

ORD Tissue Banking Webinar

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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 including information on Material Transfer Agreements and banking at a for-profit institution

Material Transfer Agreement (MTA)

- MTA's are commonly used when biospecimens are shared or transferred to show a chain of custody and ensure that they are used in a manner that respects the Veterans preferences and wishes if they were consented for their use
- This is NOT currently ORD policy when VA biospecimens are banked or stored outside the VA
- NIH mandates the use of MTA's and it is considered best practice

Material Transfer Agreements, cont.

- An MTA does not create authority for the use of the VA biospecimens. The use must be consistent with the approved research activity and if biospecimens are identifiable must meet applicable Privacy requirements
- MTA's cannot be used in place of a Data Use Agreement or DUA, but a combined version (MTA/DUA) may be used if data will also be sent off-site. **Refer to VHA Handbook 1200.12 if data will go into a data repository.**

Material Transfer Agreements, cont.

- If VA biospecimens will be sent to an outside testing laboratory and either returned or tested until used up an MOU or document of the transfer would be advisable, not an MTA
- If VA biospecimens are being sent outside the VA on behalf of a for-profit company, a Cooperative Research & Development Agreement or CRADA must have been established and an MTA would NOT be necessary

Stewardship

- Stewardship or custodianship is a care-taking responsibility for VA biospecimens whether they are stored at VA site or outside the VA
 - What if the Primary Investigator leaves?
 - What if the study the biospecimens were collected for ends or loses funding?



Discussion

What are the issues involving storage of VA specimens at a non-VA Facility (or a VA Facility)?