**Department of Veterans Affairs**

# Memorandum

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From: Chief Research and Development Officer (12)

Subj: HIPAA Privacy Rule Compliance Steps

To: Associate Chiefs of Staff/Research (151)
Administrative Officers/Research (151)

1. This memorandum details the steps being taken by the Office of Research and Development (ORD) of the Department of Veterans Affairs Veterans Health Administration to achieve compliance with the Standards for Privacy of Individually Identifiable Health Information 45 CFR Parts 160 and 164 ("Privacy Rule").

2. Compliance with the Privacy Rule, like any regulation, is an on-going process. The procedures for achieving and maintaining compliance with the Privacy Rule are evolving. This memorandum will identify the minimum, critical steps that must be implemented by April 14, 2003 to ensure that VHA research will not suffer any disruption due to non-compliance with the Privacy Rule. Some facilities may have initiated further steps or more stringent processes. ORD will enhance the minimum steps identified in this memorandum as it identifies the best practices for compliance with the Privacy Rule within the VHA research program.

**CRITICAL STEPS**

3. The following steps, in combination with existing VHA policies and other future guidelines, constitute the reasonable steps that the VHA has taken and will be taking to achieve total compliance with the Privacy Rule.

4. The Privacy Rule requires that an authorization, containing elements enumerated in the Privacy Rule, be obtained from research subjects who are asked to sign an informed consent beginning on April 14, 2003, unless the researcher has obtained a waiver of authorization from an IRB or Privacy Board. The two steps, then, that MUST be taken are adoption of an authorization form and adoption of procedures for granting waivers of authorization.

**Authorizations**

5. To ensure that a research program can continue recruiting subjects, researchers must use an authorization in conjunction with the previously approved informed consent or an approved form that combines both informed consent and authorization. Attachment A is a research-specific authorization form that is based on the official VHA authorization form. This form contains language that the VHA Office of General Counsel has determined is necessary for compliance with several privacy laws to which the VHA is subject. ORD strongly urges all researchers and

research programs to use the attached authorization form, completed with information required to make it study-specific. If another form is used, Office of General Counsel advises that it must include this language to be legally sufficient. A facility that uses a form other than the form in Attachment A must assume the risk of the form not being legally sufficient.

**Waivers of Authorization**

6. The second critical element that must be addressed to ensure uninterrupted research within VHA is a procedure for the IRB to grant waivers. The following is the recommended procedure, including templates that can be employed by researchers and IRBs to comply with the provisions of the Privacy Rule.

7. To use or disclose a patient's identifiable health information for research based on a waiver, a VHA researcher must have documentation of a waiver from the IRB. To obtain the waiver, the researcher must provide adequate justification to the IRB to allow the IRB to make its determination. ORD recommends that the researcher write a memorandum to the IRB detailing his or her request and justification. Attachment B is a template for a memorandum that will provide the information necessary for the IRB's decision, based on the Privacy Rule's description of the documentation requirement.

8. The IRB may receive a memorandum (like the one in Attachment B) in support of a waiver of authorization for new studies that are submitted after April 14, 2003 or for an existing study that does not meet the transition provisions (i.e., is not "grandfathered" under the Privacy Rule). In either case, the board may use either normal review procedures (38 CFR 16.108(b)) or expedited review procedures (38 CFR 16.110) as defined in the Common Rule. In any circumstance, the criteria for granting the waiver remain the same. The IRB must determine that a request for a waiver of authorization satisfies **all** the following criteria:

1. The use or disclosure of the requested information involves no more than a minimal risk to the privacy of individuals based on, at least, the presence of the following elements:
    a. An adequate plan to protect the identifiers from improper use and disclosure
    b. An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
    c. Adequate written assurances that the requested information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the requested information would be permitted by the Privacy Rule;
2. The research could not practicably be conducted without the waiver or alteration; and

3. The research could not practicably be conducted without access to and use of the requested information.

9. The Privacy Rule prescribes the contents of the documentation that the IRB must provide upon making its determination to grant a waiver of authorization. Attachment C enumerates the elements of that documentation. ORD recommends that the IRB document the approval of the waiver of authorization (1) in the minutes of its proceedings where the protocol or request for waiver of authorization was considered and (2) to the researcher directly, in a letter of approval. Attachment D includes suggested language the IRB may use to document the approval of a waiver of authorization.

10. NOTE: Because of the size and complexity of the VHA research program, an IRB may not be able to grant waivers of authorization for all existing protocols by the April 14, 2003 compliance date. **AS LONG AS THE RESEARCH PROGRAM IS TAKING REASONABLE STEPS TO DETERMINE THAT ALL AFFECTED PROTOCOLS ARE GRANTED WAIVERS AS SOON AS POSSIBLE, RESEARCH MAY CONTINUE UNINTERRUPTED, AS THE COMPLIANCE PROCESS IS ONGOING.**

**Further Guidance**

11. ORD will be issuing further guidance regarding Privacy Rule compliance. Questions about the guidance document or any information contained in this memorandum should be directed to Patricia L. Watts, Office of Research and Development at 202-254-0281 or patricia.l.watts@hq.med.va.gov.

Signed
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