OFFICE OF RESEARCH AND DEVELOPMENT

VETERANS HEALTH ADMINISTRATION

ORD Guidance on Stewardship of VA Research Biorepositories and Biospecimen Collections

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SCOPE: Stewardship of biorepositories and biospecimen collections is an important principle for their responsible management. Stewardship, or custodianship, is a care-taking responsibility for the biorepository or biospecimen collection from the time human biological specimens, http://www.research.va.gov/programs/tissue_banking/Humanbiospecimen-guidance.pdf, or biospecimens, are collected through their use, distribution, and destruction (when applicable). Responsible stewardship involves careful planning prior to establishing a biorepository. It requires the establishment of policies and procedures to ensure the long-term physical quality of the biospecimens and the privacy of human research participants. In addition, responsible stewardship helps ensure that biospecimens are used appropriately. The steward, or custodian, works with other key individuals in the management of the biorepository. Biorepository management includes controlling access to biospecimens, keeping records of all biospecimens in a biorepository, and ensuring that standard operating procedures or SOPs needed for the biorepository are developed and implemented appropriately**. NOTE***: This is intended to be used a guidance document, or best practice, and not an ORD requirement.*

1. What are the duties of a Biorepository Steward?

- The steward should maintain records (paper or electronic) for all biospecimens collected including, but not limited to, the type(s) of biospecimens, use, transfer and sharing of biospecimens, when applicable.

- The steward should ensure that copies of the protocol(s), informed consent(s) under which biospecimens were collected (when applicable), and HIPAA authorization(s) if PHI is involved, are retained along with information about the destruction of biospecimens (when applicable). If the biorepository contains biospecimen collections from several studies, copies of the protocol(s), informed consent(s), and/or HIPAA authorization(s) under which they were collected, along with information about the destruction of biospecimens should either be kept at the biorepository, at a designated coordinating center, or with the main PI or institution where the biospecimen collection originated from. If copies of the protocols and informed consents are not kept at the biorepository, there should be regular communication between the main PI, coordinating center, etc. and the biorepository in the case of participant withdrawal, any new use that requires confirmation in the informed consent(s), protocol(s), and/or HIPAA authorization(s) if the biorepository must close, etc.

2. What are the Elements to include in a Stewardship Plan?

- A stewardship plan should be included in the biorepository protocol or other supplemental document, such as an IRB application or SOP, and should be included in all amendments to those documents.

- A stewardship plan should identify who will serve as the steward of the biorepository or biospecimen collection.

- A stewardship plan should describe what happens to the biospecimens if the biorepository must be closed (e.g., funding issues, the designated steward leaves the institution). **NOTE:** *If a biorepository has been funded by or is stored at a VA facility, ORD should be notified before the entire collection is destroyed.*

- A stewardship plan should describe what happens to the biospecimens if the steward of the biorepository leaves the institution. ***NOTE:*** *Investigators who leave VA employment may not remove any biospecimens from the VA and subsequently carry them to their new institution, if applicable. Investigators may only carry specimens to an affiliate university, institution, company, etc. if this is explicitly stated in the protocol, informed consent and HIPAA authorization, when applicable.*