

Department: UAMS Institutional Review Board
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SUBJECT: Elements of Informed Consent

I. Purpose

The purpose of this policy is to outline the required elements for the informed consent process. 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. The required elements for the assent process, when children are involved, are referenced in IRB policy 17.1, Children in Research.

II. Definitions

A. **Coercion** occurs when an overt threat of harm is intentionally presented by one person to another to obtain compliance.

B. **Exculpatory language** is language that waives or appears to waive any legal rights of the subject or that releases or appears to release the Institution, Sponsor or Investigator from liability.

C. **Informed consent process** assures that prospective human subjects will understand the nature of the research and can knowledgeable and voluntarily decide whether or not to participate in the research. Informed consent is an ongoing process. The informed consent document is not consent in and of itself; it serves as written documentation of what has been communicated.

D. **Legally Authorized Representative (LAR)** means 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 research. See UAMS IRB Policy 17.13 Legally Authorized Representatives and 17.1 Research in Children for further information.

E. **Mandated Reporter** is anyone required to report suspected abuse. You are a mandated reporter if you are a: child care worker or foster care worker; coroner; day care center worker; dentist; dental hygienist; domestic abuse advocate; domestic violence shelter employee; domestic violence shelter volunteer; employee of DHHS; employee working under contract for DYS; foster parent; judge; law enforcement official; licensed nurse; any medical personnel who may be engaged in admission, examination or treatment; mental health professional; osteopath; peace officer; physician; prosecuting attorney; resident intern; school counselor; school official; social worker; surgeon; teacher; court appointed special advocate - staff member or volunteer; juvenile intake or probation officer; child advocacy center employee; clergyman.

F. **Undue influence** occurs through an offer of an excessive, unwarranted, inappropriate or improper reward or other overture in order to obtain compliance.

III. Policy

A. The Consent Process

1. Informed consent must be legally effective. If a subject is not able to consent on his/her own behalf due to age or cognitive ability, refer to UAMS IRB Policy 17.13, Legally Authorized Representatives, to ensure

permission is obtained from a legally authorized representative. Refer to UAMS Policy 17.1, Children in Research, for information on the process for obtaining consent and assent in children.

2. Informed consent must be sought only under conditions that a) provide the prospective subject or representative sufficient opportunity to consider whether or not to participate and b) minimize the possibility of coercion or undue influence.

3. Informed consent must be in a language understandable to the subject or legally authorized representative (LAR) and at a level understandable to all subjects. No complex scientific or technical language should be used without an explanation in lay or common terms. The consent document should be written in language that is at or below an eighth grade level.

4. Informed consent may not include any exculpatory language that waives or appears 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”, “you will not be compensated” or “I authorize the use” in the consent process.

5. Informed consent must be prospectively obtained and documented unless requirements outlined in UAMS IRB Policy 15.3, Waivers of Signed Informed Consent Documents and Waivers of Informed Consent Elements, apply.

6. Informed consent documents should be consistently written in the second person when referring to the subject or representative, with the exception of the final paragraph. Using terms such as “you” or “your” rather than “I” or “me” helps convey the voluntary nature of the process.

7. Informed consent for research studies should use terms like “participant” or “subject” and “research procedures” rather than “patient” and “treatment”.

B. Elements of Informed Consent.

1. Unless specifically waived by the IRB, the following elements must be addressed in the informed consent process and included in the written informed consent document.

- a. A statement that the study involves research.
- b. An explanation of the purpose of the research.
- c. The expected duration of the subject’s participation in the research.
- d. A description of the procedures to be followed.
- e. Identification of any experimental procedures.
- f. The number of subjects involved in the study.
- g. An age range for subjects to be studied.
- h. A description of any reasonable foreseeable risks or discomforts to the subject.
- i. A description of benefits, if any, to the subject or to others that may reasonably be expected from the research. Benefits refer to health or well-being, not payment for participation.
- j. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
- k. A statement that significant new findings developed during the course of research, which may relate to the subject’s willingness to continue, will be provided to the subject.
- l. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained, noting as applicable that certain entities, as outlined below, may inspect the records.

- i) The UAMS Institutional Review Board (IRB) must be listed;
- ii) The phrase "Other Institutional oversight offices" must be listed;
- iii) The Office for Human Research Protections (OHRP) a Federal agency must be listed;
- iv) Any funding source or sponsor that may access the records should be listed;
- v) If the study is subject to FDA oversight, the Food and Drug Administration must be listed;
- vi) If any member of the study team is a mandated reporter, an explanation of this limit to confidentiality must be present in the informed consent document. See section III (E) (4) of this policy for a suggested clause;
- vii) In studies where subject will be tested for HIV or other communicable diseases, a statement must be included that describes how the subject and Department of Health will be notified of a positive test result and that subject will be given information about counseling options if HIV positive or have any other communicable disease.

m. Contact information for both the research team as well as the IRB. The purpose of this contact information is to provide a means for the research subject to ask questions regarding the research or their rights as a research subject, to voice concerns, to file a complaint, or to notify the research team in the event of a research related injury. See section III (E) (2) of this policy for a suggested clause.

n. A statement that the participation is voluntary; that refusal to participate involves no penalty or loss of benefits to which the subject is otherwise entitled; that no rights have been waived; and that the subject may discontinue participation at any time without penalty or loss of benefit to which the subject is otherwise entitled. For clinical trials regulated by the FDA, see section III (C) (16) for issues related to subject withdrawal.

