**Protocol ID:**        **Protocol Director:**

**Answer all questions in section (A). If a Waiver of HIPAA Authorization is requested, complete**

**section (B).**

| **(A) VA Sensitive Information**  - **Security Review Checklist For Research Projects** | | | | |
| --- | --- | --- | --- | --- |
| **The VA Information Security Officer must verify the storage and/or transfer outside of VAPAHCS of VA sensitive information collected on a research project meets all VA regulations**.  VA Sensitive Information is defined as: *All VA data, on any storage media or in any form or format, which requires protection due to the risk of harm that could result from inadvertent or deliberate disclosure, alteration or destruction of the information.* ***This includes individually identifiable information (III) and protected health information (PHI).***  For questions on the storage or transfer outside of VAPAHCS of VA sensitive information contact  the VA Information Security Officers at V21PAL ISO@va.gov | | | | |
| Review Item |  |  |  |  |
| 1. Is all portable IT equipment (i.e., laptops, USB thumb drives, external hard drives and other removable storage media) used in the research encrypted and registered as required? | N/A | Yes | No | *Note: VA policy requires all portable IT equipment to be registered and encrypted. Contact the VAPAHCS ISO for assistance in satisfying this policy.* |
| 2. Please confirm: Any unauthorized access to VA sensitive information (including unauthorized use, disclosure, transmission, removal, theft or loss) will be reported to the ACOS for Research, the facility ISO and the facility Privacy Officer within one hour of when such an event is discovered? | N/A | Yes | No | *Note: This is required by VHA Handbook 1058.01, Research Compliance Reporting Requirements* |
| 3. If you will maintain **paper** research records, where will you store the **paper** research records at VAPAHCS when not in use (i.e., Room number, locked file cabinet)? | N/A |  | | |
|  | | | | |
| 4. If you will maintain **electronic** research records, where will you store the electronic research records at VAPAHCS (i.e., Palo Alto, Menlo Park, server name? | N/A | ***Note****: The VA must retain a copy of any VA data disclose outside the VA, including data transferred via the Stanford LAN extension, stored on a Stanford/PAVIR computer or entered into a secure web-based system (e.g. REDcap).* | | |
|  | | | | |
| 5. Will VAPAHCS investigator(s) share VA III or PHI with non-VAPAHCS investigator(s) (i.e., Stanford collaborators)? | | Yes | No | ***Note:*** *VA III is any information collected on a VA research study that is individually identifiable, which includes PHI (Identifiable Protected Health Information)* |
| 6. Will VA PHI be shared in accordance with an signed HIPAA Authorization? | N/A | Yes | No | ***Note:*** *VA PHI can only be shared with non-VA entities/individuals (i.e., Stanford) via a signed HIPAA authorization that includes Stanford as an entity who may receive the data.* |
| 7. Will VA III or PHI be stored off-site (i.e., at an office or computer not physically located at VAPAHCS? | | Yes | No | ***Note****: To store VA III or PHI offsite, an offsite storage authorization must be approved by ACOS, CIO, ISO and Director.*  *Contact the ISO.* |
| 8. Will VA III or PHI be stored /transferred via the Stanford LAN extension? | | Yes | No | ***Note****: The VA must retain a copy of any VA data disclose outside the VA, including data transferred via the Stanford LAN extension, stored on a Stanford/PAVIR computer or entered into a secure web-based system (e.g. REDcap).* |

|  |
| --- |
| **(B) Supplemental Information Required for a Waiver of HIPAA Authorization**  Complete this section if you have requested a waiver of HIPAA Authorization (full or for recruitment). |
| 1. Provide the following additional information: 2. Describe why the research could not be practicably conducted without the waiver.   *(i.e., why it is not possible/practicable to get signed HIPAA Authorizations)*     1. Describe why the research could not practicably be conducted without access to and use of the protected health information.   *(i.e., how the PHI being accessed relates and is necessary to the study )* |
| 1. Will information related to drug and alcohol abuse, HIV infection or sickle cell anemia be accessed/used pursuant to the Waiver of HIPAA Authorization?   **Yes  No**  If “*yes*”, confirm the following:  The above-referenced information will be maintained in accordance with all VA information security policies *(Paper records are maintained in a secure room, locked file cabinet when not in use. Access to electronic versions of data is be limited to authorized VA researchers who need access to conduct the research)*.    The above-referenced information will not be re-disclosed, except back to the VA.  The above-referenced informationwill not identify any individual patient in any report of the research or otherwise disclose patient identifiers. |