

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

POLICY

Except as allowed in IRB Policy 15.3 and applicable federal regulations, no investigator may involve a human being as a subject in research unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative.

This policy's informed consent requirements 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.

Additional requirements for consent and/or assent for specific populations are described in IRB Policy 17.1, Children in Research, and IRB Policy 17.8, Pregnant Women, Human Fetuses, and Neonates Involved in Research. The IRB may also have additional requirements for informed consent elements for prisoners.

DEFINITIONS

- A. **Coercion** is an overt threat of harm 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 that involves an exchange of information. 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 Policies 17.13 Legally Authorized Representatives and 17.1 Research in Children for more information.

- E. **Mandated Reporter** is anyone required to report suspected abuse. Mandated reporters are defined in state law and include: 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 encourage 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.

PROCEDURE

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. For English-speaking potential participants who cannot read or write, whether due to disability or low/no literacy, the informed consent process should include both oral presentations and consent materials understandable to the prospective subject or LAR.
 - a. An unbiased witness must observe the consent process, and a study team member should present the consent materials orally.
 - b. If the participant verbally agrees to participate in the study, the subject should mark an "X" on the consent signature page. For those who physically cannot sign or make a mark, they may indicate their agreement in a predefined manner such as blinking the eyes or raising an arm. Their agreement can be noted on the participant's signature line.
 - c. If the approved consent document does not include a witness signature line, the witness may sign and date anywhere in the signature block and add a notation clarifying that is the witness signature.
 - d. Investigators must be prepared to adapt their consent processes to accommodate potential participants with limited ability to read or write English.
5. For potential participants who are deaf or hard of hearing and able to read and/or write English, informed consent must be obtained using the IRB-approved English consent form and any necessary communication services provided through the UAMS Interpreter Program, including qualified sign

language interpreters, to ensure the consent information is presented in a manner understandable to the participant.

6. 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.
7. 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, organized and presented in a way that facilitates the prospective subject's or LAR's understanding of the reasons why one might or might not want to participate, rather than be merely a list of isolated facts.
8. 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" in the consent process.
9. 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. Documentation may be written or electronic.
10. 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.
11. 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 or electronic 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. The following entities shall be listed, as applicable:
 - The UAMS Institutional Review Board (IRB);
 - The phrase "Other Institutional oversight offices";
 - The Office for Human Research Protections (OHRP), a Federal agency, if applicable;
 - Any funding source or sponsor that may access the records, if applicable;
 - The Food and Drug Administration, if applicable.
- 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 F of this policy for a suggested clause. For studies reviewed by an xIRB, the IRB contact information should include both the reviewing IRB and the UAMS IRB.
- 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 C-22 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 (including electronic forms) 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. A statement that the particular treatment or procedure may involve risks, which are currently unforeseeable, to the subject, or to the embryo or fetus if the subject is or may become pregnant. This language is required for all drug and device studies.
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 F 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.
6. 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.
7. 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.
8. Any additional costs to the participant that may result from participation in the research. See Section F for cost language to be used for UAMS studies when separate language is not negotiated with a study funder or sponsor.
9. For drug, device or nutritional products at UAMS, consent language related to sponsor agreement to pay for subject injury must be negotiated by the legal department. The contract and consent clause must be consistent but the consent clause must be written in plain language.
10. 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.
11. 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.
12. If any information will be collected after the subject's active involvement, the informed consent document must state the duration of the collection.
13. If subjects will be compensated for participation, the consent form must describe the compensation to include the amount and the method given and, if applicable, how it will be pro-rated.
The consent should include the standard State law tax statement, as well as if you need to collect any additional personal information and/or if you will need to share this information with a third party.
14. 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.
15. 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.
16. 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.

17. In studies where ionizing radiation is used, include in lay terms the increase of radiation exposure over the current standard of care.
18. 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.
19. 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).
20. In studies where there is potential for gene linkage, an explanation of risks will be included. See UAMS IRB Policy 19.1, Human Genetics.
21. 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 requires this clause to 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.
22. Clinical trials regulated by the FDA are subject to specific data retention requirements when a participant 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.
23. If any member of the study team is a mandated reporter, and the IRB determines mandated reporting is relevant to the study, given the study's nature and its target population, disclosure of this mandated reporting requirement shall be included in the consent form. See section F.4 of this policy for a suggested clause regarding mandated reporting of suspected abuse.
24. In studies where subjects 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.

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 and are described in the UAMS Administrative Guide policy 2.1.12, *HIPAA Research Policy*. HIPAA required elements may be incorporated into the informed consent document or may be submitted in a separate HIPAA authorization.

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 if/when institutional processes are 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 paper informed consent document pages must include page numbers, date and version number. Electronic consent forms are to include information clearly associating the consent form with the study, and a version number and date.
4. The informed consent document must include lines for the signature and date of consent for:
 - Subject; and/or
 - Parent or LAR signature for studies enrolling children or individuals that are cognitively impaired (See UAMS IRB Policies 17.1, Children in Research; 17.2, Persons with Diminished Functional Capacity; and 17.13, Legally Authorized Representatives. NOTE: For studies subject to Federal regulations, both parents' signatures are required for studies determined to be pediatric risk category 3 unless one parent is deceased, unknown, or not available.; and
 - Person obtaining consent (POC).
 - If a parent or LAR is signing on behalf of the participant, the participant's name should be documented on the consent form.

