Continuing Review Checklist (Board Member)

Recommendation:

	Name
○	Continuing Review - Approve
○	Continuing Review - Provisional Approval
○	Continuing Review - Disapprove
○	Continuing Review - Table
○	Continuing Review - Postpone
	Clear

Reviewer Recommended Continuing Review Frequency:

	Review Interval	Description
○		
○	12 Months	Other human research studies that help define potential subject risk have been conducted. The study presents no special protocol, ethical or safety concerns that would require more frequent review
○	6 Months	Other human research studies that help define potential subject risks are limited and/or the study presents special protocol, ethical or safety concerns that require more frequent review.
○	Other:	Other human research studies that help define potential subject risks are limited or unavailable and/or the study presents special protocol, ethical or safety concerns that require more frequent review.
	Clear	

If you selected **Other** - enter your recommended review frequency:

Protocol and Continuing Review Questions and Issues:

Consent Form Review

	Institutional header or letterhead
	Study Title
	Use of lay language, defined as language understandable to the people being asked to participate (usually 6th to 8th grade). The use of second person (e.g., "You will receive…") is preferred; the use the first person (e.g., "I understand that...") is discouraged. Individual involved in the study should be referred to as subjects or participants not patients. The informed consent should state facts rather than require attestations on the part of the subject.
	A statement that says a research study is being performed.
	An explanation of the purpose of the study.
	The expected duration of the subject's participation.
	A description of the procedures to be followed
	Identification of any procedures or interventions that 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 that may reasonably be expected from the research.
	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. Include all entities that might review the records of the subject, such as FDA, the sponsor, DHHS, and OHRP as appropriate.
	A statement of any additional costs, if any, to subjects that may result from participation in the research and an explanation of those costs.
	An explanation as to whether any compensation is available to subjects for participation
	An explanation of whom to contact, with phone number, for answers to pertinent questions about the research and whom to contact in the event of a research-related injury.
	A statement that the Chairman of the Institutional Review Board should be contacted for answers to questions about research subjects' rights.
	A statement that participation is voluntary, refusal to participate will not involve penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled.
	If 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 and/or a pregnancy clause (Use of standard pregnancy clause is preferred).
	Appropriate liability clause containing 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 (standard language is preferred).

	A line for the subject’s signature and date and time.
	A line for the signature of the person obtaining consent and the date and time.

The Following additional elements should be included as appropriate

	Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.
	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 at this site and/or at all sites.
	If appropriate, a section containing standard HIPAA Authorization Language.

The following determination must be met in accordance with OHRP Guidelines:

	The number of subjects accrued
	A summary of adverse events and any unanticipated problems involving risks to subjects or others and any withdrawal of subjects from the research or complaints about the research since the last IRB review
	A summary of any relevant recent literature, interim findings, and amendments or modifications to the research since the last review
	Any relevant multi-center trial reports
	Any other relevant information, especially information about risks associated with the research
	A copy of the current informed consent document and any newly proposed consent document
	The currently approved or proposed consent document is still accurate and complete
	Any significant new findings that may relate to the subject's willingness to continue participation are provided to the subject in accordance with HHS regulations at 45 CFR 46.116(b)(5).

Comments: