**<Repository Name>**

**Repository Standard Operating Procedure (SOP)**

*INSTRUCTIONS FOR THIS REPOSITORY SOP TEMPLATE:*

1. ***NOTE: This Repository SOP is meant to be used as a GUIDE. Please be sure to go through all text and modify, as appropriate and in accordance with current regulations and guidance.***
2. **Instructions** are indicated in ***red italics.*** Any **blue text (with or without greater and less than symbols, </>)** should be replaced/customized to include the repository-specific information and the symbols removed from the final SOP. All text in the final document should be **black.**
3. **Required items -** All items in the template must be included unless the instructions indicate otherwise. Please do not change the order of the items in the template.
4. **Entering text -** In the body of the SOP you may either: 1.) type directly; 2.) copy and paste text from another document; or 3.) insert an existing text file. As new text is entered, new form pages will be created automatically to accommodate the added text.
5. **Remove Instructions/Notes in *red italics and/or* blue text**prior to submission to the IRB.
6. **Page numbering -** Page numbering is automatic.

**6. Header and Footer** - To complete the header and footer, select “View” in the toolbar at the top of your screen, then “Header and Footer.”

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**Purpose:**

This research repository will be comprised of <type of specimens and/or data>that will be used prospectively for research in the following area(s): *[list examples of possible research areas]*

# Receiving <Specimens and/or Data> from <Contributing Investigators>:

In order to request permission to contribute <data and/or specimens> to the repository, a potential contributing investigator must have an appropriately approved protocol for this purpose.If the specimens and/or data are to be identifiable in some manner, the contributing investigator will provide documentation of IRB approval and <documentation of IRB-approved waiver of consent process, waiver of HIPAA authorizations and/or copy of the signed informed consent form (ICF) and HIPAA authorization from each participant > for <data and/or specimen(s)> that are to be contributed. The <IRB- approved waiver and/or signed ICF and HIPAA authorization must indicate the participant’s permission for their> <data and/or specimen(s)> to be used for future research and may include restrictions placed on future research that may be conducted without further consulting with the participant; these <documentation(s) of IRB-approved waiver(s), signed ICFs and HIPAA authorizations> will be stored in *[indicate the appropriate, secure storage location, including the building and room number]*

The process for requesting to contribute to the repository is as follows: *[describe the process, what types of documentation will be obtained from the contributing investigator and where that documentation will be maintained]*

When <specimens and/or data> are received, information regarding the <specimens and/or data> will be tracked and maintained by *[describe methods and storage location]*. The following information will be tracked for each individual’s<specimens and/or data set>from a study: 1) source of <data and/or specimens> deposited in the repository *[e.g., medical record, data warehouse, study title]*; 2) type of <data and/or specimens> *[e.g., labs, x-rays, diagnostic codes, medications, blood samples]*; 3) date of deposit into the research repository; 4) copies of the protocols under which <data and/or specimens> were collected; and 5)if the <data and/or specimen(s)>is identifiable, the approved, <waiver(s), signed ICF and HIPAA authorization> under which they were collected. The <approved waiver(s), signed ICF and HIPAA authorization for each participant> will be reviewed by *[indicate appropriate repository staff titles]* in order to ensure appropriate permission for storage in a repository and to determine and track the type(s) of permitted future uses.

The repository has <a/no> process to track the <specimens and/or data> when they are used in future studies and to then disclose the <research data and/or findings> to participants. So, the research repository will <not> accept <specimens and/or data> from participants who have requested to be notified of <research data and/or findings> from future studies. ***AND/OR*** Participants may be notified of information learned from their <specimens and/or data> if *[describe circumstances]*. The process for tracking and communicating this information to participants will involve *[describe process]*

<Specimens and/or data> for which there is no corresponding <IRB approved waiver(s), signed, IRB-approved ICF and HIPAA authorization> will not be accepted, unless the <specimens and/or data> have been de-identified (e.g. coded, and the repository does not receive a key to the code). <Specimens and/or data> will be accepted <only from Veterans> ***AND/OR*** <from Veterans and non-Veterans>; ***AND/OR*** <specimens and/or data from non-veterans> will be obtained *[describe from where and how]*

To help ensure that the Research Repository Director will never accept <specimens and/or data> unless they were collected under an appropriately approved protocol, the contributing investigator will be required to log the contribution of the <coded specimen and/or individual’s data set>, along with the Repository/Project ID#, into a tracking log. For specimens, contributing investigators will additionally be asked to submit updated versions of their <specimen and/or data> log to the Research Repository Director on a quarterly basis. This log will be reviewed by the Research Repository Director, alongside their records and/or copies of the <signed ICFs, HIPAA Authorizations, waiver(s)>.

