IRB#: _____ Principal Investigator: _____

Meeting Date: _____ Reviewer: _____

Federal regulations require all of the Basic Elements of Informed Consent to be present in Informed Consent forms. Additional elements must also be present when appropriate. INSTRUCTIONS: please verify that the Basic Elements and any appropriate Additional Elements are present in the attached Informed Consent Form.

BASIC ELEMENTS OF INFORMED CONSENT (REQUIRED)	
☐	A statement that the study involves research
☐	An explanation of the purposes of the research
☐	The expected duration of the subject's participation
☐	A description of the procedures to be followed
☐	Identification of any procedures which are experimental
☐	A description of any reasonably foreseeable risks or discomforts to the subject
☐	A description of any benefits to the subject 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 subject
☐	A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
☐	For FDA-regulated research, a statement that notes the possibility that the Food and Drug Administration may inspect the records
☐	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
☐	An explanation of whom to contact for answers to pertinent questions about the research
☐	An explanation of whom to contact for answers to pertinent questions about research subjects' rights

☐	An explanation of whom to contact in the event of a research-related injury to the subject
☐	A statement that participation is voluntary
☐	A statement that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled
☐	A statement that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled
ADDITIONAL ELEMENTS OF INFORMED CONSENT, WHEN APPROPRIATE	
☐	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
☐	Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent
☐	Any additional costs to the subject that may result from participation in the research
☐	The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject
☐	A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject
☐	The approximate number of subjects involved in the study
FOR VA RESEARCH	
☐	For VA research, a statement that in the event of a research-related injury, the VA has to provide necessary medical treatment to a subject injured by participation.
☐	For VA research, a statement that a veteran-subject does not have to pay for care received as a subject in a VA research project except in accordance with federal law and that certain veterans have co-payments for medical care and services provided at the VA.

Consent Documentation: Long Form	
☐	Signature and date line for person obtaining consent and authorization
☐	Signature and date line for person consenting and authorizing
☐	For VA research, signature and date line for witness

Consent Documentation: Short Form	
☐	UF Short Form Template submitted
☐	Written summary submitted (normally long form ICF)
☐	Signature and date line for person obtaining consent (Summary only)
☐	Signature and date line for person consenting (Short Form only)
☐	Signature and date line for witness (Short Form and Summary)

Notes:

Signature: _____ Date: _____