

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.

Submission Requirements for Full Board Review: **Collate all copies**

Amendment Form	PH1	<ul style="list-style-type: none"> • PH1: Submit 1 copy • With original signatures • Submit electronically to ph1board@wayne.edu • See additional e-mail submission instructions for what to submit at IRB website on forms page. http://irb.wayne.edu/forms-requirements-categories.php
	M1, PH1 & B3	<ul style="list-style-type: none"> • M1 & B3: Submit 3 copies • With original signatures • Submit electronically to m1board@wayne.edu or b3board@wayne.edu • See additional e-mail submission instructions for what to submit at IRB website on forms page. http://irb.wayne.edu/forms-requirements-categories.php
	MP2 & MP4	<ul style="list-style-type: none"> • MP2 & MP4: Submit 19 copies • With original signatures
Amended Item	Currently Approved Version	Amended Version
Advertising Materials & items given to participants (eg, diaries)	<u>PH1:</u> 1 copy <u>M1, MP2, MP4 & B3:</u> 3 copies	<ul style="list-style-type: none"> • <u>PH1:</u> 1 copy; <u>M1 & B3:</u> 3 copies; <u>MP2 & MP4:</u> 19 copies • Highlight all changes on all copies • 2 clean copies (unhighlighted) for IRB approval stamp • 3 copies of the current document
Protocol Revisions	<u>PH1:</u> 1 copy <u>M1, MP2, MP4 & B3:</u> 3 copies	<ul style="list-style-type: none"> • <u>PH1:</u> 1 copy; <u>M1, MP2, MP4 & B3:</u> 3 copies • Highlight all changes on all copies • 3 copies of a “Summary of Changes” from sponsor or PI (<i>if applicable</i>). The summary should include the specific page number of the revisions. • 3 copies of the current document
Consent, Assent, Information Sheets	<u>PH1:</u> 1 copy <u>M1, MP2, MP4 & B3:</u> 3 copies	<ul style="list-style-type: none"> • <u>PH1:</u> 1 copy; <u>M1 & B3:</u> 3 copies; <u>MP2 & MP4:</u> 19 copies • Please update the footer with the revised date • Highlight all changes on all copies • 2 clean (unhighlighted) copies for IRB approval stamp • 3 copies of the current consent
HIPAA Forms	<u>PH1:</u> 1 copy <u>M1, MP2, MP4 & B3:</u> 3 copies	<ul style="list-style-type: none"> • 3 copies of the signed HIPAA Summary Form with all changes highlighted • 3 copies of the HIPAA Authorization Form (if not part of the consent document) with all changes highlighted on all copies • 2 clean (unhighlighted) copies of the HIPAA Authorization Form (if not part of the consent document) • 3 copies of the current document • <u>PH1:</u> 1 copy of all HIPAA documents listed above
Drug Brochure / Package Insert	<u>PH1:</u> 1 copy <u>M1, MP2, MP4 & B3:</u> 3 copies	<ul style="list-style-type: none"> • <u>PH1:</u> 1 copy; <u>M1, MP2, MP4 & B3:</u> 3 copies • Highlight all changes on all copies
Other	<u>PH1:</u> 1 copy <u>M1, MP2, MP4 & B3:</u> 3 copies	<ul style="list-style-type: none"> • 3 copies of each item (including a cover memo, if applicable) with all changes highlighted on all copies • 3 copies of the current document • <u>PH1:</u> 1 copy of all other documents

Clean copies of the revised consent must be single sided

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)	<input type="checkbox"/> Wayne State Faculty <input type="checkbox"/> Oakwood Staff <input type="checkbox"/> Graduate Student* <input type="checkbox"/> DMC Staff <input type="checkbox"/> J. D. Dingell VAMC Staff <input type="checkbox"/> Undergraduate Student* <input type="checkbox"/> Karmanos Staff <input type="checkbox"/> Resident/Fellow/Trainee* <input type="checkbox"/> Other*: _____	<i>*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.</i>		
	PI's Home Address:		PI's Home Phone:	()	
	Faculty Supervisor/ Sponsor:		Supervisor/ Sponsor E-Mail:		
	3.	Protocol Coordinator	<input type="checkbox"/> 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 ?	<input type="checkbox"/> Yes (<i>Please attach VA CIC approval memo if the amendment affects the VA site/veterans</i>) <input type="checkbox"/> 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	<input type="checkbox"/> Yes <input type="checkbox"/> No (including studies initially approved, exempted, or received its most recent continuation approval prior to March 15, 2016) <input type="checkbox"/> Unable to determine		