2. The subject or subject's legally authorized representative shall receive a copy of the signed and dated written informed consent form and any other written information provided to the subjects prior to participation.

C. Additional Elements of Informed Consent When Applicable

1. All drug or device studies will include in the informed consent a statement that the particular treatment or procedure may involve risks, which are currently unforeseeable, to the subject, embryo or fetus if the subject is or may become pregnant.

2. If the study is greater than minimal risk, there must be an explanation as to whether or not any compensation and/or medical treatment is available for injury. See section III (E) (1) of this policy for a suggested clause.

3. If the Investigator anticipates the subject may be terminated from the study without regard to the subject's consent, the informed consent will include the specific anticipated circumstances under which the subject's participation may be terminated by the Investigator.

4. When there are anticipated consequences to withdrawing from a study that may put the subject at greater risk, the informed consent will include the specific consequences of the subject's decision to withdraw from the research and procedures for the orderly termination of participation by the subject.

5. When additional costs to the subject are anticipated as a result from participation in the research, the informed consent will describe these additional costs. See section III (E) (3) (a),(b),or (c) for a suggested clause.

6. If the study is being conducted at multiple sites, the informed consent will include the approximate number of subjects involved in the study locally and nationally.

7. If the study involves the use of a placebo, the informed consent will include a statement describing the use of a placebo and the probability of being assigned to the placebo arm.

8. When test articles (i.e., drugs, devices) are being used in the project, include a statement as to status of the article (i.e., FDA approved for use in cardiology patients aged 16 years and older), and whether or not the study is testing the safety or effectiveness of the test article. If the study is testing the safety or effectiveness of the test article, the consent form cannot make any claims that the test article is safe or effective.

9. If any information will be collected after the subject's active involvement, the informed consent document must state the duration of the collection.

10. If subjects are to be contacted for future research, the IRB requires that the informed consent document include a yes/no option to being contacted in a separate section of the consent form that allows the subject to consent to the primary study but decline to be re-contacted for future studies.

11. If data or specimens will be stored for future research, the protocol and consent must describe:

- a) How the data or specimens are to be stored,
- b) Why the information is being collected,
- c) The protocol must describe in detail the types of future research that are anticipated,
- d) How long the data or specimens will be stored,
- e) A description of how subjects may request to withdraw data or specimens.

12. If data or specimens are stored for future research, the IRB requires that a yes/no option be provided in a separate section of the informed consent document or in a separate document. The option should provide for future use of data or specimens in a way that allows a subject to consent to the primary study but decline to allow the storage of samples if s/he desires. See UAMS IRB Policy 17.11, Stored Data or Tissues.

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

14. In studies where there is potential for gene linkage, an explanation of risks including social and financial will be included. See UAMS IRB Policy 19.1, Human Genetics.

15. All drug studies (except for Phase I studies) and all device studies (except for feasibility studies) require the informed consent documents and processes to include a specific statement that clinical trial information will be entered into the clinical trial registry databank maintained by the National Institutes of Health/National Library of Medicine (NIH/NLM). The FDA has emphatically stated that this clause must be exactly as follows:

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

16. For clinical trials regulated by the FDA, there are specific data retention requirements when a subject withdraws from the study.

- a) The data collected on the subject to the point of withdrawal remains part of the study database and may not be removed. The consent document cannot give the subject the option of having data removed.
- b) A researcher may ask a subject who is withdrawing whether the subject wishes to provide continued follow-up and allow further data collection after their withdrawal from the interventional portion of the study. The discussion with the subject must distinguish between study-related interventions and continued follow-up of associated clinical outcome information, such as medical course or laboratory results obtained through noninvasive chart review; and address the maintenance of privacy and confidentiality of the subject's information.
 - i) The subject's informed consent must be obtained for this limited participation in the study. If this situation was not described in the original informed consent, the IRB must approve a consent document for the limited participation.
 - ii) If a subject does not consent to continued follow-up of associated clinical outcome information, the researcher may not access the subject's medical record, or other confidential records requiring the subject's consent, for purposes related to the study. Researchers may

review study data collected prior to the subject's withdrawal and may consult public record, such as those establishing survival status.

NOTE: If Protected Health Information (PHI) is being collected, HIPAA requires an Authorization for Use, unless specifically waived by the IRB in its role as the privacy board. The requirements for a valid HIPAA authorization are in addition to the requirements for informed consent. You may incorporate the HIPAA required elements into your informed consent document or you may submit a HIPAA authorization as a separate document. See UAMS Administrative Guide 3.1.27 for the HIPAA Research Policy.

