

**Department of
Veterans Affairs**

Memorandum

Date: February 22, 2006

From: Chairman, Research and Development Committee, Jesse Brown VA Medical Center (537/151)

Subj.: Reminder: Documentation of the Informed Consent Signature Page and Clarification of witnesses for Consent documents

To: All Human Subjects Research Investigators and their Research Staff

1. At the meeting of the Research and Development Committee held on February 22, 2006, the Committee discussed in detail the "Documentation of the Informed Consent Signature Page and clarification of witnesses for the consent document." The Committee passed a motion unanimously to inform all investigators that according to the VHA Handbook 1200.5, Appendix C, Item 3, "Documentation of Informed Consent," the consent form must be signed by:

- (a) The subject or the subject's legally-authorized representative
- (b) A witness whose role it is to witness the subject's or the subject's legally-authorized representative's signature, and
- (c) The person obtaining the informed consent.

And per JBVAMC Policy:

- (d) The Principal Investigator

2. To ensure compliance with VA regulations, the JBVAMC R&D Committee is revising its policy to require the Principal Investigator to review and sign all consent documents. By signing the consent document, the PI is verifying that the subject was properly consented and is eligible for enrollment into the research.

3. The signature of the subject's Legally Authorized Representative should only be included in the consent document when the IRB approved protocol designates that a legally authorized representative may provide permission for a prospective subject.

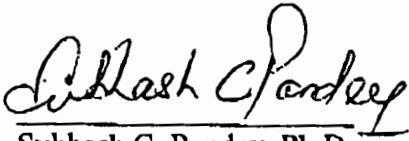
4. It is preferred that the witness be unaffiliated with the research (such as a family member or friend of the subject), but the research study coordinator or other research staff are acceptable as witnesses. However, the witness should never be another research subject since raises privacy and/or confidentiality concerns.

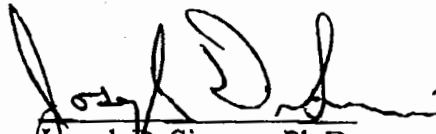
Please note that VA Consent Form 10-1086 signature page should be written as follows:

Signature of Subject	Date
Signature of Witness	Date (must be same as subject's)
Print Name of Witness	
Signature of Legally Authorized Representative	Date (must be same as subject's)
Print Name of Legally Authorized Representative	Relationship
Signature of Person Obtaining Consent	Date (must be same as subject's)
Print Name Person Obtaining Consent	
Signature of Principal Investigator	Date

4. A separate amendment to incorporate these changes does not need to be submitted to the IRB at this time. The signature page changes may be made to the JBVAMC consent document at the time of continuing review or when a revised consent document is submitted as part of a protocol amendment to the research.

5. If you have any questions or need further assistance, please do not hesitate to call Subhash C. Pandey, Ph.D., at 312-569-7418


Subhash C. Pandey, Ph.D.
Chairman, R&D Committee


Joseph DeSimone, Ph.D.
Acting ACOS

cc: UIC-IRB
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