



Application for Biospecimen Storage at a For-Profit Institution

INSTRUCTIONS

This form may be filled in and saved using Adobe Reader version 6.0 or higher. The full version of Adobe Acrobat is not needed.

Additional information that would help us review your application should be added on page 3, #8 under comments.

To apply for storage of biospecimens at a for-profit institution for >90 days, the response to each of the following **MUST** be YES:

- Only analysis/tests described in the protocol and informed consent will be performed. The specimens will not be used for future studies. YES NO
- All specimens and associated data will be de-identified. (They must be labeled with a code that does not contain any of the 18 HIPAA identifiers listed on page 4.) YES NO
- The key to the code that links the biospecimens to the subject's identity will be stored ONLY at the VA Medical Center. YES NO
- If genetic material, (e.g., DNA, RNA, other) is studied, only unique clearly delimited genetic products will be studied. Genome-wide association studies will not be performed. YES NO
- Biospecimens will be destroyed within 1 year of the study completion date. YES NO
- The company will inform the PI in writing when samples are destroyed. YES NO
- The subject's biospecimens will be destroyed upon his/her request. YES NO
- Case reports will not contain initials if they leave the VA Medical Center. YES NO

1. VA MEDICAL CENTER

Station no.	Name and location (city, state)
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2. VA PRINCIPAL INVESTIGATOR

Last name, first name	Degree(s)	VA paid status
Telephone	E-mail	

3. ACOS FOR RESEARCH AND DEVELOPMENT

Last name, first name	Degree(s)
Telephone	E-mail

4. PERSON COMPLETING THIS FORM

Last name, first name	Title
Telephone	E-mail

5. BIOSPECIMEN STORAGE	
Name of institution where the biospecimens will be stored	
Location of institution where biospecimens will be stored (city, state/country)	
6. INFORMATION ABOUT THE STUDY	
Title of the study	No. of subjects you plan to enroll at this site:
Study sponsor(s)	Start date
	End date
Please describe in detail the studies/analyses that will be performed on the biospecimens.	
Are other VA Medical Centers participating in this study?	<input type="checkbox"/> YES <input type="checkbox"/> NO
Is IRB and R&D Committee approval contingent upon this waiver?	<input type="checkbox"/> YES <input type="checkbox"/> NO
7. INFORMATION ABOUT THE BIOSPECIMENS	
Types(s) of biospecimens collected and stored (<i>e.g., blood, lung tissue, buccal swab, DNA</i>)	How long will the biospecimens be stored? (<i>They may be stored up to 1 year after the completion of the study.</i>)
How are the biospecimens secured? (<i>locked freezer, locked room, etc.</i>)	

The biospecimens MUST be labeled with a code that does not contain the subject's name, initials, SSN, or anything derived from the 18 HIPAA identifiers listed on page 4.

Describe the code used to identify the samples (e.g., bar code or study site number followed by a hyphen and 5 random numbers and letters). **Note: Subject's initials are a HIPAA identifier and may not be used as part of the code.**

8. INFORMATION ABOUT THE STUDY DATA

Will any data be sent or stored outside of the VA? (Data includes clinical and/or demographic data, as well as x-rays and scans.)

YES

NO

If YES, state where and why it needs to be outside the VA.

Comments (additional information that would help us review your application)

9. DOCUMENTATION

The following documentation is required, in addition to this completed form:

- Research protocol
- Informed consent form and accompanying HIPAA authorization
- IRB approval letter*
- Written notification of approval from the ACOS for R&D, or R&D Committee approval letter *

*If IRB and R&D Committee approval are contingent upon this waiver, these approval letters may be sent to us after this application has been approved.

10. RESEARCH OFFICE CONTACT

Person in the research office who forwarded this application

Last Name, First Name

Phone

E-mail

11. PI CERTIFICATION

By typing his/her name in the space below, the PI verifies that he/she has reviewed this application for accuracy and completeness.

SUBMISSION OF APPLICATION	
<p>Forward this completed application and the documentation listed in section 9 to your Research Office.</p> <p>The Research Office should forward the application to Kristina Hill in Central Office.</p> <p><i>Electronic applications (via e-mail) are preferred.</i></p>	<p>Kristina Hill, MPH, MT(ASCP) Department of Veterans Affairs Biomedical Laboratory R&D Service (121E) 810 Vermont Avenue, NW Washington, DC 20420 E-mail: offsite.tissuebanking@va.gov Phone: 202-443-5675 Fax: 202-495-6181</p>
DEFINITIONS	
HIPAA Identifiers	
<ul style="list-style-type: none"> ▶ Names and initials ▶ All geographic subdivisions smaller than a state ▶ All elements of dates (except year) for dates directly related to an individual ▶ Telephone numbers ▶ Fax numbers ▶ E-mail addresses ▶ Social security numbers or parts of them, scrambled or unscrambled ▶ Medical record numbers ▶ Health plan beneficiary numbers ▶ Account numbers ▶ Certificate/license numbers ▶ Vehicle identifiers and serial numbers, including license plate numbers ▶ Device identifiers and serial numbers ▶ Web URLs ▶ Internet Protocol (IP) address numbers ▶ Biometric identifiers, including fingerprints and voiceprints ▶ Full-face photographic image ▶ Any other unique identifying number 	
De-identified Data	
<p>De-identified data is health information that does not identify an individual and there is no reasonable basis to believe that the information can be used to identify an individual.</p> <p>VHA would consider health information no longer protected health information (PHI) if it has been appropriately de-identified in accordance with the HIPAA Privacy Rule as outlined in VHA Handbook 1605.1, Appendix B.</p> <p>For protected health information to be de-identified, all of the 18 HIPAA identifiers listed above must be removed. HIPAA identifiers also pertain to the person's employer, relatives, and household members. Along with removing the 18 identifiers, HIPAA also states that for the information to be considered de-identified, the entity does not have actual knowledge that the remaining information could be used alone or in combination with other information to identify an individual who is the subject of the information.</p> <p>According to the Common Rule (http://www.access.gpo.gov/nara/cfr/waisidx_98/38cfr16_98.html), de-identification involves removal of all information that would identify the individual or would be used to readily ascertain the identity of the individual.</p> <p>Note: For VA research purposes, VA research data are considered to be “de-identified” only if they meet the de-identification criteria of BOTH HIPAA (i.e., removal of all 18 identifiers) AND the Common Rule.</p> <p>Note: If the recipient of the biospecimens or the data has access to the key to the code, the coded information is not considered “de-identified.”</p>	