

DEPARTMENT OF VETERANS AFFAIRS
South Texas Veterans Health Care System
7400 Merton Minter Boulevard
San Antonio, Texas 78229-4404

RESEARCH SERVICE
MEMORANDUM 07-36

April 24, 2007

POLICY AND PROCEDURES FOR PRINCIPAL INVESTIGATOR'S CERTIFICATION:
STORAGE AND SECURITY OF VA RESEARCH INFORMATION

1. PURPOSE: To outline the policy and procedures for review of research protocols to ensure the security of VA-sensitive research data and protected health information and the process of certification of Principal Investigators (PIs) for compliance with VA policy and data security standards.
2. POLICY:
 - a. In the Department of Veterans Affairs Memorandum dated February 6, 2007, the Deputy Under Secretary for Health Operations and Management (DUSHOM) and Chief Research and Development Officer (CRADO), established the requirement that PIs be certified as meeting the Security Requirements for Veterans Affairs (VA) Research Information.
 - b. A research protocol may not start until all the data security requirements are met and the *Principal Investigator's Certification: Storage and Security Of VA Research Information* form is signed by the PI and approved by the Associate Chief of Staff (ACOS) for Research and Development and Information Security Officer (ISO).
3. ACTION:
 - a. With submission of a new research protocol to the Research and Development Committee, an administrative pre-review will be performed by Research Office staff to ensure that all necessary information related to data security, including the *VA Research Data Security Checklist* and *Appendix C: Data Security Checklist for Principal Investigators*, is submitted with the protocol. These documents will be reviewed with the protocol by the ACOS for Research and Development, or his/her designee, to ensure that procedures are in place to provide adequate data security. If the proposed research protocol is identified as providing inadequate data security, with consultation with the Information Security Officer (ISO) as necessary, the Research Office staff will communicate this information to the Principal Investigator so that corrections can be made prior to R & D Committee review.
 - b. The R & D Committee will review and address any data security issues identified in the protocol, and if deficiencies are identified, may only approve the protocol with the stipulation that the identified deficiencies must be corrected prior to approval.
 - c. The *Principal Investigator's Certification: Storage and Security Of VA Research Information* form must be signed by the PI and approved by the ACOS/Research and ISO prior to final approval of the R & D Committee and activation of the research protocol.

- d. By April 15 of each year, the PI will confirm, by completing the *Principal Investigator's Certification: Storage and Security Of VA Research Information* form, that all his/her active research protocols meet the VA data security standards and requirements and attend security training.
 - e. By May 1 of each year, the ACOS for R&D will ensure that all PIs have met the VA data security standards and requirements, and have submitted their Certifications, and forward a written certification to the medical center Director that all PIs have completed the required Certification.
 - f. By May 15 of each year, the Medical Center Director will certify to the VISN Director that all PIs have met the certification requirements related to storage and security of VA research information.
 - g. If a research project will be funded by VA ORD, the *Principal Investigator's Certification: Storage & Security of VA Research Information* will be submitted to ORD during the Just-In-Time process.
4. REFERENCES: Memorandum from the Deputy Under Secretary for Health Operations and Management (DUSHOM) and Chief Research and Development Officer (CRADO), (February 6, 2007).
 5. RESPONSIBILITY: Associate Chief of Staff for Research and Development (151)
 6. RECISSION: None.
 7. RECERTIFICATION: April, 2010.



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