IRB #: _____ ICF Name:_____ Version:_____

Basic Elements of Informed Consent - Per 21 CFR 50.25		
	Element	Comments
_____	1a. A statement that the study involves research	
_____	1b. An explanation of the purposes of the research	
_____	1c. The expected duration of the subject's participation	
_____	1d. A description of the procedures to be followed	
_____	1e. Identification of any procedures which are experimental	
_____	2. A description of any reasonably foreseeable risks or discomforts to subject	
_____	3. A description of any benefits to the subject or to others which may reasonably be expected from the research	
_____	4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject	
_____	5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the FDA may inspect the records	
_____	6. For research involving more than minimal risk, an explanation as to whether any compensation, and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained	
_____	7. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related emergency to the subject	
_____	8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty of loss or benefits, to which the subject is otherwise entitled	

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Additional Elements As Appropriate		
_____	1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable	
_____	2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent	
_____	3. Any additional costs to the subject that may result from participation in the research	
_____	4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject	
_____	5. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participating will be provided to the subject	
_____	6. The approximate number of subjects involved in the study	
	7. For applicable clinical trials, the following statement should be included verbatim: "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."	