SOP 701: GENERAL REQUIREMENTS OF INFORMED CONSENT

PURPOSE

The University of Utah Institutional Review Board (IRB) adheres to the regulatory requirements for informed consent. This SOP outlines how the University of Utah IRB determines that the applicable requirements for informed consent are met.

SCOPE

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

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.

POLICY

Investigators are required to obtain legally valid informed consent from each participant or their legally authorized representative before involving them in research. The University of Utah IRB may approve a consent procedure which does not include, or which alters some or all the elements of informed consent as outlined in IRB SOP 703: Waiver or Alteration of Consent.

The University of Utah IRB reviews the research application and any written consent documents to ensure that the required elements of informed consent and when appropriate, the additional elements of informed consent are included in the informed consent process. Additional information or language to be included in informed consent may be required based upon the study. The University of Utah IRB provides investigators with informed consent checklists which outline required elements, and sample language or information that must be provided during the consent process.

The University of Utah IRB adheres to the following regulations, as applicable:

- Department of Health and Human Services (DHHS): 45 CFR 46.116
  - *The University of Utah IRB does not utilize the option for broad consent (45 CFR 46.116(d)).*
- Food and Drug Administration (FDA): 21 CFR 50.25
  - The informed consent requirements related to the content, organization and presentation of information included in the consent form and process as well as the basic and additional elements of informed consent in the Final Common Rule are not inconsistent with the FDA's current policies and guidance. The University of Utah IRB may approve a consent process for an FDA-regulated study that is consistent with the Final common Rule.
- Veterans Affairs (VA): 38 CFR 16.116

- Department of Defense (DoD): 32 CFR 219.116

For studies that are not federally funded, the pre-2018 Common Rule requirements for informed consent are required. The informed consent requirements related to the content, organization and presentation of information included in the consent form and process as well as the basic and additional elements of informed consent in the Final Common Rule are not required but may be included.

Whether written or oral, the general requirements for informed consent are:

- Before involving a human subject in research, the investigator must obtain legally effective informed consent from the participant or the participant's legally authorized representative.
- Consent is sought under circumstances which provide the prospective participant or the legally authorized representative with sufficient opportunity to ask questions and consider whether to participate. Further, the possibility of coercion or undue influence must be minimized.
- The information that is given to the participant or the legally authorized representative shall be in language understandable to the participant or legally authorized representative.
- Any information that a reasonable person would want to have in order to make an informed decision about participation should be provided to the participant or legally authorized representative.
- For studies subject to the Final Common Rule, consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective participant or legally authorized representative in understanding the reasons why an individual may or may not want to participate in the research.
- The information must be presented in sufficient detail and organized and presented in a way that does not merely provide lists with isolated facts, but rather facilitates the understanding of why one may or may not want to participate.
- No informed consent may include any exculpatory language through which the participant is made to waive or appear to waive legal rights or releases or appears to release the Investigator, the Sponsor, or the University of Utah from liability for negligence.
- In seeking informed consent, the required elements of informed consent must be provided to the prospective participant or their legally authorized representative.

PROCEDURES

1. General Requirements for Informed Consent

1.1. Based on the investigator's proposal for obtaining informed consent, the IRB determines whether the plans for obtaining consent meet the general requirements for informed consent (see above). Documentation is made using the reviewer checklist in the University of Utah Electronic Research Integrity and Compliance Administration system (ERICA).

2. Basic and Additional Elements of Informed Consent

2.1. The IRB determines whether the information provided to the potential participant includes the basic required elements of informed consent and when appropriate, the additional elements of

informed consent as provided in the applicable regulations cited above. Documentation is made using the reviewer checklist in ERICA.

2.2. For studies that are no more than minimal risk, the additional elements of informed consent provided in the regulations cited above will not be required. However, if the IRB determines any of the additional elements of informed consent should be included, it will be documented using the reviewer checklist.

2.3. For studies that are greater than minimal risk, the additional elements of informed consent provided in the regulations cited above are generally required. The IRB determines if any of the additional elements of informed consent may be omitted. Such a determination will be based upon situations in which the elements are not applicable as defined in the reviewer checklist.

2.4. Any elements of informed consent required specifically for VA or DoD studies will be required as outlined in the respective regulations.

3. University of Utah Requirements for Informed Consent

3.1. The IRB determines that the University of Utah IRB requirements are included in the informed consent process. Documentation is made using the reviewer checklist.

3.2. The University of Utah IRB requires the use of standard language (e.g., research-related injury, etc.), as applicable. Any change to the standard language may be subject to ancillary review and must be approved by the IRB.

3.3. The IRB follows applicable Federal, State, or local laws, which require additional information to be disclosed for informed consent to be legally valid. If applicable, this information must be provided.

3.4. In addition to information specifically required by applicable regulations, the IRB may require that information, be given to the participants when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of participants.