D. Format Requirements for Consent Form

1. All informed consent document pages must include the protocol title; or if the protocol title is more than two lines long, the full title is to appear on the first page and an appropriate protocol identifier, such as the IRB protocol number, may be used on all subsequent pages.
2. All informed consent document pages must include the name of the sponsor.
3. All informed consent document pages must include the institutions where the research is being conducted.
4. All informed consent document pages must include page numbers, date and version number.
5. The informed consent document must include lines for the signature and date of consent for:
 - a) Subject; and/or
 - b) Parent or LAR signature for studies enrolling children or individuals that are cognitively impaired (See UAMS IRB Policies 17.1, Research in Children; 17.2, Cognitively Impaired Persons; and 17.13, Legally Authorized Representatives. NOTE: Both Parent signatures are mandated by regulation for studies determined to be pediatric risk category 3 or 4.); and
 - c) Person obtaining consent (POC).
6. The last paragraph will address the voluntary nature of the study and that time has been given to ask questions and express concerns. See section III (E) (5) of this policy for a suggested clause.

E. Suggested Clauses. The following are suggested examples of language that may be considered acceptable. These clauses should not be considered required clauses. Any statement used must be applicable to the study and consistent with any sponsor or funding agreement.

1. Injury Clauses

a) For studies that do not have an Industry Sponsor: "In the event you are hurt by being in this research, treatment will be available. This treatment may include: first aid, emergency treatment and/or follow-up care. This treatment may be billed to you or your insurance company in the normal manner. Normally, no other form of compensation is available. If you think you have been hurt by this research, let the study Investigator know right away by calling <<<insert PI name and contact number>>> or <<<24 hour number when applicable>>>".

b) For studies that have an Industry sponsor who has agreed to pay for some injuries: "In the event you are hurt by being in this research, treatment will be available. This treatment may include: first aid, emergency treatment and/or follow-up care. The Sponsor agrees to pay for all reasonable and customary diagnosis, care, treatment, or hospitalization costs to address any injury or illness you may sustain as a result of your participation in the Study. Normally, no other form of compensation is available. If you think you have been hurt by this research, let the Study Investigator know right away by calling <<<insert PI name and contact number>>> or <<<24 hour number when applicable>>>. <<<Research Support Center will insert any additional negotiated language>>>. This language needs to match the Sponsor agreement and must be consistent with any other language in the consent form.

2. Contact Clause

"If you have questions during the study about the research, you should contact <<<PI name and contact number>>> or <<<24 hour number when applicable>>>. 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 subject 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"

3. Additional Cost Clauses

a) "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 service that you will not incur some financial liability."

b) "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."

c) "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. Mandated Reporter

"By law, the study team must release certain information to the appropriate authorities if at any time during the study there is concern that child abuse or elder abuse has possibly occurred or you disclose a desire to harm yourself or others."

5. Voluntary Participation

"The purpose and voluntary nature of this study, as well as the potential benefits and risks that are involved have been explained to me. I have been able to ask questions and express concerns, which have been satisfactorily responded to by the study team. I have been told I will be given a copy of the informed consent document."

IV. Procedures

A. Submission Process

1. At the time of initial submission, upload all informed consent documents (including assent documents or scripts as applicable) to be used. The form should include all of the elements required by the UAMS IRB and Federal regulations and each of the other elements as is appropriate to the type and nature of the study.
2. Investigators will describe the entire proposed consent process in the original submission. See UAMS IRB Policy 15.5, The Informed Consent Process.

B. After Initial Submission

1. In response to contingencies or after approval, submit any proposed changes to the informed consent document with changes highlighted and/or tracked along with a clean version of the informed consent

document as a “modification”. The IRB will administratively reject any modifications to documents that are submitted without an accompanying tracked change version.

2. Investigators must not use any consent form version prior to its approval by the IRB.

3. Each time the informed consent document is modified, the date and version number must be updated. Revised documents should replace previous version numbers and dates in ARIA with the next consecutive number and date of submission or revision.

4. The version number and date entered into ARIA during the upload of the document during the submission process is the number that will be displayed on the approval letter from the IRB. Therefore, the version number and date entered into ARIA should be the same as those appearing on the consent form.

5. When the IRB approves amendments to a previously approved consent form, the previous version must be retired and can no longer be used to consent subjects. The IRB will provide guidance regarding the need to re-consent current subjects using the new form in accordance with IRB Policy 7.4, Review by the Convened IRB and IRB Policy 7.5 Expedited Review.

6. The IRB does not generally stamp consent forms; but, if the Sponsor requires a stamped consent, the Investigator should contact the IRB office to obtain a stamped copy of the approved consent form.

C. IRB Responsibility

1. Review consent form document

a) Ensure all required UAMS elements are addressed as applicable to the research.

b) Ensure consistency with all other submitted forms such as protocol, advertisement, or investigator’s brochure.

2. Review consent process

a) Ensure process allows sufficient opportunity to consider participation and the possibility of coercion or undue influence is minimized.

b) Ensure process includes all elements necessary to protect the safety and welfare of the subjects participating in the study.

c) Ensure the review is documented sufficiently by referring to the consent form review checklist in the presentation of the protocol review during the IRB meeting.

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