|  |
| --- |
| **Application for On-Site Human Biological Specimens (HBS) Bank/Repository at the Atlanta VAMC** |
| PLEASE NOTE: THIS HBS BANK MUST BE REVIEWED ANNUALLY. 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. “HBS” and “Tissue”, as well as “bank” and “repository” are used interchangeably in this document. |
| **Before using this application, check both boxes to ensure that the following two items apply:**[ ]  The biological specimens will be collected and stored at the Atlanta VAMC 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 in a laboratory inside the Atlanta VAMC in Decatur, GA.**EXCEPTION:** If biospecimens are banked offsite, DO NOT USE THIS FORM. |
| 1. **ATLANTA VA PRINCIPAL INVESTIGATOR**
 |
| 1. Last name, First name

       | 1. Degree(s)

       | 1. PI’s VA appointment (Full, Part time or WOC)

       (?/8ths) |
| D. Telephone       | E. E-mail       |
| 1. **CONTACT PERSON**
 |
| 1. Last name, first name

      | 1. Degree(s)

      |
| C. Telephone (Day):      Emergency/24 hour Contact:       | D. E-mail      |
| 1. **TISSUE BANK**
 |
| A. Name of tissue bank (or Protocol Title) IRB No.              |
| B. Location of tissue bank Floor:       Room #:       Freezer description:       |
| **4. INFORMATION ABOUT THE BIOSPECIMENS** |
| 1. Types(s) of biospecimens collected and banked (e.g., *blood, lung tissue, buccal swab, DNA, etc.)*

List:       | 1. How long will the biospecimens be banked?

      |
| 1. Are the biospecimens being sent out of this facility for testing before being banked? [ ]  No [ ]  Yes\*\*

\*\* If Yes, indicate where they are being sent and for how long they are outside of the AVAMC:       |
|  D. Does the informed consent under which the biospecimens were collected specify that they will be used for future research? (please note: future use **must** be addressed in the consent form) [ ]  Yes; specify the type of future use (e.g., any study on this disease/condition, any future study, genetic studies, etc.):        [ ]  No\*\* \*\*If No, please see the Research Office for further guidance.  |
|  E. Will all future uses of VA biospecimens only be done at VA institutions? [ ]  Yes [ ]  No\*\* If YES – Skip to Section F. |
|  E.1. \*\* If No, provide a clear description of the reasons and the mechanisms used by the bank to distribute biospecimens to researchers outside of the VA system, including a description of the oversight:       E.2. When biospecimens are released to other researchers outside of the AVAMC, the recipient is **required** to sign a materials transfer agreement (MTA) \*You must process an MTA through the Director of Research Operations (DRO) in the Research Office each time samples are released outside of the VA\*. |
|  F. Will samples be made available to researchers other than the PI and his/her co-investigators?  [ ]  Yes [ ]  No\*\*\*\* If No, please skip to Section G.  |
|  F.1. If biospecimens are to be released to other researchers outside of this project, will IRB approval for the new project be obtained prior to release of the biospecimens?  [ ]  Yes [ ]  No\*\* \*\*If No, please explain:       |
|  F.2. Will the biospecimens be made available to researchers at for-profit institutions? [ ]  Yes\*\* [ ]  No\*\*If Yes, the consent form must clearly spell this out. |
|  F.3. Will the biospecimens be sold? (This **does not** include a fee to recover the cost of processing and shipping biospecimens.) [ ]  Yes\*\* [ ]  No\*\*If Yes, please see the Research Office for further guidance.  |
| G. How are the biospecimens secured? (*locked freezer, locked room, in a restricted access area, etc.):*       |
| H. Will a biospecimen tracking log be created and kept current? [ ]  Yes [ ]  No [A sample log is available on the AVAMC research website under “Tissue Banking and Data Repositories”]\*\*If No, please explain the method used to track specimens:       |
| **5. ADDITIONAL INFORMATION** |
| 1. Provide justification for banking veteran biospecimens at the Atlanta VAMC:
 |
| 1. Upon termination/closing of the bank, what will happen to veterans’ biospecimens?

[ ]  Biospecimens will be destroyed.[ ]  Biospecimens will be transferred to another VA Repository. If so, where and why:      [ ]  Other, please provide explanation:       |
| 1. Describe what will happen if a subject requests destruction of his/her biospecimens (check all that apply)?

[ ]  Biospecimens that can be linked to a subject will be destroyed.[ ]  Biospecimens collected without identifiers will not be destroyed. [ ]  Other (please explain):        |
| 1. Comments (additional information that would help us review your application):
 |
|  **6. PI CERTIFICATION** |
|  By typing his/her name in the space below, the PI verifies that:1. He/she has reviewed this application for accuracy and completeness.
2. The key to the code that links the biospecimens to the subject's identity will be maintained ONLY at the Atlanta VAMC.
3. Acknowledges that **any** identifiable data belonging to these samples will remain at the Atlanta VAMC.
4. Changes cannot be made to the bank/repository without IRB approval.
 |
| *Typed Principal Investigator’s Name*       |  *Date*       |
| **AFTER COMPLETING THIS FORM AND TYPING YOUR NAME ABOVE – PLEASE SAVE A COPY.****THIS FORM SHOULD BE UPLOADED INTO YOUR ERRRP SUBMISSION.** |