Enrolling Subjects Who Are Legally Blind, Illiterate, or Cannot Talk or Write

Important note: It is always the investigator?s responsibility to judge the subject?s comprehension of the consent information including the understanding that participation is voluntary and that the subject has the right to withdraw at any time during the study. If you doubt the subject?s consent comprehension, do not enroll the subject in the study.

Legally Blind Subjects

If you are enrolling subjects who cannot read the consent materials due to blindness, or if the subject?s legally authorized representative is legally blind:

Oral presentation of consent materials

Orally present the IRB-approved consent materials. Allow sufficient time for questions to be asked and answered, both by the subject and by the person obtaining consent to ensure the subject comprehends the consent information.

Note: The California Experimental Subject?s Bill of Rights [1] (required for biomedical studies) is available in Braille. Call the IRB office at 415-476-1814 for a copy.

Impartial witness

It is recommended that an impartial witness observe the consent process.

Video/audio recording

Consider using a video/audio recording of the consent discussion as part of the documentation of informed consent.

Documentation/signatures

These recommendations are consistent with guidance endorsed by the FDA and set forth by the ICH E-6 4.8.9 [2]. If the subject (or subject?s legally authorized representative) verbally agrees to participate in the study:

- Subject (if capable of doing so): Signs and personally dates the consent form.
- Witness: Signs and personally dates the consent form. By doing so, the witness attests that the consent information was accurately explained and that the subject apparently understood the information, and informed consent was given freely.
- Person obtaining consent: Signs and dates the consent form.
- Give a signed copy to the subject.

Illiterate Subjects

If you are enrolling subjects who cannot read the consent materials due to illiteracy:

Oral presentation of consent materials

Orally present the consent materials, including the California Experimental Subject?s Bill of Rights [1] if enrolling in a biomedical study. Allow sufficient time for questions to be asked and answered, both by the subject and by the person obtaining consent to ensure the subject comprehends the consent information.

Impartial witness

It is recommended that an impartial witness observe the consent process.

Video/audio recording

Consider using a video/audio recording of the consent discussion as part of the documentation of informed consent.

Documentation/signatures

These recommendations are consistent with guidance endorsed by the FDA and set forth by

the ICH E-6 4.8.9 [2]. If the subject verbally agrees to participate in the study:

- Subject (if capable of doing so): Signs or marks an X to signify consent.
- Witness: Signs and personally dates the consent form. By doing so, the witness attests that the consent information was accurately explained and that the subject apparently understood the information, and informed consent was given freely.
- Person obtaining consent: Signs and dates the consent form.
- Give a signed copy to the subject.

English-Speaking Subjects Who Cannot Talk or Write

Consistent with the FDA guidance "A Guide to Informed Consent [3]," a person who can understand and comprehend spoken English, but is physically unable to talk or write, can be entered into a study if they are competent and able to indicate approval or disapproval by other means.

If the person (1) retains the ability to understand the concepts of the study and evaluate the risk and benefit of being in the study when it is explained verbally (still competent) and (2) is able to indicate approval or disapproval to study entry, he/she may be entered into the study. Obtain and document informed consent as follows:

Oral presentation of consent materials

Orally present the consent materials, including the California Experimental Subject?s Bill of Rights [1] if enrolling in a biomedical study. Allow sufficient time for questions to be asked and answered, both by the subject and by the person obtaining consent to ensure the subject comprehends the consent information.

Impartial witness

An impartial witness should be present during the entire consent discussion.

Video/audio recording

Consider using a video/audio recording of the consent discussion as part of the documentation of informed consent.

Documentation/signatures

If the subject indicates agreement to participate in the study:

- Annotate the consent form by hand to describe the method used for communication with the subject and the specific means by which the subject communicated agreement to participate in the study.
- Witness: Signs and personally dates the consent form. By doing so, the witness attests that the consent information was accurately explained and that the subject apparently understood and informed consent was given freely.
- Person obtaining consent: Signs and dates the consent form.
- Give a signed copy to the subject.

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Links
[1] http://irb.ucsf.edu/experimental-subjects-bill-rights
[2] http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R1_Guideline.pdf
[3] http://www.fda.gov/RegulatoryInformation/Guidances/ucm126431.htm