Data Management and Access Plan

FAQs

1. Question:

What is a Data Management and Access Plan (DMAP)?

Answer:

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). For more information, please see the White House Office of Science and Technology Policy (OSTP) directive found at https://www.whitehouse.gov/sites/default/files/microsites/ostp/ostp_public_access_memo_2013.pdf

All new VA research proposals submitted to the IRB, IACUC, or RDC on or after January 1, 2016, regardless of funding status or funding source, must include a Data Management and Access Plan (DMAP). The plan must describe the conditions and mechanisms under which the publications and final data sets resulting from research will be shared with the public.

The VA Office of Research and Development (ORD) and other VA program offices that fund research have developed or are developing guidelines which address the use of DMAPs for research funded by those offices. ORD will provide guidance for DMAPs for studies it will fund in its Requests for Applications (RFAs) and/or as part of other guidance for its applications. Contact the applicable VA program office for further guidance on DMAPs for studies funded by the particular VA program office.

Given the broader federal initiative, other government funding agencies should also have their own guidance and requirements for stating how research results will be shared. The term used for these plans may vary.

In some cases, such as unfunded VA research, VA research funded by a non-VA entity, or VA research funded by a VA Program Office without data management guidelines, DMAP elements may not be known. Therefore, ORO in collaboration with ORD developed an optional sample DMAP template.

The sample DMAP template addresses the requirements of *VA's Policy and Implementation Plan for Public Access to Scientific Publications and Digital Data from VA-Funded Research.*

Although the above policy primarily addresses VA-Funded Research, the policy does set forth requirements applicable to all VA research, *regardless of* funding. Specifically, all new proposals for VA research must include a data management plan that conforms to the requirements laid out in the plan. Slide #3 of the PowerPoint presentation available on the ORO internet site describes these requirements and can be viewed via this link.The template developed by ORO/ORD enables users to create a DMAP that conforms to the VA policy requirements.

2. Question:

Is use of the sample Data Management and Access Plan (DMAP) template mandatory?

Answer:

No. Use of the template is not mandatory and investigators should follow all available guidance from the funding program/agency for meeting DMAP requirements; however, a DMAP must be included in all new VA research proposed after January 1, 2016. This includes human, animal, and basic science research.

3. Question:

When in the process should the DMAP be used/submitted?

Answer:

The DMAP (whether it is provided by the VA funding office, adopted through use of the DMAP template, or otherwise created using the elements outlined in the template) should be submitted with the application for new research.

Federal funding agencies/offices will evaluate the DMAP included in new proposals to ensure the adequacy and appropriateness of the plan relative to the specific criteria established by the funding agency/office. If the research is

unfunded or is funded by a non-federal entity, the DMAP should be evaluated by a locally designated official or committee in accordance with local SOPs.

4. Question:

Does this mean that all VA research data must be made available to the public?

Answer:

No. The DMAP simply describes the extent to which, and the mechanisms under which, the research team decides that the public can access results (i.e., publications and data sets) from the research. VA's policy does not create or mandate any new mechanisms or requirements forcing data access, and it does not require release of sensitive information without the currently required protections. See slides 9 through 14 of the PowerPoint presentation referenced in Question #1 and available on the ORO internet site via this link.

5. Question:

Is this a spin-off of Dr. Breeling's Research Data inventory last spring? Or will that be a separate and distinct action too?

Answer:

The Data inventory effort was initiated in response to an OIG requirement to *inventory* VA research data. The Data Management and Access Plan was initiated in response to the OMB Open Data directive to make certain data *available* to the public. Although these are separate efforts, there is definite overlap and we anticipate that a VHA policy will eventually be developed that addresses in a more comprehensive and integrated manner the inventory, management, and access of VA data.

6. Question:

Does this replace/negate the data inventory tool and data security checklist which sites have to also submit with redundant information?

Answer:

As indicated above, the Data Management and Access Plan is separate from the data inventory effort. The DMAP is also separate from any data security checklists that may be required by local policy at your facility to facilitate the information security and privacy reviews of research protocols.

