

**Federally Required Elements - Review consent for the following criteria, as applicable**

A statement that the study involves research
An explanation of the purpose of the research
Safety and efficacy define as a purpose (required by the FDA)
The expected duration of participation (include active & follow-up)
Number of visits
A description of the procedures, including: Procedures at each visit matches protocol Procedures clearly described (in lay language) Laboratory adequately described Experimental procedures defined
The following described: Reasonably foreseeable risks/discomforts of the study article Reasonably foreseeable risks/discomforts of the procedures Reasonably expected benefits to subjects/others
Appropriate alternative treatments defined
Confidentiality statement, including: Sponsor / funder and/or CRO access to records FDA access IRB access Other (e.g. interview service)
Injury statement (if more than minimal risk), including: Description of available compensation Description of available medical treatments What treatment consists of, if applicable Who to contact for a research-related injury
Participation statement, including: Participation is voluntary Refusal to participate will involve no penalty or loss of benefits Subject may stop participation at any time – without penalty / loss of benefits
Who to contact for information about research
Contact information for questions about research subject's rights (IRRC Chair & contact info)
24-hour emergency contact number

**Additional Elements, as Appropriate:**

Research may involve unforeseeable risks to the subject
Risks to pregnant women / embryo / fetus or nursing baby
Costs / additional costs to subject from participation
Circumstances under which the subject's participation may be terminated without regard to the subject's consent
Payment for participation described (pro-rated, reasonable)
Procedures for orderly termination of participation
Medical / scientific terminology defined
A statement that significant findings during the course of research that might affect the subject's willingness to continue participation will be provided to the subject
The approximate number of subjects in the study
Legal guardian consent, if needed / Assent consent, if appropriate
Institutional/Organization Required Elements ( <i>see IRRC's Informed Consent Guidelines and Basic Elements and Consent Template</i> )

**COMMENTS:**