Department: **UAMS Institutional Review Board**
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Section: **Consent**
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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 knowledgeably 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.

G. **Clinical trial** means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

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 (LAR). 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 LAR sufficient opportunity to discuss and consider whether or not to participate and b) minimize the possibility of coercion or undue influence.

3. Informed consent must be in language understandable to the subject or 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. The prospective subject or LAR must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.

5. Informed consent must:

a. Begin with a concise and focused presentation of key information that is most likely to assist a prospective subject or LAR in understanding reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a manner that facilitates comprehension.

b. As a whole, present information in sufficient detail relating to the research, and must be organized and presented in a way that facilitates the prospective subject's or LAR's understanding of the reasons why one might or might now want to participate, rather than merely a list of isolated facts.

6. Informed consent may not include any exculpatory language that waives or appears to waive any legal rights of the subject or LAR, or releases or appears to release the institution, sponsor, investigator, or its agents from liability for negligence. Avoid phrases like "you give up all rights", "you will not be compensated" or "I authorize the use" in the consent process.

7. 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.

8. 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.

9. 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. A description of any reasonably foreseeable risks or discomforts to the subject.

g. 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.

h. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

i. 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 reportable 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 reportable disease.

j. Contact information for the research team and 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.

k. 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) (6) for issues related to subject withdrawal.

l. One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or LAR, if this might be a possibility; or
ii) A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for

future research studies.

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 Appropriate.

1. The approximate number of subjects involved in the study

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

3. 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.

4. 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.

5. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.

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

6. 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. 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.

7. For drug, device or nutritional products at UAMS, consent language related to sponsor agreement to pay for subject injury must be negotiated by the Contracts Unit within the Office of Research Regulatory Affairs. The contract and consent clause must be consistent but the consent clause must be written in plain language.

8. If the study involves assigning or randomizing subjects to a study group, the informed consent will include an explanation of the probability of being assigned to one of the groups.

9. 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.

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

11. If subjects may 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.

12. If data or specimens will be stored for future research, the consent must describe:
    a) Where the data/specimens will be stored (e.g. at UAMS, at an offsite facility managed by the study sponsor, etc.) and the steps to be taken to minimize risks to confidentiality;
    b) Why the information is being collected;
    c) A description of the anticipated types of future research;
    d) How long the data or specimens will be stored; and
    e) A description of how subjects may request to withdraw data or specimens.

13. If data or specimens are stored for future research, and such storage is optional, 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 allowed by the protocol. See UAMS IRB Policy 17.11, Stored Data or Tissues.

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

15. If biospecimens are being collected, a statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.

16. For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

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

18. 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.Clinical Trials.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.

19. 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. Broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens will be addressed in a separate policy once institutional processes have been established.

E. 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. When a study is industry sponsored, all informed consent document pages must include the name of the sponsor.

3. All informed consent document pages must include page numbers, date and version number.

4. 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).

F. 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

   For studies that are greater than minimal risk and 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>>>.

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.

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.

4. The document title entered into the IRB e-system during the submission process will be displayed on the approval letter from the IRB. Therefore, it is important to name the document accurately and in sufficient detail.

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 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 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.

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

D. Posting of Clinical Trial Consent forms

1. One IRB-approved consent form used to enroll subjects must be posted by the awardee or the federal department or agency conducting the trial on a publicly available Federal Web site that will be established as a repository for such informed consent forms.
2. If the Federal department or agency supporting or conducting the clinical trial determines certain information should not be made publicly available on a Federal Web site (e.g. confidential commercial information), the Federal department or agency may permit or require redactions to the information posted.
3. The informed consent form must be posted on the Federal Web site after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subjects, as required by the protocol.