

## The Consent Form Witness

Many informed consent documents provide a signature line for a Witness Signature, but when is a witness actually required to sign the consent form?

The FDA IRB Information Sheets state that “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. The consent form should document the method used for communication with the prospective subject and the specific means by which the prospective subject communicated agreement to participate in the study. An impartial third party should witness the entire consent process and sign the consent document.” A witness signature is also required when using the “short form” written consent document. [21 CFR 50.27 and 45 CFR 46.117]

So, what exactly is the role of the witness? “The witness is required to attest to the adequacy of the consent process and to the subject’s voluntary consent. Therefore, the witness must be present during the entire consent interview, not just for signing the documents.” Once the consent interview is completed, the witness will sign the appropriate documentation required by the regulations. FDA GCP Guidance (ICH E6 4.6.9) also provides guidance regarding witness requirements:

- “By signing the consent form, the witness attests that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject or the subject’s legally authorized representative.”
- The witness must be impartial
- The witness dates his/her signature.

In this instance, the witness must have some knowledge about what is being presented to the subject and able to determine if the subject understands the information.

In addition to federal regulations for obtaining witness signatures for consent forms, it is important to also check with state and local laws prior to obtaining consent from prospective subjects.

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## Harrison IRB Q&A

**Question:** Do both parents need to provide permission for their child to participate in research?

**Answer:** In general, it is recommended that both parents provide permission for their child to participate in research prior to enrollment in research. The regulations allow the IRB to determine that the permission of one parent is sufficient for research to be conducted under 46.404 or 46.405 or FDA 50.55(e)(2) if one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child [if consistent with State law (FDA)]. The permission by the parent(s) or guardian(s) shall be documented in accordance and with the extent required by 45 CFR 46.117 of subpart A or 21 CFR 50.27. Parental permission should be documented in a manner similar to that used to document informed consent.

## New IRB-Related Regulations

**Registration:** The FDA and HHS Office for Human Research Protections (OHRP) are working on a final rule that will require the registration of Institutional Review Boards (IRBs). (5/9/08, FDA News)

**AE and UP Reporting:** The FDA will soon issue a final guidance that differentiates between unexpected problems (UPs) and adverse events (AEs) in clinical trials and will explain when to report side effects to Institutional Review Boards (IRBs). (5/19/08, FDLI SmartBrief)