

VAMHCS RESEARCH SERVICE HOT TOPIC

Vol. 2 No. 2
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HOT TOPICS UPDATES

Based on the feedback we have received from readers, here are some updates and clarifications on past Hot Topics. In general, you can expect similar updates after every 10 Hot Topics or so.

■ Enrollment Notes (Vol.1 No.2)

■ Clarification #1: All participants must have enrollment notes and Research Subject Clinical Warnings entered into CPRS unless:

- The subject's participation in the study involves only the use of a questionnaire or the use of previously collected biological specimens;
- The identification of the patient as a subject in a particular study would place the subject at greater than minimal risk;
- If a Certificate of Confidentiality has been obtained for the protocol.

■ Clarification #2: We have heard that some participants (particularly non-veterans) do not wish to be registered into CPRS.

For some studies, this may prevent an individual from participating. For example:

studies where participants must be registered in order to have laboratory tests performed or study medications dispensed.

However, for studies where it is possible for the research to be performed without CPRS registration, a participant may be enrolled without being registered in CPRS. This means that your study file becomes extremely important as documentation. Your study file **MUST CONTAIN** the signed informed consent form(s), signed HIPAA forms, enrollment notes and visit notes.

You must write an enrollment note containing all required elements and keep the note in your study files.

Be aware that by not documenting your participant in CPRS, hospital staff will not know to alert you about hospital admissions, etc.

▣ Study Closeout (Vol.1 No.5)

▣ Clarification: Along with notifications to the Research Service (R&D Committee) and the IRB when you close a study, **YOU MUST ALSO NOTIFY THE INVESTIGATIONAL DRUG PHARMACIST (IDP)** if your study has involved study medications. This is a required element for AAHRPP accreditation!!!

Aside from being an accreditation requirement, notifying the IDP of your study closure:

- Facilitates study closure for your Sponsor

- Saves work for the IDP who must continually check expiration dates and other documentation
- Is a courteous thing to do.

▣ Research Service Website (Vol.1 No.7)

www.maryland.research.va.gov

- ▣ Addition #1: “Contact Us” page including: whom to contact for complaints, reports of possible noncompliance, and emergencies
- ▣ Addition #2: “Policies & Procedures” tab that takes you directly to a comprehensive list of human research related SOPs
- ▣ Addition #3: There are several revised/updated SOPs and at least 1 new SOP
- ▣ Addition #4: “Training & Education” page has been updated with new 2008 instructions for VA employees and WOCs
- ▣ Addition #5: “Research” page now contains a link to laboratory safety and security policies

▣ Participants Who Cannot Sign Their Names (Vol.2 No.1)

- ▣ Clarification: The short form consent process may also be used for non-English speaking participants. It is preferable that an IRB-approved translation of the consent form be used. However, in some circumstances an oral presentation (in a language understandable to the participant) with a written consent document and a written summary of the oral presentation

may be used. Someone who is fluent in English and the language understandable to the participant must be present.

Details are in IRB Policy 4B, Par III.G.

For questions concerning this or other Research
Service Hot Topics

OR

if you know of research staff and colleagues who
should be on the Hot Topics mailing list, contact

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