Expedited Amendment Reviewer Checklist

PI's Name:	IRB#:	IRB Committee:
Initial Review Type:	☐ Expedited ☐ Exempt	☐ Full Board

Expedited Review meets the following criteria			
Select all that apply			
☐	A change that does not substantially alter the specific aims or design of the study		
☐	The addition of procedures that meet the applicability criteria and fall into one or more categories defined in "categories of research that may be reviewed by the IRB through an expedited review procedure"		
☐	A change that does not involve adding vulnerable subjects including children, prisoners, cognitively impaired, or mentally disabled participants		
☐	An increase or decrease in the proposed human research participant enrollment (for investigator initiated studies, the increase or decrease is supported by a statistical justification)		
☐	Modification to the inclusion or exclusion criteria that does not increase risks to participants, decrease potential benefits, or add a vulnerable population, or negatively impact the equitable selection of subjects.		
☐	Alterations in oral forms of administration of a drug, providing the dose remains constant		
☐	Changing data collection points or amounts of data collected as long as it does not alter safety evaluations		
☐	An increase in safety monitoring resulting in more frequent visits or an increase in the length of hospital stay		
☐	Changes to improve the clarity of statements or to correct typographical errors, provided that such a change does not alter the content or intent of the statement		
☐	Changes in compensation with proper justification		
☐	Study Closed to Accrual (No new participants will be enrolled)	☐ Study Title Change (all impacted documents are updated with the new title)	
☐	Administrative Changes	☐	Addition or deletion of study sites
☐	Data Safety Monitoring Minutes/Memo	☐	Funding Source
☐	Minor changes specifically requested by the IRB	☐	Minor changes specified by DMC Affiliate review
☐	Recruitment Methods	☐	RecruitmentMaterials/Participant Materials
☐	Addition of Non-English Speaking Participants or Addition of Documents for Non-English Speaking Participants Check for translated consent/assent documents. Check for translated data collection tools and recruitment materials, if applicable. See WSU IRB's Informed Consent for Non-English Speaking Participants policy for information regarding non-English speaking participants.		
☐	Key Personnel Deletion	☐	Key Personnel Addition (**for Change in PI see checklist below**) **Full Board Studies Change in PI must be reviewed at full board meeting.**

☐	Public Health Pandemic Submission of In-Person Mitigation Documents ☐ COVID-19 Participant Information Sheet ☐ COVID-19 Phone Script ☐ Other items to address Public Health Pandemic:		
☐	**Other Changes:**		

Study Location Modifications ☐ Yes ☐ No

Addition of the following sites:

☐ DMC (DMC Review/Approval required-see attachments for amendment)
☐ Karmanos (PRMC Approval required-see attachments for amendment)
☐ VA (CIC Approval required-see attachments for amendment)
☐ Psychiatry (Psychiatry Approval required-see attachments for amendment)

☐ Other:

If research is taking place outside of the PI's department a letter of support from that site/department will need to be provided.

Addition or Deletion of Off-Site locations:	☐ Yes ☐ No
If addition of Off-site are letters of support provided? **Letter of Support Guidance Tool for researchers**	☐ Yes ☐ No ☐ N/A If Yes, is WSU the Coordinating Center? ☐ Yes ☐ No If Yes, complete the Coordinating Center Checklist below.

Does this amendment meet the criteria for expedited review per 45 CFR 46.110? ☐ Yes ☐ No
If No, for full board studies, the amendment must be referred to Full Board review

Waivers or Alteration of Consent/Assent

If not applicable Select N/A and go to next section ☐ N/A

Waiver/Alterations of Consent Worksheet/Guidance Tool for researchers

	Yes	No	N/A
Using a Research Information a waiver of written documentation of consent/assent is requested.	☐		
Waiver for written documentation of consent/assent	☐		
Waiver of consent/assent and waiver of written document of consent to screen	☐		
Alteration of informed consent	☐		

(*Removing elements of consenting/or elements from the Research Information Sheet*)			
If a waiver or alteration of consent/assent is requested (e.g., secondary data, database, chart review), has the PI provided protocol specific justification and have all the regulatory criteria been met?	☐		
If there is an alternative to written consent requested, is the justification stated and appropriate?	☐		

Expedited Studies Amendment Submission

If not applicable Select N/A and go to next section ☐ N/A

Does all changes fall within one or more expedited review categories or include changes that do not affect participants (or their identifiable information)? ☐ Yes ☐ No

Are all the proposed changes no greater than minimal risk (everyday life)? ☐ Yes ☐ No

If No to any of the above, the study must be referred to Full Board review

Exempt Studies Amendment Submission

If not applicable Select N/A and go to next section ☐ N/A

Exempt Categories 2 & 3: Does the proposed changes include adding elements of Limited IRB review? ☐ Yes ☐ No

Limited IRB Review includes: Information being obtained in such a manner that the identity of the participants can be readily ascertained directly through identifiers linked to the participants for exempt categories 2 & 3. For example, this can include changing data from coded, de-identified to identifiable.

