POLICY

Informed consent must be legally valid and prospectively obtained. Except as described in SOP 703 and SOP 506, no Investigator may involve a human being as a research participant unless he or she has obtained legally valid informed consent from the participant or the participant's legally authorized representative.

These policies apply adult consent or parental permission.

PROCEDURES

1. Informed Consent

1.1. The IRB determines whether the information provided to the potential participant includes the required elements of informed consent and when appropriate, the additional elements of informed consent as provided in the applicable regulations. Determinations are made in the Reviewer Checklist. The IRB adheres to the following:

- Department of Health and Human Services (DHHS) Common Rule: 45 CFR 46.116
- Food and Drug Administration (FDA): 21 CFR 50.25
- Veterans Affairs (VA): 38 CFR 16.116
- Department of Defense (DoD): 32 CFR 219.116

1.1.1. 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. The IRB determines if any of the additional elements of informed consent should be included in the Reviewer Checklist.

1.1.2. 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.

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

1.2. The IRB documents in the Reviewer Checklist that the following are included in the consent process:

Please contact the IRB Office at (801) 581-3655 or irb@hsc.utah.edu for additional guidance.
• Consent is sought under circumstances which provide the prospective participant or the representative sufficient opportunity to ask questions and consider whether or not to participate. Further, the possibility of coercion or undue influence must be minimized.
• No informed consent, whether oral or written 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.
• The information that is given to the participant or the representative shall be in language understandable to the participant or representative.

2. Additional University of Utah IRB Requirements for Informed Consent

The IRB determines that the University of Utah IRB requirements are included in the informed consent process. Documentation is made in the Reviewer Checklist.

2.1. The University of Utah IRB requires the use of standard template language. Required language is outlined in the appropriate template (e.g. Consent and Authorization – HIPAA Biomedical, Main Campus Consent, Parental Permission, etc.). Any change to the standard template language must be approved by the IRB at the time of review.

2.2. The University of Utah IRB requires adherence to specific instructions and guidelines when using a written informed consent document. The guidelines are outlined in the appropriate template (e.g. Consent and Authorization – HIPAA Biomedical, Main Campus Consent, Parental Permission, etc.) provided on the IRB web site. Any exception to the guidelines must be approved by the IRB at the time of review.

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

2.4. The IRB may require that information, in addition to that specifically required by applicable regulation, 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.