c. Is this a COVID-19 modification request?		<input type="checkbox"/> Yes (If yes, please also Complete Q#15)
		<input type="checkbox"/> No
10.	Is this protocol closed to recruitment?	<input type="checkbox"/> Yes <input type="checkbox"/> No – go directly to Q#11
	a. If the study is closed to recruitment, is anyone still on treatment or in follow-up?	<input type="checkbox"/> No <input type="checkbox"/> 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	<input type="checkbox"/> Yes <input type="checkbox"/> No
12.	Indicate the number of participants consented to date for the Wayne State/affiliate study:	
13.	Current Source of Funding	<input type="checkbox"/> N/A – no funding
14.	Amendment originates from:	<input type="checkbox"/> Sponsor <input type="checkbox"/> 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.	<input type="checkbox"/> Yes <input type="checkbox"/> 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.	<input type="checkbox"/> Advertisement, notice, or flyer <input type="checkbox"/> Pamphlet/Brochure <input type="checkbox"/> Participant recruitment letter <input type="checkbox"/> Press release <input type="checkbox"/> Recruitment script <input type="checkbox"/> Other recruitment materials
		<input type="checkbox"/> New <input type="checkbox"/> Revised <input type="checkbox"/> New <input type="checkbox"/> Revised <input type="checkbox"/> New <input type="checkbox"/> Revised <input type="checkbox"/> New <input type="checkbox"/> Revised <input type="checkbox"/> New <input type="checkbox"/> Revised <input type="checkbox"/> New <input type="checkbox"/> Revised <input type="checkbox"/> New <input type="checkbox"/> Revised
	c. Describe how the new or revised recruitment documents will be used (i.e. recruitment methods, location, etc.):	<input type="checkbox"/> 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.)?	<input type="checkbox"/> Yes <input type="checkbox"/> No – go directly to Q#17

