MUSC
Medical University of South Carolina

IRB Reviewer Checklist
Full Board Initial Application

Reviewer:	**PRO#:**	**PI Name:**		
1.	**Purpose and Background**			
a.	Adequate statement of the research problem and specific aims.	◯ Yes	◯ No	
b.	Suitable justification for study involving humans.	◯ Yes	◯ No	
2.	**Subject Populations(s)/Recruitment**			
a.	Justifiable source of subject population (medical records, private physicians, advertising).	◯ Yes	◯ No	
b.	Equitable subject selection with inclusion/exclusion criteria.	◯ Yes	◯ No	
c.	Recruitment procedures which ensure voluntary participation.	◯ Yes	◯ No	
d.	Rationale/justification for using special population (including children, prisoners, cognitively impaired individuals, pregnant women, fetuses). *(Complete additional sections on Special Populations)	◯ Yes	◯ No	◯ NA
e.	Additional safeguards have been incorporated to protect the rights/welfare of participants likely to be vulnerable to coercion/undue influence.	◯ Yes	◯ No	◯ NA
3.	**Methodology/Data Disposition**			
a.	Adequate description of all activities involving human subjects.	◯ Yes	◯ No	
b.	Clear explanation of frequency and duration of each activity.	◯ Yes	◯ No	
c.	Detailed summary of data collection (questionnaires, interviews, observations, standardized tests, other) and methods of data recording (field notes, audiotape, videotape, computer entry, etc.).	◯ Yes	◯ No	
4.	**Potential Risks/Benefits**			
a.	Risks (including physical, psychological, social, legal and economic) to subjects are minimized:			
(1)	by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk;	◯ Yes	◯ No	
(2)	when appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes;	◯ Yes	◯ No	
b.	Risks to subjects are reasonable in relation to:			
(1)	anticipated benefits to subjects; and,	◯ Yes	◯ No	
(2)	the importance of the knowledge that may reasonably be expected to result.	◯ Yes	◯ No	
c.	Adequate provisions will be made to protect the privacy of subjects and to maintain the confidentiality of the data.	◯ Yes	◯ No	

5.	**Investigational New Drugs**	◯ Yes		◯ NA
a.	Toxicity data provided	◯ Yes	◯ No	
b.	Animal studies reports provided	◯ Yes	◯ No	
c.	Description of previous studies on humans provided.	◯ Yes	◯ No	
d.	Review of literature provided by the investigator.	◯ Yes	◯ No	
6.	**Investigational New Device**	◯ Yes		◯ NA
a.	Name and source provided.	◯ Yes	◯ No	
b.	Description of purpose and how it will be used.	◯ Yes	◯ No	
c.	Status with the FDA.	◯ Yes	◯ No	
d.	Relevant material on the device provided by the investigator.	◯ Yes	◯ No	
7.	**Non-Significant Device Determination**	◯ Yes		◯ NA
a.	Agree with determination of "non-significant risk".	◯ Yes	◯ No	
8.	**Informed Consent Process**			
a.	Person(s) from whom informed consent will be obtained is/are appropriate.	◯ Yes	◯ No	
b.	Person(s) obtaining informed consent are appropriate for this project.	◯ Yes	◯ No	
c.	Informed consent is sought under circumstances that give the subject sufficient opportunity to consider whether to participate and that minimize possible coercion or undue influence.	◯ Yes	◯ No	
9.	**Data Safety Monitoring**	◯ Yes		◯ NA
a.	Adequate provisions for monitoring the data collected to ensure the safety of subjects.	◯ Yes	◯ No	
10.	**Multi-Site Studies**	◯ Yes		◯ NA
a.	Management of information from multi-site study relevant to the protection of participants is adequate	◯ Yes	◯ No	
11.	**Transnational Research**	◯ Yes		◯ NA
a.	The researcher has complied with local laws	◯ Yes	◯ No	
12.	**Review Period Recommendation**			
	◯ 12 months ◯ 6 months ◯ Other:			

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