7. Question:

Since staff from ORO and ORD worked on this document, I assume it has been vetted for use and that word is being disseminated through the ISO and Privacy Officers so they are on board and aware of the action?

Answer:

Efforts are underway to more broadly inform about the principles driving access and sharing of research results and VA's approach to achieving these principles. VA's research data access requirements, the optional sample DMAP template, and ongoing guidance will be distributed as widely as possible.

VA's Policy and Implementation Plan for Public Access to Scientific Publications and Digital Data from VA-Funded Research was developed in response to a mandate by the White House. The VA Privacy Office and the VA Office of Information and Technology were represented in the VA Open Data and VHA Research Open Data efforts to develop those plans. The sample DMAP template is in line with the VA and VHA Plans that have been approved by OMB to support the White House directive.

Note that while the inclusion of a DMAP is mandatory in applications for new VA research, use of the sample DMAP template is not.

8. Question:

Is there an all-encompassing Data Use Agreement between VA ORD and the National Library of Medicine (NLM) PubMed Central website that documents this data will be shared to the public?

Answer:

ORD and NLM have executed a written agreement for this purpose. Instructions for depositing publications can be found on the ORD website. Currently, a central

repository for VA research data sets is not available. Individually identifiable private information, protected health information (PHI), and other VA sensitive data should not be uploaded to PubMed Central. Any data posted to the PubMed Central should be the type of data that are *currently* posted to that site in support of research articles in journal publications.

9. Question:

It looks like the PubMed website belongs to HHS. Who will have access to this website? Does the term "public" mean general public or public organizations such as state universities?

Answer:

Public means the general public. Individually identifiable private information, protected health information (PHI), and other VA sensitive data should not be uploaded to PubMed Central. Any data posted to the PubMed Central should be the type of data that are *currently* posted to that site in support of research articles in journal publications.

Note that other agencies (e.g., DoD, NSF) may use other publication repositories and investigators should follow guidance of their respective funding organization on access to publications.

10. Question:

Regarding the PubMed Central internet site, since sensitive information used in these research projects may be subject for viewing by the national public, are the systems compliant with NIST 800-53 Revision 4, i.e. data will be secured while in transit and at rest? Is the website Section 508 Compliant? If there is a security breach on the website, how will the VA be notified? If PII/PHI was involved in the breach, how will the Veterans be notified?

Answer:

As federal agencies, NLM, PubMed Central, and VA are subject to the same federal-wide information security and access requirements. The PubMed Central Website is for research publications and aggregate data sets, not individually

identifiable subject-level data. Individual subject data containing PII/PHI should not be uploaded to PubMed Central. See Questions 8 and 9 above.

The VA and VHA plans supporting the White House Open Data effort address specific circumstances and considerations for the release of sensitive information. **Sensitive information is not subject to the general public release provision in support of this effort and should *not* be uploaded to PubMed Central or any other public information systems.**

11. Question:

Will VACO provide a similar form/template in the future that may be used for submission as part of a VACO-ORD Merit award application?

Answer:

Yes. Please refer to the respective ORD service's RFA for further information. Additionally, the ORD template can be found at http://vaww.research.va.gov/funding/electronic-submission.cfm

12. Question:

What does this form mean by the term "Publications"? Is that a document with just the results of the research without any PII/PHI or will publications include PII/PHI?

Answer:

Publications (final published papers documenting the reasoning, manner, and results of how the research was conducted) and final data sets will be released using mechanisms currently in place. These mechanisms have safeguards to protect the PII/PHI of subjects. Slides 9-14 of the PowerPoint presentation (referenced in Question #1 and available on the ORO internet site via this link) describe the 6 current mechanisms in place and how VA-funded research can be shared.

13. Question:

Since this is a requirement for all new research including animal protocols, how do you classify a 3 year review or *de novo* review which includes a new ACORP? Would the three year ACORP review require the Data Access and Management Plan?

Answer:

The 3-year ACORP review would not require a DMAP. Since that review is technically a continuation of a previous effort and intends to provide a standard for review as if the project were new, but is not actually new, it would not fall under the requirement that DMAPs be submitted for new studies (submitted after Jan 1, 2016).