

Minneapolis VAHCS Privacy and Data Security Questionnaire

Principal Investigator:

Last:

First:

Title:

Protocol Number:

Protocol Title:

Date Prepared:

I. List the VA location(s) where you will store non-human subjects study records.

I.A. Hardcopy records: List room and storage location(s)

I.B. Electronic records: List network storage path(s)

II. Does your study involve nonhuman primates, human subjects, or human subjects data?

NO: This study does NOT collect or use any nonhuman primate or human subject data

STOP HERE. No further information is needed.

YES: This study uses but does not save, collect, copy, or record any nonhuman primate or human subjects data

STOP HERE. No further information is needed.

YES: This study does collect or record nonhuman primate or human subjects data (*check one*)

This data may be VA Sensitive Information (VASI): Go to section III

III. Will hardcopy nonhuman primate or human subjects data be stored for this study?

(Hardcopy data includes paper, tape recording, film, etc.)

NO: **Go to Section IV**

YES: List the VA locations where you will store hardcopy data. For each location, list security measures used to protect data (e.g. "in locked cabinet inside locked room when unattended").

IV. Will electronic nonhuman primate or human subjects data be stored for this study?

NO: **Go to section V**

YES

IV.A. Are electronic nonhuman primate or human subjects data stored on the VA secure network? (Do not include data stored in CPRS)

NO: **Go to section IV.B**

YES: Identify the locations (server/folder etc.).

IV.B. Are electronic nonhuman primate or human subjects data stored on a computer local hard drive (even temporarily) such as by specially obtained software?

- NO: [Go to section IV.C](#)

- YES: Identify the computer system and describe the sensitive data and how it is secured.

IV.C. Will electronic nonhuman primate or human subjects data be stored outside of the VA secure network?

(Examples: On portable devices or removable media, at another institution, or collected by external web application)

- NO: [Go to section V](#)

- YES: Describe the storage method (e.g., in 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.

For nonhuman primate data: STOP HERE.

For human subjects data: Continue to Section V.

V. For human subjects data, will images with personal identifiers be used?

(Example: Research [not clinical] records containing x-rays with patient names or record numbers)

- NO: [Go to section VI](#)

- 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
 - Other location (specify):

VI. Will photos with faces or recordings be stored?

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

- NO: [Go to section VII](#)

- YES: Indicate where photos or recordings are stored:
 - With the study secured hardcopy information
 - With the study electronic sensitive information
 - Other location (specify):

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

- NO: [Go to section VIII](#)

- YES: Indicate where they are stored and the security measures employed.

VIII. Will human subjects data be collected outside of the VA?

(Note: An approved Authorization to Transport will be required.)

- NO: [Go to section IX](#)

- YES: Describe what is collected outside the VA and how it is secured in transit back to the VA

IX. Will human subjects data be transported outside of the VA for any purpose other than sharing?

(Note: An approved Authorization to Transport will be required.)

- NO: [Go to section X](#)

- YES: Describe what is transported outside the VA, for what purpose, and how it is secured in transit

X. Can human subjects data be disclosed to monitoring/auditing agencies by HIPAA Authorization?

(Note: The Research Office must be notified when monitors come to audit)

- NO: [Go to section XI](#)

- YES: Indicate the monitors/auditors that will have access by HIPAA Authorization

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

- NO: [Go to section XII](#)

- YES: Describe what is shared, who receives a copy of human subjects data, and how it is secured in transit

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

- NO: [Go to section XIII](#)

- YES: Describe what is shared, who receives a copy of human subjects data, and how it is secured in transit

XIII. 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)

- NO: **Go to section XIV**

- YES: Indicate where the code key is stored (choose one):
 - With the study hardcopy human subjects data, but separate from the coded data
 - With the study electronic human subjects data, but separate from the coded data
 - Both of the above

XIV. Other Relevant Details

(Add any other privacy or information security details here)