Contemporary Issues in Biobanking: Forum on Research Involving Tissue and Biobanking – Domestic and International Considerations

Hynes Convention Center- Boston, MA
November 12, 2015

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 fields to keep pace. Broad sharing of specimens and data is absolutely critical to scientific and medical advancement, but this raises privacy concerns and other ethical issues. Furthermore, global specimen and data sharing presents considerable challenges given differences in global regulations and policies, cultural considerations, and local logistical. What practical approaches can be used to address these issues? What innovative approaches have been developed to facilitate global specimen and data sharing? During this advanced level educational program, faculty and participants will examine contemporary issues in biobanking, focusing on practical strategies for addressing challenging ethical and human subjects protections issues in a global environment.

November 12, 2015

7:00-8:30 AM  Registration (breakfast on your own)

8:30-8:35 AM  Welcome and Introduction

8:35-9:05  Notice of Proposed Rulemaking Proposed Changes Related to Specimen Research

Faculty: Michele Russell-Einhorn, JD

9:05-9:50 AM  Differences in Biobanking/Repository and Consent Models

Faculty: Marianna J. Bledsoe, MA; William E. Grizzle, MD, PhD
Faculty will review the broad variation in biobanking/repository and consent models and how policies may differ depending upon the type of repository.

9:50-10:30 AM  Advanced Issues Regarding Consent

Faculty: Linda A. Ehler, RN, MN, William E. Grizzle, MD, PhD; Michele Russell-Einhorn, JD; Alberto (Betto) Antonio Ortiz-Osorno, MS, PMP, CIPM
Faculty will discuss the challenges in obtaining consent, including “Front Door” consent and broad consent for future use of specimens. They will also address issues related to the timing of seeking consent for future use of specimens collected during the course of routine care.

10:30-10:45 AM  Break

10:45-11:05 AM  Audience Questions and Answers/ Panel Discussion

11:05-12:30 PM  Governance and Specimen and Data Access Policies
Faculty: Marianna J. Bledsoe, MA; William E. Grizzle, MD, PhD; Amelia Wall Warner, PharmD
Faculty will discuss the importance of good governance and oversight of biobanks, as well as specimen and data access policies, when institutions rely on broad consent. Governance and oversight systems used by industry will also be discussed. In addition, issues related to specimen utilization will be addressed.

November 12, 2015 (cont.)

12:30-1:00 PM  Lunch (provided)

1:00-1:30 PM  Continuation of Audience Questions and Answers/Panel Discussion over lunch

1:30-2:30 PM  Challenges of Global Specimen Collection and Data Sharing  
Faculty: Linda A. Ehler, RN, MN; Alberto (Betto) Antonio Ortiz-Osorno, MS, PMP, CIPM; Amelia Wall Warner, PharmD, RPh; Aminu Adamu Yakubu, MPH
Faculty will review global variations in regulations, policies and IRB requirements; practical approaches for specimen collection in developing countries, and the complexities of conducting multi-site trials with pharma, academia, and host countries.

2:30-3:15 PM  Return of Research Results in Biobanking  
Faculty: Mark Barnes, JD, LLM; Linda A. Ehler, RN, MN; William E. Grizzle, MD, PhD; Alberto (Betto) Antonio Ortiz-Osorno, MS, PMP, CIPM; Michelle Russell-Einhorn, JD
Faculty will review the complexities regarding return of research results in biobanking. They will then discuss issues related to the return of research results from research vs. non-research labs, Health Insurance Portability and Accountability Act (HIPAA), and Clinical Laboratory Improvement Amendments (CLIA) in the context of return of research results and the return of results in developing countries.

3:15-3:30 PM  Break

3:30-4:20 PM  Return of Research Results in Biobanking (cont.)

4:20-4:30 PM  Wrap-Up

4:30 PM  Adjournment

Please note the agenda is subject to change.