SOP 702: GENERAL REQUIREMENTS OF DOCUMENTATION OF CONSENT

PURPOSE

This SOP outlines the requirements and acceptable methods for documentation of informed consent. The University of Utah Institutional Review Board (IRB) may also approve a waiver of documentation of consent under limited circumstances as outlined in this policy.

SCOPE

This policy applies to non-exempt human subject research conducted at the University of Utah. This policy applies to investigators obtaining adult consent and parental permission for participation in research.

DEFINITIONS

A. A **legally authorized representative (LAR)** is an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. The University of Utah IRB will accept consent from an LAR given that the researcher has established that the consenting individual has legal authority to do so (provided the IRB determined there is adequate justification for the inclusion of an LAR in the consent process).

POLICY

Documenting informed consent occurs after the investigator or designated study personnel has conducted a consent process (i.e., explains the research, answers questions, etc.). The signature of the participant or the participant's legally authorized representative indicates consent to participate. The signature of the person obtaining consent indicates that they conducted a consent process, and the research has been explained to the participant.

The University of Utah IRB may approve procedures for documentation of informed consent which involves (a) a written consent document signed and dated by the participant or the participant's legally authorized representative; (b) a short form written consent 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 University of Utah IRB to determine whether the proposed method of documentation of consent or waiver of documentation of consent is appropriate in protocols that it reviews. Investigators must describe the method of documentation of consent or request a waiver of documentation of consent in the IRB application submitted in the Electronic Integrity and Compliance Administration system (ERICA).

PROCEDURES

1. Documentation of Informed Consent with a Written Consent Document

1.1. In most circumstances, the University of Utah IRB requires that informed consent is documented using a written consent document approved by the IRB. The written consent document should be signed and dated by the participant or the participant's legally authorized representative prior to enrollment or any participation in the study. The investigator should allow the participant or the participant's 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.

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 or video call when the participant or the participant's 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 by 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 document must be signed and dated by:

- 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 with a Short Form

The University of Utah IRB approves a standard short form document (written in English) for general use. All panels must vote for approval of the standard short form document at a convened meeting prior to the document being made available for use on the IRB website.

Once the English version of the standard short form has been approved by the University of Utah IRB, translated versions are certified by the Research Translation Office and are also made available for use general on the IRB website.

The short form consent documentation process must be approved by the IRB on a per study basis prior to the use of short forms. Once the process is approved for a study, any standard University of Utah short form may be used. The short form documents do not need to be attached to the ERICA application. If an investigator wishes to use an alternative to the standard short form or translate their own version, it must be reviewed and approved by the IRB prior to use.

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 CFR50.27(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 participant's legally authorized representative must sign and date the short form written consent document.

2.4. The person obtaining consent 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. An oral presentation may be documented using the short form with participants who do not speak English or have limited English proficiency (LEP).

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. Interpreters may serve as the witness.

2.5.4. Once a consent process using a short form for documentation of consent is approved for a study, use of the University of Utah IRB approved short form in any of the languages posted on the IRB website is permitted.

2.5.5. If an investigator wishes to use their own translation, expedited review 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.

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 document 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 participants or the participant's 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.

3.2. There may be circumstances in which the investigator requests that the IRB waive the requirement for the investigator to obtain a signed consent document and would like to use translated versions of the University of Utah IRB-approved short form to facilitate a consent process with participants who do not speak English or have limited English proficiency (LEP). In these cases, investigators may use the University of Utah IRB-approved short form(s) without obtaining signatures on the short form once a waiver of documentation of consent and the consent procedure including the interpretation process is approved by the IRB.