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
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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

7:00–8:30 AM	*On-Site Check-In (breakfast on your own)*
8:30–8:40 AM	**Welcome and Introduction (Marianna J. Bledsoe, Michele Russell-Einhorn, and 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 broadvariation in biobank design and how policies may differ depending upon the type of biobank and the research it supports.** **Bill Grizzle - role of biospecimen research and biobanking in research towards precision medicine (15 min); precision medicine research vs. precision medicine; what does precision medicine research require as to biobanks and biospecimens.** **Marianna Bledsoe –variation in biobank design and how policies may vary depending upon the type of biobank and the research it supports (15 min).**

E-materials Link: http://bit.ly/aer18-biobanking
E-materials password: AER18!biobank

9:10–9:25 AM	**Audience Questions/Panel Discussion**
9:25–10:15 AM	**That's mine! Commercial Use of Biospecimens, Ownership, Custodianship, and Benefit Sharing** **Speakers will provide an overview of ownership of and requirements for retention of biospecimens. In addition, they will discuss issues arising from commercial use of biospecimens and associated data. They will also provide an overview of the concept of custodianship and discuss how benefits can be shared in lieu of ownership** **Mark Barnes – ownership (20 min)** **Marianna Bledsoe – custodianship and benefit sharing (10 min)** **Sarah Dry– requirements for biospecimen retention and other practical issues related to biospecimen sharing (20 min)**
10:15–10:30 AM	**Audience Questions/Panel Discussion**
10:30–10:45 AM	*Break*
10:45 – 11:00 AM	**Common Rule Revisions that Impact Biobanking** **Speakers will discuss certain changes to the Common Rule that will impact biobanking including changes to the definition of human subject, additional elements of consent as well as new exemptions.** **Michele Russell-Einhorn – (15 min)**
11:00–11:30 AM	**Broad Consent for Biobanking Under the Final Rule** **Speakers will discuss the pros and cons of "regulatory" broad consent and how biospecimens can be collected, stored and used under a non-regulatory broad consent. They will also discuss what a non-regulatory broad consent should look like and what an IRB should consider when reviewing consents for future use of biospecimens.** **Mark Barnes – (30 min)**
11:30 – 11:45	**Audience Questions/Panel Discussion**
11:45 –12:15 PM	**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.**

	How it is done at UCLA (including consent video) – Sarah Dry (15 min) **How it is done at UAB – Bill Grizzle (15 min)**
12:15 PM–12:30 PM	**Audience Questions/Panel Discussion**
12:30–1:15 PM	**Working Lunch (provided)**
1:15–3:00 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.** **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.** **Presentations and Case Studies TBA** **All faculty will participate**
3:00–3:15 PM	*Break*
3:15–4:15 PM	**Specimen Utilization, Best Practices for Biobank Governance and Biospecimen Access Policies and Procedures and Stakeholder Engagement in an Era of Research Towards Precision Medicine.** **Speakers will discuss the ethical and practical issues related to biospecimen utilization. In addition, they will review the importance of good governance and oversight of biobanks, as well as biospecimen and data access policies when institutions rely on broad consent. Finally, they will share practical experience governing biobanks, the importance of engaging participants in biobanking and various ways in which this may be accomplished.** **Design and operational issues related to biospecimen utilization – Bill Grizzle (15 min)** **Marianna Bledsoe – Best Practices for Biobank Governance and Biospecimen Access Policies and Procedures and impact on biospecimen utilization (15 min)** **Sarah Dry – Governance in Action and Stakeholder Engagement (30 min)**
4:15–4:30 PM	**Audience Questions, Panel Discussion, and Workshop Wrap-Up**
4:30 PM	*Adjournment*