

Department of
Veterans Affairs

Memorandum

Date: May 14, 2009
From: Chief Officer, Office of Research Oversight (ORO)(10R)
Subj: Further Guidance on ORO Implementation of VA Handbook 6500 §6c(4)(j):
Update to ORO Memoranda dated May 29, 2008 and February 2, 2009
To: All ORO Staff

1. The ORO memorandum on *Compliance Oversight Procedures For Use And Storage Of VA Sensitive Research Information* (May 29, 2008) cites the VA Handbook 6500 requirement at §6c(4)(j) that **“VA sensitive information may not reside on non-VA owned Other Equipment (OE) without . . . a waiver from the VA CIO”** Absent a waiver, the memorandum states that ORO will require a written statement from the ISO and the facility Director justifying the storage of VA sensitive information on non-VA OE.
2. The memorandum goes on to state (§ G5) that this ORO procedure does not apply to use or disclosure of information in accordance with legally effective informed consent and properly executed authorization under the Health Insurance Portability and Accountability Act (HIPAA).
3. The ORO memorandum on *Further Guidance on ORO Implementation of VA Handbook 6500 §6c(4)(j)* (January 30, 2009) stated that, for purposes of ORO oversight, ORO should not cite noncompliance with §6c(4)(j) in the “Regulatory Concerns” section of a review report, but should indicate in the “Additional Observations” section that the facility should communicate with the VA CIO to clarify its obligations with respect to the waiver requirement.
4. Discussions with the Office of General Counsel (OGC) have clarified that if research subjects properly execute a HIPAA authorization for disclosure of their protected health information (PHI) to an affiliate institution, transfer of the information to an affiliate server constitutes a “disclosure” under HIPAA, **after which VA no longer owns the transferred information.** Absent an agreement that restricts the affiliate’s further use or disclosure of the information (e.g., contract, MOU, data transfer or data use agreement), **VA cedes control over the information.**
5. **Thus, with a valid HIPAA authorization (or IRB-approved waiver of authorization), the subjects’ PHI stored on the affiliate’s server is not considered “VA sensitive information” under VA Handbook 6500 because the data no longer belong to VA. According to OGC (written opinion pending), a VA CIO waiver is not required under these circumstances.**
6. ORO compliance procedures are revised accordingly:
 - (a) If research subjects have properly executed a HIPAA authorization (or the IRB has properly approved and documented a waiver) for disclosure of PHI to an affiliate, ORO should not cite noncompliance with VA Handbook 6500 for storage of the PHI on affiliate servers.
 - (b) If PHI is stored on affiliate servers without a properly executed authorization or IRB-approved waiver (whether or not a VA CIO waiver is obtained), the noncompliance to be cited relates to the HIPAA authorization or waiver, rather than noncompliance with VA Handbook 6500.
7. ORO should continue to assess compliance with VA Handbook 6500 §6c(4)(j) where applicable. For example, a VA CIO waiver is still required if a VA investigator stores PHI or other VA sensitive information on a personal non-VA laptop).


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