.

Under HIPAA, genetic information is health information protected by the Privacy Rule.

Informed Consent Approaches

- General consent
  - Can get consent from subjects to bank specimens and indicate that for future research either their specimens will not be identified, an IRB will waive consent, or their consent will be obtained.
- Tiered consent
  - Subjects can specify the types of research for which their samples/data will be used
  - Have to be able to track subject choices
- Research study specific consent
- Broad consent

Discussion Question #1

- An IRB has approved a tissue bank for oncology specimens. Consent, which includes use for future research, has been obtained from subjects who provide tissue samples. An investigator wants 20 breast cancer specimens from the bank from subjects treated with the cancer drug paclitaxel. There will be no identifying information provided to the investigator. She will use DNA probes to measure the number of copies of the Her-2 gene and determine whether increased number of copies predicts successful treatment with paclitaxel. Does this investigator's research require IRB review and approval?
  - Yes
  - No
  - Not Sure
  - Depends

Discussion Question #2

The IRB has approved a project with a consent that states: "Drs. Lewis and Smith will collect tumor and normal adjacent tissues from you to investigate and measure the level of MAP-kinase protein levels compared to the stage of your cancer disease. We will also collect and store your associated clinical data. Biospecimens will be stored indefinitely."

Discussion Question #2

Drs. Lewis and Smith have finished their primary research project and now have new funding to study a different gene, the MET gene. They plan to use the remainder of tissues that they have in their biorepository.

- *Are Drs. Lewis and Smith allowed to do this MET gene research under the current project?*
- *What are the regulatory steps they need to complete to proceed with their research?*

QUESTIONS?