

ORD Tissue Banking Webinar #2

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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 1st)
- 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



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