

**§46.116 - Informed Consent Checklist - Basic and Additional Elements**

<b>Required Elements</b>	
	A statement that the study involves research
	An explanation of the purposes of the research
	The expected duration of the participant's participation
	A description of the procedures to be followed
	Identification of any procedures that are experimental
	A description of any reasonably foreseeable risks or discomforts to the participant
	A description of any benefits to the participant or to others which may reasonably be expected from the research
	A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant
	A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained and the required HIPAA authorization language
	For research involving more than minimal risk, an explanation as to whether any compensation and/or any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained
	An explanation of whom to contact for answers to pertinent questions about the research and research participants' rights, and whom to contact in the event of a research-related injury to the participant
<b>Additional elements, as appropriate</b>	

	A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and the participant may discontinue participation at any time without penalty or loss of benefits, to which the participant is otherwise entitled
	A statement that the particular treatment or procedure may involve risks to the participant (or to the embryo or fetus, if the participant is or may become pregnant), which are currently unforeseeable
	Anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's consent
	Any additional costs to the participant that may result from participation in the research
	The consequences of a participant's decision to withdraw from the research and procedures for orderly termination of participation by the participant
	A statement that significant new findings developed during the course of the research, that may relate to the participant's willingness to continue participation, will be provided to the participant
	The approximate number of participants involved in the study