<p>a. Select all types of protocol changes that will occur:</p> <p><i>*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.</i></p>	<p><input type="checkbox"/> COVID-19 MODIFICATION REQUEST</p> <p><input type="checkbox"/> Administrative</p> <p><input type="checkbox"/> Editorial (written protocol)</p> <p><input type="checkbox"/> Project Title (<i>new title</i>): _____</p> <p><input type="checkbox"/> Accrual (number of participants enrolled)</p> <p><input type="checkbox"/> Enrollment criteria (i.e. inclusion/exclusion criteria)</p> <p><input type="checkbox"/> Adding vulnerable participants (prisoners, cognitive impairment, minors, etc.) – submit appropriate Appendix</p> <p><input type="checkbox"/> Study procedures</p> <p><input type="checkbox"/> Risks and/or Benefits</p> <p><input type="checkbox"/> Data collection methods/Data collection instruments</p> <p><input type="checkbox"/> Participant compensation</p> <p><input type="checkbox"/> Adding or removing a research site*</p> <p><input type="checkbox"/> Adding an <u>international</u> site – submit Appendix A and contact export control: http://research.wayne.edu/export-control/</p> <p><input type="checkbox"/> Other (<i>specify</i>): _____</p>																
<p>b. Provide a detailed description of the proposed changes to the protocol or study design:</p>																	
<p>c. State the reason(s) for the protocol or study design changes:</p>																	
<p>d. State how this amendment will affect currently enrolled study participants:</p>																	
<p>e. State if the proposed change affects privacy or confidentiality:</p>																	
<p>f. Provide references to support this revision, if applicable:</p>	<input type="checkbox"/> None																
<p>17. Does this amendment include changes to informed consent documents or the informed consent process?</p> <p><i>NOTE: If changing accrual (number of participants enrolled), also answer #16.</i></p>	<p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No – go directly to Q#18</p>																
<p>a. Select all informed consent documents that will be added or changed:</p>	<table border="1"> <tr> <td data-bbox="617 1243 1169 1329"><input type="checkbox"/> Informed Consent Form (Adults)</td> <td data-bbox="1169 1243 1542 1329"><input type="checkbox"/> New <input type="checkbox"/> Revised</td> </tr> <tr> <td data-bbox="617 1329 1169 1415"><input type="checkbox"/> Information Sheet (Adults)</td> <td data-bbox="1169 1329 1542 1415"><input type="checkbox"/> New <input type="checkbox"/> Revised</td> </tr> <tr> <td data-bbox="617 1415 1169 1501"><input type="checkbox"/> Oral Consent Script (Adults)</td> <td data-bbox="1169 1415 1542 1501"><input type="checkbox"/> New <input type="checkbox"/> Revised</td> </tr> <tr> <td data-bbox="617 1501 1169 1587"><input type="checkbox"/> Parental Consent Form</td> <td data-bbox="1169 1501 1542 1587"><input type="checkbox"/> New <input type="checkbox"/> Revised</td> </tr> <tr> <td data-bbox="617 1587 1169 1673"><input type="checkbox"/> Assent Form (Children)</td> <td data-bbox="1169 1587 1542 1673"><input type="checkbox"/> New <input type="checkbox"/> Revised</td> </tr> <tr> <td data-bbox="617 1673 1169 1759"><input type="checkbox"/> Oral Assent Script (Children)</td> <td data-bbox="1169 1673 1542 1759"><input type="checkbox"/> New <input type="checkbox"/> Revised</td> </tr> <tr> <td data-bbox="617 1759 1169 1845"><input type="checkbox"/> Information Sheet (Children)</td> <td data-bbox="1169 1759 1542 1845"><input type="checkbox"/> New <input type="checkbox"/> Revised</td> </tr> <tr> <td data-bbox="617 1845 1169 1915"><input type="checkbox"/> Addendum to an Informed Consent Document</td> <td data-bbox="1169 1845 1542 1915"><input type="checkbox"/> New <input type="checkbox"/> Revised</td> </tr> </table>	<input type="checkbox"/> Informed Consent Form (Adults)	<input type="checkbox"/> New <input type="checkbox"/> Revised	<input type="checkbox"/> Information Sheet (Adults)	<input type="checkbox"/> New <input type="checkbox"/> Revised	<input type="checkbox"/> Oral Consent Script (Adults)	<input type="checkbox"/> New <input type="checkbox"/> Revised	<input type="checkbox"/> Parental Consent Form	<input type="checkbox"/> New <input type="checkbox"/> Revised	<input type="checkbox"/> Assent Form (Children)	<input type="checkbox"/> New <input type="checkbox"/> Revised	<input type="checkbox"/> Oral Assent Script (Children)	<input type="checkbox"/> New <input type="checkbox"/> Revised	<input type="checkbox"/> Information Sheet (Children)	<input type="checkbox"/> New <input type="checkbox"/> Revised	<input type="checkbox"/> Addendum to an Informed Consent Document	<input type="checkbox"/> New <input type="checkbox"/> Revised
<input type="checkbox"/> Informed Consent Form (Adults)	<input type="checkbox"/> New <input type="checkbox"/> Revised																
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<input type="checkbox"/> Oral Assent Script (Children)	<input type="checkbox"/> New <input type="checkbox"/> Revised																
<input type="checkbox"/> Information Sheet (Children)	<input type="checkbox"/> New <input type="checkbox"/> Revised																
<input type="checkbox"/> Addendum to an Informed Consent Document	<input type="checkbox"/> New <input type="checkbox"/> Revised																

