

Date: February 2, 2009

From: Chief Officer, Office of Research Oversight (ORO)(10R)

Subj: Further Guidance on ORO Implementation of VA Handbook 6500 Section 6.c.(4)(j)

To: All ORO Staff

1. The May 29, 2008, ORO Memorandum entitled "COMPLIANCE OVERSIGHT PROCEDURES FOR USE AND STORAGE OF VA SENSITIVE RESEARCH INFORMATION" cites at Paragraph A.5. the VA Handbook 6500 Sec. 6.c.(4)(j) requirement that "VA sensitive information may not reside on non-VA owned Other Equipment (OE) without specific designation and approval in advance by the relevant VA supervisor and a waiver from the VA CIO." Paragraph B.2. of the Memorandum states that "ORO will verify the existence of written permission from the relevant VA supervisor and the ISO and a waiver from the VA CIO. In the absence of such documentation, ORO will require a written statement from the ISO and the facility Director as to why the existing arrangement is acceptable."
2. However, the ORO Memorandum goes on to state at Paragraph G.5. that "These ORO procedures do not apply to use or disclosure of information in accordance with legally effective informed consent and properly executed HIPAA authorization."
3. The May 29 ORO Memorandum is published on the ORO website with the accompanying disclaimer: "ORO has adopted these procedures for oversight of compliance with VA policies. Note: This memorandum reflects ONLY ORO's procedures and does not address policies issued by other VA or VHA offices."
4. Taken together, all of the above statements indicate that if a VA facility's affiliate (non-VA) server contains VA sensitive information (e.g., individually-identifiable subject information) and the VA CIO has *not* issued a waiver for such storage, but properly executed HIPAA authorization for the disclosure of that information has been obtained, ORO will not issue a finding of noncompliance. From a privacy standpoint, the facility would be in compliance. With respect to VA Handbook 6500, however, the facility may in fact be noncompliant with Sec. 6.c.(4)(j).
5. For purposes of ORO oversight, however, and until the meaning of Sec. 6.c.(4)(j) is definitely established, ORO Regional Offices should not cite this possible noncompliance in the "Regulatory Concerns" section of their report, but should indicate in the "Additional Observations" section that the facility should communicate with the VA CIO's office to clarify their obligations with respect to the 6500 waiver requirement.
6. As a reminder, a properly executed HIPAA authorization must contain a statement that "individually-identifiable health information disclosed pursuant to the authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient."



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