Directions for Expedited Protocol Amendment Submissions

(NOTE: Please do not include directions with your submission)

1. **IF YOUR STUDY IS ON HOLD** FOR REASONS THAT MAY INCLUDE SAFETY, TOXICITY AND/OR EFFICACY—do not complete this form—complete the Unexpected Problem Form.
2. **Changing personnel?** Use the *Key Personnel Change* form or the *Change in PI* form
3. The following applies to ALL amendments:
   - Any proposed modification to an IRB-approved research protocol or informed consent document must be approved by the IRB **prior** to implementation of the proposed change (unless there is an urgent need for safety reasons to implement the change prior to IRB approval); and
   - Approval of an amendment by the IRB does not alter the original approval or expiration date assigned to the research protocol.
   - **If there are substantial changes from the original approved version,** the IRB may require submission of a *new* protocol.

Amendments that may qualify for Expedited Review:

Expedited review may be used when there are MINOR revisions involving procedures that are no more than minimal risk, or risks to subjects are not increased or newly identified, and/or the revision is not a significant alteration of the study design. For more details, see the Amendment policy: http://irb.wayne.edu/policies-human-research.php. Some examples of expedited review materials:

- 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
- Increase or decrease to enrollment.
- Adverse events added to the pkg insert (medical), **but** risks are already listed on the consent **or** they do not apply to the study (pediatric info., but only adults are enrolled in this study)
- Protocol, IB, or package inserts with updated risk or safety info that was not already listed on the consent **but** it does not pertain to the WSU site **or** the WSU site is permanently closed to accrual, **and** no one is receiving treatment/active, **and** no one is in follow-up.
- Administrative changes to the consent, such as moving sections, changing personnel names, formatting, etc.
- Administrative changes to the Investigator Brochure (medical), such as moving sections, clarifying language, formatting, etc.
- Alteration in oral forms of administration of a drug (e.g., tablet to capsule or oral liquid) provided the dose remains constant
- A change that does not substantially alter the specific aims or design of the study
- Addition or deletion of data collection instruments as long as they pose no more than minimal risk.
- Change in data collection points or amount of data collected as long as it does not alter safety evaluations
- Increase in the length of confinement or number of study visits for the purpose of increased safety monitoring
- Alteration in the participant compensation or liberalization of the compensation schedule
- Changes to improve clarity of statements or correction of typographical errors provided that such a change does not alter the content or intent of the statement
- Addition or deletion of study sites
- A change that does not involve adding vulnerable participants.

NOTE STUDIES ORGINALLY REVIEWED VIA eProtocol MUST SUBMIT AMENDMENTS VIA eProtocol

AMENDED ITEMS	CURRENTLY APPROVED DOCUMENTS	Number of Copies
Advertising Materials and items given to participants (eg, diaries)	1 copy	• 3 copies (1 copy with **highlighted** changes & 2 clean copies)
Protocol Revisions	1 copy (may submit just the revised pages if only a few)	• 1 copy with **highlighted** changes with a "Summary of Changes" from sponsor or PI. The summary should include the specific page number(s) of the revisions.
Consent, Assent, or Info Sheet	1 copy	• 3 copies (1 copy with **highlighted** changes & 2 clean copies)
HIPAA Forms	1 copy	• 1 copy of revised and signed ***HIPAA Summary Form*** with all changes **highlighted.** • 2 copies of the revised ***HIPAA Authorization Form*** (if not part of the consent document) 1 with **highlighted** changes
Drug Brochure or Package Insert	1 copy	• 1 copy of the revised version **highlighted**
Other	1 copy	• 1 copy of the item **highlighted**

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Detroit, MI 48201
(313) 577-1628
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Expedited Medical/Behavioral Amendment Form

- All IRB submission forms must be the current form date (download from http://irb.wayne.edu/forms-requirements-categories.php) and typed or computer generated.
- Submit Amendment Form with original signatures—no faxed or copied signatures.
- **Forward your@*wayne.edu*** e-mail to your ***@med.wayne.edu, @karmanos.org***, etc. e-mail in order to receive important e-mail communications regarding your study if you do not access your@wayne.edu e-mail ***OR*** go to ***Pipeline*** and enter the e-mail account that you wish to use. Non-WSU employees, please enter your e-mail. An e-mail address is required.

