SUBJECT: Transfer of Research Data or Materials

1. PURPOSE:

This SOP establishes the procedures for transferring research data and/or materials between the Minneapolis VA and other external entities.

2. DEFINITIONS:

ACOS/R: Associate Chief of Staff for Research
AO/R: Administrative Officer for Research
PI: Principal Investigator
PO: Privacy Officer
ISO: Information Security Officer
HRPP: Human Research Protection Program
R&D: Research and Development
VA-NPC: VA-affiliated Non-Profit Corporation
DUA: Data Use Agreement
MTA: Materials Transfer Agreement
CRADA: Cooperative Research and Development Agreement
MT-CRADA: Materials Transfer Cooperative Research and Development Agreement
STAR: Special Team Advising Research

3. OVERVIEW:

Transfer of data or materials between the Minneapolis VA Health Care System (MVAHCS) and external entities such as our academic affiliate, other universities, private corporations, other VA facilities, or other Federal agencies requires approval prior to the transfer. The specific approval process is dependent upon both the item(s) being transferred *(identifiable or de-identified data, physical samples or specimens, live research animals, etc.)* and the external entity *(not-for-profit institutions, private for-profit companies, other Federal agencies, etc.)*. Appropriate approvals must be in place whether MVAHCS is the provider or recipient of data or materials.

4. PROCEDURES:

a) Transfer of Research Data

i) VA mandates that data obtained from VA-approved studies be made available to the public upon request. However, data sharing must be appropriately reviewed and approved prior to transfer to ensure privacy and confidentiality of protected human subjects data. PIs must also note that in absence of a Data Use Agreement, the recipient of VA data is under no obligation to credit VA as the source of the data, and has no restriction on further sharing data with third parties.

ii) Requests from an external organization to share VA data must be sent directly to the MVAHCS Privacy Officer (PO), not to the Principal Investigator (PI). If the PI receives a request for data, s/he should ask the external organization to send the request to the PO instead. The PI should not forward the request to the PO on behalf of the external entity.

iii) **A Data Use Agreement (DUA) is required for most transfers of VA research data** to external entities. Exceptions to this may be made only when:

(1) Data were collected under a HIPAA authorization that explicitly requested permission for VA to share the data with the external entity; or

(2) MVAHCS is a participating site in a study under the oversight of another VA, and data are being shared only with the lead study site.

iv) For datasets that do not contain identifiable human subjects data:

(1) If data were obtained from human subjects, the PI must obtain assurance that the data are truly de-identified prior to transfer. S/he should complete a "PHI De-Identification Certification Form" (see link in Appendix A) and submit this to the PO for review. The PO will determine whether data are considered de-identified using the "safe harbor" method, or may instead recommend that the PI work with a statistician or other qualified individual to obtain an expert opinion affirming that data are not identifiable. Refer to Appendix A for details on this process.

(2) The PI should request the appropriate DUA template from the PO. S/he should complete the DUA template and then route to the PO for review. Questions regarding content of the DUA may be referred to the PO, the HRPP administrator, or the Research Information Protection & Security (RIPS) working group, as appropriate.

(3) Completed DUA templates will be reviewed by the PO, ISO, and RIPS as needed to ensure that data are not identifiable, that transfer mechanisms used to send data meet VA security requirements, and that terms of transfer are acceptable to VA.

(4) After the PO and ISO have signed, the DUA will be routed to the external organization and ACOS/R or delegate (such as the Deputy ACOS/R) for signature.

(5) The PI must ensure that no data are sent prior to completion of the DUA.

v) **For datasets containing identifiable data from human subjects:** Approval to share identifiable data is granted only under limited circumstances. Generally, this only occurs when the HIPAA authorization explicitly asked for permission to share identifiable data. Some data, such as that obtained from VINCI, cannot be shared outside of VA. The MVAHCS PO should be consulted prior to considering any transfers of identifiable data.

b) Transfer of Research Materials

i) **When provider or recipient is a not-for-profit entity:** Transfers to or from a not-for-profit entity such as a public university or other Federal agency typically require a Materials Transfer Agreement (MTA). However, a MT-CRADA may be required if compensation or intellectual property rights are involved (see below).

(1) For these transfers, the Deputy ACOS/R (dACOS) is the point of contact for the MVAHCS PI. The PI should inform the dACOS that a transfer is requested, and provide as much of the following information as possible (see examples in Appendix B):

(a) **Name and address of the external institution** that will provide or receive the materials.

(b) **Type (and number, if applicable) of materials being transferred**. If materials were obtained from humans, the Human Welfare Assurance Number (FWA number) of the providing institution must also be included.

