

## Reviewer Criteria for IRB Approval

The IRB agreed with the PI's written informed consent document and confirms that the form meets general regulatory requirements and includes required elements and applicable additional elements of informed consent.

[See "[Federally Required Elements of Informed Consent](#)" to review the required and additional elements of informed consent which applies to, for example, consent form, cover letter and/or phone script when used alone or in combination with a debriefing and permission to use data form when applicable.]

Yes  No

# IRB Review\*

Protocol Review

## Full Initial Review - Primary Reviewer Determinations

Review Details

Other Reviewers

Approval Checklist

Attachment(s)

Finish

- > Refer to this [Criteria for IRB Approval Checklist](#) as needed.
- > Refer to this [Elements of Informed Consent Checklist](#) as needed.
- > Refer to this [Determinations Guidance List](#) for info about what each determination means.

### Select Your Determination

- Approve
- Minor Revision
- Eligible for Expedited Process
- Major Revision
- Major Revision and invite PI to meeting
- Disapprove
- Withdrawn
- Serious/Continuing Non-compliance or Suspension/Termination.

### Comments / Requested Revisions

- I am not aware of any *conflict of interest* that would prohibit me from reviewing and/or making a determination about the IRB application materials.

Save

Complete Review

**CRITERIA FOR IRB APPROVAL:  
Reviewer Checklist**

1. ● 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).
- 
- Risks to subjects are minimized by using procedures that are consistent with sound research design and which do not unnecessarily expose subjects to risk.
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- When possible, risks to subjects are minimized by using procedures already being performed on the participants for diagnostic or treatment purposes.
- 
- The research proposal addresses the likelihood of harm and magnitude of harm (encompassing potential physical, psychological, social, and/or economic risks to the subjects).
- 
- The research is likely to achieve its proposed aims.
- 
- The importance of the knowledge expected to result is clear.

2. ● Subject selection is equitable (in relation to:)
- 
- Objectives of the research;
- 
- The setting in which the research is to take place;
- 
- The special problems of research involving special populations;
- 
- Recruitment methods
- 
- Inclusion/exclusion criteria

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

3. ● 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\* ■
- 
- The proposed consent process provides the subject/subject's LAR with sufficient opportunity to consider whether to participate. N/A\* ■
- 
- The proposed consent process minimizes the possibility of coercion or undue influence. N/A\* ■
- 
- The information to be relayed during the consent process is in a language understandable to the subject/subject's LAR. N/A\* ■
- 
- 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\* ■
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- 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, a request for waiver/alteration of documentation of informed consent must be completed by the PI and the criteria met.

4. The provisions for documenting informed consent/assent are appropriate. N/A\*\* ■
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5. The research proposal describes adequate provisions for protecting the privacy of subjects.
- 
6. The research proposal describes adequate provisions for maintaining confidentiality of the data.
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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.

**CRITERIA FOR IRB APPROVAL:  
Reviewer Checklist**

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, economically or educationally disadvantaged persons, etc.).	N/A	■
 10.	For greater than minimal risk research or NIH funded/FDA regulated clinical investigations, adequate provisions are in place for monitoring the data collected to ensure safety of subjects. Where applicable, the following may be considered in evaluating whether the data and safety monitoring is adequate: <ul style="list-style-type: none"> <li>• <i>Is the proposed plan commensurate with the nature, size, and complexity of the research as well as the degree of risk involved?</i></li> <li>• <i>Does proposal include procedures for promptly detecting harm and mitigating potential injuries?</i></li> <li>• <i>What safety information will be collected? How will safety information be collected (e.g. at study visits, by monthly telephone calls, etc.)?</i></li> <li>• <i>What data will be monitored and who will monitor the data?</i></li> <li>• <i>What is the frequency of review or analysis of cumulative safety data to determine whether harm is occurring?</i></li> <li>• <i>Are there procedures for ensuring appropriate reporting of findings to the IRB?</i></li> <li>• <i>Are there any conditions or criteria that could trigger an immediate suspension/ termination of the research and if so are their procedures for reporting the suspension/ termination to the appropriate entities?</i></li> <li>• <i>Is establishment of an independent individual or data and safety monitoring board (DSMB) warranted? If so, is there a plan for providing DSMB reports, (routine and urgent), to the IRB?</i></li> </ul>	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 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), has been conducted.	N/A	■
15.	Approval from external institutions has been obtained from an authorized official.	N/A	■
16.	<b>A signature assurance statement signed by the Principal Investigator and his/her Department Chairperson (or appropriate equivalent) is on file.</b>		

1/14/19

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 Denotes regulatory criteria