# Storing Specimens: *[if applicable]*

Research repository specimens will be comprised of *[indicate type, e.g., blood and gastrointestinal tumor]* samples. The samples will be [*describe any required processing that will occur and indicate whether this will be performed prior to receipt by the repository and by whom it will be performed.]* ***Example:*** 18 mL of whole blood in two 9 mL tubes will be obtained from each individual. Plasma will be obtained from one of the 9 mL tubes by centrifugation to be performed by the contributing investigator’s team. The plasma will be placed in cryovials immediately and stored in *[indicate an appropriate location]* until contribution to the repository. Upon contribution, specimens will be stored in *[indicate location(s)]*;***Example:***a -80 degree refrigerator located at Building xxx, Room xxx, which is secured by card access only*.*

**Storing Data:** *[if applicable]*

# Data in the research repository will consist of *[indicate data points]*. The data will be stored *[identify electronic and/or hard copy locations]*. The data will be protected by *[indicate protection methods, e.g., encryption, password protection, etc.]*

# Individually Identifiable Health Information (IIHI):

# The research repository <specimens and/or data> will be *[indicate how identifiable the specimens and/or data will be and, if coded, how the linking documentation will be stored; if any identifiable information will be stored, indicate how it will be kept secure]. Example:* coded and will not be labeled with any of the HIPAA identifiers. A key to the code will link the <specimens and/or data> with identifiers, and the key will be kept in a locked cabinet in the locked office of Dr. <name>. Additionally, an electronic copy of the key will be stored on the VA network and in a secure location behind the VA firewall. *[Identify applicable repository staff titles]* will have access to this *[indicate identifiable specimens and/or information, e.g. linking documentation, data]*. Identifiable <information and/or specimens> will be protected by *[describe methods]*.

# Labeling of <*Specimens and/or Data*>:

<Specimens and/or data> will be labeled with *[specify identifiers or code]*. The coding of the<data and/or specimens>will be determined as follows: ***Example:***The code will be made up of a 10-digit number starting with the number "4" and a letter, either "B," "H," or "X," representing blood, urine and saliva, respectively. Ex: 4000000015-X, 4000000015-Y.>

*[if applicable]*

It <may/will> be necessary to anonymize the <data and/or specimens> *[describe conditions under which this might/will be necessary]* . This will be done by *[describe the process and when and by whom it will performed].*

# Releasing <Specimens and/or Data> to Recipient Investigators:

This repository may be accessed for the purpose of testing various hypotheses regarding [*indicate disease, disorder, etc.].* Interested researchers with such hypotheses may request to become recipient investigators by [*describe process*]

For all identifiable <specimens and/or data> distributed from the repository, the recipient investigator must present documentation of a <VAPORHCS IRB-approved protocol>l allowing the use of directly identifiable <specimens and/or data> or, coded <specimens and/or data>, if the recipient will have access to linking documentation. In cases where the recipient investigator would like only <specimens and/or data> that are de-identified (i.e., not linkable by the recipient investigator), the recipient investigator and the Research Repository Director should work with the VAPORHCS Research Administration Office to determine which committee approvals are required for the recipient project to meet the applicable requirements.

The adequacy of a recipient investigator’s request for release of <specimens and/or data> will be determined by the Research Repository Director. That process will involve [*describe process]*. Prior to release of identifiable <data and/or specimens> for use under a recipient investigator’s approved protocol, the following process will occur in order to help ensure that all parameters set by the participant in their signed ICF will be honored: *[describe process]*

* Prior to releasing data from the research repository to a recipient, the Research Repository Director will initiate and ensure completion of a **Data Use Agreement (DUA)** with the recipient (as per current requirements). ***NOTE:*** *A Data Use Agreement between the Repository Director and Data Recipient(s), regardless if they are the same person, is required* ***prior*** *to releasing any repository data. Links to the following DUA templates are located at:* [*https://www.va.gov/portlandresearch/piservices/rd\_forms.asp*](https://www.portland.va.gov/Research/piservices/rd_forms.asp)DUA to Share Data within VAPORHCS
* DUA to Share Data between VA Facilities
* DUA to Share Data with a Non-VA Entity

The Research Repository Director will keep a log, which may be maintained by repository staff, to track the release of <specimens and/or data>. The log will contain a method for verifying that each <specimen and/or individual’s data set> was released only in a manner that meets the parameters of theapproved <protocol and/or approved waiver and/or signed ICF>under which it was collected. This method will involve [*describe method]*

Identifiable information will not be transmitted to recipient investigators unless the <approved waiver(s), signed ICF and HIPAA authorization from the participant (reviewed on a case–by-case basis)> gave permission for this to occur. Any identifiable information will be transmitted to recipient investigators electronically, using *[describe method].*

***OR***

Recipient investigators will only receive <data and/or specimens> that is coded as described above.

