**ATLANTA VETERANS AFFAIRS MEDICAL CENTER**

**DECATUR, GEORGIA**

**Atlanta VA Medical Center**

 **Research Data Repository SOP**

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| **Principal Investigator:**  |  |
| **Repository Protocol Title:**  |  |
| **eIRB #:** |  |
| **SOP Version Date(s):** |  |

|  |  |
| --- | --- |
| **Repository Role**  | **Approved Research Staff** |
| **Repository Administrator:** |  |

Heading & Section Titles are underlined and **bolded black**,suggested language is in green (please remove quotations), *instructions are in blue italics*, and **required language is in bolded red. Please ensure that your “final /clean” version has black text, consistent font size and all comments/tracked changes removed from the margins.**

1. **Administrative Structure:**
2. **Requirements**: *The* ***administrative structure*** *of VA research data repositories* ***must always******include*** *a VA investigator who is responsible for all activities of the data repository. An investigator under a WOC or IPA may not serve as the sole administrator of a VA data repository. VA research repositories oversight may involve a number of persons and committees including, but not limited to a repository administrator, assistant repository administrator, IRB, and R&DC.*

“The Repository Administrator will be a VA employee. Their job duties will include being responsible for all activities of the data repository.”

1. **Administrative Changes**
2. **Requirements** *If an investigator or repository administrator no longer holds an appointment as an employee or IPA, all research records, data, and data in repositories must remain at the VA and under VA control. All data and records are the property of the VA. The data* ***may not*** *be copied or removed unless all requirements for use of VA data by non-VA investigators are met*.

**Should Dr. \_\_\_\_\_\_\_\_\_\_\_\_\_\_ leave the VA all research records and data in the repository will remain at the VA and under VA control. All data and records are the property of the VA. The data will not be copied or removed without proper approvals.**

1. **Requirements**. *The R&DC and IRB must review, approve and/or acknowledge any proposed changes to the administrative oversight of VA research repositories to ensure stable administrative oversight (e.g., reappointment of or transferring repository administrative duties, requests to combine repositories, requests for termination of repositories).*

“The R&DC and IRB will review and approve any proposed changes to the administrative structure of this repository to ensure stable administrative oversight.

1. **Conflict of Interest (COI)**

**All applications for VA research are reviewed by the Research Service Office for conflict of interest. If a conflict exists, the R&D Committee will create and approve a management plan to be approved by the IRB of record, as appropriate. Other resources that may be consulted include the ACOS for R&D, VA ethics officials, and Regional Counsel.**

1. **Purpose**

*Describe why this research data repository will be created.*

“This research repository will be comprised of data to be used prospectively for research in the following areas: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_”

**OR**

“This database will contain specific information on patients seen within the \_\_\_\_\_\_\_\_\_\_\_\_\_ at the VA. It will be available to query for feasibility of participation in certain studies as well as for new projects to be conducted by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. The clinical data alone, or in combination with basic science parameters, will be used to study the \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_of specific disease processes treated by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.”

1. **Data Description and Source**
2. **Data Type**: *Describe the type of data (identified or de-identified) and include what protected health information (PHI) will be obtained. The data obtained for the research must be reasonable and necessary to conduct the research. Provide a justification for use of any identifiers.*

“Data collected will be identified and include protected health information (PHI). The following is a list of the specific fields in the database:

* Name
* SSN
* Address
* Date of Birth
* Age
* Sex
* Race
* Weight/Height
* Medical Record Number
* Physicians (i.e., urologist, pediatrician, referral physician, surgical team)
* Diagnoses/Dates/Codes
* Past Medical History/Family History
* Hospital Admissions/Dates/Units Hospitalized in
* Medications
* Allergies
* Lab Results
* X-Rays
* Symptoms/Scores
* Post-op Care/Treatment
* Current Research Patient – study

The data obtained for the research is necessary to conduct the research. Name, date of birth, and medical record number will be used to assist in ensuring the correct patient’s data is being collected. Address will be collected in case there is a need to contact a patient to verify data.”

1. **Data Source**: *Describe the source of data (e.g., subjects, non-research data repositories, research data repositories, publicly available, VA source, non-VA source).*

“Data in the repository will be come from study visits as well as CPRS. Data will not be accepted in this data repository without a signed approved informed consent document and HIPAA authorization.”

1. **Data Collection**: *Explain the data collection process (how and by whom data are collected.*

“The data fields specified will be collected via medical record review by an approved study team member.”

