Required Statements				
15.1 Policy Reference	**Required Elements**	**Present**		**Comments**
		Y	**N**	
B.1.a	A statement that the study involves research.	Y ○	N ○	
B.1.b	An explanation of the purpose of the research.	Y ○	N ○	
B.1.c	The expected duration of the subject's participation in the research.	Y ○	N ○	
B.1.d	A description of the procedures to be followed.	Y ○	N ○	
B.1.e	Identification of any experimental procedures.	Y ○	N ○	
B.1.f	A description of any reasonably foreseeable risks or discomforts to the subject.	Y ○	N ○	
B.1.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.	Y ○	N ○	
B.1.h	A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.	Y ○	N ○	
B.1.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:			
B.1.i (i)	• The UAMS Institutional Review Board (IRB)	Y ○	N ○	
B.1.i (ii)	• The phrase "other institutional oversight offices"	Y ○	N ○	
B.1.i. (iii)	• The Office for Human Research Protections (OHRP), a Federal agency, if applicable	Y ○	N ○	

B.1.i (iv)	• Any funding source or sponsor that may access the records, if applicable	Y ◯	N ◯	
B.1.i (v)	• The Food and Drug Administration, if applicable;	Y ◯	N ◯	
B.1.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.	Y ◯	N ◯	
B.1.l	One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:			
B.1.l (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	Y ◯	N ◯	
B.1.l (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.	Y ◯	N ◯	
B.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.	Y ◯	N ◯	

Additional Elements, When Applicable				
15.1 Policy Reference	**Required Element, When Applicable**	**Present**		**Comments**
		Y	**N**	
C.1	The approximate number of subjects involved in the study.	Y ○	N ○	
C.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	Y ○	N ○	
C.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.	Y ○	N ○	
C.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.	Y ○	N ○	
C.5	A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.	Y ○	N ○	
C.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.	Y ○	N ○	
C.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.	Y ○	N ○	

C.8	When additional costs to the subject are anticipated as a result from participation in the research, the informed consent will describe these additional costs.	Y ◯	N ◯	
C.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.	Y ◯	N ◯	
C.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.	Y ◯	N ◯	
C.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.	Y ◯	N ◯	
C.12	If any information will be collected after the subject's active involvement, the informed consent document must state the duration of the collection.	Y ◯	N ◯	
C.13	If subjects will be compensated for participation, the consent form must describe the compensation and, if applicable, how it will be pro-rated.	Y ◯	N ◯	

C.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.	Y ○	N ○	
C.15	If data or specimens will be stored for future research, the consent must describe:			
C.15.a	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;	Y ○	N ○	
C.15.b	b) Why the information is being collected;	Y ○	N ○	
C.15.c	c) A description of the anticipated types of future research;	Y ○	N ○	
C.15.d	d) How long the data or specimens will be stored; and	Y ○	N ○	
C.15.e	e) A description of how subjects may request to withdraw data or specimens.	Y ○	N ○	
C.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.	Y ○	N ○	
C.17	In studies where ionizing radiation is used, include in lay terms the increase of radiation exposure over the current standard of care.	Y ○	N ○	

C.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.	Y ○	N ○	
C.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).	Y ○	N ○	
C.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	Y ○	N ○	
C.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.	Y ○	N ○	
C.22	For clinical trials regulated by the FDA, there are specific data retention requirements when a subject withdraws from the study.			

C.22.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.	Y ○	N ○	
C.22.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	Y ○	N ○	
C.22.b (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	Y ○	N ○	
C.22.b (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.	Y ○	N ○	
C.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.	Y ○	N ○	

C.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	Y ◯	N ◯	
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.	Y ◯	N ◯	

Format Requirements for Consent Form				
15.1 Policy Reference	**Element**	**Present**		**Comments**
		Y	**N**	
E.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.	Y ◯	N ◯	
E.2	When a study is industry sponsored, all informed consent document pages must include the name of the sponsor.	Y ◯	N ◯	

E.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.	Y ○	N ○	
E.4	The informed consent document must include lines for the signature and date of consent for:			
E.4.a	• Subject and/or	Y ○	N ○	
E.4.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.)	Y ○	N ○	
E.4.c	• Person obtaining consent (POC)	Y ○	N ○	