This is a PDF fillable form, to complete an electronic/digital signature, this form must be saved and opened in Adobe.

WSU IRB eProtocol

Continuation Reviewer Form

Please complete all sections of the checklist

Submit Comments/Revision Requests via eProtocol

Reviewer		Assigned IRB		Meeting Date	
Principal Investigator		Department			
IRB#	Continuation Review Cycle/#:			Expiration Date:	
Study Title:					

Is this a minimal risk study? ☐ Yes ☐ No

Risk category at time of last IRB review: ☐ Level 1 ☐ Level 2 ☐ Level 3

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 at the end of this form.
Was the study approved prior to January 21st 2019?	*☐ Yes ☐ No
Does the study meet criteria for transition to the revised Common Rule? Please see the investigator's responses to the Common Rule Transition Appendix?	☐ Yes ☐ No ☐ Transition Appendix was not submitted
Study Sponsor:	
Review Type:	☐ Full Board ☐ Expedited ☐ Administrative (Specify Type):

*Transition Criteria 5/2021

Overall Study Status:

☐ No Participants Enrolled	☐ Actively accruing participants	☐ Closed to accrual (but with research related intervention or follow-up still ongoing)	*☐ Closed to accrual and active intervention completed
☐ Expedited Continuation of Full Board study, no new risks have been identified.	* ☐ Data Analysis only	* ☐ Sponsored by a Federal Agency	
Number of Participants Accrued Since Study Initiation:			

1.	**Study Location:**	Yes	No	N/A	Reviewer's Response/Comments
Is WSU identified as the Coordinating Center for this research? If yes, a "Continuation" Coordinating Center Application Form must be included with this submission. **See the eProtocol Study Location section**		☐	☐	☐	
2.	**Protocol Checklist: Flexible Review**	**Yes**	**No**	**N/A**	**Reviewer's Response/Comments**
Is the proposed study eligible for flexible review? **Flexible Review Eligibility criteria:** • Study is minimal risk. • Study is not federally funded. • Federal funding will not be submitted in the future. • The PI is not paid or supported from a federal training grant. • The PI is not paid or supported from a supervisors or advisors' federal funds. • The study does not have Food and Drug Administration regulated components (drugs, biologic, medical devices, etc.). • The is not a Department of Veteran Affairs (VA) study. • This study will not target prisoners as participants. • The study sponsor, outside collaborators or other entities do not require annual IRB review. • Contractual obligations with the study sponsor, outside collaborators or other entities do not adhere to federal research regulations regarding IRB review.		☐	☐	☐	

3.	**Protocol Modifications:**	**Yes**	**No**	**N/A**	**Reviewer's Response/Comments**
Are modifications being made to the study? • **If Yes, go to 3a** • **If No go to question 4.**		☐	☐	☐	

3a. **If Yes**, is a summary of the modifications attached? ☐ Yes ☐ No (***if No, this must be requested***)

If modifications are extensive an additional reviewer can be assigned to review the modifications portion of the submission. Please request from pre-reviewer.

Modifications being made to the following:
Select all that apply:

☐ Consent	☐ Assent	☐ Participant Materials/Advertisements	☐ Data Collection
☐ Protocol	☐ Other:		

Are the modifications acceptable? ☐ Yes ☐ No

Do the modifications change the risk/benefit determination? ☐ Yes ☐ No (**If yes, complete item 15**)

Does the modification reflect addition of a vulnerable population? ☐ Yes ☐ No

If yes:

Has the Participant Checklist section been modified to include the new population?	Has the Protocol Information Participant Population section been modified and vulnerable population justification updated?
☐ Yes ☐ No	***For full board submissions present during meeting discussion.*** ☐ Yes ☐ No

4.	**Conflict of Interest:**	**Yes**	**No**	**N/A**	**Reviewer's Response/Comments**
Has the PI indicated a FCOI? **If yes, the management plan must be attached in the Protocol Information Attachments section.**		☐	☐	☐	

5.	**Study Status: Participant Enrollment:**	**Yes**	**No**	**N/A**	**Reviewer's Response/Comments**

Have participants have been accrued within the last year? If no, is the explanation sufficient?	☐	☐	☐	
Participants are still being enrolled	☐	☐	☐	
Participants have completed their study participation	☐	☐	☐	
Participants are in long term follow-up	☐	☐	☐	
Study is closed to accrual	☐	☐	☐	
Do the number of participants consented since the study was initiated match what is indicated for the Summary Chart's total?	☐	☐	☐	
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 and Unanticipated Problem submission is required.	☐	☐	☐	
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?	☐	☐	☐	
Is there a vulnerable group indicated as being enrolled?	☐	☐	☐	
Have participants from vulnerable populations been recruited that were not previously identified? Check if modification is requested) ***If yes***, an amendment may be required	☐	☐	☐	
6. Study Status: Progress to Date:	**Yes**	**No**	**N/A**	**Reviewer's Response/Comments**
Is sufficient information provided regarding the study's progress?	☐	☐	☐	
Is the progress report complete and concise and does it reflect any changes or amendments that have occurred since last review?	☐	☐	☐	
Is sufficient justification provided regarding why the study should continue to receive IRB approval?	☐	☐	☐	