F. **Suggested Clauses.** The following are suggested examples of language that may be considered acceptable. Please also see the IRB consent template found on the IRB's website for additional suggested language. Any statement used must be applicable to the study and consistent with any legal, sponsor or funding agreement.

1. Injury Clause

For studies that are greater than minimal risk and do not have an Industry Sponsor: If you get hurt or sick when you are here for the study, we will help you get the care you need. This may include first aid, emergency care, and any follow-up care you need.

If you are not here and get hurt or sick, and you think it is because of the study, do these things: call your doctor – or if an emergency, call 911; give your doctor or ER staff: the name of this study (insert name of study, the name of the lead researcher for this study (insert researcher name), a copy of this form if you have it; call (insert the name and 24 hour phone number of a medical member of the research team, if available).

Also, choose from these options:

This treatment will be billed to you or your insurance company. No other form of payment is available.

OR

Insert details of agreement negotiated with sponsor.

2. Contact Clause

You can also call the office at UAMS that supervises research if you cannot reach the study team, have questions about your rights as a research participant, or want to speak to someone not directly involved with this study. To do so, call the UAMS Institutional Review Board at 501-686-5667 and leave a message or email irb@uams.edu. Your message will be returned during normal work hours.

3. Cost Clauses-required language at UAMS, as applicable (Please check with ACRI for cost language to be used for studies where UAMS patients will not be enrolled.)

a. For studies that include both research services and Standard of Care services:

This research study includes both research items and services and standard of care items and services. Research items and services include study drugs, tests, or medical procedures done only to collect information for the study and are not tests or medical procedures you would normally have for the standard care for your disease or condition. There will not be an expected cost to you for the research items and services that are paid for by the study or by the research sponsor.

Even if the study or the research sponsor pays for the research items and services, any normal medication, tests, and medical procedures used for your standard of care while you are in the study (meaning those items and services that you would normally have even if you were not in the study) may be billed to you and/or your insurance company. You will be responsible for the co-pay, deductibles or other costs for these items and services. Some insurance companies will not cover your standard of care items and services when you participate in a research study or if you are participating in a research study outside of your insurance network. You can check with your insurance company before you join this study. The study team can help you contact your insurance company with questions about what may be covered by your insurance under this study. If your insurance company does not cover the standard of care items and services under this study, these costs may be billed to you individually. Note: If there are costs that may reasonably occur, add a statement reflecting those costs, e.g. parking costs, costs or medical supplies, etc.

b. For Studies that do not involve drugs or medical procedures or hospital services and are standard of care only:

This study is not expected to cost you anything for any research items or services. You will be responsible for the standard of care medication, tests, and medical procedures (if any) used to treat your disease or condition. This will include any co-pay, deductibles or other costs that would normally be your responsibility. Joining a research study may result in additional costs to you, even if the study does not involve any research items or services. You can check with your insurance company before you join the study. The study team can help you contact your insurance company with questions about what may be covered by your insurance under this study.

c. For Studies that do not involve any disease or condition:

This study is not expected to cost you anything for any research items or services.

4. Suggested Mandated Reporter Language for Suspected Abuse or Neglect

By law, the study team must release certain information to the appropriate authorities during the study if the study team suspects abuse or neglect involving children or endangered or impaired adults.

G. Investigator Responsibilities

1. At the time of initial submission, all informed consent documents (including assent documents, supplementary materials, or scripts as applicable) to be used are to be included in the submission. Materials 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 are to describe the entire proposed consent process in the original submission. See UAMS IRB Policy 15.5, The Informed Consent Process.
3. After initial submission:
 - a. In response to contingencies or after approval, submit any proposed changes to the informed consent document with changes highlighted and/or a tracked version of the informed consent document as a "modification". The IRB will administratively reject any modifications to documents that are submitted without a tracked change version.
 - b. Investigators must not use any consent form version prior to its approval by the IRB.
 - c. When the informed consent document is modified, the date and version number must be updated from its previously approved date and version number.
 - d. Enter a complete document title, to include the date and version number, into the IRB e-system, as this title will be displayed on the IRB approval letter.
 - e. When the IRB approves amendments to a previously approved consent form, the previous version 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.
 - f. The IRB does not stamp consent forms.

H. IRB Responsibilities

1. Review consent process
 - a. Confirm process allows sufficient opportunity to consider participation and the possibility of coercion or undue influence is minimized.
 - b. Confirm process includes all elements necessary to protect the safety and welfare of those being approached for participation.
2. Review consent form document and related materials
 - a. Confirm all required elements are addressed as applicable to the research.
 - b. Confirm consistency with all other submitted forms such as protocol, advertisement, or investigator's brochure.
3. Request revisions as necessary to ensure that proposed activities are clear and the intended subjects can make a fully informed decision.

REFERENCES

45 CFR 46.116 and 117

21 CFR 50 Subpart B

2023 FDA Guidance *Informed Consent. Guidance for IRBs, Clinical Investigators, and Sponsors.*

OHRP Informed Consent FAQs

FDA Guidance titled *Data Retention When Subjects Withdraw from FDA-Regulated Clinical Trials*

AAHRPP Elements I.4.A; I.4.B; I.8.A; II.3.C; II.3.F; III.1.E; III.1.F; III.1.G

AAHRPP Tip Sheet: Following the Guideline of the International Conference on Harmonisation – Good Clinical Practice (E6)