WAYNE STATE UNIVERSITY

Continuation Reviewer Form

Reviewer		Assigned IRB		Meeting Date	
Investigator		Department			
IRB#		Coeus #		Expiration Date	
Study Title					
Is this a minimal risk study? Risk category at time of last IRB review: ☐ Level 1 ☐ Level 2 ☐ Level 3				☐ Yes ☐ No	
Is this a minimal risk study subject to FDA regulations (Investigational Drug or Device)?				☐ Yes *☐ No: Include justification for continuing review of minimal risk research in #24	
Was the study approved prior to January 21st 2019?				*☐ Yes ☐ No	
Does the study meet criteria to be transitioned to the revised Common Rule according to the investigator's responses to the Common Rule Transition Appendix?				☐ Yes ☐ No ☐ Transition Appendix was not submitted	
Sponsor					
Review Type	☐ Full Board ☐ Expedited ☐ Administrative (Specify Type):				
Study Status:	☐ No Participants Enrolled ☐ Expedited Continuation of Full Board study, no new risks have been identified. ☐ Actively accruing participants ☐ Closed to accrual (but with research related intervention or follow-up still ongoing) *☐ Closed to accrual and active intervention completed *☐ Data Analysis only *☐ Sponsored by a Federal Agency				
Number of Participants Accrued Since Study Initiation:					

*Transition Criteria

Reviewer's Recommendation
(Please complete after meeting discussion and decision is made)
See Continuation and Transition to the RCR Decision Trees for guidance

☐ Approve ☐ 12 months ☐ 6 months ☐ Eligible for Status Update ☐ Flexible Review
☐ Other:

List reason for approval less than 12 months:

☐ Specific Minor Revisions *(i.e., The response to issues can be reviewed by the Chair or his/her designee)*	☐ Tabled *(i.e.The response to issues will be brought back to the Committee for review)*	☐ Disapprove *(i.e., This study as written is rejected. PI must address the issues and resubmit as a new study**. Note**: Expedited studies requiring continuing review cannot be disapproved)*	☐ Deferred *(i.e., Study not reviewed due to internal snafu: not given to reviewers, both reviewers unable to review study.)*

Reviewer's Signature: Date:

Reviewer Notes: Summarize your review findings, areas of concern (discrepancies between the protocol, protocol summary form, and/or consent/assent/information forms), comments and any further information required.

Risk Assessment Update: What is the current risk category? - Indicate current risk category assessment and justification in #24.	**Minimal Risk** ☐ Level 1 **Greater than Minimal Risk** ☐ Level 2 ☐ Level 3
Following your review of the submitted materials, has the risk to participants, *in your opinion*, changed from the time of the last IRB review?	☐ Yes - New Risk Level: ☐ No

	Question	Yes	No	N/A	Reviewer's Response/Comments
1.	**Q10**: Is WSU identified as the Coordinating Center for this research? If yes, a "Continuation" Coordinating Center Application Form must be included with this submission.	☐	☐		
2.	**Q16b:Flexible Review** is the proposed study eligible for flexible review?	☐	☐	☐	

	Question	Yes	No	N/A	Reviewer's Response/Comments
3.	**Q17/18**: Are the current number of participants less than or equal to the number approved for recruitment at WSU?	☐	☐		
	If this number exceeds the approved enrollment, an amendment is required.				
4.	**Q18/19:**Do the number of participants enrolled (Q19) add up to the same number in Q18?	☐	☐		
5.	**Q20**: Is the Vulnerable Group Table Complete?	☐	☐	☐	
6.	**Q20:** Have subjects from vulnerable populations been recruited that were not previously identified? (look at narrative summary) ***If yes***, an amendment may be required	☐ ☐	☐ ☐		
7.	**Q22/23**: Has there been an equitable distribution of participants based on ethnic groups/race/gender since the last review?	☐	☐		
	If no, are the inequities satisfactorily justified	☐	☐		
8.	**Q24**: Since at continuing review the IRB is required to conduct substantive and meaningful review and must determine that all the regulatory criteria continue to be met: Does this study require re-review for Radiation Safety? In reviewing the amendments or modifications to the research study, has there been a significant change in the design, focus, or purpose of the research?	☐ ☐	☐ ☐	☐ ☐	
	If yes, please comment:				
9.	**Q25**: Has the Non-English short form been used?	☐	☐	☐	
	If yes, should a foreign language consent be used? (i.e., there has been more than 6 uses of the short form), please comment.				
10.	**Q26** (for investigator-initiated studies): If required by the FDA or IRB, has a recent, relevant, and adequate literature search been submitted with this continuation?	☐	☐	☐	
11.	**Q27:** <u>If a non-significant risk device</u> study, is the PI abiding by the criteria for use as approved?	☐	☐	☐	
12.	**Q28**: Are reportable adverse reactions or unexpected events identified? If yes, they should match those reported in the IRB file (Problem Report tab). Please summarize any trends.	☐	☐	☐	

