

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

Guidance on What to Include in an Informed Consent Document When Banking or Storing VA Biospecimens for Research Purposes

Date: October 19, 2016

SCOPE: Informed consent for the collection of biospecimens must be obtained in accordance with VHA Handbook 1200.5. **NOTE:** *This is a guidance document set forth as a best practice and not an ORD requirement. This guidance document only refers to biospecimens. For details related to data repositories refer to VHA Handbook 1200.12.*

Elements to include in an informed consent document when banking or storing VA biospecimens for research

- (1) A description of the biospecimens to be banked/stored and the process for banking/storing them.
- (2) A description of the research to be conducted with the biospecimens including what future research may be performed, if known at the time of collection. It should be stated if DNA and/or RNA will be collected and stored for future studies, when applicable. *Note: If the future research is not known at the time of the research study under which the biospecimens are collected or the biorepository's inception, a generalized or broad description of the future research is acceptable; however, if genetic testing is anticipated, it should be mentioned.*
- (3) A description of the conditions under which biospecimens will be released to other researchers and whether they will be released outside the VA. These conditions might include the requirement of a Material Transfer Agreement, an IRB approved protocol for use of the biospecimens, etc.
- (4) A description of the risks from biospecimen banking/storage including any risks to privacy and confidentiality, for example, specimen identifiers on the specimen labels, or any data that may be linked to the biospecimens.
- (5) Information about possible consequences of DNA/RNA analyses (such as disclosure of paternity, potential identifiability, implications for family members, etc.) if genetic or genomic

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research is anticipated. Potential risks may include breach of confidentiality, which may lead to discrimination in the areas of employment, insurability, social stigmatization, or psychological stress caused by disclosure of adverse information to the subject or the subject's family.

(6) When and under what conditions research results will be conveyed to the participant, the participant's family, or the participant's physician. **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. This does not apply to the mandated reporting of results on Clinical Trials.gov.*

(7) Whether biospecimens may be provided to a for-profit company for the development of products and, if so, whether commercial benefits may be expected for the company and a statement that the participant should not expect to receive any of those benefits.

(8) What will happen to the biospecimens if the individual withdraws from participation in the biorepository, or research study, before its completion. The informed consent form should clearly state how participants may withdraw their consent and what will happen to their biospecimens if they do withdraw consent. Conditions under which it is not possible to withdraw biospecimens should be clearly explained. *For example:* Biospecimens may not be able to be withdrawn if they have already been sent out for testing or to outside investigators.

(9) When biospecimens are collected for future use, or the creation of a biorepository, as an optional component of participation in a research study, the informed consent for banking biospecimens should be a separate section of the main research study informed consent form. Alternatively, there could be a separate informed consent form for the optional biobanking component.

(10) If the biorepository or biospecimen collection will be stored outside of the United States at **the time of study initiation**, the country of storage should be stated in the informed consent.