PRIM&R PUBLIC RESPONSIBILITY IN MEDICINE AND RESEARCH

Biobanking in an Era of Precision Medicine Research: Approaches to the Ethical, Regulatory, and Practical Challenges

Manchester Grand Hyatt San Diego

November 14, 2018

The collection, storage, distribution, and use of biospecimens from human individuals and the subsequent sharing of biospecimens and data is absolutely essential for scientific discoveries to advance precision medicine. Research subject consent for use of their biospecimens is a critically important component. However, biobanking in an era of precision medicine raises significant challenges for IRBs, institutions, investigators regulators and policy makers, research repository managers, and funding agencies and sponsors. For example, biobanking for future research uses of biospecimens can be challenging depending upon the specificity or broadness of the consent, as well as data sharing restrictions. New regulatory requirements apply to the use of human biospecimens in research, including the new tool of "regulatory" broad consent which carries with it a host of logistical and substantive issues. Other challenges include the need to establish sound governance and oversight mechanisms for biobanks generally and to ensure oversight of data sharing and data limitations as well as complex issues such as ownership of biospecimens and data, return of research results, and other ethical issues.

During this workshop, speakers and participants will examine these contemporary challenges, focusing on practical strategies for addressing them. 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 biospecimen banking issues and IRB regulatory criteria, as fundamentals are not included in this course. Please note that this preconference program may include similar content provided in past programs with updates to reflect changes in applicable regulations and emerging issues and approaches.

AGENDA

7:30–8:30 AM	*On-Site Check-In (breakfast on your own)*
8:30–8:40 AM	**Welcome and Introduction** (Marianna J. Bledsoe, Michele Russell-Einhorn, Co-facilitators)
8:40–9:10 AM	**Role of Biospecimens and Biobanking in Research Towards Precision Medicine; and Biobank Design** Speakers will discuss the role of biospecimen research and biobanking in research focused on precision medicine. They will also review the broad variation in biobank design and how policies may differ depending upon the type of biobank and the research it supports.
9:00–9:45 AM	**Audience Questions/Panel Discussion**
9:45–10:15 AM	**That's mine! Commercial Use of Biospecimens, Ownership, Custodianship, and Benefit Sharing** Speakers will discuss ownership of biospecimens and issues arising from commercial use of biospecimens and associated data. They will also provide an overview of the concept of custodianship and how benefit can be shared in lieu of ownership.

Please note this agenda is subject to change.

10:15–10:30 AM	**Audience Questions/Panel Discussion**
10:30–10:45 AM	*Break*
10:45–11:15 AM	**What is Meaningful Consent for Future Use of Biospecimens? What an IRB Should Look for in a Broad Consent and Consider When Performing a "Limited IRB Review."** Speakers will discuss what constitutes meaningful consent for future use of biospecimens and what an IRB should look for when it reviews consent for future use of biospecimens, including "regulatory" broad consent, and when it performs "limited IRB review."
11:15 –11:45 AM	**Approaches for Implementing and Tracking Consent for Future Use of Biospecimens.** Speakers will discuss how consent for future use of biospecimens may be implemented and tracked within an institution to facilitate research, while at the same time protecting subject autonomy and the ability to withdraw consent.
11:45 AM–12:00 PM	**Audience Questions/Panel Discussion**
12:00–1:00 PM	*Lunch (provided)*
1:00–3:00 PM	**Tell me, Tell me: Return of Research Results in Biobanking – When and How to do it, Efficient, Effectively, and Ethically.** Speakers will review the complexities and challenges regarding the return of research results in biobanking. They will share actual experiences returning results in practice. A small breakout session is planned to help illustrate principles and approaches guiding policy development and practical implementation issues regarding the return of individual research results.
3:00–3:15 PM	*Break*
3:15–4:15 PM	**Best Practices for Biobank Governance and Biospecimen Access Policies and Procedures; Stakeholder Engagement in an Era of Research Towards Precision Medicine.** Speakers will discuss the importance of good governance and oversight of biobanks, as well as biospecimen and data access policies when institutions rely on broad consent. They will also discuss the importance of engaging participants in biobanking and various ways in which this may be accomplished. In addition, issues related to biospecimen utilization will be discussed.
4:15–4:30 PM	**Audience Questions, Panel Discussion, and Workshop Wrap-Up**
4:30 PM	**Adjournment**

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