Do you agree with the PI's justification for continuation?		☐	☐	☐	
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? (see Event History for listing of modifications)		☐	☐	☐	
7.	**Publications/Abstracts/Presentations /Findings**	**Yes**	**No**	**N/A**	**Reviewer's Response/Comments**
Since the last IRB approval have any publications, abstracts, and/or presentations resulted from this research protocol?		☐	☐	☐	
Are there complete copies of any publications, abstracts, and/or descriptions of presentations that have resulted **from this** research study? **If yes documents must be attached at the end of the continuation form**.		☐	☐	☐	
Are there other publications relevant to this study from other investigators? **If yes documents must be attached at the end of the continuation form**.		☐	☐	☐	
Do any of the publications, abstracts or presentations indicate increased risks or benefits? ***If yes,*** **please complete the risk determination section on the last page of this form.**		☐	☐	☐	
Is there a summary of any recent findings, literature, or other relevant information (especially pertaining to risk) provided?		☐	☐	☐	
Does the summary of recent findings indicate increased risk? ***If yes,*** **please complete the risk determination section on the last page of this form.**		☐	☐	☐	
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?	☐	☐	☐	
8.	**Investigator Initiated Studies**	**Yes**	**No**	**N/A**	**Reviewer's Response/Comments**
If involving an IND or IDE has the IRB determined a literature review is required on an annual or other basis?		☐	☐	☐	
If required by the FDA or IRB, has a recent, relevant, and adequate literature search been submitted with this continuation?		☐	☐	☐	

If a non-significant risk device study, is the PI abiding by the criteria for use as approved?	☐	☐	☐	
Is the literature search and results information sufficiently described?	☐	☐	☐	
9. Clinical Trials Reporting	**Yes**	**No**	**N/A**	**Reviewer's Response/Comments**
Is this a clinical trial?	☐	☐	☐	
If yes, has the clinical trials registration number been provided (**see eProtocol Checklist tab**)?	☐	☐	☐	
10. Event Reporting	**Yes**	**No**	**N/A**	**Reviewer's Response/Comments**
Has the study's IRB approval lapsed?	☐	☐	☐	
If yes, is there appropriate corrective action to prevent future lapses?	☐	☐	☐	
Are there any reportable adverse reactions or unexpected events reported?	☐	☐	☐	
If yes, do the events listed on the continuation form match those reported in the IRB file? Please summarize any trends of concern.	☐	☐	☐	
Have there been any participant complaints?	☐	☐	☐	
If yes, was the complaint resolved?	☐	☐	☐	
If no, was the unresolved complaint reported to the IRB?	☐	☐	☐	

REPORTED EVENTS

Have any of the events in the following table occurred? ☐ Yes ☐ No

Select all events that apply.

☐ Period of non-IRB approval (approval lapse)	☐ Unresolved participant complaints	☐ Audits	☐ Hold Notifications
☐ Death happened at WSU or one of its affiliates within 30 days of the last study intervention and not related to progressive disease	☐ Death that the PI feels is significant regardless of when it occurred	☐ Protocol violations or deviations	☐ Event that required prompt reporting go the sponsor
☐ Suspension (institution)	☐ Suspension (sponsor)	☐ Information that indicates a change to the risk or potential benefits of the research	☐ Breach of Confidentiality
☐ Change in FDA labeling or withdrawal from marketing of drug or device	☐ Change in study without IRB review/approval	☐ Incarceration of a participant in the study which was not approved for prisoners	☐ Unanticipated adverse device effect
☐ Other:			

If yes, summarize areas of concern and comment on whether the plan to address is adequate.

