

Research Data Inventory Form

The Research Office is required to maintain a Research data inventory which will be made available to the auditing entities with the primary purpose to be able to trace back any data collected during the course of a VA approved study.

For the purposes of this inventory, VA sensitive data (VASI) is data collected that contains any elements of Protected Health Information and/or Personally Identifiable Information. Further, the term includes information whose improper use or disclosure could adversely affect the ability of an agency to accomplish its mission, proprietary information, records about individuals requiring protection under various confidentiality provisions such as the Privacy Act and the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, and information that can be withheld under the Freedom of Information Act (FOIA). Examples of VA sensitive information may include:

- Individually-identifiable medical, benefits, and personnel information; VHA HANDBOOK 1200.01
- Intellectual property related to research
- Non-human primate research data (a risk assessment should be done to determine sensitivity level)
- Other information which, if released, could result in violation of law or harm or unfairness to any individual or group, or could adversely affect the national interest or the conduct of Federal programs.

Suggestions for Completing the Attached Form:

1. Note that while we are looking for data at rest, if you move data frequently and store it on a flash drive for a period of time, then we will need this detailed as well.
2. When stating the location of where the data will be stored, please use the following examples: VA Computer Room 5a122, encrypted flash drive, file cabinet room 12c188. If the data will be located on a server, please use the appropriate server information (eg, V07.med.va.gov\atg\atlanta_research\Clinical_Research2\hart_research).
3. In Section 1, please state what room number you store any Non-Sensitive data. This includes lab books, de-identified paper data, animal data etc., research equipment data that is not immediately moved from the machine. If the data is electronic, then state the computer or server, VINCI, SAS Server. If the data reside on a PC that is part of a system (PC tied to microscope) indicate the system. If stand alone, then identify the EE number.
4. Sections 2-6 are fairly self-explanatory.
5. Section 7 For the first two questions in this section, if you transport VASI then please provide the process of moving the data (flashdrive, blue bag, iPad, laptop, etc.), For the next two, if you disclose, then enter SEE AUTHORIZATION). For the last question, if you say yes, then put in SEE DATAUSE AGREEMENT and attach a copy of the agreement.
6. Section 8 and 9 are self-explanatory.

Privacy and Data Security Plan

Principal Investigator:

Title:

RCMS ID:

Project ID Number:

Date Prepared:

Section 1 - Non-sensitive and Sensitive Data Use

List the VA location(s) [Room and Building] where you will store non-sensitive study records (such as: VA computer room 5a122, file cabinet in room 12c188). Include location of electronic non-sensitive data as well (such as on encrypted flash drive or VA server. eg, V07.med.va.gov\atg\atlanta_research\...your folder name).

Select the VA Sensitive Information (VASI) use category (choose one)

☐ This study does not collect or use any VASI [Stop here]

☐ This study uses but does not save, collect, copy, or record any VASI [stop here]

☐ This study does collect or record VASI

Section 2 - Hardcopy VASI

Will VASI in hardcopy form be stored for this study (includes paper, tape recording, film, etc.)?

☐ Yes

☐ No

If yes, list the VA locations where you will store hardcopy VA Sensitive Information (VASI) for this study. Include the security measures such as in a locked cabinet inside a locked room when unattended.

Section 3 - Electronic VASI

Is VASI stored on the VA secure network (do not include CPRS)?

☐ Yes

☐ No

If yes, identify the locations (\\v07.med.va.gov\atg\atlanta_research\...your folder name).

Is VASI stored on a computer local hard drive (even temporarily) such as by specially obtained software?

☐ Yes

☐ No

If yes, identify the computer system and describe the sensitive data and how it is secured.

Will electronic VASI be stored outside of the VA secure network (such as in portable devices, on removable media, at another institution, or collected by external web application)?

Yes No

If yes, describe the storage method (e.g., in a VA encrypted laptop) and security details, including the device/media location and ownership. Identify backup procedures for portable devices/media. If applicable, identify the web applications, their security features, the nature of the data involved, and the research purpose. Identify any agreements related to the protection of this data.

Section 4 - Images

Will images with personal identifiers (e.g. research [not clinical] records containing x-rays with patient names or record numbers) be used?

Yes No

If yes, indicate where images with identifiers are stored

 In the medical record (e.g., VistA imaging)

 With the study secured hardcopy information

 With the study electronic sensitive information

Section 5 - Photos with Faces or Recordings

(Note: If patients are involved, a special consent form (VA form 10-3203) will be required.)

Will photos with faces or recordings be stored?

Yes No

If yes, indicate where photos or recordings are stored

 With the study secured hardcopy information

 With the study electronic sensitive information

Section 6 – Identified Biological Specimens

Will biological specimens with subject identifiers (not code numbers) be stored?

Yes No

If yes, indicate where they are stored and the security measures employed.

Section 7 - Transporting and Sharing VASI

Is VASI collected outside of the VA? *(Note: An approved Authorization to Transport will be required.)*

Yes No

If yes, describe what is collected outside the VA and how it is secured in transit back to the VA

Is VASI transported outside of the VA for any purpose other than sharing (covered below)? *(Note: An approved Authorization to Transport will be required.)*

Yes No

If yes, describe what is transported outside the VA, for what purpose, and how it is secured in transit

Can VASI be disclosed to monitoring/auditing agencies by HIPAA Authorization? *(Note: The Research Office must be notified when monitors come to audit)*

Yes No

If yes, indicate the monitors/auditors that will have access by HIPAA Authorization

Will a copy of VASI be shared outside the VA for other purposes (e.g. collaborators or sponsors) by HIPAA Authorization?

Yes No

If yes, describe what is shared, who receives a copy of VASI, and how it is secured in transit

Will a copy of VASI be shared or disclosed without HIPAA Authorization? *(This is rarely approved).*

Yes No

If yes, describe what is shared, who receives a copy of VASI, and how it is secured in transit

Section 8 - Use of Coded Data

Will coded data that excludes personal identifiers be used? *(Note: Coded data excludes all HIPAA identifiers per VHA Handbook 1605.1 Appendix B, which includes dates)*

Yes No

If yes, indicate where the code key is stored (choose one)

With the study hardcopy VASI, but separate from the coded data

With the study electronic VASI, but separate from the coded data

Both of the above

Section 9 - Any Other Relevant Details

Add any other privacy or information security details here