Department: **UAMS Institutional Review Board**
Policy Number: **15.1**
Section: **Consent**
Effective Date: **July 31, 2002**
Revision Date: **September 22, 2005, June 1, 2005; August 25, 2004**

Subject: Informed Consent

Policy: Informed consent is an ongoing process, not just a piece of paper or a one time event. Informed consent assures that prospective human participants will understand the nature of the research and can knowledgeably and voluntarily decide whether or not to participate. The informed consent requirements in this policy are not intended to preempt any applicable Federal, State, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

This policy primarily addresses the most common method of obtaining informed consent where it is documented in writing with a form detailing each required element and the "short form" method. Studies involving deception, waivers to documentation of consent and waivers or alterations of consent elements are outlined in Policies 15.3.

All consent processes must:

1. Be legally effective. If a participant is not able to consent on his/her own behalf due to age or cognition, refer to IRB Policy Section 17, especially Policy 17.13, to ensure permission is obtained from a legal representative.

2. Be sought only under circumstances that a) provide the prospective participant or representative sufficient opportunity to consider whether or not to participate and b) minimize the possibility of coercion or undue influence.

3. Be in a language understandable to the participant or LAR (See Policy 15.4 for information on Non-English speaking subjects) and at a level understandable to all participants. No complex scientific or technical language should be used without an explanation in lay or common terms. At or below an eighth grade level is recommended.

4. Not include any exculpatory language waiving or appearing to waive any legal rights of the subject or releasing the Institution, Sponsor or Investigator from liability. Avoid phrases like "you give up all rights" or "you will not be compensated". More acceptable phrases are "no plans have been made to compensate" or "I authorize the use of".

"Short Form" consent documents require:

1) A statement that the elements of informed consent required for the specific type of research have been presented orally to the participant or the participant's legally authorized representative (LAR). The participant or LAR signs the short form and receives a copy of the short form and the written summary.

2) A written summary of what is to be said to the participant or LAR. A copy of this summary must be signed by the person obtaining consent and the witness.

3) A witness to the oral presentation, who must sign both the short form and a copy of the summary.

The IRB must approve both the short form and the summary. This process is most often approved for non-English speaking participants. See Policy 15.4 for more information.

All other consent forms must a) be prospectively obtained and documented, unless requirements outlined in 15.3 apply, b) be consistently written in the second person when referring to the participant or representative, with the exception of the final paragraph. Using terms such as you or your rather than I or me helps to convey the voluntary nature of the process, and c) use consistent and appropriate terms throughout. Research consents should not use terms like “patient” or “treatment”. Acceptable and more accurate terms are “subject” or “participant” and “research procedures” and:

1. Contain the following federally required elements:

    1.1 A statement that the study involves research;

    1.2 An explanation of the purposes of the research;

    1.3 The expected duration of participation;

    1.4 A description of the procedures to be followed;

    1.5 Identification of any procedures which are experimental and those that are standard of care;

    1.6 A description of any reasonably foreseeable risks or discomforts to the participant;

    1.7 A description of benefits, if any, to the participant or to others which may reasonably be expected from the research;

    1.8 A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant;

    1.9 A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained, noting as applicable that certain entities, including FDA, may inspect the records;

        IRB requires that the Institutional Review Board, Office for Human Research Protections, and as applicable Food and Drug Administration and Sponsor be listed in this statement.

    1.10 For research involving **more than minimal risk**, an explanation as to whether any compensation and an explanation as to whether any medical

treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

IRB required statement:

In the event of complications, injury or illness requiring emergency medical treatment resulting from your participation in this study, appropriate acute medical care will be provided at no cost to you. However, the Principal Investigator and this institution have made no provision to reimburse you for the cost of medical care beyond emergency medical treatment or to pay for any lost wages, pain and suffering, hospitalization, or other expenses you may incur as the result of any such complication, injury or illness.

1.11 An explanation of whom to contact (and how) for answers to pertinent questions about the research, research participants' rights and in the event of a research-related injury.

IRB required statement:

"If you have questions during the study about the research, you should contact <<<PI>>> at <<<phone>>> or <<<24 hour pager>>>. You may call the Institutional Review Board (IRB) at 501-686-5667 regarding a research-related injury, with questions about your rights as a research participant or to discuss any problems or concerns about the research. Also, you may call this number if you are unable to reach the Investigator or you wish to speak to someone not directly related to this study."

1.12 A statement that participation is voluntary;

1.13 A statement that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled;

1.14 A statement that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled;

2. Contain, as applicable, these additional elements:

2.1 A statement that the particular treatment or procedure may involve risks to the participant (or to the embryo or fetus, if the participant is or may become pregnant) which are currently unforeseeable. (Must be included in investigational drug and device studies.)

2.2 *Anticipated circumstances* under which participation may be terminated by the investigator without regard to the participant's consent. (Must list the specific anticipated circumstances, not just that there are some.)

2.3 The *consequences* of a participant's decision to withdraw from the research and *procedures* for orderly termination of participation. (Must list the specific consequences of withdrawing and the specific procedures for termination.)

2.4 When test articles are being used in the project, a statement as to status of the article, whether the study is testing the safety or effectiveness of the test article.If the purpose of the study is to test the safety or the purpose is to test the effectiveness, no claims that the test article is safe or effective, asapplicable, should be made.

