

## VAMHCS RESEARCH SERVICE BULLETIN

April 17, 2009

### Witness Signatures on Informed Consent Forms

#### **PLEASE REMEMBER TO OBTAIN A WITNESS SIGNATURE ON ALL VA INFORMED CONSENT FORMS!**

This has been one of the most frequent findings from our audits of signed informed consent forms, and the VA considers this a serious issue.

PLEASE obtain witness signatures on ALL VA consent forms.

- If your study involves mailing of consent forms, please be sure your cover letter stresses the importance of the participant finding someone to witness his/her signature before mailing the form back to you.
- If your study involves only the mailing of surveys to be returned by the participant (no study visits involved), consider requesting a “waiver of documentation of informed consent” from the IRB at the time of protocol submission. This can eliminate the need for mailed consent forms at all.
- If you consent participants in their homes or other places where witnesses can be difficult to locate, you may need to consider bringing someone else with you on the study visits in order to act as a witness.
- If the participant refuses to have their signature witnessed (for example, for confidentiality reasons), they will not be able to participate in the study.
- The witness is only a witness to the signing of the form...NOT to the informed consent process itself. Therefore, it is possible for the signatures to be witnessed without the witness becoming knowledgeable about the document being signed, its contents, or even the identity of the participant.

- It is not required for the witness to know the participant or to verify their identity (therefore, it is possible for the participant to maintain confidentiality).
- It IS permissible for witnesses to be members of the research team EXCEPT FOR “COOPERATIVE STUDIES PROGRAM” PROTOCOLS. It is recommended for witnesses not to be members of the research team, but if necessary, it is permissible to use members of the research team.

In preparation for future audits or ORO visits, please report all deviations in documentation of informed consent to the IRB. Also, for active research participants whose original ICFs are missing a witness signature, please consider re-consenting them at their next visit.

A more detailed Hot Topic will follow soon. We will also forward any clarifications from ORO as soon as we know of them.

If you have further questions, please contact:  
Jessica Mendoza, Acting Research Compliance Officer  
Room 3A-125  
410-605-7000 x6512

Thank you for your cooperation.