1. **PURPOSE** This policy establishes procedures to ensure data obtained for the creation and/or use of research data repositories are responsibly collected, managed, stored, and distributed.

2. **SCOPE** This policy applies to all AVAMC human subject research repositories established for the purpose of storing data for future research purposes. This policy does not apply to data collected for specific research protocols which are not maintained for use in future research (i.e., for studies other than that under which they were collected).

3. **POLICY** This policy ensures the AVAMC has authorized adequate provisions to protect research data repositories and adheres to all applicable policies and regulations.

4. **DEFINITIONS**
   
   A. **Data Repository.** The term data repository means a database or a collection of databases that have been created or organized to facilitate the conduct of multiple research protocols, including future protocols not yet envisioned. It may also have been created for other purposes such as administrative and clinical purposes. The terms “data repository and “data warehouse” have the same meaning.

   B. **Data Use Agreement.** This term means a written agreement between the provider and the recipient of data that are transferred from one to the other. It defines what data may be used, how the data will be used, who may access and use the data, how the data must be stored and secured, and how the recipient will dispose of the data after completion of the research.

   C. **Preparatory to Research.** Within VHA “preparatory to research” refers to activities that are necessary for the development of a specific protocol. PHI from data repositories or medical records may be reviewed during this process, but only aggregate data may be recorded and used in the protocol application. Within the VA, preparatory to research does not involve the identification of potential subjects and recording of data that would be used to recruit these subjects or to link to other data. The preparatory to research activity ends once the protocol has been submitted to the IRB and the Research and Development (R&D) Committee for review. **NOTE:** Pilot studies are not considered to be activities preparatory to research.

   D. **Repository Administrator.** The study team member that conducts the day-to-day operations of either a data repository or research data repository per the delegation of authority and responsibilities listed in this policy. The person can be the Principal Investigator, a Co-Investigator, the Research Coordinator, or other study team member but must be approved by the IRB and R&D Committee and credentialed through Research Service to work on the study.

   E. **Research Data Repository.** The term “research data repository” means a data repository created from data obtained either to conduct a research protocol(s) or gathered in the course of conducting a research protocol and is maintained after the completion of the research protocol. The protocol may be a primary research project designed to prove or disprove a specific hypothesis or it may be a protocol specifically designed to collect data (either a one-time-only collection of data or an ongoing collection) that will be placed in a research data repository for future use.
5. **DELEGATION OF AUTHORITY AND RESPONSIBILITY**

A. The **R&D Committee** will:

1) Comply with all requirements in VHA Handbook 1200.01.

2) Review and provide final approval for the establishment and operations of all AVAMC research repositories to include the administrative structure and standard operating procedures.

3) Approve research protocols for local investigators that propose to use data from any research or non-research repository housed at the AVAMC before data can be accessed.

4) Conduct annual reviews of all research repository activities.

5) Provide technical and scientific recommendations to the research repository administrator and investigators wishing to access data in data repositories.

B. The **Institutional Review Board** of record will:

1) Comply with all requirements in VHA Handbook 1200.05 and all conflict of interest policies.

2) Review and approve the establishment and operations of all AVAMC research repositories to include the administrative structure and standard operating procedures.

3) Approve research protocols for local investigators that propose to use data from any research or non-research repository housed at the AVAMC before data can be accessed.

4) Conduct annual reviews of all research repository activities.

C. The **Investigators** will:

1) Adhere to all applicable policies and procedures in designing and conducting research involving the use of data repositories.

2) Obtain all of the required approvals in writing before initiating research involving data repositories.

3) Maintain the privacy and confidentiality of all PHI and sensitive data in accordance with all applicable VA and VHA policies and procedures.

4) Notify the Research Administrative Office and relevant research oversight committees of any intention to leave VA employment, so administrative structure of any repositories may be properly transferred. Other situations may include investigators that no longer hold an appointment as an employee or IPA. Any investigator that is no longer an employee must relinquish all access to research records, data, and data in repositories. All data and records are the property of the VA and must remain at the VA under VA control. This data **may not** be copied or removed unless all requirements for the use of VA data by a non-VA investigator are met.
5) Submit a written request to the repository administrator requesting access to the repository data (i.e., complete the Request for Access form if available).

6) Provide data broker services if necessary.

D. The **Repository Administrator** will:

1) Adhere to all applicable policies and procedures associated with conducting research involving the use of research repositories. If the protocol involves human subjects then all policies related to human subject’s research, including those in VHA Handbooks 1200.05 and 1605.1.

2) Develop standard operating procedures to include the repository’s administrative structure and mechanisms for verifying committee approvals and releasing data from the repository. Ensure all research data repository personnel meet all training requirements. The administrative structure must always include a VA investigator who is responsible for all the activities of the data repository. **NOTE:** An investigator under a WOC or IPA may not serve as the sole administrator of a VA data repository. Ensure the repository’s standard operating procedures at minimum addresses each of the following:
   a) Administrative activities (e.g., Administrative structure, approval verification…);
   b) Conflict of Interest (COI);
   c) Tracking of data (e.g., data source, data type…);
   d) Reuse of data;
   e) Disclosure to subjects and conditions under which disclosure is or is not allowed;
   f) Data disposition plan due to repository termination and/or destruction per VA policies;
   g) Access agreements (i.e., combined DUA-DTA);
   h) Original protocol, amendments, IRB and R&DC approvals;
   i) Security and oversight plan, including data location and storage

3) Relinquish access to all research records, data, and data in repositories if the investigator no longer holds an appointment as a VA employee or IPA. 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 a non-VA investigator are met.

4) Review the request for access and verify the required approvals are granted prior to approving and providing access to the repository data. The approval verification can be accomplished by reviewing the project/protocol file(s) in the Research Administrative Office. A copy of the written request should be filed in the repository’s Research Administrative Office original project/protocol file. The Privacy Officer will be consulted if a request is received from a non-VA investigator.

5) Maintain records to include requests for access and disclosure logs for new uses of the data; including:
   a. A copy of new use protocol
   b. Protocol’s PI
c. Official IRB and R&D Committee approval notifications:
   i. Initial and continuing review
   ii. Documentation of waivers of Informed Consent and HIPAA authorizations (when applicable)
d. Access Agreements/DUAs
e. Records of disposition of data after termination of the protocol

6) Provide an annual status report of the research data repository to the IRB and R&DC at continuing review. The report must include, but not be limited to, a description of the following:

   a) The sources of data being added to the research repository and the protocol(s) under which they were collected.

   b) The type of data released to others for use, the protocol(s) under which they were used and the planned disposition of the data once the protocol is terminated.

   c) Any privacy and security incidents.

   d) Findings linking a negative impact on the health of individuals in the data repository with identified causal factors, including whether there may be a clinical intervention.

   e) All reporting requirements for active protocols according to VHA Handbook 1200.05.

E. The Privacy & Information Security Officers will:

   1) Serve as resources and subject matter experts in areas of privacy & confidentiality and information security in research. The PO and ISO will provide consultation and assistance to the AVAMC research oversight committees and research community.

   2) Will review data repository security plans to include repository location, access controls, and standard operating procedures.

   3) Will review request for access from non-VA investigators and in other instances when a combined DUA-DTA may be required.

6. REFERENCE(S).