OFFICE OF RESEARCH AND DEVELOPMENT (ORD) VETERANS HEALTH ADMINISTRATION (VHA)

ORD Guidance on Registration of VA Research Biorepositories

Date: May, 2017

This guidance document represents the current position of the VHA Office of Research and Development on this topic. This finalized guidance is not binding as ORD policy. This guidance only refers to biospecimens. For questions relating to data associated with the biospecimens refer to VHA Handbook 1200.12.

For questions regarding this guidance, send them to offsite.tissuebanking@va.gov.

PURPOSE: The Global Registry of Scientific Collections (GRSciColl) is the first-ever consolidated, comprehensive clearinghouse of information about biological collections in natural history museums, herbaria, and other biorepositories. It is designed to improve access to information about biorepositories, the collections and specimens in those biorepositories, and the researchers who work with the biorepositories. Voluntary registration of biorepositories, including VA biorepositories, into the GrSciColl can help provide an inventory of biological specimen collections that may be made available for broad sharing and future research consistent with the applicable human subject protections and privacy regulations. It is important that Veteran biospecimens collected with the intent to be shared for future research purposes are made available when possible and consistent with the subject's informed consent and HIPAA authorization, so their contribution is not wasted. The GrSciColl is a voluntary mechanism that allows researchers to obtain information about biorepositories.

SCOPE: This guidance applies to all VA research biorepositories involving biospecimens from human beings. This guidance does not apply to non-human or data repositories. Please refer to VHA Handbook 1200.12 for ORD policies regarding data repositories.

- 1. What is a VA research biorepository?
- 2. What is registration?
- 3. Why should a VA research biorepository be registered?
- 4. Which VA research biorepositories should be registered?
- 5. What if a VA research biorepository is not registered?
- 6. VA research biorepository case-study examples

1. What is a VA research biorepository?

A VA research biorepository is considered to be a collection of human biological specimens, or biospecimens, which are maintained in VA space, or otherwise financially supported by VA, for the intended purpose of future research use. In order to be considered a VA research

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biorepository, the biorepository must be approved by the VA Facility's Research and Development Committee, as well as any other applicable subcommittees.

NOTE: A VA research biorepository does not include the following:

- 1) Any biospecimen collections stored strictly for clinical purposes or clinical care, OR
- 2) Research biospecimen collections stored for routine testing to complete the aims of a single study protocol, and not planned for future research use.

2. What is registration?

Registration is the process of entering detailed information regarding the VA research biorepository into the Global Registry of Scientific Collections (GRSciColl) website at http://grscicoll.org, managed by the Smithsonian Institute. Guidance for entering information onto the website can be found at,

<u>http://www.research.va.gov/programs/tissue_banking/default.cfm</u>. **NOTE:** The GRSciColl website was not created and is not maintained by the Department of Veterans Affairs.

3. Why should a VA research biorepository be registered?

VA research biorepositories should be registered so these resources may be used more broadly by researchers in the scientific community, whenever possible.

4. Which VA research biorepositories should be registered?

VA research biorepositories should be registered if they meet any of the following criteria:

- 1) The VA research biorepository is NOT already listed on another publically accessible website such as the NCI resource locator, NIH NeuroBioBank, etc.
- 2) The VA research biorepository meets one of the case examples in Paragraph 6 of this guidance document.

5. What if a VA Research Biorepository is not registered?

Registration is voluntary. There are no federal regulations or VA requirement that requires a VA Research Biorepository to be registered. A VA Investigator who chooses to register his or her VA research biorepository is providing information for other researchers regarding broad sharing and future research use of that specific biorepository, but a VA Principal Investigator would not be in noncompliance with federal regulations or VA requirements if he or she does not register a VA research biorepository that may fall under the guidelines of this guidance document.

6. VA research biorepository case-study examples

A VA research biorepository should be registered in all of the following cases:

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Case-study 1: The research biorepository is 100% funded by VA and stored in VA space. VA space includes space leased or owned by VA.

Case-study 2: The research biorepository is 100% funded by VA and biospecimens are stored in non-VA space due to insufficient space at the VA facility. NOTE: VA should not be financially supporting the indefinite off-site banking or storage, in non-VA space, of biospecimens without prior ORD approval.

Case-study 3: The research biorepository is partially funded by VA and partially funded by another institution. The percentage of funding from either institution is not relevant. The biorepository is located at the VA or in VA space. NOTE: The other funding institution should be aware of the intent to register the biorepository.

Case-study 4: The research biorepository is 100% funded by a non-profit institution such as NIH, DOD, or other source and is located at a VA facility or in VA space. **Example:** The affiliate university funds a study to create a research biorepository that will be stored or housed in VA space. NOTE: The other funding institution should be aware of the intent to register the biorepository.

Case-study 5: The research biorepository is unfunded and is located at the VA or in VA space.