11. Public Health Crisis	Yes	No	N/A	Reviewer's Response/Comments
Were in-person activities performed during the public health crisis?	☐	☐	☐	
If yes, was standard operating procedures sufficiently described for in-person activities?	☐	☐	☐	
12. Consents/Assents/Additional Documents for Approval	**Yes**	**No**	**N/A**	**Reviewer's Response/Comments**
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.**	☐	☐	☐	
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 the consent/ assent/information sheet.**	☐	☐	☐	
Has the Non-English short form been used?	☐	☐	☐	
If yes, should a foreign language consent be used (i.e., there have been more than 6 uses of the short form)? Please comment.	☐	☐	☐	
13. Ancillary Reviews	**Yes**	**No**	**N/A**	**Reviewer's Response/Comments**
PRMC Approval provided	☐	☐	☐	
VA CIC Approval provided	☐	☐	☐	
Does this study require re-review for Radiation Safety? If yes, please provide reviewer comment.	☐	☐	☐	

14.	**Pre-Review Notes to IRB Reviewer:**	☐ None

15.	Criteria for Approval

Have all applicable criteria for IRB approval of Research been met? ☐ Yes ☐ No

(If No, indicate in notes for reviewer recommendations and submit via eProtocol).

Criteria for IRB Approval or SMR of Research
45 CFR 46.111 & 21 CFR 56.111

•	**(1) Risks to Subjects are minimized:** (a) By using procedures that are consistent with sound research design and that do not unnecessarily expose participants to risk and (b)Whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes
•	**(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result**. When evaluating risks and benefits, the IRB should: (a) Consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies participants would receive even if not participating in the research) (b)The IRB should not consider possible long-range effects of applying knowledge gained in the research (e.g., the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
•	**(3) Selection of participants is equitable:** (a)Take into account the purposes of the research and the setting in which the research will be conducted (b)The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as: i) Children, ii)Pregnant women, iii) Prisoners, iv)individuals with impaired decision-making capacity, v)economically or educationally disadvantaged persons
•	**(4) Informed Consent will be sought from each prospective participant or the participant's legally authorized representative, in accordance with, and to the extent required by 45 CFR 46.116 and 21 CFR 50**
•	**(5) Informed Consent will be appropriately documented in accordance with 45 CFR 46.117 and 21 CFR 50.27.**
•	**(6)When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of participants**
•	**(7)When appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.**
•	**(8)When some or all of the participants are likely to be vulnerable to coercion or undue influence, additional safeguards have been included in the study to protect the rights and welfare of these participants.**

16. Reviewer's Recommendation

(For full board submissions please complete this section following full board deliberation and vote)
See Continuation and Transition to the RCR Decision Trees for guidance

Check all that apply:

☐ **Approve** ☐ 12 months ☐ 6 months ☐ Eligible for Status Update ☐ Flexible Review

☐ Approve with Transition to Revised Common Rule ☐ Other:

List reason for approval less than 12 months:

Are there changes in the risk/benefit ratio that might require this study to be reviewed **more often** than annually?

☐ Yes ☐ No

Risk Category Determination: ***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 - Indicate the New Risk Level **above** and go to question 17 to complete the Risk Category Justification section.

☐ No

☐ **Specific Minor Revisions (SMR)** *(i.e., The response to issues can be reviewed by the Chair or his/her designee)*	☐ **Tabled** *(Full Board Review ONLY i.e. The response to issues will be brought back to the Committee for review)*	☐ **Disapprove** *(Full Board Review ONLY 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** *(Full Board Review ONLY:, Not reviewed due to internal error, not posted/given to reviewers, or appropriate membership not in attendance.)*

Reviewer's Signature: **Date:**

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

***REVISED COMMON RULE NOTE:**
If this is a minimal risk Revised Common Rule study (initially approved after 1/21/2019) please indicate why continuing review is still recommended. If full board, indicate why the study should remain as a full board submission.

This is a PDF fillable form, to complete an electronic/digital signature, this form must be saved and opened in Adobe.

17. RISK CATEGORY DETERMINATION AND JUSTIFICATION

(For full board submissions please complete this section following full board deliberation and vote)

IRB Reviewer must provide protocol specific examples to justify the selected risk level (and met the conditions, if children are enrolled).

☐ **Level 1: 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:*
  - Required by other applicable regulations (e.g., FDA);
  - Required by the terms of a grant, contract, or other agreement;
  - The research involves topics, procedures, or data that may be considered sensitive or controversial;
  - The research involves particularly vulnerable subjects or circumstances that increase subjects' vulnerability;
  - An investigator has minimal experience in research or the research type, topic, or procedures; and/or
  - An investigator has a history of noncompliance.

Justification:

***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.

IF CHILDREN ARE ENROLLED: The following condition must be met *for children* in order to qualify for risk Category 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.

☐ **Level 2: Research involving greater than *minimal risk but presenting the prospect of direct benefit to the participant.**

Justification:

IF CHILDREN ARE ENROLLED: All 3 of the following conditions must be met *for children* 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.

☐	**Level 3: 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:

IF CHILDREN ARE ENROLLED: All 4 of the following conditions must be met *for children* 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.

See Continuation and Transition to RCR Decision Trees for guidance.