

New VHA Handbook Expands Investigator Responsibilities

The VHA Office of Research & Development (ORD) recently issued a revision of [VHA Handbook 1200.05, "Requirements for the Protection of Human Subjects in Research"](#) (10/15/10).

- The major new requirement for investigators is that they are now required to maintain master lists for all individuals who sign research consent forms.

The handbook also contains many specific or new details on an extensive list of investigator responsibilities. [The list of investigator responsibilities is now almost 12 pages long](#) (see the excerpt attached to this Hot Topic). [Subpar 9&10, p.20-33].

- VHA HB 1200.05 lays out VA requirements for [investigators](#), IRBs and others.
 - Among the topics it covers are: IRB operations, informed consent, HIPAA authorization, investigational test articles, CPRS charting for research, vulnerable populations, engagement in research, biological specimens, data, international research, non-veterans as research subjects, research-related injuries, credentialing/privileging/training, students, and accreditation. A copy of the table of contents is attached to this Hot Topic. [p. i-iv of the Handbook]
 - This handbook compiles a number of regulatory changes into one document. The last version of 1200.05 was published in July 2008. Since then, there had been a number of VA directives and other revised handbooks that affected human subjects research but were scattered in numerous documents. *Therefore this revision makes it easier to find guidance in VA regulations for human subject research.*
 - **The revision also expands investigator responsibilities for human subjects research.**
- New or little-known items of particular interest to investigators are:
 - [Requirement for master lists of all participants](#) (NEW). This means **anyone who signs the research informed consent form**. Therefore, the master lists include screening failures, drop-outs, etc. The IRB may grant a waiver to this requirement. There is further detail in the handbook. A Hot Topic will be issued in the near future. [Subpar 9u, p.26]
 - [Ensuring consistency among the ICF, protocol, and HIPAA authorization](#). This is now a specific VA requirement. [Subpar 9k, p.24]

- Ensuring that potential subjects receive the “Volunteering in Research” brochure. This refers to the VAMHCS “[Participant Outreach Program](#)” that was directed by VHA in 2008 (VHA Directive 2008-079), sent to the VAMHCS research community in a [Hot Topic](#) in January 2009 and is formalized in the Research Service SOP. Also note that the requirement is for “**potential subjects**” to receive the pamphlets, **not enrolled/consented participants**. This pamphlet is intended to help potential participants *during their recruitment process*. [Subpar 9m, p.25]
 - Initial contact for recruitment can never be by phone. It must be in person or by letter (a privacy waiver for recruitment purposes would be necessary), and social security numbers may never be asked for over the phone. [Subpar 9n, p.25]
 - If someone other than the investigator conducts the consent process, the investigator must **prospectively designate in writing** in the **protocol itself or the CICERO application**, the individual who will have this responsibility. This applies whether or not the IRB has granted a waiver of documentation of informed consent. The designees **must be a member of the research team**. The designation may be made in terms of role of the individual or in terms of specific individuals. [Subpar 9j(1) p.23]
 - An Accounting of Disclosure must be maintained for each and every disclosure of PHI from the study to a non-VA entity. (Further information on this is being developed by the Research Service and VAMHCS Privacy Officer). [Subpar 9i(3) p.23]
 - If the investigator leaves the VAMHCS, all research records must stay at the VAMHCS unless an approval to transfer the records is obtained. In our program, where VA research activities are frequently integrated with UMB research activities, please contact the Research Service for guidance. [Subpar 9t, p.26]
 - The investigator must dedicate specific sections of the protocol to privacy, confidentiality and information security, or must develop an additional document that specifically addresses all privacy, confidentiality and information security issues in the protocol; this becomes part of the IRB protocol file (CICERO). There is more detail on pages 29-30 of the handbook. [Subpar 10i, 10j, p. 29-30]
- Additional changes that will probably be welcomed by the research community are:
- Elimination of the witness signature on research informed consent forms. **DO NOT STOP OBTAINING WITNESS SIGNATURES AT THIS TIME!** A Hot Topic will arrive soon that will inform you of the procedures that must be followed before you can stop obtaining witness signatures. [Subpar 33c, p. 61]
 - The requirement for human research protections training (CITI or equivalents) and GCP training is now every two years. That now means that VAMHCS required HRP/GCP trainings can synchronize with the UMB HRPO’s biannual requirement. A Hot Topic will follow on details for this

change. Be aware that other required VA trainings remain as annual trainings. [Subpar 61bl, p. 92]

- “Close friend” has been added to the list of “legally authorized representatives” (LAR) for consent. The hierarchy is now: 1) health care agent (DPA), 2) legal guardian or special guardian, 3) next of kin (in order and >18yo): spouse, child, parent, sibling, grandparent, grandchild and 4) close friend. Remember that LAR is *NOT synonymous with HIPAA’s “personal representative.* [Subpar 36c, p. 65]
- This Hot Topic has only scratched the surface of the content of this 100 page handbook. We highly recommend that you read through the handbook and pay special attention to the sections that apply to your studies or that have been sources of confusion for you in the past. Remember that principal investigators are responsible for all relevant items in this handbook. Audits conducted by the Office of Research Compliance (ORC) in the past have examined many of these items, often to the surprise of research teams and PIs unaware of the requirements. Upcoming audits will begin to incorporate the new requirements. Your awareness will help us all.

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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