Directions for Full Board Protocol Amendment 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 Unanticipated Problem and Event Reporting 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
- Resumption of In-Person Research or Change for In-Person mitigation plans for studies initially reviewed by the full board

Please refer to Expedited Amendment form for what can be expedited.

Submission Documents Details/Instructions

Amended Item	Amended Version
Amendment Form	• Please complete all applicable section in entirety • Principal Investigator digitally signs form
Advertising Materials & items given to participants (eg, diaries)	• 1 copy of current document • 1 clean revised copy for IRB approval stamp (revised documents revision/version dates must be updated) • 1 highlighted revised version
Protocol Revisions	• 1 highlighted version with revised protocol/proposal date and version number • 1 "Summary of Changes" from sponsor or PI (*if applicable*). The summary should include the specific page number of the revisions.
Consent, Assent, Information Sheets	• 1 copy of current document • 1 clean copy for IRB approval stamp (revised documents revision/version dates must be updated) • 1 highlighted revised version
HIPAA Forms	• 1 current approved version • 1 highlighted revised version indicating the changes
Drug Brochure / Package Insert	• 1 current approved version • 1 highlighted revised version indicating the changes
Other	• 1 copy of current document • 1 clean revised copy for IRB approval stamp, if documents will be provided to participants (revised documents revision/version dates must be updated) • 1 highlighted revised version

Submissions Instructions

A digital signature is required for this form.
Open and save form using Adobe or software that allows for digital signature.
Instructions: Steps for Signing a PDF Form with a Digital ID

Clearly label all documents with the name of the document and version number/date.

Place the amendment form, any attachments (e.g. consents, assents advertisements, information sheets), and supporting documents in a single zip file and email to: eIRBManager@wayne.edu

Email Subject Line should indicate: NEW FULL BOARD AMENDMENT (PI Name and IRB #).

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 (download from http://irb.wayne.edu/forms-requirements-categories.php) and typed or computer generated.
- **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 **WSU Academica** 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.
- 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):	**Open and save form using Adobe or software that allows for digital signature. The Principal Investigator's signature is attesting to the accuracy of the submission and requesting approval of the modifications indicated.**		
	PI's E-mail:		Phone:	
	Department:			
	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:	

Section B: Protocol Information

5.	IRB # Example #####M1F	Coeus#
6.	Current Project Title:	
7.	Is this research being conducted at the **VAMC**?	☐ Yes (*Please attach VA CIC approval memo if the amendment impacts the VA site/veterans)* ☐ No
8.	Expiration Date or Status Check-In Date: ***See the initial or last IRB approval memo for date.*** ☐ N/A (*Exempt studies initially approved before 1/21/2019 there is not a Status Check-In 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
9.	Is this protocol closed to recruitment?	☐ Yes ☐ No **– go directly to Q#10**
	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):	
10.	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 Registration Number: ☐ No
11.	Indicate the number of participants consented to date for the Wayne State/affiliate study:	

12.	Current Source of Funding		☐ N/A – no funding
13.	Amendment originates from:	☐ Sponsor ☐ Principal Investigator ☐ Other:	

Section C: Proposed Amendments

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. Describe how the new or revised documents/materials will be used (i.e. recruitment methods, location, etc.):		
	If no new or revised documents/materials select N/A and go to question 15, N/A ☐		
	c. Select all recruitment documents that will be added or changed. If the amendment relates to internet recruitment, complete **Appendix B**.	☐ Advertisement, notice, or flyer **Name of Document(s):**	☐ New ☐ Revised

	NOTE: If recruitment is done at a non-WSU affiliate or a location outside of the PI's department a letter of support may be required.	☐ Pamphlet/Brochure **Name of Document(s):**	☐ New ☐ Revised
		☐ Participant recruitment letter **Name of Document(s):**	☐ New ☐ Revised
		☐ Press release **Name of Document(s):**	☐ New ☐ Revised
		☐ Recruitment script **Name of Document(s):**	☐ New ☐ Revised
		☐ Other Recruitment Materials **Name of Document(s):**	☐ New ☐ Revised
		☐ Participant Materials or Participant Information **Name of Document(s):**	☐ New ☐ Revised

Public Health Pandemic

15.	Does the research include any in-person activities (i.e. in-person recruiting, in- person data collection, in-person treatments or interventions)?	☐ Yes ☐ No **– go directly to Q#16**

a. Does the site (location of in-person recruitment and research activities) have *procedures to mitigate the spread of a virus that has risen to the level of a public health pandemic. ☐ Yes ☐ No

b. If No, provide justification to omit mitigation procedures:

See the IRB's COVID-19 Website for more information.

