VHA POLICY IS MORE RESTRICTIVE THAN NIH GUIDANCE REGARDING RECRUITMENT OF STUDY SUBJECTS UNDER THE HIPAA PRIVACY RULE

Under VHA Policy, accessing patient records for recruitment into research requires prior Institutional Review Board (IRB) approval, IRB waiver of HIPAA Privacy Rule Authorization, IRB waiver of informed consent, and Research and Development (R&D) Committee approval. These steps are required even when records of one's own patients are accessed for recruitment purposes.

In the VA, identifying prospective subjects as part of recruitment into a research protocol is not considered part of the activities "preparatory to research" described in the HIPAA Privacy Rule. (NOTE: Activities preparatory to research would include, for example, reviewing records to determine whether there is a sufficient number or type of record or a sufficiently large pool of prospective subjects to conduct the research. This activity takes place during the course of preparation of the research protocol.)

The Office of Research Oversight (ORO) has clarified with the Privacy Office and the Office of Research and Development (ORD) that this is the case. See below.

Q: Is the guidance the National Institutes of Health (NIH) provided on recruitment of subjects under the Health Information Portability and Accountability Act of 1996 consistent with VA requirements?

A. No, not entirely.

- NIH Guidance at http://privacyruleandresearch.nih.gov_research.asp on *Contacting Research Participants* permits members of a covered entity's workforce (or a covered entity's business associates) to *contact potential study participants* for recruitment into research.

- **VA does not permit this practice unless** an IRB has specifically (i) waived the requirement for an authorization under the HIPAA Privacy Rule relative to use or disclosure of Protected Health Information (PHI) to recruit subjects for the proposed research **and** (ii) waived the informed consent requirement under the Common Rule to allow use of identifiable private information for recruitment into the research. The R&D Committee must also approve the research.

Q. What is the practice that is expected in the VA? Can the physician/PI use his/her patients' records to recruit research subjects without a waiver of authorization? Can the physician/PI's research coordinator or another person be given permission by the physician/PI to use patient records for recruiting research subjects without a waiver of authorization? Isn't this permitted as an "activity preparatory to research"?

A. Again, VA policy is more restrictive than the NIH Guidance regarding research recruitment activities and "activities preparatory to research."

Since recruitment is a part of a research protocol, recruitment cannot occur until after the IRB has approved the protocol, VA does not consider recruitment to be an "activity preparatory to research." If PHI is needed for recruiting, then IRB and R&D Committee review and approval must have been obtained, and the IRB must have also approved an appropriate waiver of authorization and waiver of informed consent before PHI may be obtained and used for recruitment. It does not matter if the PI or his/her agent is obtaining information from his/her own patients' records or not. VHA requirements are stricter in this regard than NIH guidance. The following references are important:

VHA Handbook 1605.1: Privacy and Release of Information:

13. Research

a. ***Release of Information (ROI) to VHA Investigators (Intramural****). …*

(1) ***Reviews Preparatory to Research*** *…*

(b) Neither written authorization from the research subject nor an Institutional review board (IRB) or Privacy board waiver of authorization is required for a VHA Investigator to conduct a review of individually-identifiable information in preparation of a research protocol (See 45CFR164.512(i)(1)).

NOTE: The contacting of potential research subjects or conducting pilot studies are not activities Preparatory to research. [Bolding supplied.]

(2) VHA-Approved Research…

(b) All VHA Investigators conducting VHA-approved research must obtain the authority to use individually-identifiable information as follows: …

2. If there is no prior written authorization, VHA individually-identifiable health information involving non-employee research subjects may be used by a VHA Investigator for research purposes when there is an IRB or Privacy Board waiver of authorization in accordance with 45CFR164.512(i).