Section A: Administrative Information

1.	Principal Investigator (PI):		Date:	
	PI's Signature (required):		**E-mail:**	
	Department:		Phone:	( )
	Campus Address:		Pager:	
2.	PI Status: (Select all that apply)	☐ Wayne State Faculty ☐ DMC Staff ☐ Karmanos Staff ☐ J. D. Dingell VAMC Staff ☐ Resident/Fellow/Trainee* ☐ Other*: ____ ☐ Graduate Student* ☐ Undergraduate Student*		
	*PI home address, PI home phone number, and a faculty supervisor/sponsor is required if the PI is a resident, fellow, trainee, student, part-time faculty, adjunct faculty, or not faculty/staff at Wayne State University, Detroit Medical Center, Karmanos Cancer Institute, or J. D. Dingell VAMC.			
	PI's Home Address:		PI's Home Phone:	( )
	Faculty Supervisor/ Sponsor:		Supervisor/ Sponsor E-Mail:	
3.	Protocol Coordinator	☐ N/A	**E-mail:**	
4.	Form completed by:		**E-mail:**	
	Research Role:		Phone:	( )
5.	Current Project Title:			

Section B: Protocol Information

6.	Coeus #		
7.	IRB #		
8.	Is this research being conducted at the VAMC?	☐ Yes (*Please attach VA CIC approval memo if the amendment affects the VA site or veterans*) ☐ No	
9.	Expiration Date or Status Check-In Date		a. Is the current approval period more than 364 days? ☐ Yes ☐ No
	b. Was this study previously determined to be eligible for flexible review and oversight by the WSU IRB? NOTE: Studies that are minimal risk, do not have federal funding, are not FDA-regulated, and are not conducted at the VA may be eligible for flexible review and oversight. See the "Flexible Review and Oversight of Research Not Covered by Federalwide Assurance" policy: http://irb.wayne.edu/policies-human-research.php		☐ Yes ☐ No (including studies initially approved, exempted, or received its most recent continuation approval prior to March 15, 2016) ☐ Unable to determine
c.	**Is this a COVID-19 modification request?**		☐ Yes (**If yes, please also Complete Q#15**) ☐ No

d. Is this amendment adding a VA Site(s) or Federal Funding?		☐ Yes (**If yes, this study is not eligible for flexible Review, please Complete Q#15**) ☐ No
10.	Is this protocol closed to recruitment?	☐ Yes ☐ No **– go directly to Q#11**
	a. If the study is closed to recruitment, is anyone still on treatment or in follow-up?	☐ Yes ☐ No
11.	Indicate the number of participants to date for the Wayne State/affiliate study:	
	a. Is WSU the Coordinating Center for this study? NOTE: If adding or deleting centers, submit a Coordinating Center Form with this submission	☐ Yes ☐ No
	b. Is this a Single IRB NIH multi-site research study?	☐ Yes ☐ No
	c. Is this study a clinical trial? https://clinicaltrials.gov/ct2/about-studies/learn#WhatIs	☐ Yes Provide ClinicalTrials.gov Registration Number: ☐ No
12.	Current Source of Funding	☐ N/A – no funding
13.	Amendment originates from:	☐ Sponsor ☐ Principal Investigator ☐ Other:

Section C: Proposed Changes (Questions 14-20)

14.	**Recruitment Methods & Participant Materials** Does this amendment include changes to recruitment methods, recruitment materials or participant materials? NOTE: If changing accrual (number of participants enrolled), answer #15.		☐ Yes ☐ No **– go directly to Q#15**
	a. State the reason(s) for changing recruitment methods:		
	b. Select all recruitment documents that will be added or changed. If the amendment relates to internet recruitment, complete **Appendix B**. NOTE: If recruitment is done at a private location, a letter of support may be required.	☐ Advertisement, notice, or flyer	☐ New ☐ Revised
		☐ Pamphlet/Brochure	☐ New ☐ Revised
		☐ Participant recruitment letter	☐ New ☐ Revised
		☐ Press release	☐ New ☐ Revised
		☐ Recruitment script	☐ New ☐ Revised
		☐ Other Recruitment or Participant materials	☐ New ☐ Revised
	c. Describe how the new or revised recruitment documents or participant materials will be used (i.e. recruitment methods, location, etc.):		☐ N/A – recruitment documents or participant materials are not being added or changed

