Contemporary Issues in Biobanking: Governance, Consent and Practical Approaches to Current Challenges

Baltimore Convention Center ∙ Baltimore, MD
December 4, 2014 ∙ 8:30 AM–5:00 PM

This day-long program will explore advanced issues in the research collection, processing, storage, and use of biological specimens, DNA, clinical and other data. Biobanking is a rapidly evolving landscape—particularly as information technology continues to advance research capabilities and alter socio-cultural climates—making it difficult for the ethical and regulatory field to keep pace. Broad sharing of data is absolutely critical to scientific and medical advancement but raises privacy concerns and other ethical issues. What practical approaches can be used to address these issues? What innovative approaches have been developed? During this program, faculty and participants will examine contemporary issues in biobanking, focusing on practical strategies for addressing challenging ethical and human subjects protections issues. This course will be an interactive, advanced educational workshop that will seek to integrate speaker and participant experiences and concerns. Program attendees should come with a thorough understanding of tissue banking issues, as fundamentals are not included in this course.

Agenda
Please note this agenda is subject to change.

7:00–8:30 AM Registration and Continental Breakfast

8:30–10:15 AM Welcome and Introduction

Overview of Biobanking, Models of Consent and Privacy Best Practices

Informed consent is critical and can be challenging when biobank collections have unspecified future uses. In this discussion, we will explore various consent models and strategies that maximize understanding and choice. Best practices for privacy practices will also be addressed.

- Overview of biobanking
- Various models of informed consent (e.g. study-specific, tiered consent, broad consent, dynamic consent, opt-in, and opt-out), including discussion of when and how to implement them.
- “Front-door consent” (i.e. institutional centralized biospecimen research), educational efforts and challenges associated with this approach, as well as examples of how to overcome these challenges.

Agenda continues on the following page.
Program Agenda

- Best Practices for Privacy Protections
  - Authorizations for future research
  - Combining authorizations and informed consent forms
  - Avoiding the “sale” of protected health information
  - De-identification and coding
  - Honest brokers and de-identified cohort discovery tools
  - Treatment of genetic information as protected health information
  - State law
- Pediatric Biobanking

10:15–10:30  Break

10:30 AM–12:30 PM  Panel and Audience Discussion
The panelists will discuss their experiences and also invite participants to contribute examples of what is working in their home institutions.

12:30–1:00 PM  Lunch

1:00 PM–3:00 PM  Governance and Emerging Standards of Best Practices
An overview of governance models and best practices implemented in today’s biobanking.

- Governance of Biobanks
  - Components of governance and their relationship to institutional review board (IRB) and investigator responsibilities and oversight
  - Steering and scientific oversight committees
  - Ethics and community advisory boards
  - Data access committees
  - Material Transfer Agreements
  - Biobank access policies

Access and Distribution of Specimens: A Case Example

Other Challenging Issues:
- Secondary Use of Specimens and Legacy Collections
- Return of Research Results

3:00 –3:15 PM  Break

3:15–4:45 PM  Panel and Audience Discussion
The panelists will discuss their experiences and also invite participants to contribute examples of what is working in their home institutions.

Wrap-Up Discussion, Questions, and Answers

5:00 PM  Adjournment