From Collection to Collaboration:
Making the most of Repositories and Retained Samples

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Learning Objectives:

By the end of this session, you will be able to:

- Distinguish between a repository and a study that retains data/samples for "extra use"
- Describe the limitations of repository studies, including why they cannot have their own scientific aims
- Identify when consent for future unspecified use is required and how it applies to recipient studies
- Determine when a recipient study qualifies as “not human subjects research”
- Recognize key operational considerations (maintenance, funding, DUAs/MTAs)

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definitions

Repository:
A system that collects, stores, and distributes data/samples without research aims of its own. Non-exempt review.

Retention for Extra Use:
A research study that retains leftover samples/data beyond original study endpoints, often with a plan for future use. Studies with retention for extra use may qualify for exempt review in certain categories (9, 10, 12, and 13)

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Quick Check: which is which?

Scenario A: A PI wants to store leftover samples from a funded trial for future exploratory work.
Scenario B: An investigator sets up a new protocol to collect tissue and share it with colleagues but has no analysis plan of their own.

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Repositories cannot have scientific aims

- No hypothesis, endpoints, or analytic plans
- Not a data analysis project; it's collection, storage, and sharing only
- This is mostly to prevent studies from being overly complicated.
- Important note: Studies created for the sole purpose of establishing a repository require non-exempt review (expedited or full board)

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Recipient studies:

Where the analysis happens!

Often qualifies as *not human subjects research* if data is coded and recipient has no access to identifiers and isn't a member of the repository study team

If recipient needs identifiers, has access to the mastercode, or is a member of the study team on the repository:

- If unfunded: almost certain be exempt
- If funded: likely requires non-exempt review

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Quick check: recipient studies – review path?

A: A PI of a repository wants to use her own samples for an analysis. She submits what kind of study for review?

- o Not Human Subjects Research
- o Exempt
- o Non-Exempt
- o Not Sure

B: A PI of a repository wants to let a colleague down the hall use her own samples for an analysis. This colleague gets coded samples and has nothing to do with the repository. The colleague submits what kind of study for review?

- o Not Human Subjects Research
- o Exempt
- o Non-Exempt
- o Not Sure

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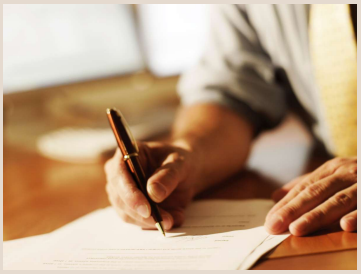
Consent and unspecified future use



Supports future research and data/sample sharing

Generally expected when:

- Use goes beyond current study aims
- Samples/data are identifiable
- External sharing is planned

May not be required if:

- Data are fully de-identified
- IRB approves a waiver
- Use falls within original consent scope

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BMC/BUMC IRB Expectations for Consent Language

Describe how samples/data are obtained and what research they support

State whether **genetic info** is included

Clarify:

- Who can request access
- Who reviews release requests
- What information accompanies release (e.g., demographics)

If direct benefit is offered, retention **must** be **optional**

In confidentiality section: describe SOPs and storage/sharing protections

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What's your advice #1: *Consent is Silent*

You receive a request to share samples collected under a consent form that doesn't mention future use.

Can you share them? What's the ethical issue? Regulatory issue?

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Operational Considerations

- Storage and maintenance: who pays, who tracks?
- Adequate sample annotation/associated data to ensure utility
- Oversight: what happens if PI leaves?
- Sharing: DUAs and MTAs required **before** sharing
- Justification: is a new repository really needed?

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What's your advice #2: *Enough to go around?*

A PI wants create repository for COVID biospecimens. One already within the same department that targets the same population.

What issues arise? What questions would you ask?

