Repository & Open-Ended Consent

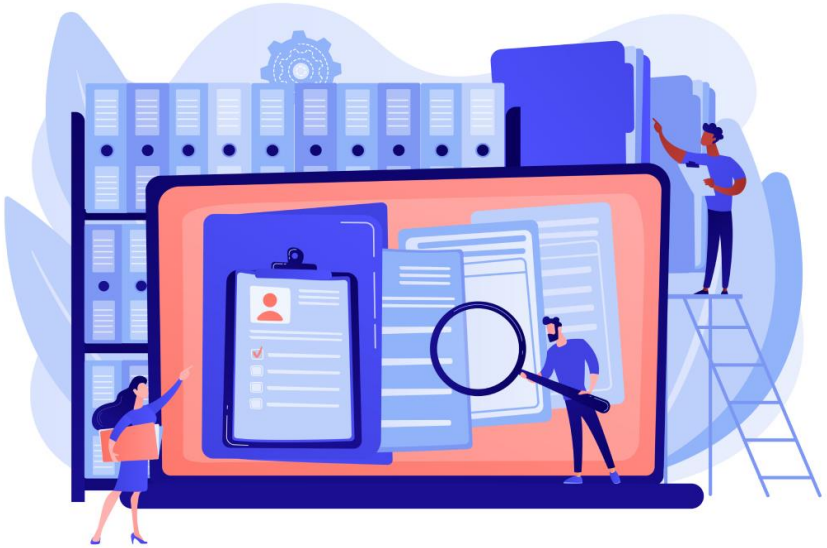
October IRB Education

Setting Mindset

Questions to ponder:

1. What was the healthiest period of your life?
2. Describe how you felt when you were so healthy.
3. What was going on in your life during this time?

Research repository



Department of Health and Human Services (HHS) describes a research repository as “a systematic collection of human biological materials and/or data, including medical information, that are individually identifiable and maintained for future research purposes. These repositories enable the collection, storage, and distribution of data and specimens, with their operation overseen by an Institutional Review Board (IRB) to ensure proper data protection and privacy for human subjects, as required by HIPAA Privacy Rule and other HHS regulations.”

Source of Considerations

Rothstein, M.A., et al. "Reconsidering Open-Ended Consent for Biospecimen and Health Record Research in the United States and Europe." *Ethics & Human Research* 47, no. 4 (2025): 43-50

NCI Best Practices for Biospecimen Resources

HHS Broad Consent Guidance Video

Core Problem Identified in Article

Traditional Consent: Designed for simple, immediate, small-scale studies with singular, static consent

- Single moment
- Specific study
- Limited scope

Modern biobank research: Large-scale, longitudinal studies using secondary research with biospecimens and health records over decades

- Decades-long data collection
- Multiple future uses
- Evolving health conditions

Fundamental Issue: Participants who consent to unlimited health record access when healthy may develop sensitive conditions (mental illness, substance use, STIs, domestic violence, reproductive issues) that they would not want disclosed to researchers if asked again years later.

Illustration in Article

Scenario: A 25-year-old healthy individual consents to giving a blood sample for a research biobank. When the sample is collected, the individual is in relatively good health and does not have any particularly sensitive health conditions. The participant perceives little privacy risk so they also permit researchers to have unlimited access to their current and future health records.

Years later—This individual's health status changes and their health record includes mental health treatment, substance abuse, STI diagnoses, domestic violence records.

- **QUESTION** → Would they consent again if asked today?

Problem=They're rarely asked, few remember giving indefinite consent

Key Issue

Current practice places burden on participants to remember and opt out rather than protecting their evolving privacy interests.

Resource Requirement	Financial Burden	Withdrawal Complexity
• Lifetime tracking systems for all participants • Extensive database capacity and maintenance • Specialized personnel for consent management • Legal/compliance oversight infrastructure • Age of majority transition procedures	• High setup and maintenance costs • Ongoing personnel expenses • Technology infrastructure needs • Audit and compliance requirements	• Broad consent withdrawal = no future use of ANY specimens/data • Includes de-identified materials • Must be tracked across lifetime • Affects all past, present, and future research

Alternatives to Consider

Before using broad consent, ask: “Can research goals be met through..”

1. **Study-specific consent**: Clear, defined research uses
2. **De-identification:** Remove identifiers, no consent needed
3. **IRB waiver of consent**: Minimal risk secondary research
4. **Coded specimens:** Investigators cannot readily identify participants

Key Takeaways

- Broad consent creates lifetime institutional obligation
- Many institutions avoid broad consent due to resource requirements and other limitations
- Most research goals are achievable through alternatives
- IRBs need to assess institutional readiness before approval of broad consent

Thank you

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