

VAPHS RESEARCH & DEVELOPMENT

POLICY NUMBER: 022

TITLE: Research Data Management and Access Plan (DMAP) Policy

1.0 PURPOSE

The purpose of this policy is to describe the requirements surrounding the plan for public access to scientific publications and digital data from VA research. The data management access plan describes how and where final research results resulting from the research will be made available to the public.

2.0 DOCUMENT HISTORY

R&D Committee Approval Date	Version	Change	Reference Section(s)
09JAN2018	1.0	NEW POLICY	

3.0 SCOPE

This policy applies to all VA and externally funded research projects conducted under the jurisdiction of the VA Pittsburgh Healthcare System (VAPHS) Research and Development (R&D) Committee and describes the requirement to develop data management and access plans for research.

4.0 DEFINITIONS

- A. Data Management and Access Plan (DMAP): DMAPs are part of VA’s efforts under a larger federal initiative to enable greater access to research results (i.e., publications and data sets).
- B. VA-Funded. VA-funded research are activities funded as research by:
 - Office of Research Development (ORD)
 - Any other VHA Program Office

NOTE: Research funded and/or supported entirely by a VISN and/or Facility is not currently considered to be “VA-Funded.” Future policy is under development and will be addressed as relevant VHA Handbooks are revised.
- C. Externally funded research. For the purposes of this policy, externally funded research refers to activities funded as research by a non-VA source, including but not limited to, the National Institutes of Health (NIH), National Science Foundation (NSF), Department of Defense (DoD), and private foundations.
- D. Research Results. Research Results include:
 - All Publications reporting the results of VA-Funded research
 - Final Data Sets underlying all such publications (i.e., data underlying the published results)

5.0 RESPONSIBILITIES

The relevant VA funding office is responsible for evaluating the data management plans for the research that it funds.

The VAPHS R&D Committee or applicable subcommittee [i.e. Institutional Review Board (IRB), Institutional Biosafety Committee (IBC), Institutional Animal Care and Use Committee (IACUC), or Research Scientific Evaluation Committee (RSEC)] will ensure a data management access plan is submitted with all new VA and externally funded VA research. The subcommittee will evaluate the data management plans for VA research under its purview to ensure it is consistent with the local protocol, consent form, and HIPAA authorization, as applicable.

6.0 POLICY

A. EXTERNALLY FUNDED VA RESEARCH

Effective the date of this policy, all new externally funded proposals, submitted to the VAPHS R&D Committee or one of its subcommittees must include a data management plan.

The data management plan must describe the conditions and mechanisms under which publications and data resulting from the research will be shared with the public.

The plan should specifically state whether or not final data sets underlying published results will be shared with the public and, if so, include details on how, where, and the extent to which the data will be made available

The data management plan must be consistent with the protocol, consent form, HIPAA authorization, etc. (as applicable).

Each federal agency will have its own requirements for research results access as part of its implementation of the White House Directives. Currently, there are no reciprocity agreements between federal agencies. Therefore, the data management plan should follow any requirements and/or guidance of the non-VA funding entity (federal or non-federal). There are no additional requirements relative to the VA research data access policy. The research must still comply with all other applicable VA requirements.

Evaluations of data management plans may include the adequacy and appropriateness of the plan relative to applicable VA and VHA research, privacy, confidentiality, proprietary information, and information security requirements, as applicable.

The applicable VAPHS R&D Committee subcommittee will evaluate all data management access plans under its purview to ensure consistency with the local protocol, consent form, and HIPAA authorization, as applicable. The plan is required to be included in the initial application to the relevant subcommittee. It is acceptable to include the resource sharing information from the grant.

B. VA-FUNDED RESEARCH

VA-Funded research must comply with the requirements of relevant ORD or other Program Office Funding Guidelines and/or Requests for Applications (RFAs). Evaluations of newly proposed research by the VA funding office must include an evaluation of the adequacy and appropriateness of the plan relative to the specific criteria established by the funding office.

1. In addition to the requirements described in 6.A above, Data Management Plans for VA-Funded research must also:

- Describe protections for individual privacy, confidentiality of data, and security of proprietary information
- Specify that publications and related metadata will be made available to the public through the National Library of Medicine **PubMed Central website within one year after the date of publication**

NOTE: PubMed Central accessibility for ORD-funded research has been required under VHA Handbook 1200.19 §5 since July 10, 2014. VA's agreement with PubMed Central has been extended to include publications resulting from all other VA-Funded research.

For more information, please review VAPHS R&D Policy #005, Presentation of Research Results and visit the ORD website at

http://www.research.va.gov/resources/policies/public_access.cfm

- Specify how the final research data set(s) will be made available (if at all) in machine/computer readable form (i.e., how the final research data set(s) will be made available electronically, as opposed to on paper)
- Explain how the data available for sharing or other means of access will permit validation of results
- Specify that final data sets will be maintained locally until enterprise-level resources become available for long-term storage and access (unless the relevant ORD or Program Office Funding Guidelines/RFAs state otherwise; e.g., as for the Cooperative Studies Program)

2. Final study data resulting from VA-Funded research may be shared in six ways:

- (1) **Individually Identifiable Data** may 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.
- (2) **Individually Identifiable Data**, excluding Veterans' names and 38 USC §7332-protected information, may 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.

- (3) **Individually Identifiable Data**, including 38 USC 7332-protected information, may 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.
- (4) **A Limited Dataset (LDS)** may be created and shared pursuant to a Data Use Agreement (DUA) appropriately limiting use of the dataset and prohibiting the recipient from identifying or re-identifying (or taking steps to identify or re-identify) any individual whose data are included in the dataset.
- (5) **A De-identified, Anonymized Dataset** may be created and shared.

NOTE: Where practicable, ORO recommends that such sharing take place under a written agreement prohibiting 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.

- (6) All Non-Exempt, Reasonably Segregable Data must be shared pursuant to a valid **Freedom of Information Act (FOIA)** request, as determined by the FOIA Officer.
3. The applicable VAPHS R&D Committee subcommittee will review all data management access plans for VA-funded research to ensure they are consistent with the local protocol, consent form, and HIPAA authorization, as applicable. The plan is required to be included in the initial application to the relevant subcommittee. It is acceptable to include the DMAP submitted to the VA funding agency.
 4. Failure to implement the approved plan may result in loss of current or future funding or other restrictions on the investigator's research activities.

C. AMENDING DATA MANAGEMENT PLANS

Data management plans can be modified or amended after the study begins if the modifications are consistent with other applicable VA and VHA requirements. Investigators of non-VA funded studies should check with their funding sources regarding any required permissions. The applicable VAPHS R&D subcommittee will need to review modifications to data management plans.

7.0 REFERENCES

Policy and Implementation Plan for Public Access to Scientific Publications and Digital Data from Research Funded by the Department of Veterans Affairs. (July 23, 2015)

https://www.va.gov/ORO/Docs/Guidance/VA_RSCH_DATA_ACCESS_PLAN_07_23_2015.pdf

https://www.va.gov/ORO/Docs/Presentations/VA_RESEARCH_DATA_%20ACCESS_PLAN_Revised_Jan_2016.pptx

https://www.va.gov/ORO/Docs/Guidance/DMAP_FAQs.pdf

VHA Handbook 1200.05

VHA Handbook 1200.12

VHA Handbook 1200.19

VAPHS R&D Policy #005

VAPHS R&D Policy #017

8.0 SIGNATURES

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