CRITERIA FOR IRB APPROVAL:
Reviewer Checklist

Primary Reviewer: _____ **IRB #:** _____ **PI:** _____
Title of Project: _____

Criteria for Approval

1. o 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 (achieved from research interventions).

o Risks to subjects are minimized by using procedures that are consistent with sound research design and which do not unnecessarily expose subjects to risk.

o When possible, risks to subjects are minimized by using procedures already being performed on the participants for diagnostic or treatment purposes.

o The research proposal addresses the likelihood of harm and magnitude of harm (encompassing potential physical, psychological, social, and/or economic risks to the subjects).

o The research is likely to achieve its proposed aims.

o The importance of the knowledge expected to result is clear.

2. o Subject selection is equitable (in relation to:)

o Objectives of the research;

o The setting in which the research is to take place;

o The special problems of research involving special populations;

o Recruitment methods

o Inclusion/exclusion criteria

* If N/A for any of #3 below, "Form E" (a request for waiver/alteration of the informed consent process) must be completed by the PI and the criteria met.

3. o Adequate provisions are in place for seeking informed consent from each prospective subject ("subject), or the prospective subject's legally authorized representative ("subject's LAR"). N/A* ☐

o The proposed consent process provides the subject/subject's LAR with sufficient opportunity to consider whether to participate. N/A* ☐

o The proposed consent process minimizes the possibility of coercion or undue influence. N/A* ☐

o The information to be relayed during the consent process is in a language understandable to the subject/subject's LAR. N/A* ☐

o The information being communicated during the consent process does not include exculpatory language through which the subject/subject's LAR waives or appears to waive any of the subject's legal rights. N/A* ☐

o The information being communicated during the consent process does not include exculpatory language through which the subject/subject's LAR releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence. N/A* ☐

** If N/A for #4 below, "Form F" (a request for waiver/alteration of documentation of informed consent) must be completed by the PI and the criteria met.

4. o The provisions for documenting informed consent/assent are appropriate. N/A** ☐

5. o The research proposal describes adequate provisions for protecting the privacy of subjects.

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⚑ 6.	○	The research proposal describes adequate provisions for maintaining confidentiality of the data.	
7.	○	The credentials and/or described qualifications of the research staff/ investigators are representative of the appropriate expertise needed to perform their responsibilities in the study.	
8.	○	The research setting (e.g., location of research, facilities, drug/device controls & accounting) supports adequate safeguards for protection of human subjects.	
⚑ 9.	○	Additional safeguards have been included in the study to protect the rights and welfare of subjects vulnerable to coercion or undue influence (e.g., children, prisoners, adults with impaired consent capacity).	N/A ☐
⚑ 10.	○	If the study is greater than minimal risk, clinical research, or is a NIH funded/FDA regulated clinical trial, adequate provisions are in place for monitoring the data collected to insure safety of subject.	N/A ☐
11.	○	If the proposal is a multicenter study in which the lead PI or UK is the coordinating institution, the plans for communication among sites are adequate to protect the participant (e.g., consider communication of protocol modifications, data and safety monitoring reports, and unanticipated problems).	N/A ☐
12.	○	Proposed payment to participants and/or cost to subjects for participation is appropriate.	N/A ☐
13.	○	If PI/research staff conflict of interest is identified, the conflict of interest in relation to human research protections is appropriately minimized or managed (e.g., limit who obtains informed consent; add disclosure(s) in informed consent process; University or VA COI management plan appropriate, etc...).	N/A ☐
14.	○	Review and approval by other committees/units, as applicable for medical research (e.g., RDRC, IBC, RSC, MCC PRC, VA R&DC), has been conducted.	N/A ☐
15.	○	Approval from external institutions has been obtained from an authorized official.	N/A ☐
16.	○	**A signature assurance sheet signed by the Principal Investigator and his/her Department Chairperson (or appropriate equivalent) is on file.**	

⚑ Denotes regulatory criteria