

Data Management and Access Plan (DMAP) for Unfunded VA Research or VA Research Funded by Entities Without a Specific DMAP Format

Effective January 1, 2016, all **new proposals** for VA research (regardless of how the research is to be supported) must include a **Data Management and Access Plan (DMAP)** that describes how **PUBLICATIONS** resulting from the research and the **FINAL DATA SETS** underlying such publications will be made available to the public. Proposals for **funded** research should use the specific DMAP format required by the funding office or agency. **This DMAP form is to be used for research that (i) is not funded or (ii) is funded by an entity that does not require a specific DMAP format.** Contact VHAMINResearchOffice@va.gov for assistance.

1. **Title of Proposal:** _____

2. **Principal Investigator:** _____

3. **Funding:**

- a) VHA Program Office **without Specified DMAP Format** – Name of Program Office: _____
- b) External Funder **without Specified DMAP Format** – Name of Funder: _____
- c) Unfunded

4. **PUBLIC ACCESS TO PUBLICATIONS RESULTING FROM THE RESEARCH** – *Please check all applicable boxes*

- a) The proposed research **is to be funded by VA**. Publications resulting from the research will be made available to the public through the National Library of Medicine (NLM) **PubMed Central** website within one year after the date of publication. *[Submission procedures are provided on the Office of Research and Development (ORD) website at http://www.research.va.gov/resources/policies/public_access.cfm.]*
- b) The proposed research **will not be funded by VA**.
 - i) Publications will be made available to the public through **PubMed Central** within one year after the date of publication. *[See ORD website noted above]*
 - ii) Publications will be made available to the public in another way. *[Please briefly describe plans below]*
 - iii) Publications will not be made available to the public. *[Please provide a brief rationale below]*

Additional details related to plans for public access to publications results from the research as indicated in Item #4 above:

5. **PUBLIC ACCESS TO FINAL DATA SETS UNDERLYING PUBLICATIONS RESULTING FROM THE RESEARCH** – *Please check all applicable boxes*

- a) Final data sets underlying publications resulting from the proposed research **will be shared** outside VA in **electronic format** through the mechanism(s) indicated in Items #6 through #10 below.
- b) Final data sets underlying publications resulting from the proposed research **will be shared** outside VA **ONLY in hard copy** through the mechanism(s) indicated in Items #6 through #10 below. *[please provide a brief rationale below]*
- c) Final data sets underlying publications resulting from the proposed research **will not be shared** outside VA, except as required under the Freedom of Information Act (FOIA) *[please provide the rationale below]*

Additional rationale(s) for plans to access data sets underlying publications as indicated in Item #5 above.

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6. MECHANISMS FOR PUBLIC ACCESS TO FINAL DATA SETS UNDERLYING PUBLICATIONS RESULTING FROM THE RESEARCH – Please check all applicable boxes

- a) As indicated in Item #5 above, final data sets underlying publications resulting from the proposed research **will not be shared** outside VA.
- b) The project involves **animal research and/or basic science research**. Final data sets underlying publications resulting from such research will be shared as described in the space below. *[Please describe mechanisms for sharing, e.g., upon request, through a databank or repository, via a website]*
- c) The research involves **human subjects**. Data sets based on information obtained from human subjects will be shared as follows:
 - i) **Individually Identifiable Data** will be shared pursuant to valid HIPAA Authorization, Informed Consent, and an appropriate written agreement limiting use of the data to the conditions described in the authorization and consent.
 - ii) **A Limited Dataset (LDS)** will be created and shared pursuant to a Data Use Agreement (DUA) that indicates adherence to any applicable Informed Consent provisions, appropriately limits use of the dataset and prohibits the recipient from identifying or re-identifying (or taking steps to identify or re-identify) any individual whose data are included in the dataset. *NOTE: An LDS does not necessarily imply de-identified data per HIPAA.*
 - iii) **A De-identified, Anonymized Dataset** will be created and shared. *NOTE: ORO recommends that such sharing take place under a written agreement that adheres to any applicable Informed Consent provisions and prohibits the recipient from identifying or re-identifying (or taking steps to identify or re-identify) any individual whose data are included in the dataset. However, it is permissible for final datasets in machine-readable format to be submitted to and accessed from PubMed Central (and similar sites) provided that care is taken to ensure that the individuals cannot be re-identified using other publicly available information.*
 - iv) It is likely that requests for data from outside researchers (or other entities) may correspond to one or both of the following **special conditions**:
 - 1) **Individually Identifiable Data**, excluding Veterans' names and 38 USC §7332-protected information, will be shared, pursuant to a written request and IRB approved waiver of HIPAA authorization, with the approval of the Under Secretary for Health, in accordance with VHA Handbook 1605.1 §13.b(1)(b) or §13.b(1)(c) or superseding versions of that Handbook. *Note: Subject to all other listed requirements, Veterans' names may be shared with other Federal agencies (38 USC §5701), and with non-Federal investigators who provide the names and addresses of the individual subjects.*
 - 2) **Individually Identifiable Data**, including 38 USC 7332-protected information, will be shared, pursuant to the above requirements and a written assurance from the recipient that the information will be maintained in accordance with the security requirements of 38 CFR Part 1.466, or more stringent requirements, the information will not be re-disclosed except back to VA, and the information will not identify any individual patient in any report of the research or otherwise disclose patient identities.

Additional details on mechanisms for sharing final data sets as indicated above in Item #6 above.

7. Please briefly summarize below **how, where, when, to whom, and the extent to which data resulting from the research will be made available outside VA.**

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8. Please describe **how and where** data resulting from the research will be **stored and maintained** (e.g., data will be stored and maintained in a secure ORD data repository or resource; data will be stored on VA servers behind the VA firewall and backed up to a hard drive maintained and secured in the investigator's lab; etc.).

9. Please describe the mechanisms for ensuring the **protection of personal privacy**, the **confidentiality of individually identifiable information**, and the **security of propriety data and information**.

10. Please (a) describe the **scientific and/or public purposes** for making the data available (i.e., how will scientists and/or the public benefit from making the data available) and (b) explain how the data available for sharing will permit **validation of results** by the recipients (e.g., sufficient data and descriptors will be made available to confirm conclusions in the publication, duplicate statistical analysis, perform additional analyses, etc.).

11. As **Principal Investigator** for the proposed research, I **attest** to the accuracy of the information provided above, and I understand that –

- a) Data sets will not be shared without first consulting facility Privacy Officer for approval
- b) Data storage locations will be kept current in the facility Data Inventory
- c) Final data sets will be maintained locally in accordance with VA Records Control Schedule 10-1 or until enterprise-level resources become available for long-term storage and access (unless otherwise required or permitted by the relevant VHA Program Office)
- d) Failure to implement this DMAP may result in restrictions to subsequent research activities

Signature of Investigator: _____

Date: _____