

Myths About Veterans Health Administration (VHA) Research

1. The VHA cannot share data outside of VHA.

FALSE. There are numerous examples where the VHA has successfully partnered to conduct research with industry, academic affiliates, and academic-non-affiliates, and with other federal agencies. Prior planning and appropriate agreements are the key to a successful data sharing arrangement. The VHA is developing templated data use agreements and material transfer agreements. VHA Directive 1200.12 is the relevant research policy for data sharing and data repositories. For non-research data (e.g., QA/QI) VHA directive 1080.01 is applicable and has its own templates for agreements. **NOTE:** As an Executive Agency, and a covered entity, the VHA is subject to the requirements of the Privacy Act of 1974, The HIPAA Privacy Rule, 38 USC 5702, 38 USC 5701, 38 USC 7332, and 38 CFR 1.488. The application of these regulations is described in VHA Directive 1605.01: Privacy and Release of Information (August 31, 2016).

2. The VHA cannot share identifiable data, including VA sensitive information, outside of VHA.

FALSE. The VHA can share identifiable data, including VA sensitive information, with both federal and non-federal partners with the appropriate authorizations and agreements as applicable, including any applicable human subject protection regulations and policies. However, there are differences in data sharing requirements between federal and non-federal partners as required by privacy laws, regulations, and VHA policies. VHA Directive 1605.01 describes VHA's requirements for sharing or disclosing VA identifiable data to non-VA Researchers. The VHA Privacy Office has also developed Privacy Fact Sheets on sharing identifiable data both within and outside of VA, including the Privacy Fact Sheet: Privacy Requirements for Disclosures for Research to VHA Researchers (January, 2017) and the Privacy Fact Sheet: Privacy Requirements for Disclosures for Research to Non-VA Researchers (January 2017). These are located at <https://vawww.vets.vaco.portal.va.gov/sites/privacy/vhapo/Pages/research.aspx>.

3. The VHA cannot store deidentified data after a research study concludes.

FALSE. The limitations of storing data after a study closes are based on what was approved in the research protocol and whether there is any content in the executed informed consent document (unless informed consent was waived) for non-exempt studies that would not allow storage and use of deidentified data for secondary purposes. If the storage of VA de-identifiable data is for secondary research purposes, ORD policies in VHA Handbook 1200.12: Use of Data and Data Repositories in VHA Research (March 9, 2009) must be followed.

4. When VA data is transferred, it remains subject to VA information security requirements.

IT DEPENDS. Ownership of the transferred data determines whether or not the data are subject to VA's information security requirements. If VA is processing or storing VA data at a non-VA location, the data are subject to VA's information security requirements – the data are owned by VA. When VA discloses

or shares a copy of VA data to another institution or agency, such as to an industry collaborator, VA's information security requirements do not apply to the storage of the copy if VA relinquishes ownership. However, VA is responsible for transmission of data securely when VA data are shared or disclosed. If the data are a copy of the original VA data, there are no further information security requirements once the transfer is complete.

5. Only individuals with VA appointments can have access to VA data.

FALSE. Only individuals with authority to access VA information systems are allowed access to VA's electronic systems, such as the Computerized Patient Record System (CPRS). However, when VA researchers are collaborating with non-VA researchers as part of a collaborative study, there is no requirement for the non-VA researchers to obtain a Without Compensation (WOC) appointment if VA is sharing data with the appropriate authority and consent as applicable to the research activity. For example, if a VA researcher and a non-VA researcher were conducting a study in which the VA subject signs a consent and authorization allowing identifiable information to be shared with the non-VA researcher, VA can share the identifiable information with the non-VA investigator without that individual being required to obtain a WOC appointment.

6. For profit institutions, such as industry, cannot be permitted to store and use VA biospecimens for unspecified future uses.

FALSE. In the past, ORD had procedures in place that would not allow for profit institutions to store biospecimens supplied by VA for future unspecified uses. ORD policies no longer have the restriction and allow the local VA facility's research committees to make the evaluation dependent upon the specific research activity, including whether the subjects are given adequate information to make an informed decision.

7. The VHA cannot rely on a non-VA Institutional Review Board (IRB).

FALSE. The VA medical centers have relied on VA-affiliated academic IRBs for many years. The most recent version of VHA Directive 1200.05 (Jan 7, 2019) allows for reliance on IRBs not affiliated with a VA Facility if that IRB is affiliated with a medical or dental school. Procedures are being put in place to allow implementation of this ORD policy, including review of the information security systems utilized by the non-affiliated IRBs. Reliance on commercial IRBs is currently not allowed by policy but is being considered for policy change.

8. Non-VHA institutions cannot rely on VHA IRBs.

FALSE. The non-profit corporations that support the research mission of the VHA are often engaged in the conduct of the research and rely on either the VHA IRB or the IRB on which the VHA medical center is relying for a particular study. VHA allows specified federal agencies to rely on VHA; Department of Energy (DOE) and Department of Defense (DOD) may rely on VHA with an institutional agreement for

September 2019

Version 1

IRB reliance or an MOU with equivalent language. Current policy in ORD does not permit other types of non-VA institutions, such as universities, to rely upon VA IRBs.

9. VHA requires AAHRPP accreditation or equivalent for non-VHA facilities to rely on VA IRBs.

FALSE. The VA does not require non-VHA facilities or institutions such as the VA non-profit corporations or the DOD or DOE, to be AAHRPP accredited (or equivalent) for that institution to rely on a VHA IRB.

10. VHA investigators are always subject to the DOD Human Research Protections Office (HRPO) requirements in accordance with the Defense Federal Acquisition Regulation Supplement (DFARs) when DOD is funding a study.

FALSE. If DOD is funding a study and the DOD IRB is the reviewing IRB and VHA is relying on that DOD IRB review and funds are transferred directly from DOD to VA, there is no HRPO review required. HRPO review is required when DOD funds a study when:

1. The reviewing IRB is not a DOD IRB, **OR**,
2. There is a non-federal partner involved in the receipt of DOD funds.