*All in-person research activities must include precautions and procedures to mitigate the spread of a virus that has risen to the level of a public health pandemic (i.e. COVID-19). **The plan must include the following procedures/precautions:**

I. A means to inform participants/patients, staff and visitors about the health pandemic's risks;
II. A method to screen participants/patients, staff and visitors;
III. Provide guidance for the conduct of person to person visits that includes social distancing, PPE, handwashing and disinfection

For research activities occurring at a WSU campus site or non-affiliate site that are not standard of care medical facilities: The following tools are available to assist in informing participants of in-person precautions:

- COVID-19 Participant Information Sheet Template
- COVID-19 Phone Script Template

If these documents or other documents will be used to inform participants of in-person precautions:

- Include the documents with this submission
- Complete the Consents/Assents/Scripts/Information Sheets section of this form.
- If applicable, complete and include a description for the Protocol Document/Design section of this form below.

☐ Participant documents are attached for this submission

☐ **N/A**

Protocol/Proposal Document & Study Design Changes

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.

☐ 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 for vulnerable population**
☐ Study procedures
☐ Risks and/or Benefits
☐ Data collection methods changes/Data collection instruments
☐ Public Health Mitigation Procedure Changes
☐ Participant compensation
☐ Adding or removing a research site*
☐ Public Health Pandemic Precautions/Procedures
☐ 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:

☐ **Protocol/Proposal document not revised** (specify why):

	c. State the reason(s) for the protocol or study design 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

Consents/Assents/Scripts/Information Sheets

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 #15.		☐ Yes ☐ No **– go directly to Q#18**
	a. Select all informed consent documents that will be added or changed. Provide name of document and the version or revision date.	☐ Informed Consent Form (Adults) **Name of Document(s) & revision/version date:**	☐ New ☐ Revised
		☐ Information Sheet (Adults) **Name of Document(s) & revision/version date:**	☐ New ☐ Revised
		☐ Oral Consent Script (Adults) **Name of Document(s) & revision/version date:**	☐ New ☐ Revised
		☐ Parental Consent Form **Name of Document(s) & revision/version date:**	☐ New ☐ Revised
		☐ Assent Form (Children) **Name of Document(s) & revision/version date:**	☐ New ☐ Revised
		☐ Oral Assent Script (Children) **Name of Document(s) & revision/version date:**	☐ New ☐ Revised

		☐ Information Sheet (Children) **Name of Document(s) & revision/version date:**	☐ New ☐ Revised
		☐ Addendum to an Informed Consent Document **Name of Document(s) & revision/version date:**	☐ New ☐ Revised
	b. Describe and justify the proposed changes and/or addition of the consent/assent 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?		

Waivers or Alteration of Consent

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#17i** ☐ No, the IRB already granted this previously **– go directly to Q#17i**

Waivers or Alteration of Consent continued.

h. Provide a written description of the information to be provided/read to participants:		☐ See attached
i. 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:	

HIPAA

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:	

Investigator's Brochure/Package Inserts

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. List the name and describe the changes to the Drug Brochure/Package Insert:

This section must be completed by providing a brief **summary** of the changes.

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?	

Other 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 other changes selected and provide justification:

21.	**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 – Adult Research Participants with Impaired Decision Making Ability ☐ 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 ☐ Appendix M – Limited IRB Review	☐ N/A – An appendix is not being added or revised

22.	**Narrative Summary** **Answers should accurately reflect the currently approved research; incorporating any previously, IRB approved amendments to the research. Do not include changes being requested at this time via this amendment.**	
	a. Briefly describe the background and rationale for the study using lay language (non-technical and simplified language):	

	b. Briefly 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. Briefly 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:	