ORD Tissue Banking Webinar #3

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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
- This is the 3rd in a series of 3 biobanking 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
  - Draft guidance located at: http://www.research.va.gov/programs/tissue_banking/default.cfm

Focus for Today: Questions/Scenarios from Biorepository Seminars

- Address different questions and scenarios on a variety of issues related to use, storage, and dispensing of biospecimens.

Question #1

Are all biorepositores populated with biospecimens from consented subject's?

Question #2

VHA Handbook 1200.12: Use of Data and Data Repositories in VHA Research contains ORD's policies for data repositories. Do I have to follow those requirements when I am storing biospecimens?

Question #3

If an Investigator describes in the IRB-approved protocol specifically where the biospecimens for a biorepository will be stored (e.g., Room 214 at VA #2), is that level of specificity required in the informed consent document which is required by the IRB for my biorepository?

Question #4

Does the Material Transfer Agreement (MTA) guidance provided by ORD overrule or supersede any existing policy or requirements and can a Principal Investigator sign a MTA?

Question #5:

Can an Investigator collect and store biospecimens without having a biorepository protocol that describes how the biospecimens will be used?

Question #6:

What is ORD's role in reviewing requests if a VA Investigator is asked by an industry-collaborator to send biospecimens for long-term storage at the collaborator's location?

Question #7:

If an Investigator does not know whether or not genetic testing is going to be done when subjects are consented into a biorepository, is it acceptable to go ahead and proceed with genetic testing after the subjects are consented?

Scenario #1:

- A subject consented to put his identifiable biospecimens (lung tissue biopsy) in my [VA Investigator] biorepository in May of 2016. He also consented to allow collection of his medical information.
- The subject has just contacted me and wants me to destroy his biospecimens in my possession and end his participation for anything else having to do with the study.
- I have sent some of the biospecimens to three different Investigators as part of the biorepository access procedures.

Questions for scenario #1

1) Do I need to get the biospecimens back from the other Investigators?

2) Can I continue to use this person's data since it is not a biospecimen?

3) Can I use the data and biospecimens if both are de-identified?

Question #9:

What is meant by GWAS?

Question #10:

What is the most difficult aspect of writing a biorepository protocol?

Summary