2.5 CAVHS studies must be on VA form 10-1086 and must include all additional VA required statements.

3. Contain all of the following institutional requirements or format:

3.1 All pages numbered and dated

3.2 All pages listing the Protocol title, Sponsor and Institutions where conducted

3.3 The approximate number of participants involved in the study, locally and nationally.

3.4 Age range for participants to be studied

3.5 The amount of time each participant will be actively involved in the study

3.6 A statement that significant new findings developed during the course of the research which may relate to the participant's willingness to continue in the study will be provided to the participant

3.7 A statement that no rights have been waived by signing the consent form

3.8 Last paragraph must read, “I have read the above statement and have been able to ask questions and express concerns, which have been satisfactorily responded to by the Investigator. I understand the purpose and voluntary nature of the study as well as the potential benefits and risks that are involved. I have been given a copy of this consent form.”

3.9 Lines for the Signature/Date/Time of consent for Participant, Parent(s) or LAR, PI, Witness, and Person Obtaining Consent

4. As applicable, contain the following institutional required elements.

4.1 If any information will be collected after the participant’s active involvement, the duration of collection.

4.2 If data or specimens will be stored for future research, how it will be stored, why, for what types of research, for how long, and how to withdraw data or specimens.

IRB requires that a yes/no option be provided for future use of samples that allows a participant to consent to the primary study but decline to allow the storage of samples if s/he desires.

4.3 If any additional costs may reasonably occur from participation in the research, the following clause,

"The study may include tests and procedures that are conducted solely for the research study. These tests and procedures will be paid for by the study Sponsor. There may be some tests and procedures which the Principal Investigator considers standard of care (meaning you would receive this care whether or not you are in the research study) and these tests and procedures are billable to you and your insurance company. Your insurance company may or may not agree with this determination. If your insurance company feels that the charges are for tests and procedures related to the research study they may deny payment, making you responsible for any charges that are not paid for by the study Sponsor. There is never any guarantee with any hospital service that you will not incur some financial liability.

In addition, the Principal Investigator or his/her representative will discuss with you any additional tests and/or procedures that may be required due to changes in your condition during your study participation. You have the right to refuse to have any additional tests or procedures. If you feel that you have been billed in error, please contact the Principal Investigator or his/her representative whose name and telephone number is included on this consent form.

A summary (***insert a narrative or table-formatted description with headings of "Covered by the Study" and "Payable by You or Your Insurance"***) of the standard and investigational study-related procedures is included below together with an indication of those items that will, or may, be your financial responsibility."

4.4 If the Sponsor has offered to pay for treatment of injury resulting from the research, the language of such offer.

4.5 In studies where ionizing radiation is used, the increase of radiation exposure over the current standard of care in lay terms.

4.6 In studies where there is potential for gene linkage, an explanation of risks including social and financial.

4.7 In studies where participant will be tested for HIV, a notice that the participant and Department of Health will be notified of a positive test result and that participants will be given information about counseling options.

Stamping Consents:

The IRB does not generally stamp consents, however, there are two exceptions. For non-CAVHS studies, if the Sponsor requires a stamped consent, the Investigator should contact the IRB office to obtain a stamped copy of the approved consent.

For CAVHS studies which require stamped consents, UAMS has delegated this duty to the CAVHS Administrative Officer for Research. CAVHS has agreed to only stamp consents upon verification in ARIA of the approved consent version.

In either case, the Investigator must remember to do this each time there is a change to the consent.

All VA Studies that are Greater than Minimal Risk:

Consent process and study participation must be documented in the Computerized Patient Record System (CPRS is the VA electronic patient record system). The VA R&D Committee will determine whether certain studies should be additionally 'flagged' based on participant safety needs.

Investigators must:

1. At the time of initial ARIA submission, upload all consent forms (or scripts as applicable) to be used. The form should include all of the elements required by UAMS and federal regulations and each of the other elements as is appropriate to the type and nature of the study.

1.1 In response to contingencies or after approval, submit any proposed changes to the consent document, with changes highlighted and/or tracked, as an ARIA Modification and receive IRB approval prior to use.

2. Explain in detail the consent process, both initial and ongoing. Investigator should identify at a minimum:

2.1 Who will conduct the consent interview;
2.2 The timing of obtaining informed consent;
2.3 The waiting period between providing information about the research and obtaining consent;
2.4 The record will be noted; and
2.5 How the Investigator will assure that there will be ongoing communication between the research team and participant.

3. Explain how the informed consent process will be documented in the permanent record. The process of informed consent must be documented by an entry in the subject's permanent or medical records. A note should be made that includes:

- The date the subject was entered into the study

- The title of the study
- The name of the Principal Investigator
- The name of the person obtaining the informed consent
- A statement that the subject had an opportunity to ask questions about the research and have those questions answered
    - Note: CAVHS has special requirements for documentation and filing of informed consent. The Investigator should consult the VA R & D Standard Operating Procedures for complete information.

4. At the time of the informed consent process, each subject must be given a copy of the signed and dated informed consent document. For those subjects that have a medical record, a copy of the subject's informed consent should be placed in the medical record. The original should be retained by the PI.

IRB Chair or Committee must:

1. Review consent form and process for:

1.1 Content, ensuring all required UAMS, federal, and VA elements are addressed as applicable.
1.2 Consistency with all other submitted forms such as protocol, advertisements, or investigator's brochure.
1.3 Process, ensuring it is appropriate for targeted population and proposed activities and that the process allows sufficient opportunity to consider participation and the possibility of coercion or undue influence is minimized.
1.4 Form, making sure VA forms are used if appropriate.

2. Request revisions as necessary to ensure that proposed activities are clear and the intended participants can make a fully informed decision.