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

Anaheim Convention Center- Anaheim, CA
November 13, 2016

The collection, storage, distribution and use of biospecimens from human individuals and subsequent data sharing is critical for the research advances and discoveries needed to advance precision medicine. However, biobanking in an era of research towards precision medicine raises significant challenges for Institutional Review Boards, institutions, regulators and policy makers, research repository managers, and funding agencies and sponsors. Methods for obtaining consent vary from institution to institution; and the prospect of new regulatory requirements raises an element of uncertainty. Broad sharing of biospecimens and data is absolutely essential for scientific discoveries to facilitate the development of precision medicine but raises a myriad of issues including those relating to obtaining meaningful consent as well as complex issues such as ownership of biospecimens and data, return of research results and other ethical issues. Finally, broad specimen and data sharing are subject to current or prospective regulatory requirements that may conflict with ethical objectives relating to meaningful consent and confidentiality of participation in research activities.

During Biobanking in an Era of Research Towards Precision Medicine: Approaches to the Ethical, Regulatory and Practical Challenges, faculty 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 tissue banking issues, as fundamentals are not included in this course.

<table>
<thead>
<tr>
<th>Time</th>
<th>Agenda</th>
</tr>
</thead>
<tbody>
<tr>
<td>7:30-8:30 AM</td>
<td>Registration <em>(breakfast on your own)</em></td>
</tr>
<tr>
<td>8:30-8:45 AM</td>
<td>Welcome and Introduction <em>(Marianna J. Bledsoe/Michele Russell-Einhorn, Co-facilitators)</em></td>
</tr>
<tr>
<td>8:45-9:30 AM</td>
<td>Role of Specimens and Biobanking in Research Towards Precision Medicine; and Biobank Design</td>
</tr>
<tr>
<td>Faculty: Mine S. Çiçek, PhD, William E. Grizzle, MD, PhD</td>
<td></td>
</tr>
</tbody>
</table>

Faculty will discuss the role of specimen research and biobanking in research towards precision medicine. They will also review the broad variation in repository design and how policies may differ depending upon the type of
repository.

9:30 - 9:45 AM  Audience Questions and Answers/Panel Discussion

9:45-10:15 AM  What an IRB Should Look for in a Repository Protocol

Faculty: Michele Russell-Einhorn, JD

Faculty will discuss what an IRB should look for when it reviews a repository protocol.

10:15 - 10:30 AM  Audience Questions and Answers/Panel Discussion

10:30-10:45 AM  Break

10:45-12:00 PM  What is Meaningful Consent for Future Use of Specimens? Best Practices in Governance and Specimen Access Policies; Stakeholder Engagement in an Era of Research Towards Precision Medicine

Faculty: Marianna J. Bledsoe, MA; Mine S. Çiçek, PhD, Michele Russell-Einhorn, JD

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. They will also discuss the importance of engaging participants in biobanking research and share their experiences engaging participants in biobanking. In addition, issues related to specimen utilization will be addressed.

12:00-12:30 PM  Audience Questions and Answers/Panel Discussion

12:30-1:30 PM  Working Lunch (Please pick up your boxed lunch and return to the course room)

Faculty: Marianna Bledsoe, MA and Michele Russell-Einhorn, JD

1:30-2:30 PM  That’s Mine! Commercial Use of Specimens, Ownership, Custodianship, Benefit Sharing, and Policies for Repositories

Faculty: Marianna J. Bledsoe, MA, William E. Grizzle, MD, PhD; Susan Stayn, JD

Faculty will discuss ownership of specimens and issues arising from commercial use of specimens and associated data. They will also provide an overview of the concept of custodianship and how benefits can be shared in lieu of ownerships. In addition, faculty will share their policies for repositories on these topics and share their experiences around these issues.
2:30-3:00 PM  Audience Questions and Answers/Panel Discussion

3:00-3:15 PM  Break

3:15-4:30 PM  Tell me, Tell me: Return of Research Results in Biobanking—When and How to do it, Efficiently, Effectively, and Ethically

Faculty: Marianna J. Bledsoe, MA, Mine Çiçek, PhD, William E. Grizzle, MD, PhD; Michele Russell-Einhorn, JD

Faculty will review the complexities and challenges regarding return of research results in biobanking. They will share experiences returning results and discuss how to return results efficiently, effectively and ethically. In addition, faculty will provide an overview of patient access rights under the Health Insurance Portability and Accountability Act (HIPAA) to individual research results.

4:30 PM – 5:00 PM  Audience Questions and Answers/Panel Discussion

Adjournment

Please note this agenda is subject to change.