VA Portland Health Care System (VAPORHCS) Institutional Review Board

APPLICATION FOR AN OFF-SITE BIOSPECIMEN
BANKING WAIVER AT A NON-VA INSTITUTION

**VAPORHCS PI Name:       Date:**

**Study/Project ID#:**

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| **Before using this application, make sure 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, for-profit or academic institution (e.g., NIH-sponsored biorepository, pharmaceutical company or university ).
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| **INSTRUCTIONS:** *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 in section 5D.***Please include the following along with this form:**[ ]  **Information regarding the bank’s repository’s policies, mechanisms of tissue biospecimen acquisition and redistribution, and all oversight mechanisms in place.**  |
| **1. BIOSPECIMEN REPOSITORY(IES)** |
| **If biospecimens are going to be stored at more than one biospecimen repository, please give the name, location, and URL for each.**  |
| A1. Name of biospecimen repository      | A2. Name of 2nd biospecimen repository, if applicable      |
| B1. Location of biospecimen repository (city, state)      | B2. Location of 2nd biospecimen repository, if applicable      |
| C1. URL of biospecimen repository web site      | C2. URL of 2nd biospecimen repository, if applicable      |
| **2. ADDITIONAL SITES INFORMATION** |
| 1. Are other VA Medical Centers participating in this study? [ ]  YES [ ]  NO [ ]  NOT SURE2. If Yes, please name the other Centers, if known.       |
| **3. INFORMATION ABOUT THE BIOSPECIMENS** |
| 1. Types(s) of biospecimens collected and banked (*e.g., blood, lung tissue, buccal swab, DNA*)

***NOTE: If biospecimens are going to be banked at more than one repository, please indicate the repository name/location for each biospecimen/type.***      |
| B. How long will the biospecimens be banked?      |
| C1. Have biospecimens from this study already been sent to the biospecimen repository named in section 1 above?[ ]  YES [ ]  NOC2. Are the biospecimens from this study being banked at the VA until the off-site biospecimen repository is approved?[ ]  YES [ ]  NO  |
| D1. Does the informed consent form (ICF) under which the biospecimens were collected specify that they will be used for future research?[ ]  YES [ ]  NOD2. If YES, specify the type of future use (*e.g., any study on this disease/condition, any future study, genetic studies, etc.*) and confirm this is clearly indicated in the ICF.      |
| E. How are the biospecimens secured from the time they are obtained through the time they are in the repository? (*locked freezer, locked room, etc.*)      |
| 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*).  |
| G1. Will anyone outside of the VA be able to link the biospecimens back to any of the individuals’ 18 HIPAA identifiers (such as dates of specimen collection)?[ ]  YES [ ]  NOG2. If YES, indicate who else and/or which other institutions will be able to link them (either directly or using a code) and why.       |
| H. How is the linking information kept secure at all locations? (*locked file cabinet, in a password-protected database that is encrypted, etc.*)      |
| **4. INFORMATION ABOUT THE STUDY DATA** |
| A1. Will any data be sent to and/or stored by the repository listed above? (*Data includes clinical and/or demographic data, as well as x-rays and scans.*)[ ]  YES [ ]  NO (skip to section 5)A2. If YES, explain why it needs to be sent and/or stored there.     A3. If YES, will the data be de-identified? (Please see the definition of de-identified below.) [ ]  YES (skip to section 5) [ ]  NO |
| B. If data/information leaving the VA is NOT de-identified according to the definition below, it must be transferred in a secure manner. Indicate how the data/information sent to the repository(ies) will be transferred *(e.g., tracked USPS mail, etc.*).      |
| C. If any of the HIPAA identifiers will be stored in an off-site database, provide assurance that the database will have limited access and be encrypted and that the ICF and HIPAA authorization clearly address what will be stored there. (Social security numbers generally should NOT be stored in an off-site database. In order to request such storage, provide a justification for doing so.)       |
| **5. ADDITIONAL INFORMATION** |
| A. Provide the justification for banking biospecimens at a non-VA repository.      |
| B. Upon termination/closing of the repository, 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 for this study may 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)      |

**Office Use Only:**

[ ]  Approved [ ]  Disapproved

**Signature of ACOS/Research and Development Date**

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| **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 to no longer be 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. 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, de- identification involves removal of all information that would identify the individual or could 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 link back to any of the 18 HIPAA identifiers, the coded information is not considered “de-identified.” |