VA Portland Health Care System (VAPORHCS) Institutional Review Board

APPLICATION FOR A BIOSPECIMEN STORAGE WAIVER AT A FOR-PROFIT INSTITUTION

**VAPORHCS PI Name:       Date:**

**Study/Project ID#:**

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| **INSTRUCTIONS:** Please answer the following questions and provide additional information that would help us review your application on page 2, #4 under comments. | **YES** | **NO** |
| Only analysis/tests for the direct aims of this project, as specified in the protocol and informed consent form, will be performed. The biospecimens will not be used for any other studies or work. |  |  |
| All biospecimens and all associated information will be de-identified (i.e. none of the 18 HIPAA identifiers, including dates of biospecimen collection, as listed on page 2, are sent to this institution). |  |  |
| Identifiers will be included in the information (as described and justified below) sent to this institution. |  |  |
| If the biospecimens and information are to be de-identified, the key to the code that links the biospecimens to any of the 18 HIPAA identifiers will be stored ONLY at the VAPORHCS. N/A – Identifiers will be sent to institution. |  |  |
| If genetic material (e.g., DNA, RNA, other) is studied, only unique clearly delimited genetic products will be studied. Genome-wide associated studies will not be performed. |  |  |
| Biospecimens will be destroyed or returned within 1 year of the study completion date. |  |  |
| Biospecimens will be retained for longer for the reasons provided below. |  |  |
| The institution will inform the PI in writing when biospecimens are destroyed. |  |  |
| The institution will return all remaining biospecimens to the VAPORHCS. |  |  |
| The subject’s biospecimens will be destroyed upon his/her request. |  |  |

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| **1. BIOSPECIMEN STORAGE** | | | | |
| Name of institution where the biospecimens will be stored: | | | | |
| Location of institution where biospecimens will be stored (city, state/country)**:** | | | | |
| **2. INFORMATION ABOUT THE STUDY** | | | | |
| Study Sponsor(s): | | | | |
| Please describe in detail the tests/analyses that will be performed on the biospecimens. | | | | |
| Are other VA Medical Centers participating in this study? | **Yes** | | **No** | |
| **3. INFORMATION ABOUT THE BIOSPECIMENS** | | | | |
| Type(s) of biospecimens collected and stored (e.g., blood, lung tissue, buccal swab, DNA): | | | | |
| How long will the biospecimens be stored? (If more than 1 year after the completion of the study, provide justification.) | | | | |
| How are the biospecimens secured from the time they are obtained through the time they are stored at the non-VA institution (or returned to the VA, if applicable)? (locked freezer, locked room, etc.) | | | | |
| Describe the code used to identify the biospecimens (e.g. barcode or study site number followed by a hyphen and 5 random numbers and letters). | | | | |
| **4. INFORMATION ABOUT THE STUDY DATA** | | | | |
| Will any data be sent to and/or stored by this non-VA institution? *(Data includes clinical and/or demographic data, as well as x-rays and scans.)* | | **Yes** | | **No** |
| If YES, explain why it needs to be sent and/or stored there and how identifiable it will be (e.g. coded, but only the local study team will be able to link back to any identifiers).  If data/information leaving the VA is NOT de-identified according to the definition at the end of this form, it must be transferred in a secure manner. Indicate how the data/information sent to the repository(ies) will be transferred *(e.g., tracked UPS mail, etc.*). | | | | |
| Comments **(additional information that would help us review your application):** | | | | |
| **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.” | | | | |

**Office Use Only:**

**Approved**  **Disapproved**

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