THE GEORGE WASHINGTON UNIVERSITY
WASHINGTON, DC

CHECKLIST: Criteria for Approval

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This checklist is used to determine whether New and Continuing Review <Human Research> can be approved. This checklist must be complete and maintained with the study file.

Protocol #: PI: Reviewer:

	1 Criteria for Approval of Research: (All must be met)
☐	Risks to subjects are minimized by using procedures, which are consistent with sound research design and which do not unnecessarily expose subjects to risk.
☐	Risks to subjects are minimized whenever appropriate by using procedures already being performed on the subjects for other purposes.
☐	Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.
☐	Selection of subjects is equitable. (Consider the purpose and setting of the research, involvement of vulnerable subjects, selection criteria, and recruitment, enrollment, and payment procedures.)
☐	The research is no more than minimal risk or the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
☐	There are adequate provisions to protect the privacy of subjects.
☐	There are adequate provisions to maintain the confidentiality of data.
☐	If necessary, additional safeguards have been included in the study to protect the rights and welfare of subjects vulnerable to coercion or undue influence.
☐	The informed consent process will be ☐ Standard ☐ Waiver or alteration of consent process (HRP-300) ☐ N/A; Permanently closed to enrollment
☐	The informed consent will be documented ☐ Standard Long Form ☐ Short Form ☐ Waiver of documentation (HRP-303)

Complete remaining items when applicable

2 Consent Process: Consider the following

-Circumstances provide the prospective subject or LAR sufficient opportunity to consider whether or not to participate.

-Consent will be obtained only under circumstances that minimize the possibility of coercion or undue influence.

-Information will be in language understandable to the subject or LAR.

-There is no exculpatory language

-The written consent document is accurate, complete, and consistent with the protocol.

-The subject or LAR will sign and date the consent document.

-The person obtaining consent will sign and date the consent document.

-A copy of the signed and dated consent document will be given to the person signing the document.

3 Elements of Consent Disclosure (All required and all appropriate additional elements must be disclosed and documented)

Required:

☐ Study involves research
☐ Purposes of the research.
☐ Expected duration of the subject's participation.
☐ Procedures to be followed.
☐ Identification of any procedures which are experimental.

- ☐ Any reasonably foreseeable risks or discomforts
- ☐ Any benefits to the subject or to others
- ☐ Any appropriate alternative procedures or courses of treatment that might be advantageous
- ☐ The extent, if any, to which confidentiality of records identifying the subject will be maintained.
- ☐ How to contact the research team for: questions, concerns, complaints about the research
- ☐ How to contact someone independent of the research team for: questions, concerns, complaints about the research, subjects' rights
- ☐ Whom to contact in the event of a research-related injury to the subject.
- ☐ Participation is voluntary.
- ☐ Refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled.
- ☐ Subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Required for research involving more than <Minimal Risk> : ☐ n/a

- ☐ Whether any compensation is available if injury occurs and, if so, what they consist of, or where further information may be obtained
- ☐ Whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained

Required for International Clinical Trials subject to ICH-GCP: ☐ n/a

- ☐ Description of IRB and its role
- ☐ The probability for random assignment to each treatment.
- ☐ Any subject responsibilities
- ☐ Reasonably foreseeable risks or inconveniences to an embryo, fetus, or nursing infant.
- ☐ The important potential benefits and risks of the alternative procedures or courses of treatment that may be available to the subject.
- ☐ When there is no intended clinical benefit to the subject, a statement to this effect.
- ☐ Monitors, auditors, IRB, and regulatory authorities will be granted direct access to the subject's original medical records for verification of clinical trial procedures and data, without violating the confidentiality of the subject, to the extent permitted by applicable laws and regulations and that, by signing the consent document, the subject or LAR is authorizing such access.
- ☐ If the results of the trial are published, the subject's identity will remain confidential.

When appropriate: ☐ n/a

- ☐ A statement that the particular treatment or procedure may involve risks to the subject, which are currently unforeseeable.
- ☐ A statement that if the subject is or becomes pregnant, the particular treatment or procedure may involve risks to the embryo or fetus, 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.
- ☐ 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.
☐ The amount and schedule of all payments.

Select one:
☐ Approved
☐ Approved with Stipulations For expedited studies: ☐ Major (to return to designee) ☐ Minor (OHR staff can sign off on)
☐ Deferred (for full board studies only)
☐ Disapproved (for full board studies only)

The Review Period is:
☐ One year
☐ Less than one year, the recommended interval is: _____
☐ Following the enrollment of a specified number of subjects:_____
☐ Other: _____

_____ _____
Reviewer Signature Date

Notes/Comments/Stipulations (or attach Word document):