Pre-Approval Informed Consent Document Review

This form is designed for use before submitting an informed consent document to the IRB for review. It is based on UAMS IRB Policy 15.1, which in turn reflects federal and institutional requirements regarding informed consent processes.

Note: The UAMS IRB is to make the final determination regarding whether an informed consent document meets all requirements. Researchers are strongly encouraged to review UAMS IRB Policy 15.1 each time they prepare a consent form.

Required Statements				
15.1 Policy Reference	**Required Elements**	**Present**		**Comments**
		Y	N	
B.1	A statement that the study involves research.			
B.2	An explanation of the purposes of the research.			
B.3	Expected duration of the subject's participation in the research.			
B.4	A description of the procedures to be followed.			
B.5	Identification of any experimental procedures.			
B.6	Number of subjects to be studied.			
B.7	Age range of subjects.			
B.8	Description of any reasonably foreseeable risks and discomforts to the subject.			
B.9	Description of benefits, if any to the subject or others that may reasonably be expected from the research. (Note: Benefits refer to health or well-being, not payment for participation.)			
B.10	Disclosure of appropriate alternative procedures or treatments, if any, that might be advantageous to the subject.			
B.11	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.			
B.12	A statement describing the extent, if any, to which confidentiality of records and Protected Health Information (PHI) identifying the subject will be maintained, noting as applicable that certain entities may inspect the records (see B.16, a-e, below, for specifics).			
B.13	Contact information for the research team and the IRB. (Note: IRB may require a 24-hour contact number for some studies, such as those in which subjects may need to reach a physician due to a medical problem.) (See Section IV. B. 2 in the policy for suggested language.)			
B.14	Statement that the participation is voluntary;			
B.14	Statement that that refusal to participate involves no penalty or loss of benefits to which the subject is otherwise entitled.			
B.14	Statement that no rights have been waived.			

15.1 Policy Reference	Required Elements	Present		Comments
		Y	N	
B.14	Statement that the subject may discontinue participation at any time without penalty or loss of benefit to which the subject is otherwise entitled.			
B.15	Subject or LAR to receive a copy of the signed and dated consent form prior to participation			
B.16.a-e	The following are to be listed as entities that may review study records: The UAMS IRB; other institutional oversight offices; the Office for Human Research Protections; any funding source or sponsor who may access the records; the Food and Drug Administration, if the study is subject to FDA oversight.			
B.16.f	If any member of the study team is a mandated reporter, an explanation of this limit to confidentiality must be present. (See Section IV. B. 4 in the policy for suggested language.)			
B.16.g	In studies where subject will be tested for HIV or other communicable diseases, a statement that the subject and Department of Health will be notified of a positive test result and that subject will be given information about counseling options in such a situation.			
When applicable, check that the following elements are present:				
C.1	Drug or device studies: Include a statement that a 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.			
C.2	Greater than minimal risk study: An explanation as to whether or not any compensation and/or medical treatment is available for injury (see Section IV. B. 1 in the policy for suggested language.)			
C.3	If Protected Health Information (PHI) is being collected, unless specifically waived by the IRB: A HIPAA Disclosure Authorization is required as part of the informed consent document or as a separate document			
C.4	If 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			
C.5	When there are anticipated consequences to withdrawing from a study that may put the subject at greater risk: The specific consequences of the subject's decision to withdraw from the research and procedures for the orderly termination of participation by the subject.			

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		Y	N	
C.6	When additional costs to the subject are anticipated as a result from participation in the research: A description of these additional costs (See Section IV. B. 3 in the policy for suggested language.)			
C.7	If the study is being conducted at multiple sites: The approximate number of subjects involved in the study locally and nationally			
C.8	If the study involves the use of a placebo: A statement describing the use of a placebo and the probability of being assigned to the placebo arm.			
C.9	When test articles (i.e., drugs, devices) are being used in the project: 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.			
C.10	If any information will be collected after the subject's active involvement: The duration of the collection.			
C.11	If subjects are to be contacted for future research: 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			
C.12.a-e	If data or specimens will be stored for future research: A description of how the data or specimens are to be stored; why the information is being collected; the protocol must describe in detail the types of future research that are anticipated; how long the data or specimens will be stored; a description of how the subject may request to withdraw data or specimens.			
C.13	If data or specimens are stored for future research: A yes/no option 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.			
C.14	In studies where ionizing radiation is used: A description in lay terms the increase of radiation exposure over the current standard of care.			
C.15	In studies where there is potential for gene linkage, an explanation of risks including social and financial will be included			

15.1 Policy Reference	Required Elements	Present		Comments
		Y	N	
Format Requirements for Written Consent Forms				
D.1	Protocol title on each page. If the full title is more than 2 lines long, a shorter protocol identifier, such as the IRB number, may be used on each page after the first page, which is to include the full title.			
D.2	Name of sponsor on each page			
D.3	Name of institutions where conducted on each page			
D.4	Page number, date, and version number on each page			
D.5	Lines for signature and date of: subject and/or parent or LAR (for studies enrolling children or people with cognitive impairments); person obtaining consent			
D.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 IV. B. 5 in the policy for suggested language.)			