Department of Veterans Affairs

# Application for an Off-Site Tissue Banking Waiver at a Non-Profit or Academic Institution

## INSTRUCTIONS

**This form may be filled in and saved using Adobe Reader version 7.0 or higher. The full version of Adobe Acrobat is not needed.**

When you have completed the application, please e-mail it to the ACOS/R or designated person in your Research Office. The Research Office should forward the application to Kristina Hill in Central Office.

Please answer all questions. If a question does not apply, please insert "N/A." Additional information that would help us review your application should be added on page 5 in section 9D.

**Before using this application, make sure that the following apply:**

The biological specimens will be collected and stored for ***future research purposes*** that are beyond the scope of work described in the original protocol and informed consent ***or*** the biological specimens will be collected under a ***protocol designed for banking*** of specimens.

Biospecimens will be banked outside of the VA at a non-profit or academic institution (e.g., university or NIH-sponsored biorepository).

The study is sponsored by a non-profit institution **or** if the study is sponsored by a for-profit company, biospecimens will not be sent to the company.

| **1. VA MEDICAL CENTER** | |
|---|---|
| A. Station no. | B. Name and location (city, state) |

| **2. VA PRINCIPAL INVESTIGATOR** | | |
|---|---|---|
| A. Last name, first name | B. Degree(s) | C. VA paid status<br>WOC |
| D. Telephone | E. E-mail | |

| **3. ACOS FOR RESEARCH AND DEVELOPMENT** | |
|---|---|
| A. Last name, first name | B. Degree(s) |
| C. Telephone | D. E-mail |

| **4. PERSON COMPLETING THIS FORM** | |
|---|---|
| A. Last name, first name | B. Degree(s) |
| C. Telephone | D. E-mail |

| **5. TISSUE BANK(S)** | |
|---|---|
| **If biospecimens are going to be stored at more than one tissue bank, please give the name, location, and URL for each.** | |
| A1. Name of tissue bank | A2. Name of 2nd tissue bank, if applicable |
| B1. Location of tissue bank (city, state) | B2. Location of 2nd tissue bank, if applicable |
| C1. URL of tissue bank web site | C2. URL of 2nd tissue bank, if applicable |

| **6. INFORMATION ABOUT THE STUDY** | | |
|---|---|---|
| A. Title of the study | | B. No. of subjects you plan to enroll at this site: |
| C. Study sponsor | D. Grant or award no. | E. Start date<br><br>F. End date |

G1. Are other VA Medical Centers participating in this study?

☐ YES ☐ NO ☐ NOT SURE

G2. If Yes, please name the other Centers, if known. ***Note: Only one application should be submitted for all participating VA Medical Centers.***

H. Is IRB and R&D Committee approval contingent upon this waiver?

☐ YES ☐ NO

| **7. INFORMATION ABOUT THE BIOSPECIMENS** | |
|---|---|
| A. Types(s) of biospecimens collected and banked ( *e.g., blood, lung tissue, buccal swab, DNA* ) | B. How long will the biospecimens be banked? |

C1. Have biospecimens already been sent to the tissue bank named in section 5 above?

☐ YES ☐ NO

C2. Are the biospecimens being banked at the VA until the off-site tissue bank is approved?

☐ YES ☐ NO

D1. Does the informed consent under which the biospecimens were collected specify that they will be used for future research?

☐ YES ☐ NO

D2. If YES, specify the type of future use (*e.g., any study on this disease/condition, any future study, genetic studies, etc.*).

E1. Will all future uses of VA biospecimens be done through VA-approved protocols?

☐ YES ☐ NO

E2. If NO, provide a clear description of the reasons and the mechanisms used by the bank to distribute biospecimens to researchers, including a description of the oversight.

F. How are the biospecimens secured? (*locked freezer, locked room, etc.*)

**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 6.**

F. 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.**

G1. Will the key to the code that links the biospecimens to the subject's identity be maintained ONLY at the VA facility?

☐ YES ☐ NO

G2. If NO, indicate where else a copy of the key will be maintained and why. (Exceptions are not routinely approved.)

H1. Who has access to the key? (*PI, study coordinator, data coordination center director, etc.*)

H2. Are any of the people who have access to the key outside of the VA?

☐ YES ☐ NO

H3. If YES, who? (*study coordinator, data coordination center director, etc*.)

I. How is the key secured at all locations? (*locked file cabinet, in a password-protected database that is encrypted, etc.*)

**8. INFORMATION ABOUT THE STUDY DATA**

A1. 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 (skip to section 9)

A2. If YES, state where and why it needs to be outside the VA.

A3. If YES, will the data be de-identified? (Please see the definition of de-identified on page 6 of this form.)

☐ YES (skip to section 9) ☐ NO

B. If data leaving the VA is NOT de-identified according to the definition on page 6 of this form, it must be transferred in a secure manner. Indicate how the data will be transferred (*VPN, encrypted e-mail*).

C. If any of the HIPAA identifiers will be stored in an off-site database, the database should have limited access and be encrypted. It should be clearly stated in the HIPAA authorization what will be stored. Social security numbers should NOT be stored in an off-site database unless required for billing purposes (any other requests will be handled on a case by case basis). Social security numbers may NOT be stored in a for-profit company's database.

**9. ADDITIONAL INFORMATION**

A. Provide the justification for banking biospecimens at a non-VA repository.

B. Upon termination/closing of the bank, what will happen to veterans' biospecimens?

- ☐ Biospecimens will be destroyed.
- ☐ Biospecimens will be returned to the originating VA facility.
- ☐ Other. Please provide an explanation.

C. If the subject withdraws from a study, what will happen to his/her biospecimens and data?

- ☐ Biospecimens will be destroyed except for any de-identified samples that have been shared with other researchers. The research team will continue to use any information that they have already collected from the subject to ensure the integrity of the research. However, no new information will be collected from the subject.
- ☐ Biospecimens and all data linked to that subject will be destroyed.

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

**10. DOCUMENTATION**

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

Research protocol

Informed consent form and separate HIPAA authorization

Information regarding the bank's policies, mechanisms of tissue acquisition and redistribution, and all oversight mechanisms in place (or complete the Tissue Bank Operations Form).

IRB approval letter*

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 ORD has approved this application.

**11. RESEARCH OFFICE CONTACT**

Person in the research office who forwarded this application

Last Name, First Name

| Phone: | E-mail: |
|---|---|

**12. 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.

**13. SUBMISSION OF APPLICATION**

| | |
|---|---|
| Forward this completed application and the documentation listed in section 10 to your Research Office.<br>The Research Office should forward the application to Kristina Hill in Central Office.<br>*Electronic applications (via e-mail) are preferred.* | Kristina Hill, MPH, MT(ASCP)<br>Department of Veterans Affairs<br>Biomedical Laboratory R&D Service (121E)<br>810 Vermont Avenue, NW<br>Washington, DC 20420<br>E-mail: offsite.tissuebanking@va.gov<br>Phone: 202-443-5675 Fax: 202-495-6181 |

## 14. DEFINITIONS

### HIPAA Identifiers

- 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

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.

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. 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.

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.

**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.

**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.”