Identifiable or de-identified <specimens and/or data> may be released to VA investigators (paid employees or those having without compensation (WOC) appointments) or to non-VA personnel or non-VA entities, in accordance with VA requirements; in the latter case, the Research Administration Office will consulted for current requirements.

1. If the Research Repository Director approves a potential recipient investigator to access or use information from the repository for purposes preparatory to research, the Research Repository Director will receive and maintain a copy of the Research Preparation Application, approved by the appropriate oversight committee and/or facility (e.g. VAPORHCS Research Administration Office in the case of a VAPORHCS recipient investigator). The application should document that the access to the information in the research repository will only be used to prepare a protocol, that no IIHI will be removed from the VAPORHCS or recorded, and that the IIHI accessed is necessary for the preparation of the research proposed. ***NOTE:*** *A Human Research Preparation Application is only needed if IIHI will be accessed.*

Prior to releasing data from the research repository to a recipient, the Research Repository Director will initiate and ensure completion of a DUA with the recipient (as per current requirements).

The Research Repository Director will track the following information for all <specimens and/or data> released to a recipient investigator:

1. Information regarding new use of the <specimens and/or data> (including a copy of the recipient protocol, the name of that protocol’s PI, and the committee approvals of the recipient protocol).
2. Information regarding <specimen and/or data> distribution, including where they will be stored and the name(s) and location(s) of the recipient investigator(s).
3. Data disposition, after the recipient study has completed, per DUA requirements.
4. All communication with investigators requesting and receiving permission to use the <specimens and/or data>.
5. Data disclosure to a participant, their family, their physician, or a third where legally permitted (e.g. FOIA request).

# Departure of Research Repository Director or Termination of the Repository:

If the Research Repository Director plans to leave the VAPORHCS, an application for a replacement director will be submitted to the IRB within an appropriate time frame to obtain approval before the current Director leaves. If a suitable replacement is not identified prior to the departure of the current Director, or if the repository is to be terminated, all <specimens and/or hard copy records>will be will be maintained according to the VHA Records Control Schedule 10-1 (RCS 10-1), including identifying data on each specimen*.* Upon consultation with the Research Administration Office, all repository records will be transferred to the Research Administration Office where they will then be stored per RCS 10-1.; any identifiable electronic records will be sent using appropriate, secured methods (e.g. via an encrypted email ).Specimens will be destroyed per guidelines for disposal of biohazardous material (i.e., placed in a red burn bag for incineration), and in accordance with RCS-10-1, if applicable.

# Biosafety Issues: *[for repositories containing human biological specimens]*

The location of the specimen storage for this repository is within a lab that has been reviewed and approved by the Subcommittee on Research Safety (SRS). All biosafety issues have been disclosed to the SRS, and this repository project, as well as any new procedures or uses for the specimens, will be submitted to the SRS for review and approval before being initiated.

**Repository Staffing:**

This application does not include any additional employees besides the Research Repository Director. For any new employees needed in the future, all required forms/documents (e.g. a Research Personnel Change Form, Scope of Work (SOW), Amendment Request form, revised SOP, Conflict of Interest in Research form) will be submitted as instructed on forms/documents, , for IRB review and approval prior to them beginning any work with this repository. Any new employee will meet all VA training requirements and will be trained by [*indicate appropriate personnel title(s)*] in the specifics of this SOP.

***OR***

This repository will be managed by [*indicate specific number or range]* employees, trained by *[indicate appropriate personnel]*. Supervision will be close and ongoing, including *[describe methods, e.g., periodically (indicate time frame, i.e., daily, weekly, etc.) checking log entries, comparing to labels, ICFs, etc.]* associated with individual <data sets and/or specimens>.

The responsibility for the security and oversight of the repository rests with the Research Repository Director.

***NOTE:*** *The following must be addressed (if they have not already been by one of the items above):*

1. *How all records will be maintained. [NOTE: In addition to the records referenced above, records of all committee actions relevant to the repository must also be kept.]*
2. *Whether the specimens and/or data received, kept and released will be identifiable or de-identified. (Note: If the research repository includes de-identified specimens and/or data that may be re-identified, VHA Handbook 1200.12, must be followed.)*
3. *Policies and procedures for receiving and releasing specimens and/or data from the repository.*
4. *Mechanisms for verifying required approval(s) of research for recipient investigators.*
5. *Administrative activities, such as hiring, training and supervising employees.*
6. *Conflict of interest.*
7. *Tracking of data.*
8. *Whether there will be any research data disclosure to participants and conditions under which disclosure may or may not be allowed.*
9. *Plans for destruction or transfer of all specimens and/or data due to the research repository’s termination or departure of Research Repository Director with no replacement.*
10. *Access agreements (i.e., data use agreements).*
11. *Requiring and maintaining all required committee approvals.*

*12. Security and oversight*