

<b>SOP: Subjects who cannot read, write, or have some impairment that hampers consent process or documentation</b>				
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## 1 PURPOSE

- 1.1 This procedure establishes the consent process for illiterate and low literacy subjects who have the capacity to consent or physically challenged subjects who have the capacity to consent.

Refer to [SOP: Legally Authorized Representatives, Children, and Guardians](#) for subjects who do **not** have the capacity to consent.

- 1.2 The process begins when the PI or IRB determines that a potential research subject is illiterate / has low literacy or a subject is physically challenged in a way that hampers the consent process or documentation of consent.
- 1.3 The process ends when the subject is no longer a research subject or potential research subject.

## 2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

## 3 POLICY

- 3.1 For subjects with apparent low literacy, oral presentation of the information contained in the ICF is especially important.
- 3.2 When the elements of informed consent are presented orally to the subject (or the subject's legally authorized representative), the Tufts Health Sciences IRB has approved the use of a short form with the IRB approved consent serving as the written summary (21 CFR 50.27(b)(2)). The short form consent process includes a witness to the oral presentation of the informed consent elements who also signs the ICF. 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 ICF (whether the long form or short form is used) unless the IRB has waived documentation of informed consent under 21 CFR 56.109(c).
- 3.3 A person who is physically challenged (for example, physically unable to talk or write or has hearing or visual loss) can enroll in a clinical investigation if the person is competent and able to signal consent. The records relating to the clinical investigation must include documentation of the informed consent process (21 CFR 50.27) unless excepted under 21 CFR 56.109(c).

## 4 RESPONSIBILITIES

- 4.1 Before asking a subject to review and sign an informed consent form (ICF), the investigator is responsible, under the informed consent process, for ensuring that potential research subjects are capable of reading the form. Investigators are not to assume that subjects are able to read and, when appropriate, are to inquire in a sensitive way as to whether the subjects are able to do so. This can be done by asking the subject, the witness, or other individuals who are familiar with the subject's mental capacity. If not, investigators are to make special arrangements without causing embarrassment to the subjects. Illiterate subjects are not to be excluded from the research because they are unable to read unless there is an overriding scientific or safety concern. Any such rationale for excluding illiterate subjects must be described in the protocol and/or Site-Specific Appendix.
- 4.2 If there are written instructions for subjects relating to any component of the research study, create a plan for conveying these instructions to subjects who cannot read. This plan could include giving an audio or video recording of the instructions to subjects or having a research team member verbally communicate these instructions to subjects over the telephone at certain required study time points. Submit a copy of these written instructions to the IRB for review.

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## 5 PROCEDURE

Either of the following options can be used to enroll a subject with low literacy without further Tufts Health Science IRB approval unless the process conflicts with information in the IRB approved protocol and/or Site-Specific Appendix.

### 5.1 **Option 1: Read the full consent to the subject and document the consent process in the research records and subject's case history**

- 5.1.1 Read the ICF to the subject and encourage the subject to ask questions.
- 5.1.2 Conduct the consent process with a witness present. The witness is to observe the entire process, not just the signature. The witness must be literate.
- 5.1.3 The witness signs and dates the ICF to document that the process took place and that the subject voluntarily consents to participate.
- 5.1.4 The person consenting the subject signs and dates the consent. (The protocol and/or Site-Specific Appendix specifies the person consenting the subject.)
- 5.1.5 The subject signs the consent, if able. If the subject is unable to sign, the subject can document consent by "making their mark", that is the subject can make an "X" on the ICF.
- 5.1.6 Give the subject a signed copy of the ICF.
- 5.1.7 Retain the original signed ICF in the subject's research record and medical record, as appropriate.
- 5.1.8 Enter a progress note in the study file and subject's case history describing the consent process and, if applicable, the reason for the "X" in place of a signature.

### 5.2 **Option 2: Use the Short Form Method of Consent**

*(This is similar to Option 1, but follows the short form consent process to document the oral presentation of the consent. If the subject is a non-English speaker, refer to the [Short Form Policy](#)).*

- 5.2.1 The short form method of consent permits a detailed discussion of the research described in the ICF. The subject (or legally authorized representative) will sign a short form that attests to the fact that the elements of consent were verbally described.
- 5.2.2 Refer to the information about [short forms](#) on the Tufts Health Sciences IRB website. An [English version of the short form](#) is located on the IRB website in the same location as the translated versions.
- 5.2.3 When enrolling an illiterate potential subject using an English short form:
  - 5.2.3.1 Insert study specific information, including department name, study title, Principal Investigator, and contact information into the short form document and then print the document for use. This information must be typed and the fields on all the pages of the short form document must be completed.
  - 5.2.3.2 Present the entire IRB-approved English ICF orally. Encourage the potential subject to ask questions.
  - 5.2.3.3 Conduct the consent process with a witness present. The witness is to observe the entire process, not just the signature. The witness must be literate. The witness could be a staff member or a family member.
  - 5.2.3.4 The witness signs and dates the ICF and the English short form.
  - 5.2.3.5 The person obtaining consent signs and dates the consent and short form.
  - 5.2.3.6 The subject signs the consent, if able. If the subject is unable to sign, the subject can document consent by "making their mark", that is the subject can make an "X" on the ICF.
  - 5.2.3.7 Give the subject signed copies of the ICF and short form.
  - 5.2.3.8 Retain the original signed ICF and original signed short form in the subject's research record and medical record, if appropriate.



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5.2.3.9 Enter a progress note in the study file and subject's case history describing the consent process and, if applicable, the reason for the "X" in place of a signature.

**5.3 Physically Challenged Subjects**

It is recommended that the subject's case history include a description of the specific means by which the prospective subject communicated agreement to take part in the clinical investigation and how questions were answered. Investigators should accommodate the specific needs of the study population. For example, the investigator could use an audio tape of the contents of the consent form or a form with enlarged font, depending on the level of impairment of the visually impaired subjects.

**6 MATERIALS**

- 6.1 Tufts Health Sciences IRB Approved [English version of the short form](#)
- 6.2 Tufts Health Sciences IRB [Short Form Policy](#)
- 6.3 [SOP: Legally Authorized Representatives, Children, and Guardians](#)

**7 REFERENCES**

- 7.1 21 CFR 50.27
- 7.2 21 CFR 56.109(c)