

## VAMHCS RESEARCH SERVICE HOT TOPIC

Vol. 9 No. 3  
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### NEW VHA HANDBOOK 1200.05: VAMHCS Transition - PART 1

VHA Office of Research & Development (ORD) issued its revision of VHA Handbook 1200.05, "Human Research Protections" on 11/17/14. We need to be fully compliant with requirements of the new handbook by 3/12/15. This Hot Topic is the first of several to notify you of the changes being put into place at VAMHCS. For the purposes of this Hot Topic, references to "VHA HB 1200.05" or "1200.05" refer to the [November 2014 version of VHA HB 1200.05](#).

This Hot Topic covers the following changes:

- I. Participant Outreach
- II. Flagging of medical records
- III. Certificates of Confidentiality
- IV. Scope of Practice
- V. New VA HIPAA authorizations

There will be additional Hot Topics as more changes are implemented.

#### I. Participant Outreach

- The pamphlet "Volunteering in Research" is no longer required.
- As it is a very informative aid for potential participants, distribution of the pamphlet *is still highly recommended* as a service to the community.
- The RDS will continue to keep a supply of the pamphlet, available in our offices (3D-150). You can also order your own supply from VA ORD: [http://www.research.va.gov/pubs/brochure\\_series.cfm](http://www.research.va.gov/pubs/brochure_series.cfm).
- Investigators and team members are encouraged to engage in activities that explain and promote research to the community.
- R&D SOP 01.16 has been revised and Hot Topic Vol.3 No.1 will be rescinded.

#### II. Flagging of Medical Records

- Flagging is now only **required when an investigational drug(s) or investigational device is used in the study**.
  - Continue to use the current procedure for "Research Subject Clinical Warnings" if your study involves the use of an investigational drug(s) or device(s).
  - Do not post the RSCW until the participant is actually on drug/device or placebo.
  - The VAMHCS RSCW template is the equivalent of VA Form 10-9012. (VA Form 10-9012 or equivalent is required in Pharmacy HB 1108.04 for studies using investigational drug(s) or device(s).)
- Flagging **is optional** for other studies.

- If use of an RSCW will contribute to the safety of research participants or will assist in the conduct of the study
- Examples of this:
  - If it is important for the research team to be notified of clinical changes in the participant's care, hospitalization, etc.;
  - If it is important for clinical staff to be aware of the individual's participation in a study;
  - Study sponsor requires it (or something like it);
  - Provision of contact information for questions to the study team.
- You **do not** need to submit a protocol modification in order to stop entering RSCWs on your studies in this category.
- R&D SOP 07.01 has been revised.

### III. Certificates of Confidentiality (CoC)

- If your study has been granted a Certificate of Confidentiality, there are restrictions in what research information should be entered into CPRS, including study enrollment notes, informed consent and HIPAA documents.
- Effective immediately:
  - When you send consent packets to the R&D Service, **make a note that a CoC is in place for your study**, and the documents will no longer be scanned into CPRS (but *will* be delivered to the Office of Research Compliance for audit).
  - If your study has a CoC and you have sent scanning packets to the RDS since January 2015, please contact Jessica Mendoza immediately.
- “When VA conducts a study that is protected by a Certificate of Confidentiality, the following **health record** (CPRS) documentation provisions apply:
  - (1) **For studies that do not involve a medical intervention** (e.g., observational studies, including interview and questionnaire studies), **no annotation may be made in the health record.**
  - (2) **For studies that involve a medical intervention, a progress note entry should indicate that an individual has been enrolled in a research study, any details that would affect the subject's clinical care, and the name and contact information for the investigator conducting the study. Subjects' informed consent forms and HIPAA authorization documents are not to be included in the health record.** [VHA HB 1200.05 §21]
- You must still create enrollment notes in your **research files**, and maintain original signed ICFs and HIPAAs (if applicable).
- Details on CoC can be found in the [November 2014 version of VHA HB 1200.05](#), revised R&D SOP 07.01, and in an upcoming Hot Topic.

### IV. Scope of Practice

- Even though “Research Scope of Practice” is no longer mentioned in the Nov 2014 1200.05, **the requirement for research scopes of practice still remains in VHA Directive 1200.**
- Therefore the local VAMHCS procedures for scope of practice remain in place.

- V. Requirement for VA Form 10-0493  
The requirement to use the new VA Form 10-0493 has already been covered in Research Service Hot Topic Vol.9, No.1.
- VI. Stay tuned for additional Hot Topics as more changes are implemented: CITI training, scanning of consent documents, master lists, and more!

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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[http://www.maryland.research.va.gov/hot\\_topics.asp](http://www.maryland.research.va.gov/hot_topics.asp)