Directions for Full Board Protocol Amendment Submission

(NOTE: Do not include directions with your submission)

1. **IF THE 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. 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 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 qualify for Full Board Review:

Full board review is required when an additional risk to participants has been identified or the proposed change poses an increased risk or there is a change in the risk or safety information to participants that significantly affect the nature of the study. Examples of revisions that would require full board review may include one or more of the following:

- Addition of a **new risk**, serious unexpected adverse event, safety information or other risks to the protocol, Investigator Brochure, packet insert or consent documents
- Investigational Brochures, protocols, or package inserts with **updated** risk or safety information that is not already in the consent and, if multiple studies are using the drug, that does pertain to this study (if WSU site is permanently closed to accrual and no one is receiving treatment/active, and no one is in follow-up, then it can be expedited).
- Changes to the consent or Investigator Brochure that are ***more*** than administrative changes
- Broadening the range of inclusion criteria
- Narrowing the range of exclusion criteria
- Significant changes to the aims or design of the protocol
- Alteration in the dosage or route of administration of an administered drug
- Substantially extending the duration of exposure to the test material or intervention
- Deletion of laboratory tests, monitoring procedures, or study visits directed at the collection of information for safety evaluations
- Changes that, in the opinion of the IRB Chair or his/her designee, do not meet the criteria or intent of a “minor” modification

Refer to Expedited Amendment form for what can be expedited.

WAYNE STATE UNIVERSITY

IRB Administration Office
87 E. Canfield, Second Floor
Detroit, MI 48201
(313) 577-1628
irb.wayne.edu

Full Board Medical/Behavioral Amendment Form

- All IRB submission forms must be the current form date (down load from http://irb.wayne.edu/forms-requirements-categories.php) and typed or computer generated.
- **Forward *@wayne.edu*** e-mail to ***@med.wayne.edu, @karmanos.org***, etc. e-mail in order to receive important e-mail communications regarding the study. Non-WSU employees, please enter your e-mail. An e-mail address is required.
- On original form only: Submit with original signatures—no faxed or copies of signatures.
- The IRB committee deadlines are at: http://irb.wayne.edu/meetings-deadlines.php

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 ☐ Oakwood Staff ☐ Graduate Student* ☐ DMC Staff ☐ J. D. Dingell VAMC Staff ☐ Undergraduate Student* ☐ Karmanos Staff ☐ Resident/Fellow/Trainee* ☐ Other*: ____		
	*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/veterans*) ☐ No
9.	Expiration Date	
	a. 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

b. Is this a COVID-19 modification request?		☐ Yes (**If yes, please also Complete Q#16**) ☐ 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?	☐ No ☐ Yes (Describe the treatment or follow-up):
11.	Is WSU the Coordinating Center for this study? NOTE: If adding or deleting centers, submit a Coordinating Center Form with this submission	☐ Yes ☐ No
12.	Indicate the number of participants consented to date for the Wayne State/affiliate study:	
13.	Current Source of Funding	☐ N/A – no funding
14.	Amendment originates from:	☐ Sponsor ☐ Principal Investigator

Section C: Proposed Amendments

15.	Does this amendment include changes to recruitment methods and/or recruitment materials? NOTE: If changing accrual (number of participants enrolled), answer #16.		☐ Yes ☐ No **– go directly to Q#16**
	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 materials	☐ New ☐ Revised
	c. Describe how the new or revised recruitment documents will be used (i.e. recruitment methods, location, etc.):		☐ N/A – recruitment documents are not being added or changed
16.	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#17**

	a. Select all types of 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.	☐ **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* ☐ 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 protocol or study design:		
	c. State the reason(s) for the protocol or study design changes:		
	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	
17.	Does this amendment include changes to informed consent documents or the informed consent process? NOTE: If changing accrual (number of participants enrolled), also answer #16.		☐ Yes ☐ No **– go directly to Q#18**
	a. Select all informed consent documents that will be added or changed:	☐ Informed Consent Form (Adults)	☐ New ☐ Revised
		☐ Information Sheet (Adults)	☐ New ☐ Revised
		☐ Oral Consent Script (Adults)	☐ New ☐ Revised
		☐ Parental Consent Form	☐ New ☐ Revised
		☐ 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#17f**	
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#17g** ☐ No, the IRB already granted this previously **– go directly to Q#17g**	
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 the study **– go directly to Q#17h** ☐ No, the IRB already granted this previously **– go directly to Q#17h**	
I. Provide a written description of the information to be provided/read to participants:	☐ See attached	
h. Is a consent procedure which does not include or **alters some or all of the required elements** of informed consent being requested (Consent will be obtained, but some or all of the elements will be altered; i.e. deception)?	☐ Yes ☐ No, this is not needed for this study **– go directly to Q#18** ☐ No, the IRB already granted this previously **– go directly to Q#18**	
I. Will the study activities conducted under an alteration of consent be more than minimal risk to participants?	☐ Yes ☐ No	
II. Will the alteration adversely affect the rights and welfare of the research participants?	☐ Yes ☐ No	
III. Can the research be practicably carried out without the alteration?	☐ Yes ☐ No	
IV. Will the participants be provided with additional pertinent information after participation, if appropriate?	☐ Yes ☐ No	
V. Provide protocol-specific justification for requesting an alteration of some or all of the elements of consent:		

18.	Does this amendment include changes related to Health Insurance Portability and Accountability Act (HIPAA) documents?	☐ Yes ☐ No **– go directly to Q#19**	
	a. Select the HIPAA documents being added or changed:	☐ HIPAA Summary Form ☐ HIPAA Authorization Form(s)	
	b. Is a Waiver of HIPAA documentation 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:		
19.	Does this amendment include changes to a drug brochure or package insert?	☐ Yes ☐ No **– go directly to Q#20**	
	a. Select the document that will be changed:	☐ Investigator's Drug Brochure ☐ Drug Package Insert	
	b. Describe the changes to the Drug Brochure/Package Insert:		
	c. If multiple studies are using this drug, do the changes apply to the study being amended?	☐ Yes ☐ No	☐ N/A – Multiple studies are not using this drug
	d. Are the proposed changes already included in the informed consent document(s)?	☐ Yes – include a copy of the currently approved consent document(s) ☐ No	
	e. Will the proposed changes affect previously enrolled participants?	☐ Yes ☐ No	
	f. Will currently enrolled participants be notified of this change?	☐ Yes ☐ No – State why participants will not be notified: _____	
	g. How will currently enrolled participants be notified of changes?		
20.	Are there other changes to the study not covered in Q#15 – 19?	☐ Yes ☐ No **– go directly to Q#21**	
	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:		
21.	**Narrative Summary** **Answers should accurately reflect the currently approved research; incorporating any previously IRB approved amendments to the research.** NOTE: *Q#21* should be a total of **1-3 pages** in length. If the response to Q#21 exceeds 4 pages, the submission will be returned to the PI.		
	a. Describe the background and rationale for the study using lay language (non-technical and simplified language):		

	b. State the goals/aims/ hypothesis for the study using lay language (non-technical and simplified language):		
	c. List inclusion criteria:		
	d. List exclusion criteria:		
	e. Describe the methods and procedures of the study using lay language (non-technical and simplified language). Include data collection, study variables, sample size justification, and statistical considerations:		
22.	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:	☐ 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	☐N/A – An appendix is not being added or revised