(c) **Purpose of the transfer**, including a brief description of the project for which materials will be needed, and any terms or stipulations to be included in the transfer.

(d) **Name and title of the provider/recipient**, e.g. the person who is providing or requesting the transfer for the external entity; include the mailing address for this individual.

(e) **Name and title of the authorized signatory** (the person authorized to enter a legal agreement on behalf of the external provider/recipient's institution).

(2) When the information above has been provided, the dACOS will create a draft MTA template and route it to VA STAR Attorney for review. If the transfer involves an entity located outside the United States, the MTA must also be reviewed and approved by the US Trade Representative.

(a) VA prefers that the VA MTA template be used regardless of whether VA is the provider or the recipient of materials. Using the VA MTA template simplifies the legal review process and expedites the transfer.

(b) If VA is the recipient, the external organization's MTA can be used, but this may result in a lengthier review by VA legal counsel. Deputy ACOS will review the providing institution's draft MTA and route to VA STAR Attorney for approval.

(c) After VA legal review, the draft MTA will be routed to the external organization for review and approval of the terms and language. Amendments to the terms will require a second review by VA STAR Attorney (and US Trade, if applicable).

(3) Once all parties have agreed to the MTA language, the dACOS will route the MTA for signature.

(a) The recipient and recipient's authorized signatory must sign the MTA first. The provider should not sign until the recipient has agreed to the terms. The dACOS will ensure a fully executed copy is made available to all parties.

(b) If a MVAHCS PI is the provider, s/he must not send any materials until after the fully executed MTA has been completed.

ii) **When provider or recipient is a for-profit entity**, or if recipient is compensating MVAHCS for the materials: Transfers involving a for-profit entity require a Materials Transfer Cooperative Research and Development Agreement (MT-CRADA). This agreement is necessary even if materials are being transferred at no cost to VA, or without VA receiving compensation from the recipient.

(1) The VA non-profit corporation (VA-NPC) Center for Veterans Research and Education (CVRE) handles MT-CRADAs for MVAHCS. The CVRE Grants and Contracts Manager is the point of contact for a MT-CRADA.

(2) As with a MTA, the MT-CRADA requires review and approval by the VA STAR Attorney. The CVRE Grants and Contracts Manager will coordinate communication with VA legal counsel for the MT-CRADA.

(3) In some cases, when sending materials from MVAHCS to a for-profit recipient, it may be appropriate to use a licensing agreement rather than an MT-CRADA. Licensing

agreements are handled by the VA Technology Transfer Program (TTP). The CVRE Grants and Contracts Manager may refer the PI to TTP as needed for these cases.

iii) **When transfer involves live research animals:** Any transfer of live research animals other than purchase from an approved commercial vendor requires consultation with the Veterinary Medical Officer (VMO) prior to initiating the transfer.

(1) Considerations such as the health of the animals, the suitability of space in the MVAHCS Veterinary Medical Unit for the specific species, the schedule, mechanism and cost of transfer, and quarantine time upon arrival must be determined prior to agreeing to send or receive live animals.

(2) All other requirements regarding transfers of live research animals follow the procedures above for not-for-profit or for-profit entities.

5. REFERENCES:

VHA Directive 1200.02(1) "Research Business Operations" (10 March 2017)

VHA Directive 1206 "Use of a Cooperative Research and Development Agreement (CRADA)" (19 June 2018)

VHA Directive 1605.01 "Privacy and Release of Information" (31 August 2016)

VHA Handbook 1080.01 "Data Use Agreements" (20 November 2013)

VHA Handbook 1200.12 "Use of Data and Data Repositories in VHA Research" (9 March 2009)

VHA Handbook 1200.17 "Department of Veterans Affairs Nonprofit Research and Education Corporations Authorized by Title 38 United States Code (U.S.C.) Sections 7361 through 7366" (27 April 2016)

Federal Technology Transfer Act of 1986

15 U.S.C. §3710a "Cooperative Research and Development Agreements"

6. APPENDICES:

Appendix A: Verification of De-Identified Data

Appendix B: Material Transfer Agreement – examples of required components

7. R&D COMMITTEE APPROVAL: 04 August 2020

8. RECISSIONS: None - This is a new SOP.

9. EXPIRATION DATE: N/A

10. FOLLOW-UP RESPONSIBILITY: Research and Development (R&D) Committee

Appendix A: Verification of De-Identified Data

There are two methods to achieve de-identification in accordance with the HIPAA Privacy Rule. Satisfying either method would demonstrate that a covered entity has met the standard in §164.514(a) of the Privacy Rule. De-identified health information created following these methods is no longer protected by the Privacy Rule because it does not fall within the definition of PHI.