15.	**Protocol Document & Protocol Changes** Does this amendment include changes to the study design or protocol (e.g. administrative, editorial, enrollment criteria, study procedures, risks, benefits, accrual, study population, compensation, location, etc.)?		☐ Yes ☐ No **– go directly to Q#16**
	a. Select all types of study design or protocol changes that will occur: *Attach a letter of support on letterhead and/or IRB approval if the research is being done **(1)** outside of the PI's department or WSU/DMC/Practice Plans, and/or **(2)** at a location not affiliated with WSU. **Please do not submit the previously approved full Protocol Summary Form**.	☐ **COVID-19 MODIFICATION REQUEST** ☐ Administrative ☐ Editorial (written protocol) ☐ Project Title (new title): _____ ☐ Accrual (number of participants enrolled) ☐ Enrollment criteria (i.e. inclusion/exclusion criteria) ☐ Adding vulnerable participants (prisoners, cognitive impairment, minors, etc.) – submit appropriate **Appendix** ☐ Study procedures ☐ Risks and/or Benefits ☐ Data collection methods/Data collection instruments ☐ Participant compensation ☐ Adding or removing a research site* ☐ Addition of VA Site or Federal Funding (study is not eligible for flexible review) ☐ Adding an international site – submit **Appendix A** and contact export control: http://research.wayne.edu/export-control/ ☐ Other (specify): _____	
	b. Provide a detailed description of the proposed changes to the study design or protocol:		
	c. State the reason(s) for the study design or protocol changes: *If adding vulnerable participants, please indicate justification for addition.*		
	d. State how this amendment will affect currently enrolled study participants:		
	e. State if the proposed change affects privacy or confidentiality:		
	f. Provide references to support this revision, if applicable:		☐ None
16.	**Consents/Assents/Scripts/Information Sheets** Does this amendment include changes to informed consent documents or the informed consent process? NOTE: If changing accrual (number of participants enrolled), also answer #15.		☐ Yes ☐ No **– go directly to Q#17**
	a. Select all informed consent documents that will be added or changed: NOTE: If the change increases the risk to study participants *STOP*: a full board review (and form) is required.	☐ Informed Consent Form (Adults)	☐ New ☐ Revised
		☐ Information Sheet (Adults)	☐ New ☐ Revised
		☐ Oral Consent Script (Adults)	☐ New ☐ Revised
		☐ Parental Permission Consent Form	☐ New ☐ Revised

		☐ Adolescent Assent Form (Children)	☐ New ☐ Revised
		☐ Oral Assent Script (Children)	☐ New ☐ Revised
		☐ Information Sheet (Children)	☐ New ☐ Revised
		☐ Addendum to an Informed Consent Document	☐ New ☐ Revised
	b. Describe and justify the proposed changes to the consent documents:		☐ N/A – consent documents are not being added or changed
	c. Will the proposed changes affect previously enrolled participants?	☐ Yes ☐ No **– go directly to Q#16f**	
	d. Will current participants be notified of the changes?	☐ Yes ☐ No – State why participants will not be notified: ____	
	e. How and when will notification or re-consenting be done?		
	f. Is a **waiver of consent** now being requested? (e.g., chart review, database analysis) See federal regulations 45 CFR 46.116(d) and 46.408(c)	☐ Yes ☐ No, this is not needed for the study **– go directly to Q#16g** ☐ No, the IRB already granted this previously **– go directly to Q#16g**	
	I. Will the study activities conducted under a waiver be more than minimal risk to participants?	☐ Yes ☐ No	
	II. Will the waiver adversely affect the rights and welfare of the research participants?	☐ Yes ☐ No	
	III. Can the research be practicably carried out without the waiver	☐ Yes ☐ No	
	IV. Will the participants be provided with additional pertinent information after participation?	☐ Yes ☐ No	
	V. Provide protocol-specific justification for requesting a waiver of consent:		
	g. Is a waiver of the requirement to obtain written documentation of the consent process being requested (consent will be obtained, but there will be no signed form documenting consent)?	☐ Yes ☐ No, this is not needed for this study **– go directly to Q#17** ☐ No, the IRB already granted this previously **– go directly to Q#17**	
	I. Provide a written description of the information to be provided/read to participants:		☐ See attached
	II. Provide justification for waiver of written documentation of consent.		
17.	**HIPAA** Does this amendment include changes related to Health Insurance Portability and Accountability Act (HIPAA) documents?	☐ Yes ☐ No **– go directly to Q#18**	
	a. Select the HIPAA documents being added or changed:	☐ HIPAA Summary Form ☐ HIPAA Authorization Form(s)	

