

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 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 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
When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of participants.				Yes	No
When appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.				Yes	No
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
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 Signed Consent		
		Waiver of Informed 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: <u>For Category 1(a) and 1(b)</u> 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.	