

UK Office of Research Integrity Guidance on Unique Informed Consent Circumstances

Federal agencies responsible for human research protections provide answers to unique situations that occur relative to informed consent process. Such situations would need either to be described in the initial IRB submission or submitted as Modification Request requesting IRB approval for a single-subject deviation. The IRB will consider the appropriate safeguards given the context of the study and the subject or subject population involved.

Illiterate English-Speaking Subjects

A person who speaks and understands English, but does not read and write, can be enrolled in a study by "making their mark" on the consent document, when consistent with applicable state law.

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 (1) the person 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, they may be entered into the study. 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 video tape recording of the consent interview is recommended.

Source: [Guidance for Institutional Review Boards and Clinical Investigators](#)

Subjects with Low Literacy and Numeracy

Although a competent person who does not read and write well can give informed consent and enroll in a clinical investigation, the sponsor, clinical investigator and IRB should consider whether any modifications to the informed consent process are necessary to ensure that the informed consent process is understandable.

For subjects with apparent low literacy and/or low numeracy, oral presentation of the information contained in the consent form is especially important. When the elements of informed consent are presented orally to the subject or the subject's legally authorized representative(LAR), the IRB may want to consider approving the use of a short form and written summary (21 CFR 50.27(b)(2)), which includes a witness to the oral presentation of the informed consent elements who also signs the consent form (see [section III.D.4.b, Short Form](#)). It should be noted that, even if the information is presented orally, the subject or the subject's legally authorized representative is required to sign the consent form (whether the long form or short form is used) unless the IRB has waived the informed consent signature requirement under 21 CFR 56.109(c).

Subjects who cannot write can indicate their consent by "making their mark" on the consent form, when consistent with applicable law. In these situations, a note should be included in the subject case histories required to be maintained under 21 CFR 312.62(b) or 21 Contains Nonbinding Recommendations 51 CFR 812.140(a)(3) indicating the reason for the lack of a

signature and date as required by 21 CFR 50.27(a). The date consent was obtained should also be recorded in this note.

Source: [FDA Informed Consent Final Guidance – August 2023](#)

Alternative Methods of Obtaining Informed Consent

Traditionally, informed consent has been obtained in a face-to-face interview using paper consent forms. New technologies are becoming available that may serve as an alternative to the paper consent form in the informed consent process.

Even in the context of paper consent forms, there may be certain circumstances when an alternative to a face-to-face consent interview may be appropriate. For example, such an alternative may be appropriate when the subject or the subject's legally authorized representative is unable to visit the investigational site to sign the consent form, or if the screening procedures for the clinical investigation require prior activity, such as fasting, that requires consent but does not require a visit to the investigational site. When written informed consent is required, informed consent cannot be obtained solely by telephone. For studies involving no more than minimal risk, and no procedures for which written consent is normally required outside the research context, oral consent from a subject or a subject's legally authorized representative is permissible under 21 CFR 56.109(c). When oral consent is used, FDA recommends that documentation of the process (information provided, name of individual obtaining consent, date consent obtained) be included in the study records (see 21 CFR 312.62(b) and 21 CFR 812.140(a)(3)).

Methods other than a face-to-face consent interview may be acceptable if those methods allow for an adequate exchange of information and signatures, and a method to ensure that the signer of the consent form is the person who plans to enroll as a subject in the clinical investigation or is the legally authorized representative of the subject. For example, the consent form may be sent to the subject or the subject's legally authorized representative by facsimile or e-mail, and the consent interview may then be conducted by telephone when the subject or subject's legally authorized representative can read the consent form during the discussion. After the consent discussion, the subject or the subject's legally authorized representative can sign and date the consent form and return the document to the clinical investigator by fax, scanning the consent form and returning it through a secure e-mail account, or by posting it to a secure internet address. Alternatively, the subject may bring the signed and dated consent form to his/her next visit to the clinical site or mail it to the clinical investigator. The signed document should be filed with the subject's case history. See 21 CFR 312.62(b) and 812.140(a)(3). In addition, the person signing the consent form must receive a copy of the consent form (21 CFR 50.27(a)). Although FDA regulations do not require the subject's copy to be a signed copy, FDA recommends that a copy of the signed consent form be provided.

Source: [Informed Consent Information Sheet](#)

Find answers to Other Informed Consent Questions at:

- Office for Human Research Protections (OHRP) Informed Consent FAQs
<https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html>

- Food and Drug Administration (FDA) Informed Consent Information Sheet July 2014
<https://www.fda.gov/RegulatoryInformation/Guidances/ucm404975.htm>

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