	b. Is a Waiver of HIPAA documentation now being requested?	☐ Yes ☐ No, this is not needed for this study ☐ No, the IRB already granted this previously
	c. Describe the proposed changes and provide justification:	
18.	**Investigator's Brochure/Package Inserts** Does this amendment include changes to a drug brochure or package insert?	☐ Yes ☐ No **– go directly to Q#19**
	a. Select the document that will be changed: NOTE: Only administrative or editorial changes are allowed for expedited review.	☐ Investigator's Drug Brochure ☐ Drug Package Insert
	b. Describe the changes to the Drug Brochure/Package Insert:	
	c. Will the proposed changes affect previously enrolled participants?	☐ Yes ☐ No
	d. Will currently enrolled participants be notified of this change?	☐ Yes ☐ No – State why participants will not be notified: _____
	e. How will currently enrolled participants be notified of changes?	
19.	**Other Changes** Are there other changes to the study not covered in Q#14 – 18?	☐ Yes ☐ No **– go directly to Q#20**
	a. Select all additional proposed changes to the study:	☐ Funding source ☐ Data Safety Monitoring Minutes/memos ☐ Sponsor annual reports ☐ Study off-hold ☐ Study closed to accrual (no new participants will be enrolled) ☐ Study on-hold: state reason: _____ ☐ Other: _____
	b. Describe the proposed changes and provide justification:	

20.	**Updating Appendices** If the amendment involves adding or revising one or more appendix, include the appendix (or appendices) with the submission. Select all appendices included with the amendment: Please do not submit the previously approved full Protocol Summary Form. **Only provide updated & current Appendix document if changes are being made**	☐ Appendix A - International Research ☐ Appendix B - Internet Use in Research ☐ Appendix C - Children as Research Participants ☐ Appendix D - Cognitively Impaired or Mentally Disabled Research Participants ☐ Appendix E - Prisoners as Research Participants ☐ Appendix F - Use of Drugs, Biologic Agents, or Devices ☐ Appendix G - Imaging/Diagnostic Radiation ☐ Appendix H - The Use of Biological Specimens ☐ Appendix I - Research Funded by a Component of the Department of Defense (DoD) ☐ Appendix J - Studies Conducted at or by the VA ☐ Appendix K - Pregnancy, Fetuses, Neonates ☐ Appendix L-NIH Genomic Data Sharing	☐ N/A – An appendix is not being added or revised

Please print the next page, titled "IRB Use Only"

IRB Use Only

Full Board Study Qualifies for Expedited Review and meets the following:			
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
☐	Data Safety Monitoring Minutes/Memo	☐	Funding Source
☐	Minor changes specifically requested by the IRB	☐	Minor changes specified by DMC Affiliate review
☐	Other:		
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**			

Expedited Studies Amendment Submission
(if not applicable select N/A & go to next section) N/A ☐

[redacted] **Yes** ☐ **No** ☐

Does all changes fall within one or more expedited review categories or include changes do not affect participants (or their identifiable information)?

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 ☐

[redacted] **Yes** ☐ **No** ☐

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?

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

Amendment Reviewer's Determination

☐ **Approve**	☐ **Full Board Review Required**	☐ **New Study Submission Required**	☐ **Other**
Reviewer Notes:			
Reviewer's Signature	Date:		