ORD Tissue Banking Webinar #2

May 11th, 2017

Kristina Hill, MPH, MT(ASCP) (Biobanking Program Manager)

C. Karen Jeans, PhD, CCRN, CIP (Associate Director for Regulatory Affairs, CSRD)
Why are we having these webinars about biobanking?

- Off-Site Tissue Banking Waiver Program ended April 1st,
- ORD receives questions about biobanking
  - Researchers
  - Research Offices
  - Industry sponsors
- Webinars are designed to address questions related to the off-site tissue banking waiver program and address a different biobanking topic as part of each of the three webinars
Off-site tissue banking waiver program

- This was a voluntary program that has recently come to an end (April 1\textsuperscript{st})
- This voluntary program issued waivers for the banking or storage of VA biospecimens when sent off-site, or outside the VA
- Even though the program has ended VA biospecimens may continue to be banked or stored outside the VA with IRB, ACOS and VA R&D committee approvals
Off-site tissue banking waiver program

- Waivers that have previously been issued are still in effect
- If an off-site specimen storage waiver was issued on behalf of a for-profit sponsored study and they wish to store for longer than one year, ORD would need to be notified
  - The IRB and VA R&D committee would need to approve longer storage
  - Informed consent language would need to be reviewed if it specifies storage length
Tissue Banking Guidance

- Several guidance documents are posted on the tissue banking website that you can refer to when VA biospecimens are collected and banked for research
  - Elements to include in a biorepository protocol
  - Elements to include in an informed consent form when biospecimens will be banked
  - Stewardship of biospecimen collections when they are banked inside or outside the VA
  - More will follow based upon feedback received in these webinars and the questions ORD receives about biobanking
Focus for Today: Biorepository Protocols

- What is a biorepository?
  - Any collection of biospecimens (blood, tissue, saliva, urine, stool, hair, cells, genetic materials, etc.)
  - Retained for sharing and/or future use
  - May be with or without identifiers
  - May or may not involve associated data
Biorepository Basics

Collection of Biospecimens → Storage of Biospecimens → Distribution and Use of Biospecimens
Biorepository protocols

- Biobanks may be established
  1) From a single project and biospecimens may be made available for future research or,
  2) To serve as the storage facility made up of biospecimens from multiple projects that may be made available for future research.
Biorepository protocols – Initial Planning

- **Why?**
  - What is the purpose?

- **Who?**
  - Who is going to be the designated PI or director of the biorepository? Who are you collecting the biospecimens from?

- **How?**
  - Should you establish a biorepository protocol for a single-use (no future research expected) study biobank?
  - Do you need a completely separate protocol for the biorepository?

- **Where?**
  - Where are the biospecimens to be obtained, stored, and accessed?
Biorepository protocols: Critical Components - Collection

- Overall purpose and goals of the biorepository
- What types of research will be done on the biospecimens?
  - Broad (e.g. any use)?
  - Specific diseases/conditions?
  - Genetic testing/creation of cell lines?
- Who are biospecimens being obtained from?
  - Are the biospecimens identifiable?
  - Any unique or protected populations (i.e., Native Americans, rare diseases, children)?
  - Prospective or retrospective collection?
- What data may be collected along with the biospecimens?
Biorepository Protocol: Critical Components – Collection & Storage

- What specific biospecimens (e.g., whole blood, urine, biopsy tissue) will be collected?
- How will biospecimens be labeled (e.g., Barcode, biospecimen ID, etc.)? Will biospecimens be coded (e.g., linked to subject’s identity)?
- For coded biospecimens with a link to the subject’s identity, who will have access to the link, and how will that link be protected?
- How long will the biospecimens be banked (i.e. indefinitely, until they are used up, 10 years)?
- Where will the biorepository be located and how will you ensure the integrity of the conditions for storing the biospecimens?
Biorepository protocol: Critical Elements in Use & Distribution

- Is there a standard operating policy and procedure or SOP?
- Who will have access to the biospecimens?
- How will requests for access be received?
- How will decisions be made for granting or denying access?
  - Oversight committee (i.e., composition?)
  - Individual decision by the PI?
- Will an agreement be used for sharing biospecimens/data?
- How will records be maintained for requests for use, processing of requests, and distribution?
Human Subject Protection Issues

- When is the activity deemed human subjects research requiring IRB oversight?
- Is the biorepository part of a primary study protocol, and if so, is the biorepository portion a required or optional component?
- Is the type(s) of biospecimen(s) and the mechanism of collection described?
- Is there a description of the physical and procedural mechanisms for the secure receipt, storage, and transfer of biospecimens to ensure protection of subject’s privacy and confidentiality?
- Is there a description of how biospecimens may be shared?
- What happens if the PI leaves/lifespan of the protocol?
Key Human Subject Protection Issues: Informed Consent

- Are these consented specimens?
  - If so, how will consent be obtained?
- Does the consent form include all of the basic and applicable additional elements (i.e., nature and purposes of the collection)?
- Does the consent describe the biorepository’s location? How specific do you need to be?
- Will any results be returned to subjects?
- What are the conditions/requirements under which biospecimens may be shared?
- Will any associated data be shared?
Key Human Subject Protection Issues: Informed Consent (cont.)

- Can subjects agree to specific types of future uses or is it an all or nothing? Ex: Just cancer, future research on any disease.
- If genetic testing is a possibility and/or a future use, is that specified?
- What will be shared with requesting investigators?
- Can subjects withdraw or request destruction of biospecimens collected for the biorepository?
- What is the risk related to a breach of confidentiality?
- What is the lifespan of the biospecimens or how long will they be banked/stored? Indefinitely, 20 years, until used up?
Summary