Department of Veterans Affairs **VHA DIRECTIVE 2007-040**
Veterans Health Administration
Washington, DC 20420 **November 30, 2007**

APPOINTMENT OF FACILITY INFORMATION SECURITY OFFICER (ISO) AND PRIVACY OFFICER TO THE INSTITUTIONAL REVIEW BOARD (IRB) OR THE RESEARCH AND DEVELOPMENT (R&D) COMMITTEE

1. PURPOSE: This Veterans Health Administration (VHA) Directive establishes policy requiring the appointment of both the VHA facility Information Security Officer (ISO) and Privacy Officer as non-voting members to each facility's Institutional Review Board(s) (IRBs) of record or to the facility's Research and Development (R&D) Committee of record.

2. BACKGROUND

a. Appointing the VHA facility ISO and Privacy Officer as non-voting members to each facility's IRB(s) of record or to the facility's R&D Committee of record helps ensure appropriate review of research practices to maintain confidentiality and security of identifiable data obtained from human research subjects or from other sources, such as administrative or clinical databases.

b. The collection and use of identifiable private information is frequently required to conduct human subjects research. The collection and use of the information brings with it additional responsibilities for maintaining the confidentiality and security of the information. This represents an increasing concern because of advances in computerizing health and personal information, proliferation of electronic media able to store massive amounts of data, and the frequent and necessary collaborations entailed in research. These developments have created new areas of risk and vulnerability. Because the assessment of these emerging risks in human subjects research often requires specialized knowledge of applicable legal, policy, and technical requirements related to the protection of information, VHA has identified a need to add appropriate additional expertise to the review of human research, as outlined in the Common Rule (Title 38 Code of Federal Regulations (CFR) 16.107).

c. **Definitions**

(1) **Institutional Review Board (IRB).** The IRB is a committee responsible for the review, approval, and continuing oversight of research involving human subjects. The IRB is established in accordance with and for the purposes expressed in 38 CFR 16.

(2) **Human Subjects Research.** Human subjects research is research that involves human subjects.

(a) As defined in the Common Rule (38 CFR 16) and VHA Handbook 1200.5, a human subject is a living individual about whom an investigator conducting research obtains:

1. Data through intervention or interaction with the individual, or

2. Identifiable private information.

(b) An intervention includes all physical procedures by which data are gathered and all manipulations (physical, psychological, or environmental) of the subject or the subject's environment that are performed.

(c) Interaction includes communication or interpersonal contact between the researchers and the subject.

(3) **Research.** As defined by the Common Rule (38 CFR 16), research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

3. POLICY: It is VHA policy that the Medical Center Director of each VHA health care facility conducting human subjects research must appoint the facility's ISO and Privacy Officer as non-voting members to either its IRB of record or its R&D Committee of record no later than December 31, 2007. ***NOTE:*** *Facilities are encouraged to engage the facility ISO and Privacy Officer even before submission of a protocol for IRB review, optimally in the design phase of the research.*

4. ACTION

a. The Medical Center Director is responsible for appointing the facility's ISO and Privacy Officer as a non-voting member of the IRB(s) of record or the R&D Committee of record. The ISO and the Privacy Officer may serve together on the IRB or R&D Committee or one may serve on the IRB and the other on the R&D Committee. ***NOTE:*** *The facility Privacy Officer and ISO must be involved in the review of human subjects research to address and mitigate any potential concerns regarding privacy, confidentiality, and information security.*

b. The Medical Center Director must ensure that:

(1) A facility ISO and a facility Privacy Officer are appointed to the facility's IRB or R&D Committee; ***NOTE:*** *When the ISO or Privacy Officer is appointed to an IRB, the IRB roster must be updated and a copy of the roster indicating changes, sent to the Office of Research Oversight (ORO) per VHA Handbook 1058.03.*

(2) The ISO and Privacy Officer who serve on the facility's IRB or R&D Committee thoroughly review each human subjects research protocol and document the review. ***NOTE:*** *This review should preferably occur as early in the review process as possible, but it must occur before the research commences.*

(3) The facility's policies and Standard Operating Procedures incorporate these requirements.

(4) All human subjects research conducted at the facility is reviewed prior to the research being initiated by an ISO and a Privacy Officer who have been appointed to either the IRB of record or the R&D Committee of record.

NOTE: *If the IRB or R&D Committee serves as the IRB or R&D Committee of record for more than one VA, the facility may contact ORD for guidance on how best to implement this Directive. Facilities must document decisions reached with ORD about how to address specific situations.*

5. REFERENCES

a. VHA Handbook 1200.5.

b. VHA Handbook 1605.1.

c. Other VA policies that address requirements for privacy, confidentiality, and information security (see www.research.va.gov/resources/data-security/policies.cfm).

6. FOLLOW-UP RESPONSIBILITY: The Office of Research and Development (12) and the VHA Privacy Officer (19F) are responsible for the contents of this Directive. Questions may be addressed to ORD at 202-254-0183 or the VHA Privacy Office at (704) 245-2492.

7. RECISSIONS: None. This VHA Directive expires November 30, 2012.

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