	Question	Yes	No	N/A	Reviewer's Response/Comments
13.	**Q30**: Since the last review have there been any: • participant withdrawals or removal • audits • breach of confidentiality • hold notifications • period of non-IRB approval • participant complaints • suspensions • Change in study without approval • unanticipated adverse device effect • protocol violations or deviations • incarceration of a participant in the study which was not approved for prisoners (Q19) • other safety reports • change in FDA labeling or withdrawal from marketing of drug or device • interim findings • pertinent multicenter trial reports • DSMB monitoring	☐	☐		
	If yes, summarize areas of concern and comment on whether the plan to address is adequate (**Q 31**)	☐	☐	☐ N/A	
14.	**Q33**: Are there complete copies of any publications, abstracts, and/or descriptions of presentations that have resulted **from this** research study?	☐	☐	☐	
15.	Are there other publications relevant to this study <u>from other investigators</u>?	☐	☐	☐	
	If yes, are the publications and a summary attached?	☐	☐		
	Do they indicate increased risks or benefits? ***If yes,*** **please complete the risk assessment on the last page.**	☐	☐		

	Question	Yes	No	N/A	Reviewer's Response/Comments
16.	**Q34**: Is the progress report complete and concise and does it reflect any changes or amendments that have occurred since last review?	☐	☐		
17.	**Q35:** Do you agree with the PI's justification for continuation?	☐	☐		
18.	If accruing participants, is the currently approved version of the consent /assent /info sheet attached? **For VA Studies the VA Informed consent must be used.**	☐	☐	☐	
19.	Based upon your review, should the consent form be revised to reflect increased risk or additional changes? **NOTE: If changes are required, please mark requested changes on a copy of the consent/ assent/information sheet. DO NOT use sticky notes.**	☐	☐		
20.	Is a summary of any interim findings attached?	☐	☐	☐	
	If so do they indicate increased risk? ***If yes,*** please complete the risk assessment on the last page.	☐	☐	☐	
21.	Are there significant new findings that may affect a participants' willingness to continue in the study?	☐	☐	☐	
	If yes, have those findings been provided to the participant?	☐	☐		
22.	Are all of the criteria met for IRB approval of Research?	☐	☐		
23.	Are there changes in the risk/benefit ratio that might require this study be reviewed more often than annually?	☐	☐		
	If yes, what?				

24.	**RISK CATEGORY ASSESSMENT – Reviewer must provide protocol specific examples to justify the selected risk level (and met the conditions, if children are enrolled).**	
	<u>Level 1</u>: Research not involving greater than *minimal risk • *If the study was approved after 1/21/2019 or transitioned to the revised version of the Common Rule and minimal risk, and not subject to FDA regulations, include your justification for requiring continuing review of minimal risk research. The following are scenarios in which a minimal risk study would require continuing review:* o Required by other applicable regulations (e.g., FDA); o Required by the terms of a grant, contract, or other agreement; o The research involves topics, procedures, or data that may be considered sensitive or controversial; o The research involves particularly vulnerable subjects or circumstances that increase subjects' vulnerability; o An investigator has minimal experience in research or the research type, topic, or procedures; and/or o An investigator has a history of noncompliance. ***Justification:***	☐
	<u>IF CHILDREN ARE ENROLLED</u>: The following condition must be met *<u>for children</u>* in order to qualify for risk Cat. 1: • Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in §46.408.	
	<u>Level 2</u>: Research involving greater than *minimal risk but presenting the prospect of direct benefit to the participant. ***Justification:***	☐
	<u>IF CHILDREN ARE ENROLLED</u>: All 3 of the following conditions must be met *<u>for children</u>* in order to qualify for risk Category 2: • The risk is justified by the anticipated benefit to the subjects; • The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and • Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in §46.408.	
	<u>Level 3</u>: Research involving greater than *minimal risk and NO prospect of direct benefit to individual participants, but likely to yield generalizable knowledge about the participant's condition or disorder. ***Justification:***	☐
	<u>IF CHILDREN ARE ENROLLED</u>: All 4 of the following conditions must be met *<u>for children</u>* in order to qualify for risk Category 3: • The risk represents a minor increase over minimal risk; • The intervention or procedure presents experiences to participants that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations; • The intervention of procedure is likely to yield generalizable knowledge about the participants' disorder or condition which is of vital importance for the understanding or amelioration of the participants' disorder/condition; & • Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in §46.408.	

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

For your reference only: **45 CFR 46.111 Criteria for IRB Approval or SMR of Research**

1. Is a plan for data safety and monitoring necessary?
2. Is the selection of participants equitable?
3. Is there any potential for coercion or undue influence of participants?
   If so, what measures are taken?
4. Will informed consent be sought?
5. Will informed consent be documented, or a waiver of documentation w/info sheet granted?
6. Are confidentiality measures sufficient?
7. Have the risks to participants been minimized?
8. Are the risks reasonable in relation to the benefits and resulting knowledge?

See Continuation and Transition to RCR Decision Tree's for guidance.