



## SOP 702: GENERAL REQUIREMENTS OF DOCUMENTATION OF CONSENT

### POLICY

The IRB may approve procedures for documentation of informed consent which involves (a) a written consent form signed and dated by the participant or the participant's legally authorized representative; (b) a short form written consent form stating that the required elements of informed consent have been presented orally; or (c) in limited circumstances, waiver of documentation of consent. It is the responsibility of the IRB to determine whether the proposed method of documentation or waiver of informed consent is appropriate in protocols that it reviews.

These policies apply to adult consent or parental permission.

### PROCEDURES

#### 1. Documentation of Informed Consent - Written Informed Consent Document

- 1.1. In most circumstances, the IRB requires that informed consent is documented by the use of a written consent form approved by the IRB. The written consent form should be signed and dated by the participant or legally authorized representative prior to enrollment or any participation in the study. The Investigator should allow the participant or the legally authorized representative adequate opportunity to read the consent document and ask questions before it is signed and dated. A copy of the document must be given to the person signing the form.
  - 1.1.1. The IRB may approve a process that allows the written informed consent document to be delivered by mail, electronic mail or facsimile to the potential participant or the potential participant's legally authorized representative and to conduct the consent interview by telephone when the participant or the legally authorized representative can read the consent document as it is discussed. All other applicable conditions for documentation of informed consent must also be met when using this procedure.
  - 1.1.2. Illiterate persons who understand English may have the written informed consent document read to them and "make their mark," under Utah state law. If written consent is obtained from illiterate persons outside the state of Utah, persons will 'make their mark' as appropriate according to the laws applicable in each state or country.
- 1.2. For all studies, including those involving veterans, IRB approval of the written informed consent is documented through the use of an electronic stamp that indicates the date of the most recent IRB approval of the document. If the consent is amended, the date stamp must be that of the most recent approved consent.
- 1.3. For all studies, including those involving veterans, the written consent form must be signed and dated by:

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- The participant or the participant's legally authorized representative.
- The person obtaining the informed consent. The IRB may waive this requirement if no physical contact with the participant will occur.
- A witness, if required by the IRB. The role of the witness is to witness the participant's or the participant's legally authorized representative's signature only unless the sponsor or IRB requires the witness to witness the informed consent process. The witness cannot be the person who obtained informed consent from the participant, but may be another member of the study team or may be a family member.

## 2. Documentation of Informed Consent - Oral Presentation Using Short Form

- 2.1. As an alternative to standard written informed consent documents, oral presentation of informed consent information is allowed under 45 CFR 46.117(b)(2) and 21 CFR 50.27(b)(2). In such cases, the participant must be provided with IRB approved versions of both:
  - A short form written informed consent document stating that the elements of informed consent as required above have been presented orally to the participant or the participant's legally authorized representative.
  - A written summary of the information that is presented orally.
- 2.2. A witness to the oral presentation is required. The witness must sign and date both the short form written informed consent document and a copy of the written summary.
- 2.3. The participant or the legally authorized representative must sign and date the short form written consent document.
- 2.4. The person obtaining consent (e.g., the Investigator) must sign and date a copy of the written summary of the information that is presented orally. The person obtaining consent may not act as the witness to the consent process.
- 2.5. For participants who do not speak English, an oral presentation using the short form may be used with participants who do not speak English.
  - 2.5.1. The oral presentation and the short form written informed consent document should be in a language understandable to the participant.
  - 2.5.2. The IRB-approved English language informed consent document may serve as the summary.
  - 2.5.3. The witness should be fluent in both English and the language of the participant.
  - 2.5.4. The IRB must receive all foreign language versions of the short form document as a condition of approval.
- 2.6. Expedited review of the foreign language versions is acceptable if the IRB has already approved the protocol, the full English language informed consent document, the English version of the short form document and verification of translation is provided.

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### 3. Waiver of the Requirement to Obtain Written Documentation of the Consent Process

The convened IRB or a designated IRB reviewer using the expedited procedure determines and documents whether the waiver of written documentation can be granted by using the appropriate section of the Reviewer Checklist.

- 3.1. The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all participants if it is not subject to FDA regulation and it finds either:
  - 3.1.1. That the research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context; or
  - 3.1.2. That the only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant will be asked whether he/she wants documentation linking the participant with the research, and the participant's wishes will govern. In such cases, investigators must submit a description of the information that would be disclosed or a consent document for participants who wish to have their consent documented.
  - 3.1.3. If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate mechanism documenting that informed consent was obtained.

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