

**OFFICE OF RESEARCH AND DEVELOPMENT
VETERANS HEALTH ADMINISTRATION**

**ORD Guidance on Information to Include in a Biorepository Protocol
Requiring IRB Approval**

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SCOPE: This document focuses on components of a biorepository protocol for VA research biorepositories and any other biorepository established for future use. For purposes of this guidance, “future use” is when human biological specimens http://www.research.va.gov/programs/tissue_banking/Humanbiospecimen-guidance.pdf (biospecimens) are collected, stored and/or distributed specifically for the purpose of using the biospecimens for future use. **NOTE:** *This is a guidance document set forth as a best practice and not an ORD requirement. Informed consent for the collection of biospecimens must be obtained in accordance with VHA Handbook 1200.5. This guidance document only refers to biospecimens. For details related to data repositories refer to VHA Handbook 1200.12.*

Background: All biorepositories or biobanks are not the same. Some biorepositories serve as central storage and distribution facilities for biospecimens collected from multiple studies for future research use. Other biorepositories originate from a single research protocol designed solely for the purpose of future use. While this guidance aims to identify the information that may be useful for review by the IRB responsible for oversight of biorepositories, investigators and institutions may need to include additional information to assure compliance with applicable Federal, state and local laws.

1. General Information When Designing a Biorepository Protocol

- Biorepository protocols should provide enough information to allow an IRB to satisfy its obligations under applicable HHS protection of human subjects regulations (38 C.F.R. part 16)¹. In addition, these protocols should include enough information for IRBs to satisfy their obligations under applicable FDA regulations, other Federal regulations, state laws, and local laws.
- The amount of information and level of detail required for IRB review of these protocols varies depending upon numerous factors, including, but not limited to, the size and

¹ <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>

purpose of the biorepository, and the identifiability of the persons from whom the biospecimens are collected.

- A completely separate biorepository protocol may be utilized in conjunction with a main research study protocol when biospecimens will be banked for future use. Alternatively, a separate section of the main study protocol could be marked or clearly delineated for the biorepository protocol section.

2. Specific Information That Should be Included in Biorepository Protocols

- The protocol should contain the overall goals and purpose of the biorepository.
- The protocol should contain an explanation of what types of research will be conducted using the biospecimens from the biorepository. It should be specific, unless the types of future research is not clear at the time of the biorepository's creation, but a broad description should be used.
- The protocol should include a description of the biospecimen collection procedures for the biorepository. If the biorepository is storing prospective (newly collected or collected in the future) biospecimens, it should be described how the individuals from whom the biospecimens are obtained will be recruited and selected. If the biorepository is utilizing retrospective (previously collected) biospecimens, the protocol should describe how the biospecimens will be identified and selected for inclusion into the biorepository.
- The protocol should include a description of biospecimens from unique populations that may include rare diseases, particular ethnic, racial, or social groups, populations that may have a unique view about human biological specimens (e.g., certain Native American groups), or particular geographic regions.
- The protocol should describe exactly what types of biospecimens will be collected (e.g., blood, DNA, urine, biopsy tissue) along with how they will be collected. It is important to include if biospecimens will be collected specifically for the biorepository or obtained from already existing diagnostic biospecimen archives. It should be explained if biospecimens are collected during the course of routine medical care and that individual patient care will not be compromised as a result of biospecimen banking and/or biospecimen distribution.
- The protocol should describe what data will go along with the biospecimens. Refer to VHA Handbook 1200.12 regarding data repositories for more information on data.
- The protocol should include the biorepository's policy, if any, concerning when, if ever, individual research results might be returned to participants. (Be explicit about the processes proposed to evaluate the risks and benefits associated with the return of individual research results to participants, if any and requested). For example, what is the biorepository's policy, if any, concerning when, if ever, incidental findings (which may

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include clinically significant biomarkers) will be returned to participants? It is currently a requirement under HIPAA that patients may request their health information, which may include laboratory test results. **NOTE:** *Individual research results are not normally returned to participants unless directly related to their care, they have been clinically validated, or run in a laboratory that is certified under the Clinical Laboratory Improvement Amendments, or CLIA.*

- The protocol should include the biorepository's policy, if any, about returning aggregate, generalized research findings to participants and how this will be accomplished. This may be in the form of quarterly newsletters, access to a publically available website, etc. **NOTE:** *There are established guidelines for the depositing of clinical trial data on ClinicalTrials.gov.*
- If the biospecimen collection or biorepository is prospective, the protocol should include details regarding the method used to recruit participants, and how and where they will be consented.
- If the biospecimen collection or biorepository is retrospective, the protocol should include details about where and how biospecimens were obtained and if there was informed consent, or a waiver of informed consent, for their collection and use.
- The protocol should explain if participants will be able to withdraw their biospecimens from the biorepository and if they cannot what the reasoning is (e.g., biospecimens have been anonymized (the link between the biospecimen and the participants identity has been destroyed or deleted), biospecimens have already been distributed to researchers, etc.).
- The protocol should explain if the biospecimens are linked back to the participant by way of a key and where this key is located (e.g., VA, outside the VA, PI's office, etc.).
- The protocol should describe how biospecimens are labeled (e.g., Specimen ID, barcode, etc.). Biospecimens should be labeled without direct participant identifiers whenever possible to avoid privacy and confidentiality issues.
- The protocol should explain who will have access to the biospecimens while stored or banked in the biorepository. For example, will the biospecimens be banked in a locked freezer or room with restricted access?
- The protocol should state where the biorepository is located.
- The protocol should state how long the biospecimens will be retained (e.g., indefinitely, 20 years).

- The protocol should describe the potential use of the biospecimens in the biorepository, if known at the time of creation. It should be described if DNA or RNA will be tested or if permanent cell lines will be created.
- The protocol should state if the biospecimens will be sent to outside researchers and how that will be accomplished. It should be described if there will be an oversight committee approving requests for biospecimens, if the outside researcher who is applying needs IRB approval, and what types of agreements may be used when sending out biospecimens (e.g., MTA's, MOU's).
- The protocol should describe how the participants' privacy will be protected (e.g., employee confidentiality agreements, encryption techniques, Certificates of Confidentiality, <http://www.research.va.gov/services/csrd/confidentiality.cfm>, "honest broker", agreements prohibiting re-identification of biospecimens by recipients). In addition, there should be an explanation of any policies or procedures about the release of identifiable information, if applicable, and any policies or procedures to ensure that biospecimens are used consistently with informed consent (if applicable).
- The protocol should include a description of any oversight for the biorepository, if established (e.g., IRB, ethical advisory board, oversight committee, etc.). In addition, there should also be a description of the stewardship plan for the biorepository. Include an explanation of what might happen if the biorepository loses funding or the steward/custodian or biorepository director leaves the institution.
- The protocol should include or describe any standard operating procedures or SOPs for the biorepository. SOPs could be included with the protocol or in the form of a separate SOP manual.
- The protocol should include or describe a manual of operations or MOO for the biorepository. A MOO could be included with the protocol or in the form of a separate manual.