VAPHS Research Guidance
Written Agreements

Purpose: This guidance document is designed to help VAPHS Investigators determine when a written agreement must be used during collaborations with a non-VAPHS institution or investigator which involves transferring data and/or specimens for research purposes by outlining the types of agreements that may be utilized.

Applies to: All research projects and repositories under the purview of the VAPHS Research and Development (R&D) Committee and all personnel working/collaborating on such projects.

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1. Introduction

When a VA investigator wishes to send data and/or specimens obtained during the conduct of VA-approved research to a non-VA or non-VAPHS entity, an appropriate access agreement should first be in place that clearly defines the terms of data/specimen use by the named party(ies), data/specimen ownership and control, and oversight.

Non-VA entities include our academic affiliate (i.e. University of Pittsburgh), external study sponsors (e.g. private companies, non-profit research organizations), etc. Please note that UPMC and the University of Pittsburgh are separate legal entities and must always be regarded as such. Similarly, VA is a separate entity from all other federal agencies and even when dealing with another federal agency, an agreement should still be in place.

The local guidance provided in this document is primarily based on Veterans Health Administration (VHA) Office of Research and Development (ORD) Technology Transfer Program (TTP), Office of General Counsel (OGC) Specialty Team Advising Research (STAR) guidance, VHA Directive 1206 and VHA Handbooks 1200.12 and 1200.05.

**For the purposes of VAPHS research agreements, a collaborator is considered to be any non-VAPHS investigators or institutions with whom VA research data is shared. Furthermore, appropriate access agreements must be in place and fully executed prior to the release of data and or specimens from a research repository, regardless of whether or not the repository and recipient are both located at VAPHS.*

2. Most Commonly Used Types of Agreements

a. **CRADA** (Cooperative Research and Development Agreements)

i. A CRADA is an agreement between the Department of Veterans Affairs (VA) and one or more non-federal entity (i.e. pharmaceutical company/industry sponsored clinical trial) under which VA may accept, retain and use funds, personnel, services, facilities, intellectual property, equipment or other resources from the other party. In exchange, VA may provide personnel, services, facilities, intellectual property, equipment, or other resources, excluding funds, for research and development efforts that are consistent with VA's mission. A CRADA defines the responsibilities and obligations of each party in conducting collaborative research and development, and provides the collaborating parties with certain rights to any patentable invention made by a Federal employee in the performance of the agreement. VHA Directive 1206.

ii. The Veterans Research Foundation of Pittsburgh (VRFP) facilitates the CRADA process when funding for VAPHS activities will be provided through the VRFP. This is the most common way that CRADAs are executed.
    1. When funding for the VAPHS activities are not administered through the VRFP, the Research Office should be contacted for additional guidance.

iii. To initiate a new CRADA, the VAPHS Investigator must provide the following information to the VRFP (if funded through VRFP) or the Research Office (if funded through the University of Pittsburgh or unfunded):
    1. Name(s) and contact information of VAPHS PI
    2. Name(s) and contact information of external collaborator(s)
    3. Title of study
    4. Detailed Scope of Work (SOW) or protocol that clearly and thoroughly delineates the work to be conducted by VA investigators on VA time. Note: this is very important for the VA legal review. If anything is unclear, the VA legal review could be delayed.
    5. Answers to the following questions:
        a. What will VA receive from the sponsor/collaborator under the agreement (data? Money? Study drug/device?)
        b. What will VA provide to the other entity? (data?)
        c. Will the data provided by VA to the sponsor/collaborator under this agreement be identifiable or de-identified (e.g., all 18 HIPAA identifiers are removed) prior to transmission?

The VRFP contact is Jennifer.Dalton@va.gov. The VAPHS Research Office contact is Janelle.Altman@va.gov. Once all of the information above has been provided, the VRFP or VAPHS Research Office will contact OGC to start the CRADA discussion and review.

b. **RDUA** (Research Data Use Agreement)
    i. The RDUA is a VAPHS document that should be used for the transfer of data collected from human subjects, clinical studies, or laboratory experiments for research projects from a VAPHS Investigator to a non-VA person or entity who is serving as a contractor or collaborator on the PI's VA-approved protocol. The RDUA covers requirements associated with a combined Data Use Agreement/Data Transfer Agreement (DUA-DTA) as referenced in VHA Handbook 1200.12. The RDUA does not cover funding exchange, and normally stipulates that VA retains ownership of any transferred data.

    ii. There may be circumstances when use and ownership of VA data are described in another type of written agreement. If your collaboration/project already has another written agreement in place (e.g. CRADA), please contact the VAPHS Research Office to determine if you need an RDUA as well.

    iii. An RDUA must be in place prior to data being released from a repository.

    iv. To initiate an RDUA, the VAPHS Investigator must complete the RDUA template, and submit the completed agreement with the project application. The RDUA template can be found on the VAPHS Research website and on ProSPECT.
        1. For collaborations involving a human subjects research project, Investigators must complete the RDUA template and upload it to the project's ProSPECT application.

a. The IRB will review the RDUA to ensure consistency with the protocol, informed consent document, and HIPAA authorization (if applicable).

c. **RWA** (Research Written Agreement)

i. The RWA is a VAPHS document to be used when only aggregate and/or other analytic output of VA research data are being shared/transferred from a VAPHS investigator to a non-VA collaborator or entity.

ii. The RWA cannot be used if the share/transfer of data is associated with a repository.

iii. The RWA cannot be used for the release of private health information, individually identifiable information/coded, or de-identified information.

iv. The RWA cannot be used for collaborations involving a contracted service.

v. To initiate an RWA, the VAPHS Investigator must complete the RWA template and submit the completed agreement with the project application. The RWA template can be found on the VAPHS Research website and on ProSPECT.