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Ethical Minefields: Consent, Profit, and Re-use

Topics that often trip up PIs and the IRB:

- Commercialization of samples
- Consent vs. Waiver vs. Re-consent
- Return of results: when, how, and whether it's appropriate
- Use of samples from vulnerable populations

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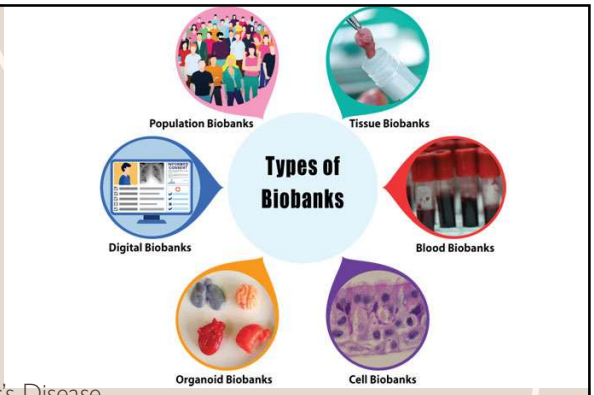
Types of Biorepositories



- Hospital based (preserving specimens collected)
- Tissue based (for transplantation)
- Disease based centralized banks
  - e.g. NCRAD: The National Cell Repository for Alzheimer's Disease
  - –Biologic Specimen and Data Repository Information Coordinating Center (BioLINCC) https://biolincc.nhlbi.nih.gov/home/
  - Coriell https://www.coriell.org/
- Population based Biobanks: e.g. Framingham Heart Study, UK Biobank
- Virtual Biobanks: e.g. Global Alliance for Genomics & Health

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Setting up the repository-Things to consider

- Where and how is it maintained
  - Best practice- redundancy always
  - Great resource: https://biospecimens.cancer.gov/resources/default.asp
- How is it being paid for?
- What is the associated data or specimens?
  - Continuous data or one-time only pull?
- What institution does the material originate from?
  - BMC?

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Biobanking is EXPENSIVE, why do it?

Centralized biorepositories at academic medical centers provide significant value to the institution and to the scientific community.

- Leverages biospecimen collection knowledge as an essential service
- Supports the Cancer Center and other centers with their missions
- Allows patients to become donors and participants in research
- Bridges connectivity with other specialties ~ e.g. radiology
- Develops relationships with partners NDRI, NCI, BBRB
- Fosters national sharing of best practices in specimen collection
- Enhances Quality Management Programs

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Quiz: Repository or Retention?

A study collects tissue during surgery and stores it for future use with associated clinical information from the surgery. No specific research questions are proposed. Samples may be shared with collaborators.

What type of submission is this?

A. Research study with retention

B. Repository

C. Quality improvement

D. Not human subjects research

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Quiz: Does this require IRB review?

A PI requests coded samples from a repository. The PI is not listed as part of the repository team and has no access to identifiers.

Does this qualify as human subjects research?

A. Yes

B. No

C. Only if consent for unspecified use was obtained

D. Only if the PI is using them for commercial purposes

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Quiz: Consent Requirements

- You want to use identifiable leftover biospecimens from a completed study on an entirely different aim, but the consent form did not address future use. What do you need?
- A. Nothing because the consent was silent and there is presumed consent
- B. IRB waiver or reconsent
- C. New repository submission
- D. Destroy the samples because you didn't get consent

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Quiz: Enough to go around?

You're the IRB. A new faculty member emails medirb@bu.edu and proposes a repository for pancreatic cancer. You know there's already a pancreatic cancer biospecimen repository in your department.

What's your first step?

A. Tell them submit a new IRB protocol
B. Approve it if it has a new scientific aim
C. Ask them to justify the need for a new repository
D. Require them to use the existing one

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final tips & takeaways

- Repositories ≠ Traditional research studies
- Retention ≠ automatic repository
- Not all recipient studies need IRB review... but some do
- Consent for future unspecified research helps... but it's not a free pass
- Maintenance, sharing, and equity require planning

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thank you

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