MUSC
MEDICAL UNIVERSITY of SOUTH CAROLINA

IRB Reviewer Checklist
Expedited Initial Application

Reviewer:	**PRO#:**	**PI Name:**

Regulatory Criteria for Approval **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 no 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 other 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 Expedited review cannot be approved.

IRB Reviewer

1	Risk: ◯ No Risk ◯ Minimal Risk
2.	Consent Form: ☐ Required ☐ Waiver of Informed Consent ☐ Waiver of Signed Consent ☐ Waiver of Alteration of Consent
3.	Child Assent: ◯ Not Applicable ◯ 12-17 years old ◯ < 12 years old
4.	Transnational Research – The research protocol will be conducted at international sites. ◯ Yes ◯ No If yes, the research protocol contains descriptions of and has complied with local laws and customs ◯ Yes ◯ No
5.	VA Medical Record Flag ◯ Not Applicable ◯ Required ◯ Waived

6.	Regulatory Requirements of Subpart B and/or D Satisfied ◯ Not Applicable ◯ Yes ◯ No
7.	Request for Expedited Review: ◯ Approved ◯ Refer to Full IRB
8.	Expedited Review Categories: For Category 1(a) and 1(b) 1(a) Confirm here that an IND is not required for use of the drug in this study. ☐ 1(b) Confirm here that and IDE is not required for the use of the device in this study. ☐ 1(b) Confirm here that the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling. ☐
9.	Continuing Review Required: ◯ Yes ◯ No
10.	Comments:

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