

## 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)*