MUSC
Medical University of South Carolina

# IRB Reviewer Checklist
# Continuing Review
# Full Board and Expedited Protocols

| **Reviewer:** | **PRO/HR #:** | **PI Name:** | |
|---|---|---|---|
| **Regulatory Criteria for Approval**<br>**In order to approve research covered by this policy, the IRB shall determine that all of the following requirements are satisfied:** | | | |
| Risks to participants are minimized by using procedures which are consistent with sound research design and do not unnecessarily expose participants to risk. | ◯ Yes | ◯ No | |
| Risks to participants are minimized whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes. | ◯ Yes | ◯ No | |
| Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result. | ◯ Yes | ◯ No | |
| Selection of participants is equitable taking into account the purposes of the research, the setting in which the research will be conducted, the special problems of research involving vulnerable populations, the selection criteria and the recruitment procedures. | ◯ Yes | ◯ No | |
| Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by the regulations. | ◯ Yes | ◯ No | ◯ NA |
| When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of participants. | ◯ Yes | ◯ No | ◯ NA |
| When appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data. | ◯ Yes | ◯ No | ◯ NA |
| When some or all of the participants are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these participants. | ◯ Yes | ◯ No | ◯ NA |
| **Reviewer: if you answered NO to any of the above, the continuing review cannot be approved. Notify the HRPP.** | | | |
| **Additional Considerations for Continuing Review** | | | |
| **1.** Does the protocol need verification from sources other than the investigators that no material changes have occurred since the last review?<br>Comment: | ◯ Yes | ◯ No | |
| 2. Are consent template(s) incorrect or incomplete?<br>Comment: | ◯ Yes | ◯ No | |
| 3. Are there significant new findings concerning this research that might affect the willingness of participants to continue to take part in the research. If there are significant new findings, state how they will be provided to participants, or if not provided, explain rationale?<br>Comment: | ◯ Yes | ◯ No | |

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| 4. | Do any reports of deviations, protocol events, non-compliance or participant complaints represent unanticipated events or problems involving risks to participants or others or serious or continuing non-compliance? | ◯ Yes | ◯ No | ◯ NA |

**Reviewer Recommendation**

1. Level of Risk (check one) ◯ Minimal risk ◯ Greater than minimal risk
2. Device Category ◯ Not applicable ◯ Significant risk ◯ Non-significant risk
3. Independent Verification of No Material Changes Since Previous IRB Review
   ◯ Not Recommended
   ◯ Recommended Comment:
4. Recommended IRB Action
   ◯ Approve as Submitted ◯ Close Study
   ◯ Approvable pending changes described below ◯ Disapprove for reasons described below
   Comments:
5. Continuing Review Frequency: ◯ 12 months ◯ 6 months ◯ Other:
6. Type of Review
   ◯ Recommend review by Full Board Convened IRB
   ◯ Determination by Expedited Reviewer Acting on Behalf of the IRB, Category No. per 45 CFR 46.110 & 21 CFR 56-110
   ◯ Study originally approved as Expedited under categories 1-7.
   ◯ No accrual **and** PI is requesting termination.
   ◯ Study originally approved by the Full Board **and**;
   (8) ◯ (a)(i) the research is permanently closed to enrollment of new subjects; (ii) all subjects have completed all research-related interventions; **and** (iii) the research remains active only for long-term follow-up of subjects; **or**
   ◯ (b) where no subjects have been enrolled **and** no additional risks have been identified; **or**
   ◯ (c) where the remaining research activities are limited to data analysis.
   (9) ◯ Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk **and** no additional risks have been identified.

☐ **I certify that I do not have any conflict of interest related to this research or my review.**