

VAMHCS RESEARCH SERVICE HOT TOPIC

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CONSENTING PATIENTS WHO CANNOT SIGN THEIR NAMES

- It is possible that some participants who are competent to give consent cannot sign their names because of physical disability or illiteracy.
- If the person is able to “make his/her mark” (such as an “X” or initial), then the mark must be witnessed by an observer not involved with the study. A note should be made on the informed consent form (ICF) stating that the participant was unable to sign and that the witness attests that the participant made the mark.
- If the person can understand and comprehend spoken English but cannot speak or write, it is possible to enter them into the study if they are competent and able to indicate approval or disapproval by other means. The informed consent form should document the method used for communication with the participant and the specific means by which the prospective subject communicated agreement to participate in the study. An impartial third party must witness the entire consent process and sign the ICF. A note should be made on the informed consent form (ICF) stating that the participant was unable to sign and

that the witness attests that the participant could listen to the information about the study and that s/he was able to communicate consent.

- If your patient population is such that these types of patients could be frequently recruited, it is best to obtain from the IRB & R&D Committee an approved “Short Form” to be used in an oral informed consent process. If this procedure is used, *an impartial third party must witness the entire consent process and sign the short form and the summary.* A copy of the summary must be given to the participant.
- In all cases, the CPRS enrollment note should also document these special circumstances for documentation of informed consent. For oral presentations of the research, the enrollment note must reflect that the impartial observer was present for the entire process and that the presentation accurately reflected the material in the IRB-approved ICF, short form and/or summary.
- Videotaped consent processes are best for these situations but not required.
- Based on:
 - FDA Information Sheet, “[A Guide to Informed Consent](#)”
 - Research Service SOP, “[Obtaining and Documenting Informed Consent](#)” (HRP 03.03)
 - Research Service Guidebook, “[Informed Consent Guidebook](#)” (HRP 03.01G)

For questions concerning this or other Research Service Hot Topics