If the proposed changes are implemented, does the study remain exempt under 45 CFR 46.101(b), the WSU "Flexible Review and Oversight of Research Not Covered by Federal Wide Assurance", & WSU IRB Exempt Policies? Please see the Exempt Guidance Tool or the Expedited Guidance Tool.

☐ **Yes** ☐ **No**

If No, request a new study submission for an expedited or full board submission. Please confer with the IRB Administration Office to provide the PI with next steps.

If Yes, the Limited IRB Appendix must be submitted for review.

Flexible Review & Oversight/Approval Period Change

If not applicable Select N/A and go to next section ☐ N/A

Full Board studies approval period changes require review by the full board.

For studies previously given flexible review and oversight
If this amendment affects the study's eligibility for flexible oversight, how is it affected:

☐	The study is no longer eligible for flexible review because:
☐	The study is assigned a new expiration date:
☐	Status Check-In Date Assigned — Other:

Change in PI (Expedited & Exempt Studies ONLY)

If not applicable Select N/A and go to next section ☐ **N/A**

	Yes	No
Is this a Change in PI? (if yes go to Change in PI Checklist below)	☐	☐

	Yes	No
COI SECTION: Has the proposed new PI indicated a conflict of interest?	☐	☐
COI SECTION: If yes, is the management plan attached? **See Protocol Information-Attachments section. Review for information that must be included in the consent**	☐	☐
COI Management Plan: If there is a management plan are there any additional conditions that should be added to the management plan? If yes, include with your eProtocol comments.	☐	☐

Change in PI checklist	Yes	No
The reason for Change in PI is provided	☐	☐
The proposed PI's professional and education experience is appropriate to become PI of the study.	☐	☐
The new PI's CV is provided for the Protocol Information-Attachment's section	☐	☐
Documents have been provided revising the contact information to include the new PI's information (consent, assent, recruitment materials)	☐	☐

Coordinating Center Checklist

If not applicable Select N/A and go to next section ☐ **N/A**

	Yes	No
Have all pertinent documents/IRB approvals/agreements been provided?	☐	☐
For new submissions or site additions has the PI submitted an adequate plan to communicate information among the sites that may affect the health or safety of participants or their willingness to continue to participate in the study? **Coordinating Center Form questions 14 & 15**	☐	☐

If No, to any of the questions above indicate revisions that are required below.

Amendment Reviewer's Determination

	Yes	No
Does this amendment meet the criteria for expedited review per 45 CFR 46.110? **If No, for full board studies, the amendment must be referred to Full Board review**	☐	☐

☐**Revisions Required**	Date(s)Revisions Requested: Date(s) Revisions Received:		
☐**Approve (Select "Recommend Approval" via eProtocol)**	☐ **Full Board Review Required**	☐ **New Study Submission Required**	☐**Other**
☐ **Addendum/Appendix Checklist completed below** ☐ **N/A**	☐ **Vulnerable Population Checklist completed & submitted to IRB Administration (available on the IRB reviewer's website)** ☐ **N/A**		
For eProtocol submissions include any notes/revision requests in eProtocol			
Reviewer Notes:			
Reviewer's Signature **To provide an electronic/digital signature open form and complete in Adobe or software that allows for digital signature**	**Date:**		

Addendum Reviewer Checklist, if applicable

eProtocol Internet Addendum Checklist If not applicable, select N/A and go to next section ☐ N/A			
	Yes	**No**	**N/A**
Internet Addendum is completed.	☐	☐	☐
Recruitment conducted via internet. If yes, procedures are described.	☐	☐	☐
Data Collection conducted via internet. If yes, procedures are described.	☐	☐	☐
Are social media platforms being used?	☐	☐	☐
If yes, site administrator(s) approval(s) has been provided from social media platforms that are being used.	☐	☐	☐
Notes: Submit notes via eProtocol			

International Addendum Checklist If not applicable, Select N/A and go to next section ☐ N/A			
	Yes	**No**	**N/A**
International Addendum is completed.	☐	☐	☐
Approval from Export control is provided.	☐	☐	☐
Local IRB review/approval provided.	☐	☐	☐
If local IRB review is not available, has the researcher provided documentation of the following: (I) lack of local IRB review and (2) plans for observing local ethical standards? DOD research requires local ethics review.	☐	☐	☐
Letters of Support provided.	☐	☐	☐
Investigator and research staff are qualified for conducting research in respective country.	☐	☐	☐
Informed consent/assent/questionnaires/surveys are written both in English and the in the native language of the proposed research site.	☐	☐	☐
Risks are minimized	☐	☐	☐
Notes: Submit notes via eProtocol			

Limited IRB Review for Exempt Studies Categories 2 or 3	Yes	No	N/A
Is the Limited IRB Review Appendix provided?	☐	☐	☐
Does the following apply? The information obtained is recorded by the investigator in such a manner that the identity of the participants can readily be ascertained, directly or through identifiers linked to the participants.	☐	☐	☐
Does the following apply? Any disclosure of participants' responses outside the research would reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, educational advancement, or reputation. **Note if yes, the study should not be Exempt.** ***These provisions also apply to VA regulated research***	☐	☐	☐
Notes: Submit notes via eProtocol			