

Approved by IRB executive committee: April 2, 2008
Supersedes Document Dated: December 12, 2005; May 1, 2004
AAHRPP Elements II.7.C

POLICY

Informed consent must be legally valid and prospectively obtained. Except as described in SOP 702 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 to any form of informed consent—adult consent or parental permission.

PROCEDURES

1. Informed Consent

- 1.1. The IRB determines the information provided to the potential participant includes the elements of informed consent described in 21 CFR 50.25(a) and 45 CFR 46.116(a) and when appropriate, the additional elements of informed consent provided in 21 CFR 50.25(b) and 45 CFR 46.116(b). The determination is made in the Reviewer Checklist.
 - 1.1.1. For studies that are no more than minimal risk, the additional elements of informed consent provided in 21 CFR 50.25(b) and 45 CFR 46.116(b) will not be required. The IRB determines if any of the additional elements of informed consent are required in the Reviewer Checklist.
 - 1.1.2. For studies that are greater than minimal risk, the additional elements of informed consent provided in 21 CFR 50.25(b) and 45 CFR 46.116(b) 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.
- 1.2. The IRB documents in the Reviewer Checklist that the following are included in the consent process:
 - Consent shall be 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.

3. Additional VA Requirements for Informed Consent

The IRB determines that the additional VA requirements are included in the informed consent process, if the study is conducted at the Veteran Affairs Salt Lake City Health Care System (VASLCHCS). Documentation is made in the Reviewer Checklist.

- 3.1. A statement that the Government Accounting Office (GAO) may have access to the records must be included.
- 3.2. A statement that in the event of a research-related injury the VA must provide necessary medical treatment to a research participant injured by participation in a research project approved by a VA R&D Committee and conducted under the supervision of one or more VA employees must be included.
 - 3.2.1. An explanation that necessary care must be provided in VA medical facilities except in limited circumstances must be included.
 - 3.2.2. An explanation of the VA's authority to provide medical treatment to research participants injured by participation in a VA research project must be included.
- 3.3. A statement outlining what medical care will be provided in case of research-related injury pertaining to non-veteran participants enrolled in VA-approved research must be included.
- 3.4. A statement that a veteran-participant will not be required to pay for care received as a participant in a VA research project except in accordance with Title 38 United States Code (U.S.C.) 1710(f) and 1710(g), certain veterans are

required to pay co-payments for medical care and services provided by VA must be included. A statement that veterans receiving medical care and services from VA that are not rendered as part of the VA-approved research study must pay any applicable co-payment for such care and services must also be included.

- 3.5. For research conducted at the VASLCHCS, if someone other than the investigator conducts the interview and obtains consent, the investigator should formally delegate this responsibility and the person so delegated must have received appropriate training to perform this activity.
- 3.6. For studies conducted at the VA, there are special requirements for storage and use of samples. The requirements can be identified by contacting the Research Compliance Officer at the VA and must be included.