I. The "Safe Harbor" Method:

- The 18 HIPAA identifiers of the individual or of relatives, employers, or household members of the individual, are removed; and
- The covered entity does not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is a subject of the information.

II. The "Expert Determination" Method:

A person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable:

- Applying such principles and methods, determines that the risk is very small that the information could be used, alone or in combination with other reasonably available information, by an anticipated recipient to identify an individual who is a subject of the information; and
- Documents the methods and results of the analysis that justify such determination.

III. The Process:

1. Requests for de-identified information must be in writing and include:
   a. Purpose of the request;
   b. Name of the individual/entity requesting the data;
   c. Assurance that the dataset will be used solely as a statistical research or reporting record;
   d. A statement that the recipient will not take steps to identify or re-identify any individual whose data are included in the dataset.
2. The study's Principal Investigator must complete a "PHI De-Identification Certification Form" (located on the Minneapolis Research website at https://www.va.gov/MINNEAPOLISRESEARCH/forms.asp).
3. The written request, the PI's certification form, and the dataset must be reviewed by the Privacy Officer who will determine whether:
   a. The dataset meets the requirements of VHA Handbook 1605.1 Appendix B. *[NOTE: The code or other means of record identification is not considered one of the identifiers that must be excluded for de-identification; however, this code needs to be removed when disclosing de-identified data to non-VA entities.]*
   b. The release of the data meets all requirements of the Privacy Act, HIPAA, and other applicable regulations.

4. If the Privacy Officer cannot verify de-identification of the dataset using the "Safe Harbor" Method, an analysis by at least two qualified experts will be conducted.
   a. The experts' CVs will be on file, describing his/her relevant professional experience, academic or other training, and actual experience using health information de-identification methodologies.
   b. The experts will conduct a review of the data and provide the Privacy Officer with documentation of the methods and results of their analysis and subsequent determination.
5. If de-identification of the dataset has been verified, the Privacy Officer will provide the PI with the appropriate Data Use Agreement template for completion. Templates may be found on the Minneapolis Research website at https://www.va.gov/MINNEAPOLISRESEARCH/forms.asp.

   The 18 HIPAA identifiers of the individual or of relatives, employers/providers, or household members of the individual, must be removed.

   Change Subject ID #s and do not create a crosswalk that provides a Code Key for re-identification.

   Dates can be substituted with duration of time from an index date, or by date-shifting the same amount of time. For example:

	Diagnosis Date	Procedure Date	Adverse Event Date
Actual	1/1/2020	2/4/2020	3/12/2020
Using Index Date	0	34	71
Shifting (by -45 days)	11/17/2019	12/21/2019	1/27/2020

   The dataset should be reviewed by the Research Privacy Officer to confirm that it meets all requirements of the Privacy Act, HIPAA, and other applicable regulations. If de-identification of the dataset has been verified, the Privacy Officer will attest to this fact by signing the completed DUA.

Appendix B: Material Transfer Agreement – examples of required components

1. **Name and address of the external institution**:

   Note that full legal name of the institution may not be the name by which it is generally known. If you only know the colloquial institution name, you or the dACOS should request the full legal name and address from the provider/recipient.

   Remember that the agreement is made on behalf of the US Department of Veterans Affairs, not by you or by the Minneapolis VA.

   Regents of the University of Minnesota
   Sponsored Projects Administration
   450 McNamara Alumni Center
   200 Oak St. SE
   Minneapolis, MN 55455

2. **Type (and number, if applicable) of materials being transferred**:

   Identify whether samples were collected from humans, and if so, the Human Subjects Protection (FWA) assurance number of the providing institution must be included. The example below uses the MVAHCS FWA number.

   25 de-identified clinical skin biopsy samples.
   Samples collected from humans. FWA number: 00001480

3. **Purpose of the transfer and terms of use:**

   The description does not have to be lengthy. Final disposition of the materials (e.g. can they be used in additional projects? Can they be further shared with other entities?) should be included.

   Materials to be used as control strains in a study of antibiotic resistance in healthy adults. Unused materials must be destroyed at the conclusion of the study. Materials provided cannot be further shared with another organization; interested third parties must contact Provider directly for a separate MTA.

4. **Name, title, and address of the provider/recipient:**

   Mailing address of the provider/recipient likely differs from the address of the institution.

   Jane Smith, MD, PhD
   Department of Integrative Biology
   Michigan State University
   222 Giltner Hall
   East Lansing, MI 48824

5. **Name and title of the authorized signatory:**

   In some cases, the authorized signatory may be the same as the provider/recipient, but this is generally an individual who handles agreements or is the supervisor of the department in which the provider/recipient works.

   John Doe, MA, Contracts and Licensing Officer