
THE IRB REVIEW

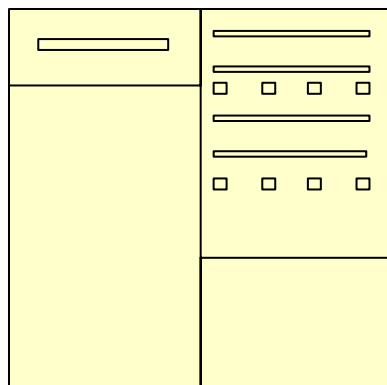
THE Office for the Protection of Human Research Subjects

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Inside This Issue

- 1 HRPP Message
- 2 Impact on future VA studies
- 3 Impact on existing VA studies
- 4 Resource; Reporting loss or theft
- 5 IRB/VA staff contact info
- 6 Calendar



New Rules for VA research studies

In May 2006, a laptop computer and hard drive with data on over 26 million veterans was stolen from a Department of Veterans Affairs employee's home. Then in 2007, an external hard drive used in research was reported to be missing. It is possible that sensitive VA related information on more than half a million people, as well as information on over 1 million non-VA physicians, was stored on this missing drive.

Note: This newsletter focuses solely on an overview of how the new rules impact IRB and VA R&D human subjects submissions for VA research. For more detailed information about the rules, or information on other types of research impacted by these rules, see page 4.



Message from the HRPP Director, Ms. Janine Richardson

As a child, I still remember touring a Bristol factory (Univac) where my dad worked. I remember being impressed that I was able to play "tic-tac-toe" with a huge computer housed in an ice-cold room. The UNIVAC I computer, with a floor size of 943 cubic feet, had a memory size of 1,000 12-digit words in delay lines (and a cost of more than a million dollars).

(source: <http://www.computerhistory.org/timeline/?category=cmptr>, accessed May 2007)

Now, 64GB USB drives that are barely larger than a key are available to consumers who have an extra \$5,000. Unfortunately, data storage and transmission technology have rapidly surpassed procedures and protections for use of that technology. Hard to misplace, or have stolen, a computer occupying 943 cubic feet. But, as the VA is painfully aware, it is easy to misplace, or have stolen, small devices holding information on millions of people.

How do the new rules impact future VA human research studies?

A. Education

The VA is requiring specific education about data safety and security to be completed by all involved personnel. PIs must ensure that all proposed study staff have completed all required training, including the new annual requirement for "The VA Research Data Security & Privacy course" (<http://www.research.va.gov/resources/data-security/>).

B. Research Plan

When planning a project, be sure that your proposed study design meets the VA requirements for data security and privacy. If you are submitting a research study that will involve the collection, use and/or storage of sensitive information (e.g., subject identifiers or protected health information), your submission to both the IRB and R&D must include specific information on:

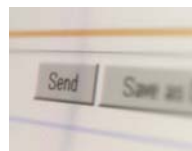
- ⇒ All sites where the data will be used or stored
- ⇒ Who will have access to the data
- ⇒ How the data will be transmitted or transported
- ⇒ How the data will be secured
- ⇒ A discussion of security measures if proposing that data be stored on laptops or portable media
- ⇒ If data will be re-used for subsequent or future research protocols, provisions for future use in the informed consent form, and HIPAA-Compliant authorization
- ⇒ If relevant, provisions to ensure sponsor data storage guidelines are met and do not conflict with VA policies
- ⇒ Provisions for controlling access to the data
- ⇒ Encryption methods
- ⇒ Plans for how long identifiable information and linkages will be kept
- ⇒ Provisions for disposition of data at the end of the study



Provide this information in the related questions in the narrative. The narrative is part of the submission packet for both the ETSU/VA IRB and the VA R&D.

Additionally, be sure that your Informed Consent and HIPAA Authorization meaningfully describe the following:

- ⇒ who will have access to the participant's data
- ⇒ where the data will be sent
- ⇒ what part of the data will be sent to another facility, a non-VA entity, and/or the research sponsor



(Source: VA Research Data Security and Privacy, Veterans Health Administration, Office of Research and Development)

C. Certification

In order to ensure that Principal Investigators understand the importance of the data security issues and the necessity of compliance with all the relevant rules and policies, the VA is requiring that PIs submit completed Appendices C and D.

Both of these forms are available on the IRB website, www.etsu.edu/irb.

Appendix C, entitled "Data Security Checklist for Principal Investigators", requires protocol-specific information about the use and storage of data, and evaluation of compliance with specific requirements.

Appendix D, "Principal Investigator's Certification: Storage and Security of VA Research Information" is a certification by the PI that to the best of his/her knowledge, all VA sensitive information associated with the project is being used, stored, and meets security requirements in accordance with all the applicable VA and VHA policies and guidance.

The completed forms must be submitted with new VA initial submissions to **both** the ETSU/VA IRB and the VA R&D.



For the ETSU/VA IRB submission, the number of copies that must be submitted depends on the pathway of the research. For studies that are requesting exemption, one original Appendix C and one original Appendix D is sufficient. If you are requesting an expedited review, submit one original and three copies of each document (collated into each packet). If you are requesting full review, submit one original and thirty copies of each document (collated into each packet).

Please note that while the PI can request a review pathway, the ETSU/VA IRB Chair reviews the protocol and determines whether the study meets the exempt or expedited criteria. If additional copies of the document are required after the Chair review, the IRB staff will contact you and request additional copies.

For submission to the VA R&D, contact the R&D Office for the number of required copies.

Keep a copy of Appendix C and D with your research files.

A. Education

How do the new rules impact existing VA human research studies?

The VA required that all proposed study staff completed "The VA Research Data Security & Privacy course" (<http://www.research.va.gov/resources/data-security/>) by June 12, 2007.

B. Certification

All PIs were required to evaluate their projects and submit their completed Appendices C and D (see section C above) to the ACOS in April. The VA required the ACOS/R&D to

compile these certifications, ensure that all PIs have submitted their forms, and then send a written certification that all PIs have met the requirement to the Medical Center Director. The Medical Center Director then had to certify that all PIs had met the storage and security certification requirements to the VISN Director. The VISN Directors were then required to notify the VISN support team that each of their facilities have met the certification requirements. This certification will be an annual requirement.

Where can I obtain information about the new VA rules?

The following website contains information and links to information concerning data security, including training, checklists, memoranda, directives and polices.

<http://www.research.va.gov/resources/data-security/>

Additionally, information is available from the Privacy Officer, Angela Mullins-Allen (phone number 423-979-7620), and the Information Security Officer, Diane Everhart (phone 423-979-7190), at the James H. Quillen VAMC.

What do I do if I need to report loss or theft?

The loss or theft of VA research data/information or portable media such as laptops or personal computers must be immediately reported (as soon as it is discovered that there has been a loss) as follows:



⇒ Report the loss to security/ police officers IMMEDIATELY. If within a VA health care facility, notify the VA police. If the loss or theft occurs while on travel or at another institution, notify the security police officers at the institution (such as hotel security, university security, etc.) as well as the po-

- ⇒ Obtain the case number and the name and badge number of the investigating officer. If possible, a copy of the case report should be obtained.
- ⇒ Report the incident IMMEDIATELY to:
 - * your immediate supervisor*
 - * VA Privacy Officer at your facility *
 - * VA Information Security Officer at your facility*
 - * ACOS at your facility*
- ⇒ Report the incident to the IRB using a Form 109 (Unanticipated Problem Involving Risks to Subjects or Others).

* The name and contact information should always be readily available. Wallet cards that list the contact name and number of the James H. Quillen VA ACOS, the VAMC Privacy Officer and the VAMC Information Security Officer are available through the VA R&D office and the IRB Office.

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September 2007						
Sun	Mon	Tue	Wed	Thu	Fri	Sat
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30						

- 4th– Medical Board Meeting
- 6th– Campus Board meeting
- 10th– Deadline for submission for full initial reviews for October 2007 meeting



Other Issues available on the IRB website for your information

- ⇒ **November 2005:** Who is AAHRPP?
- ⇒ **December 2005:** approval Criteria/New Narrative template
- ⇒ **January 2006:** Informed Consent Process
- ⇒ **February 2006:** Vulnerable Populations
- ⇒ **March 2006:** VA Submission
- ⇒ **April 2006:** Conflict of Interest
- ⇒ **May 2006:** Investigational Drug/Device
- ⇒ **June 2006:** After Approval Overview'
- ⇒ **July 2006:** Approval Process, Narrative Question of the Month, Required Elements for ICD, Additional Required Elements, and Additional Required Elements from the VA
- ⇒ **August 2006:** Definition of Research according to DHHS and FDA, Form 129, Narrative Question of the Month
- ⇒ **April 2007:** Complete description of all questions on the Project Narrative

