

Proof of Consent

By Norman M. Goldfarb

A study subject sues the research site and study sponsor for injury in a clinical trial. He claims consent was inadequate and, further, that his signature on the informed consent form (ICF) is a forgery. How do you convince a jury that the subject did, in fact, sign the informed consent form and that consent was adequate?

Signature. The subject's signature on the ICF is good evidence that he signed the form. Forging signatures can be remarkably difficult, but both sides in a legal trial can probably find handwriting experts to support their positions. Signatures are poor evidence that consent was adequate.

Initials. Initials are good evidence that the subject touched each page. However, it is common for even well-intentioned subjects to not initial every page. The person obtaining consent may neglect to confirm that all the initials are in place. Initials are poor evidence that consent was adequate.

ICF. If the ICF is too hard for the subject to read, it is good evidence that consent was inadequate. In this circumstance, documentation of the consent discussion is especially important.

Progress note. A contemporaneous progress note is good evidence that consent was obtained. It is minimal evidence that consent was adequate, except to the extent that it records adequate time. The more detailed the note, the better the evidence. However, a progress note is easy to falsify.

Witness. A signature by an independent witness is good evidence that consent was obtained. If the witness statement references the subject's signature, it is also good evidence that the subject signed the ICF. However, unless the witness is familiar with the protocol and discusses the study with the subject, his or her written statement or testimony is minimal evidence that consent was adequate. Further, few witnesses are 100% independent.

Writing on ICF. If the subject writes on the ICF, it is good evidence that he touched those pages and at least made an attempt to understand the contents. (Writings that modify the meaning of the ICF are almost always unacceptable.)

Electronic recording. An audio or video recording of the informed consent session is excellent documentation. However, electronic recordings can make subjects uncomfortable. Further, they usually demonstrate flaws in the informed consent process.

Quiz. A written comprehension quiz is excellent documentation of consent adequacy, for better or worse. However, a quiz is time-consuming and may make the subject feel uncomfortable. On the other hand, if notified in advance, the subject may take the consent process more seriously. Any wrong answers on the quiz must be followed up with a documented discussion and confirmation of understanding. A significant number of wrong answers suggests that the entire consent process was inadequate and should be repeated. "Teach back" is a superior method for educational purposes but is inferior for documentation. In this method, the person obtaining informed consent asks the potential subject to explain the study, e.g., "What will happen at the visits?" Documentation of the questions and answers is good evidence of adequate informed consent.

Each of the above methods can help persuade a jury that the subject signed the informed consent form and that consent was adequate. Some of them also help educate the subject about the study. Whatever process the site uses, it should be consistent, so the site does not have to explain to the jury why, for example, on this occasion, there was no electronic recording.

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