



VHA Handbook 1200.05 (version dated 11/12/14) Conducting and Reviewing Research at the VA

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20 January 2015



VHA Handbook 1200.05 Series Goals

- Discuss major topics as they pertain to changes in the revised VHA Handbook 1200.05
- Address questions received on the revised handbook by integrating responses into select topics

Revised VHA Handbook 1200.05

- Effective Date: November 12, 2014
- Implementation Date: March 12, 2015 (120 days post release date)
 - Facility SOPs cannot contradict requirements outlined in the revised handbook
 - Facility SOPs can include requirements that go beyond those outlined in the revised handbook
 - Facility SOPs must be consistent with practices employed at the facility

Presentation Outline

Conducting Research at the VA	Reviewing Research at the VA
Defining VA Research	Exempt Determinations
Who Can Be a VA Investigator	IRB Committee Membership
Are Research Scopes of Practice Required	ISO/PO Reviews
Training Requirements	Notification of IRB Findings
Collaborative Research	



Conducting Research at the VA

Why We Do, What We Do

- To fulfill President Lincoln's promise: "To care for him who shall have borne the battle, and for his widow, and his orphan" by serving and honoring the men and women who are America's Veterans (VA Mission Statement)
- To discover knowledge, develop VA researchers and health care leaders, and create innovations that advance health care for our Veterans and the Nation (ORD Mission Statement)

Defining VA Research

- Research that is conducted by **VA investigators** (serving on compensated, WOC, or IPA appointments) **while on VA time**. The research may be funded by VA, by other sponsors, or be unfunded. VA research must have R&D Committee approval (VHA Handbook 1200.05, para 4ii)
- Research that is conducted by **VA investigators** (serving on compensated, WOC, or IPA appointments) **while on VA time, utilizing VA resources, and/or on VA property including space leased to, and used by, VA**. The research may be funded by VA, by other sponsors, or be unfunded. (VHA Directive 1200, para 5tt)
- Why the difference?

Who Can Be a VA Investigator

- A VA Investigator is any individual who conducts research approved by the VA R&D Committee while acting under a VA appointment on VA time, including FT and PT compensated employees, trainees, WOC employees, and individuals appointed to VA under the IPA of 1970
- Contractors cannot be VA investigators
- Students/trainees eligible to conduct VA-approved research cannot serve as PI/Co-PI on the research study

Are Research Scopes of Practice Required?

- Research Scope of Practice/functional statement continues to be required for all individuals conducting VA research (VHA Directive 1200, 4c.(9)(a)):

“All individuals must be appropriately credentialed and privileged (if applicable). In any case, a Research Scope of Practice or Functional Statement must be defined for all individuals conducting VA research, including individuals who do not function as health care providers. The Scope of Practice Statement or Functional Statement must be consistent with the position to which the individual is appointed and must define the duties of the individual. The Scope of Practice Statement or Functional Statement must not include any duties or procedures for which the person is not qualified. If the individual holds clinical privileges at the facility and the research responsibilities and duties match the clinical privileges, the clinical privileges may be used in lieu of a Scope of Practice Statement. If there are additional responsibilities and duties, these should be included in the Scope of Practice Statement along with a copy of the clinical privileges”.

Training Requirements

- Requirements for VA Investigators and VA research team members involved in the conduct of VA-approved human subjects & exempt research
 - GCP mandatory training requirements have been removed
 - Refresher training mandated at least every 3 years
 - CITI modules can be used to meet training requirements
- The IRB must establish written SOPs that include training and education requirements for the IRB Chair(s) and members
- See <http://www.research.va.gov/pride/training/default.cfm>

Collaborative Research

- Each institution engaged in human subjects research must have an FWA or another assurance acceptable to VA
- Protocol and informed consent forms must clearly delineate which activities will be conducted/supported by the VA
- VA site-specific Informed consent documents and HIPAA forms must be used when required
- Protocol must describe whether VA data will be disclosed outside the VA, to whom, and how data will be transmitted
- Privacy Officer must ensure and document VA's authority to disclose PHI outside of the VA in cases where the IRB has waived HIPAA authorization and documentation of consent
- A signed written agreement between the VA and non-VA collaborating entities addressing issues such as responsibilities of each party, ownership of data, and reuse of data is required prior to starting the research study



Reviewing Research at the VA

Exempt Determinations

- VA IRB Administrators or staff with appropriate training and experience can now make exempt determinations
- Facility SOPs should clearly identify who is responsible for making exempt determinations
- The Individual making exempt determinations should be knowledgeable about regulations and have experience reviewing research
- Affiliate IRBs should indicate who can make exempt determinations at the affiliate

IRB Committee Membership

- Non-affiliated IRB members
 - Non-affiliated members no longer **have to** obtain a VA WOC appointment to serve on the IRB, but you may still want to do this
 - The following individuals are no longer prevented from serving as non-affiliated members of a VA IRB
 - Employees from institutions with academic affiliation agreements with the VA
 - Volunteers who hold a WOC appointment
- External IRBs
 - Voting members appointed to an external IRB are no longer required to be “scientific” members
 - Individuals such as RCOs; AO/R or other VA research office staff cannot serve as voting members of an external IRB

ISO/PO Reviews

- ISO/PO review is aimed at assessing whether information security or privacy issues exist and have been adequately addressed in the proposed research activity
- A preliminary report to the IRB is not required
- ISO/PO final review is required after the IRB has approved the study
- The final report must be received and reviewed by the R&D Committee prior to R&D Committee approval

Notification of IRB Findings

- IRB Notification letters no longer have to be signed by the Chair or the voting IRB member who reviewed the research
- Electronic IRB systems can be used to generate notification letters without a “wet” signature
- Waiver of HIPAA authorization still must be signed by the IRB Chair or a qualified voting member of the IRB



Available Resources

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- Crosswalk between current version and 5/2/12 version of the handbook
- Summary of significant changes
- Recently released ORD guidance documents
 - Guidance on Advertisement of Non-VA Funded Research in VA Facilities (10/20/2014)
 - Guidance on Approval of International Research (10/20/2014)
 - Guidance on Conducting Research involving Children (10/20/2014)
 - Guidance on Conducting Research involving Pregnant Women (10/20/2014)
 - Guidance on Continuing Review (10/22/2014)
 - Guidance on Exempt Research Determination (10/20/2014)

See: <http://www.research.va.gov/PRIDE/120005.cfm>

See: <http://www.research.va.gov/resources/policies/default.cfm>

Available Resources (continued)

- Recording of Cyberseminar series titled, “VHA Handbook 1200.05 rollout”:
<http://www.research.va.gov/pride/cyberseminars/pride-121114.cfm>
- VHA Handbook 1200.05 Cyberseminar titled, “Full Disclosure: Informed Consent and HIPAA” (Wednesday, February 4th @ 2:30pm EST)
- VHA Handbook 1200.05 Cyberseminar titled, “Local Site Responsibilities: VA Facility Director Approvals” (Tuesday, February 17th @ 2:30pm)

Questions & Contact Information

Questions can be submitted to vhacoordregulatory@va.gov

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