1. For collaborations involving a human subjects research project, Investigators must complete the RWA template and upload it to the project's ProSPECT application.
    a. The IRB will review the RWA to ensure consistency with the protocol, informed consent document, and HIPAA authorization (if applicable).

d. **MTA** (Basic Material Transfer Agreement)

i. The Basic Material Transfer Agreement (MTA) is for use with non-profit or academic recipients only. It is not for use where the provider or recipient is a for-profit organization or company. It is not for use when the research material will be used for screening, production or sale. The MTA may only be used when VA is the recipient or provider of material and no intellectual property (patent) rights are transferred. If VA is the recipient of a material and the provider would like a commitment of intellectual or patent rights, please use the MT CRADA. Only unmodified MTAs may be approved locally and signed by the ACOS for Research (i.e., VA legal review and MCD signature would not be required). Please contact the Research Office for questions about MTAs.

ii. Other MTAs – VA prefers to use the Basic Material Transfer Agreement described above, but it is also permissible to use a Material Transfer Agreement template provided by the recipient or provider-company or organization. The Material Transfer Agreement must go through legal review. The Uniform Biological Materials Transfer Agreement (UBMTA) is one example of a common MTA that is used by many organizations.

iii. An MTA must be in place prior to biospecimens being released to another facility.

iv. To initiate an MTA, the VAPHS Investigator should visit the VAPHS Research website to review the VAPHS R&D MTA Policy #016 and must complete the MTA template. Once completed, the template should then be sent to Dana.Roolf@va.gov in the Research Office.

1. Note: Individuals listed on an MTA must complete any applicable trainings (e.g. shipping dry ice and/or biological hazards training) prior to submitting the MTA template to Ms. Roolf. The VAPHS research website also describes relevant training requirements.

3. Frequently Asked Questions

For determining which type of written agreement to use when collaborating with a non-VAPHS individual or entity:

a. Does the collaboration involve sharing/transferring data?
   i. If a VAPHS data repository is being utilized, an RDUA must be in place.
   ii. If the collaboration involves data (which are not in aggregate or analytic output forms) collected from human subjects, clinical studies, or laboratory experiments for research projects from a VAPHS Investigator to a non-VAPHS person or entity, an RDUA must be used.
   iii. If the collaboration involves human subjects data which are in aggregate or analytic output forms only, an RWA must be used.
   iv. If the collaboration involves reuse of human subjects data, this must be detailed in the approved consent documents.

b. Does the collaboration involve transferring biospecimens?
   i. If the collaboration involves a VAPHS biorepository and a VAPHS investigator, the transfer/sharing of those biospecimens must be describe in the IRB approved protocol.
      1. If the biospecimens are being released from a VAPHS biorepository to a non-VAPHS investigator, and MTA must be used.
   ii. If the collaboration involves transferring of biospecimens or the utilization of a VAPHS biorepository with a non-VAPHS investigator, an MTA must be used.
      1. If the collaboration is with a pharmaceutical company or other non-federal entity, then a combined MTA & CRADA may be used. In this instance, please contact the VAPHS Research Office or the VRFP (as applicable) for additional guidance.
   iii. If the collaboration involves reuse of human subjects biospecimens, this must also be detailed in the approved consent documents.

c. Does the collaboration involve a contracted service (e.g. Pitt's MRRC)?
   i. If funding for the contracted service is not being facilitated through a CRADA with the VRFP, please contact the VAPHS Research Office to discuss contracting requirements. In limited circumstances, it may be possible that a contract fulfills the requirements in VHA Handbooks 1200.05 and 1200.12. If your project involves a contract, please contact the Research Office for guidance.

d. Will VA data be created or stored at the collaborator's institution? (e.x. data created from MRI scans conducted at UPMC for research as part of a VAPHS protocol)
   i. Use an RDUA, and ensure compliance with VAPHS R&D Policy #017, Research Information Protection Program and VHA Handbook 6500.

e. My collaboration involves a human subject research project. Where should I list my collaborator(s) and upload my written agreement in ProSPECT?

i. If the collaborator(s) will be working at VAPHS (i.e. on-site) and is engaged in human subjects research, the individual(s) must have a ProSPECT account and should be listed as study staff in Section 0, Question 6.0.
ii. If the collaborator(s) is not stationed at VAPHS (i.e. off-site), the individual(s) should be described in Section 1.4 (Resources, Question 4.0) and/or Section 1.6 (Multi-Site Study Section).
iii. RDUAs are to be uploaded in the applicable Multi-Site Section of the study application.
iv. RWAs are to be uploaded Section 15 of the study application.

There are circumstances in which multiple written agreements may be needed. For questions or scenarios that are not addressed in this document, please contact Kathleen.Parks@va.gov and/or Katherine.Nega@va.gov

Document History

Number	Version	Effective Date	References	Actions/Comments
G-HSR #017	1.0	0xJuly2017	VAPHS R&D Policy #016 VAPHS R&D Policy #017 VAPHS R&D Policy #018 VAPHS R&D Policy #020 VA Handbooks 1200.12, 1200.05, and 6500 VHA Directive 1206	New Guidance