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)		
☐	Administrative Changes	☐	The addition or deletion of study sites (**VA cannot be added for eProtocol Submissions**) **see below**
☐	Data Safety Monitoring Minutes/Memo	☐	Funding Source
☐	Minor changes specifically requested by the IRB	☐	Minor changes specified by DMC Affiliate review
☐	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.**
☐	Submission of Appendix N with In-Person activities mitigation plan (***Use the Appendix N reviewer checklist to complete review***)		
☐	Other Changes:		

Study Location Modifications

Addition of the following sites:

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

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 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

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 is requested.	☐	☐	☐
Waiver for written documentation of consent	☐	☐	☐
Waiver of consent 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 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 do not affect participants (or their identifiable information)? ☐ Yes ☐ No
If No, 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

If the proposed changes are implemented, does the study remain exempt under 45 CFR 46.101(b) or the WSU "Flexible Review and Oversight of Research Not Covered by Federal wide Assurance" policy?

☐ Yes ☐ No

If No, request a new study submission

Flexible Review & Oversight

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

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 given a new expiration date: _____
☐	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**
For eProtocol submissions Include any notes 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:**	