b. Describe and justify the proposed changes to the consent documents:		<input type="checkbox"/> N/A – consent documents are not being added or changed
c. Will the proposed changes affect previously enrolled participants?	<input type="checkbox"/> Yes <input type="checkbox"/> No – go directly to Q#17f	
d. Will current participants be notified of the changes?	<input type="checkbox"/> Yes <input type="checkbox"/> 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)	<input type="checkbox"/> Yes <input type="checkbox"/> No, this is not needed for the study – go directly to Q#17g <input type="checkbox"/> 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?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
II. Will the waiver adversely affect the rights and welfare of the research participants?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
III. Can the research be practicably carried out without the waiver	<input type="checkbox"/> Yes <input type="checkbox"/> No	
IV. Will the participants be provided with additional pertinent information after participation?	<input type="checkbox"/> Yes <input type="checkbox"/> 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)?	<input type="checkbox"/> Yes <input type="checkbox"/> No, this is not needed for the study – go directly to Q#17h <input type="checkbox"/> 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:		<input type="checkbox"/> 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)?	<input type="checkbox"/> Yes <input type="checkbox"/> No, this is not needed for this study – go directly to Q#18 <input type="checkbox"/> 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?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
II. Will the alteration adversely affect the rights and welfare of the research participants?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
III. Can the research be practicably carried out without the alteration?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
IV. Will the participants be provided with additional pertinent information after participation, if appropriate?	<input type="checkbox"/> Yes <input type="checkbox"/> 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?	<input type="checkbox"/> Yes <input type="checkbox"/> No – go directly to Q#19
19.	<p>Does this amendment include changes to a drug brochure or package insert?</p> <p>a. Select the document that will be changed:</p> <p>b. Describe the changes to the Drug Brochure/Package Insert:</p> <p>c. If multiple studies are using this drug, do the changes apply to the study being amended?</p> <p>d. Are the proposed changes already included in the informed consent document(s)?</p> <p>e. Will the proposed changes affect previously enrolled participants?</p> <p>f. Will currently enrolled participants be notified of this change?</p> <p>g. How will currently enrolled participants be notified of changes?</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No – go directly to Q#20 <input type="checkbox"/> HIPAA Summary Form <input type="checkbox"/> HIPAA Authorization Form(s) <input type="checkbox"/> Yes <input type="checkbox"/> No, this is not needed for this study <input type="checkbox"/> No, the IRB already granted this previously <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes – include a copy of the currently approved consent document(s) <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No – State why participants will not be notified: _____ <input type="checkbox"/> N/A – Multiple studies are not using this drug
20.	<p>Are there other changes to the study not covered in Q#15 – 19?</p> <p>a. Select all additional proposed changes to the study:</p> <p>b. Describe the proposed changes and provide justification:</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No – go directly to Q#21 <input type="checkbox"/> Funding source <input type="checkbox"/> Data Safety Monitoring Minutes/memos <input type="checkbox"/> Sponsor annual reports <input type="checkbox"/> Study off-hold <input type="checkbox"/> Study closed to accrual (no new participants will be enrolled) <input type="checkbox"/> Study on-hold: state reason: _____ <input type="checkbox"/> Other: _____
21.	<p><u>Narrative Summary</u> Answers should accurately reflect the currently approved research; <u>incorporating any previously IRB approved amendments to the research.</u></p> <p>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.</p> <p>a. Describe the background and rationale for the study using lay language (non-technical and simplified language):</p>	

	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:	<input type="checkbox"/> Appendix A - International Research <input type="checkbox"/> Appendix B - Internet Use in Research <input type="checkbox"/> Appendix C - Children as Research Participants <input type="checkbox"/> Appendix D - Cognitively Impaired or Mentally Disabled Research Participants <input type="checkbox"/> Appendix E - Prisoners as Research Participants <input type="checkbox"/> Appendix F - Use of Drugs, Biologic Agents, or Devices <input type="checkbox"/> Appendix G - Imaging/Diagnostic Radiation <input type="checkbox"/> Appendix H - The Use of Biological Specimens <input type="checkbox"/> Appendix I - Research Funded by a Component of the Department of Defense (DoD) <input type="checkbox"/> Appendix J - Studies Conducted at or by the VA <input type="checkbox"/> Appendix K - Pregnancy, Fetuses, Neonates	<input type="checkbox"/> N/A – An appendix is not being added or revised