Read Me First - Data Management and Access Plan (DMAP)

All new proposals for VA research (human/ animal/ mineral, regardless of funding status or funding source) initiated after 1/1/16 must include a DMAP. The DMAP must state whether or not final data sets 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.

In Human Subjects Research for question 5

i) In most cases, 5A will apply. If it turns out that your needs for data sharing change, you will need to submit a revised DMAP.

ii) 5B will apply when the journal to which you are submitting your manuscript requires more disclosure than permitted by 5A. This will more likely be the case for a revised rather than an original DMAP.

iii) 5C will apply if a contract (e.g. CRADA) specifies data use in accordance with HIPAA and informed consent.

iv) 5D / 5E - will almost never apply as they are requests for public release of information without subject consent. They require, among others, the approval of the Under Secretary for Health.

Definitions:

VA Funded Research: research funded by ORD or any other VHA Program Office
(Research funded and/or supported entirely by a VISN and/or Facility is not currently considered to be "VA-Funded)

Research Results: Publications reporting results of VA research + Final Data Sets

final data set = data set contributing to published results
≠ data collected but not contributing to the published results
≠ data included in final reports but not contributing to published results

38 USC §7332-protected information –includes identity, diagnosis, prognosis, or treatment of any patient or subject which are maintained in connection with the performance of any program or activity (including education, training, treatment, rehabilitation, or research) relating to drug abuse, alcoholism or alcohol abuse, infection with the human immunodeficiency virus, or sickle cell anemia

Louis Stokes Cleveland VA Medical Center
Data Management and Access Plan (DMAP) Template

Please complete and include in your new study application packet.

1. Name of Principal Investigator:

2. Title of Proposal:

This is the initial DMAP for this study ☐

This is a revised DMAP for this study ☐

If revised, please indicate which section(s) is/are being modified

3. Publication requirement (check box to acknowledge): *This is required for all VA-funded research as well as research supported by most other agencies.*

☐ **Publications** from this research will be made available to the public through the National Library of Medicine PubMed Central website within one year after the date of publication (guidance is provided on the ORD website at http://www.research.va.gov/resources/policies/public_access.cfm).

4. Public access to **final data sets** resulting from the proposed research (check A or B below):

final data set = data set contributing to published results
≠ data collected but not contributing to the published results
≠ data included in final reports but not contributing to published results

☐ A. Final data sets underlying all publications resulting from the proposed research will not be shared outside VA, except as required under the Freedom of Information Act (FOIA), for the following reasons:

(*Not recommended, except for contracted studies involving proprietary information)*

500 characters limit

If you checked 4A, STOP HERE.

☐ B. Final data sets that involve human subjects and underlie all publications resulting from the proposed research will be shared outside VA. (*Recommended for virtually all VA research)*

If you only have human studies, proceed to 5.

☐ C. Final data sets that involve animal or other basic science not involving human subjects and underlie all publications resulting from the proposed research will be shared outside VA. (*Recommended for virtually all VA research)*

If you only have animal or other non-human studies, proceed to 6.

Mechanisms that provide public access to final data sets (i.e. data contributing to published results) from this research

5. Research **involving human subjects**:

A. The data sets include research involving human subjects (check all boxes below that apply).

☐ A. Upon request, a limited Dataset (LDS) will 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. *Recommended*

☐ B. A de-identified, anonymized dataset will be created and shared publicly. *Not recommended, unless required by journal.*

☐ C. 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 as described in the authorization and consent. *Will not apply to most studies and requires IRB approval.*

☐ D. 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. *Will not apply to most studies.*

☐ E. 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. *Will not apply to most studies.*

NOTE: Where practicable, sharing should 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.

For Q6 – 8:

If your research results include data derived from both Human and Non-human research, provide a separate response for each.

6. **How and where** will final data sets underlying publications resulting from this research be made available to the public. (*e.g., upon written request, through a website, databank, or repository): Recommended:available upon written request, available from journal website*

500 Characters limit

7. Please describe **how and where** data resulting from this research will be stored and maintained: *Recommended: Data will be stored in VA secured location (physical or electronic)*

500 characters limit

8. Explanation of how data sharing and preservation will enable validation of results by recipients: *Recommended: Data sets will provide recipients opportunities to conduct independent statistical analysis*

500 characters limit

9. Description of the mechanisms to ensure the protection of personal privacy of research subjects, the confidentiality of individually identifiable private information, and the secure maintenance of proprietary data and information (as relevant): *Recommended: Shared data will not contain PHI nor proprietary data covered by a contract*

10. As **Principal Investigator** for the proposed research, **I attest** to the accuracy of the information provided above, and I understand that
    - Final data sets must 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)
    - Failure to implement this DMAP may result in restrictions to subsequent research activities

Signature of Investigator: Date:

Reviewed & Approved

Signature of ACOS: Date: