

VAMHCS RESEARCH SERVICE HOT TOPIC

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New Audit Program Mandated by VA Central Office

In October, the VA Office of Research and Development (ORD) issued a directive mandating specific types of audits to be done by all VA research programs http://www1.va.gov/oro/docs/VHA_Directive_2008-064_RCO_and_Auditing_10-16-08.pdf. VHA Office of Research Compliance (ORO) subsequently issued partial guidelines on how to fulfill the requirements and more will be issued in the coming months http://www1.va.gov/oro/docs/RCO_InformedConsent_Reporting_Requirements_11_3_08.doc. **The requirements are summarized below. These requirements directly and immediately affect all VA researchers (including laboratory and animal researchers, though those requirements have not yet been issued).**

- ❖ There two parts to the ORO requirement:
 - Annual audits of informed consent forms (ICF) signed during the previous 12 months,
 - Triannual complete regulatory audits.
- ❖ The following items are the required elements of the annual ICF audits:
 - Whether the correct version of the ICF was used
 - Whether subject signature and date signed are both present
 - Whether witness signature and date signed are both present
 - Whether signature of person obtaining consent and date signed are both present
 - Whether ICF has IRB approval stamp
 - Whether HIPAA authorization was obtained, if applicable
 - Whether consent was obtained before initiation of study procedures
 - Whether consent was documented with note in CPRS or with written progress note placed somewhere in record.
- ❖ The following are examples of informed consent noncompliance that ORO wants reported. This list is NOT all inclusive.
 - Lack of an informed consent document signed and dated by a subject,
 - Use of an unapproved, unstamped, and/or outdated informed consent document,
 - Use of an unapproved, unstamped, and/or outdated informed consent document,
 - Initiation of study procedures prior to obtaining informed consent,
 - Lack of proper Health Insurance Portability and Accountability Act (HIPAA) Research Authorization.

- All ICFs signed during the 12 months prior to the audit. For example, if we visit you on 3/1/09, we will need to see all ICFs signed from 3/1/08-2/28/09.
 - All study binders for the same set of enrolled participants,
 - A space for the auditor, including a computer jack for access to CPRS and the Research Service network.
- ❖ This Directive does not involve any changes in what investigators have always been told to do!!! Remember that obtaining informed consent prior to performing any research-related activity, using valid ICFs, obtaining signatures and dates on the ICFs, writing enrollment notes, and delivering ICFs to the Research Service to be scanned are NOT new requirements. However, mistakes can be made and research staffs can be overworked, disorganized or not knowledgeable. Therefore it is important for all of you to immediately begin self-assessments on your informed consent practices and documents. Self-assessment are available on our website:
http://www.maryland.research.va.gov/research/human/forms/self_assessment_subject_records_checklist.pdf,
http://www.maryland.research.va.gov/research/human/forms/self_assessment_investigator_records_checklist.pdf.

While all of this is not really a change in the goals and practices of our program, it means a major change for individual investigators in the following ways:

- ❖ It appears that ORD's threshold for "serious noncompliance" is very low. Whereas in the past, our office and the IRB had some leeway in deciding this, it appears that ORD's criteria are strict. For example, in the past we may have determined that 1 poorly executed consent form out of an investigator's 100 consent forms did not constitute serious noncompliance if the overall practice of the investigator appeared to be compliant. However, it now appears that ORO will require reporting of this single ICF as serious noncompliance.
- ❖ ORO's audit report requires that we individually list each investigator and study where serious noncompliance is found.
- ❖ Our Research Compliance Specialists will visit you annually to audit 100% of your consent forms signed during the previous year and, in addition, every three years for complete regulatory audits.

The take-home message is that VA Central Office is basically adopting a 'zero-tolerance' attitude toward research noncompliance.

Portability and Accountability Act (HIPAA) Research

Finally, you may have noticed that we have used verbs such as "appears to require", "seems to be", etc. throughout this Hot Topic. This IS an evolving program. ORO plans to send out specific guidelines over the next few months but VA requires our compliance beginning January 2009. While we wait for ORO's specifics, we must still try our best to interpret and implement the Directive. (Remember that we have an absolute deadline to have audited ALL consent forms signed during ~2008 by May 2009).

We expect to refine the program as more details are issued. We ask for your patience and cooperation.

We also ask for your suggestions, especially if there are special circumstances for your program that impact the audit methods we've described. Please contact Jessica Mendoza (see below).

We wish to thank the investigators and coordinators who assisted us in developing this plan.

For questions concerning this or other Research Service Hot Topics OR for adding staff or colleagues to the Hot Topics mailing list, contact:

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