

April 12, 2011

Change in the requirement for witness signatures on VA informed consent forms

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).

This revised handbook has eliminated the requirement for a witness to the participant’s signature **unless the IRB requires it.** [Subpar 33c, p. 61 of the revised handbook]

BUT WAIT! DO NOT LEAVE BLANK WITNESS SIGNATURE LINES ON YOUR CURRENT VAMHCS CONSENT FORMS!!! Doing this will be considered noncompliance.

The IRB requires witness signatures for the following reasons:

- For short form consent documents, the witness to the oral presentation signs and dates the consent document and the summary. The person obtaining consent may not be the witness to the consent.
- For participants who cannot read and whenever required by the IRB or the sponsor, a witness to the oral presentation signs and dates the consent document (the witness must have observed the consent process).
- Additional reasons as decided by the IRB.

Here are your options for saying goodbye to witness signatures:

1. For **all new studies**, use the revised VAMHCS ICF template that will be available on the HRPO and CICERO websites shortly. This template and a revised tutorial are also available on the Research Service website [“Forms” page](#).
 - a. Remove the witness signature line from the proposed informed consent form. If the IRB determines that you must have a witness signature, you will be instructed to add the witness signature line.
2. For **all currently approved projects**, if you want to discontinue witness signatures, you must first submit a consent form modification to the IRB.
 - a. Submit the request via CICERO at the time that you need to request protocol modifications for other reasons (**do not submit**

modification requests for the sole purpose of removing the witness signature).

- b. Remove the witness signature line from the proposed informed consent form. If the IRB determines that you must have a witness signature, you will be instructed to add the witness signature line.
 - c. You must continue getting witness signatures until you have received an approved modified consent form from the IRB.
3. You also have the option of continuing to obtain witness signatures for any currently approved studies and not bothering with a modification. **There is no requirement to modify your consent form.** It is your choice whether to modify your consent form or to just continue with the current practice of obtaining witness signatures.
 4. **DON'T choose** to just stop obtaining witness signature, leaving the signature line blank. VA considers this to be serious noncompliance with the approved ICF!!!!
 5. **DO choose** to either obtain a modification from the IRB or to continue to obtain witness signatures

Remember that the IRB may require a witness signature in some circumstances. If it does so, you must comply with the IRB requirement.

If you have further questions, please contact: [Jessica Mendoza](mailto:Jessica.Mendoza@va.gov) at Jessica.Mendoza@va.gov, 410-605-7000 x6512.