**F. Request to Access**

*The PI can choose not to allow other VA investigators to request access to this research data repository. If this is the case, then please modify red language to say, “Only the current PI may submit a written request to use repository data if:”*

**All local VA investigators may submit a written request to use repository data if:**

*(edit to apply to Repository PI’s specifications—options include option 1, 2, and/or 3. Any or all options can be used):*

1. “The VA Investigator’s activities are considered preparatory to research. These activities do not require a written HIPAA authorization or IRB approved HIPAA waiver. A written request must be submitted to the repository administrator. The repository administrator must then approve the request prior to providing access. The repository administrator may require a completed request form to record and certify the investigators intentions:
2. The access to Personal Health Information (PHI) is only to prepare a protocol
3. No PHI will be removed from the AVAMC
4. The PHI accessed is necessary for preparation of the research protocol
5. Only **aggregate data** may be recorded and used only for background information to justify research
6. Individually Identifiable Health Information (IIHI) will not be recorded
7. Data will not be used for recruitment

**NOTE:** Pilot studies are **not** considered preparatory to research.”

1. “The investigator has a formal, written protocol approved by the AVAMC R&DC and affiliate IRB if applicable (i.e., when human subjects are involved).

**NOTE:** If an investigator must access identifiable information in the process of recording de-identified data, informed consent and HIPAA authorization must be obtained or the IRB must waive informed consent and HIPAA authorization.”

1. “The investigator has been granted an IRB exemption under the Common Rule.

 **NOTE:** If exempt from IRB review under the Common Rule, a HIPAA authorization or IRB waiver of HIPAA authorization must be obtained.”

**The repository administrator will review all requests for access and verify all the required approvals are granted prior to providing access to repository data.**

1. **Access Agreements**

**The repository administrator will consult the PO when request for access are received from non-VA investigators or other instances occur in which a DUA may be required. These requests will be reviewed by the relevant research oversight committees prior to approval or disapproval.**

1. **Records**

*Adequate records of activities and operations of the research repository must be maintained. This SOP should state who is responsible for maintaining records and how the records must be maintained. Records include, but are not limited to:*

1. *Data sources, including type of data*
2. *Original protocol, ICD, HIPAA under which data was collected*
3. *Record involving any new use of data*
4. *Data distribution including location, where data will be stored*
5. *Research data disclosure to a subject, subject’s family, subject’s physician, or third party, where legally permitted*
6. *Minutes of scientific or ethics oversight meetings when applicable*
7. *All IRB and R&DC committee action relevant to the repository (ex. approval letters)*

“Adequate records of activities and operations of the research repository will be maintained by the PI and repository administrator. All data will be maintained on a protected VA research server with limited access to those with IRB and R&D approval to use the data. All IRB and R&DC committee actions relevant to the repository will be maintained in a regulatory binder specific to the study to include all forms filed with the IRB and VA R&D committee to use data as well as all correspondence related to the project.”

1. **Reuse of Data & Terms**

**The research oversight committees will review all project requests for reuse of repository data to ensure consistency with the original approved protocol and informed consent under which the data was collected. The IRB and R&DC must specifically approve reuse and any new use of data and specify by whom.**

1. **Disclosure to Others & Terms**

*Describe plans to share with others including other researchers (if any) and include procedures you will use to document/track who you share data with. If the data were collected through a research project, discuss whether or not the original informed consent allowed for such reuse of the data and if the reuse/sharing is consistent with the HIPAA authorization that was obtained. If you plan to share research repository data with other sites or investigators a Data Use Agreement may be required. Privacy and Information Security approval is required.*

“Use of data will only be granted with IRB and R&D approval and all such transactions will be clearly documented in the regulatory documents maintained for the study. Privacy and Information Security approval will always be secured.”

1. **Destruction of Data**

**All research data, records and documents for this study are covered under the Federal Records Act (FRA) and will be retained according to VA policy. Until such time as there is a policy developed to the contrary, all research records will be stored securely. Once the National Archives and Record Administration (NARA) approve a proposed record retention schedule, research records will be disposed of according to the policy.**

1. **Security Oversight Plan**

*The ISO must review this section to ensure security plan for all data is consistent with VA security policies. Explain the limited access and password protection for electronic data and address security methods for hardcopy records. Describe how and where the data will be stored (e.g., paper records, VA research server). The discussion is to address how the planned storage meets all applicable requirements.*

***NOTE:*** *All VA research data repositories must be physically located within space owned or leased by VA.*

“The Repository administrator and staff will maintain the privacy and confidentiality of all PHI and sensitive data in accordance with all applicable VA and VHA information confidentiality requirements. All PHI and data will be stored in a password protected environment on the VA research server with limited access to IRB and VA R&DC approved investigators. All hardcopies of data collection forms will be stored in a locked, limited access environment (behind 2 locked barriers, ex. a locked cabinet in a locked office) accessible only to the approved research team members. Should a breach of security occur, the ISO, PO, & RCO will be notified immediately and the breach will be reported to the IRB and R&D committees and others as required.”