# Directions for Expedited Protocol Amendment Submissions

1. **IF YOUR 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. **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.

# Submission Documents Details/Instructions

| Amendment Form | • Please complete all applicable section in entirety<br>• Principal Investigator digitally signs form |
|---|---|
| **Amended Item** | **Amended Version** |
| Advertising Materials & items given to participants (eg, diaries) | • 1 copy of current document<br>• 1 clean revised copy for IRB approval stamp (revised documents revision/version dates must be updated)<br>• 1 highlighted revised version |
| Protocol/Proposal Revisions | • 1 highlighted version with revised protocol/proposal date and version number<br>• 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<br>• 1 clean copy for IRB approval stamp (revised documents revision/version dates must be updated)<br>• 1 highlighted revised version |
| HIPAA Forms | • 1 current approved version<br>• 1 highlighted revised version indicating the changes |
| Drug Brochure / Package Insert | • 1 current approved version<br>• 1 highlighted revised version indicating the changes |
| Other | • 1 copy of current document<br>• 1 clean revised copy for IRB approval stamp, if documents will be provided to participants (revised documents revision/version dates must be updated)<br>• 1 highlighted revised version |

## Submissions Instructions

**A digital signature is required for this form.**
**This form must be opened and saved 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 EXPEDITED AMENDMENT (PI Name and IRB #).**

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

# 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.
- **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.

## 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.** | Current Project Title: | |
| **6.** | IRB #<br>(e.g. 123494M1F) | Coeus #<br>(e.g. 0123456891) |
| **7.** | Is this research being conducted at the VAMC? | ☐ Yes (*Please attach VA CIC approval memo if the amendment affects the VA site or veterans*)<br>☐ No |
| **8.** | Expiration or Status Check-In Date: ***See the IRB initial approval memo for date.***<br>☐ N/A (*for exempt studies initially approved before 1/21/2019 there is not a 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<br>☐ No (including studies initially approved, exempted, or received its most recent continuation approval prior to March 15, 2016)<br>☐ Unable to determine |
| **c.** Is this amendment adding a VA Site(s) or Federal Funding? | | ☐ Yes (**If yes, this study is not eligible for flexible Review, please also complete Q#15)**<br>☐ No |
| **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? | ☐ Yes ☐ No |
| **10.** | Indicate the number of participants to date for the Wayne State/affiliate study: | |
| | a. Is WSU the Coordinating Center for this study?<br>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?<br>https://clinicaltrials.gov/ct2/about-studies/learn#WhatIs | ☐ Yes Provide ClinicalTrials.gov Registration Number<br>Registration Number:<br>☐ No |
| **11.** | Current Source of Funding | ☐ N/A – no funding |
| **12.** | Amendment originates from: | ☐ Sponsor ☐ Principal Investigator<br>☐ Other: |

## Section C: Proposed Changes

**13. 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 #14.

☐ Yes
☐ No – **go directly to Q#14**

**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 14, N/A** ☐

**c.** 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 non-WSU affiliate or a location outside of the PI's department a letter of support may be required.

| | |
|---|---|
| ☐ Advertisement, notice, or flyer<br>**Name of Document(s):** | ☐ New<br>☐ Revised |
| ☐ Pamphlet/Brochure<br>**Name of Document(s):** | ☐ New<br>☐ Revised |
| ☐ Participant recruitment letter<br>**Name of Document(s):** | ☐ New<br>☐ Revised |

| | | | |
|---|---|---|---|
| | | ☐ Press release<br>**Name of Document(s):** | ☐ New<br>☐ Revised |
| | | ☐ Recruitment script<br>**Name of Document(s):** | ☐ New<br>☐ Revised |
| | | ☐ Other Recruitment Materials<br>**Name of Document(s):** | ☐ New<br>☐ Revised |
| | ☐ Participant Materials or Participant Information<br>**Name of Document(s):** | | ☐ New<br>☐ Revised |

## Public Health Pandemic

| | | |
|---|---|---|
| **14.** | Does the research include any in-person activities (i.e. in-person recruiting, in- person data collection, in-person treatments or interventions)? | ☐ Yes<br>☐ No **– go directly to Q#15** |

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

These template are available on the IRB Informed Consent/Assent Templates Website
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**

| 15. | **Protocol/Proposal Document & Study Design Changes**<br>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<br>☐ No **– go directly to Q#16** |
|---|---|---|
| | **If the IRB reviewer determines the study is no longer minimal risk, the IRB Administration Office will contact the PI with instructions to submit as a new full board study.**<br>**Please see the WSU IRB's 4-6 Amendments to the Research Protocols and Informed Consent Policy.** | |

**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.**

**Protocol/Proposal Study Design Changes: Submit a revised Protocol/Proposal to reflect the categories selected below. Submit a highlighted version of the revised document.**

☐ 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/Data collection instruments
☐ Public Health Mitigation Procedures Changes
☐ 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:

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

| | | | |
|---|---|---|---|
| | **c.** State the reason(s) for the study design or protocol changes:<br>*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 |

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| **16.** | **Consents/Assents/Scripts/Information Sheets/Waivers**<br>Does this amendment include changes to informed consent documents or the informed consent process?<br>**NOTE: If changing accrual (number of participants enrolled), also answer #15.** | | ☐ Yes<br>☐ No **– go directly to Q#17** |
| | **a.** Select all informed consent documents that will be added or changed. Provide name of document and revision or version date.<br><br>NOTE: If the change increases the risk to study participants *STOP*: a full board review (and form) is required. | ☐ Informed Consent Form (Adults)<br>**Name of Document(s) & revision/version date:** | ☐ New<br>☐ Revised |
| | | ☐ Information Sheet (Adults)<br>**Name of Document(s) & revision/version date:** | ☐ New<br>☐ Revised |
| | | ☐ Oral Consent Script (Adults)<br>**Name of Document(s) & revision/version date:** | ☐ New<br>☐ Revised |
| | | ☐ Parental Permission Consent Form<br>**Name of Document(s) & revision/version date:** | ☐ New<br>☐ Revised |
| | | ☐ Adolescent Assent Form (Children)<br>**Name of Document(s) & revision/version date:** | ☐ New<br>☐ Revised |

| | | | |
|---|---|---|---|
| | | ☐ Oral Assent Script (Children)<br>**Name of Document(s) & revision/version date:** | ☐ New<br>☐ Revised |
| | | ☐ Information Sheet (Children)<br>**Name of Document(s) & revision/version date:** | ☐ New<br>☐ Revised |
| | | ☐ Addendum to an Informed Consent Document<br>**Name of Document(s) & revision/version date:** | ☐ New<br>☐ Revised |
| | **b.** Describe and justify the proposed changes and/or addition of the consent/assent documents listed above: | | ☐ N/A<br>– consent documents are not being added or changed |

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| **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 – If 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<br>☐ No, this is not needed for the study **– go directly to Q#16g**<br>☐ 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<br>☐ No, this is not needed for this study **– go directly to Q#17**<br>☐ No, the IRB already granted this previously **– go directly to Q#17** |

## Waivers or Alteration of Consent continued.

| | | |
|---|---|---|
| | I. Provide a written description of the information to be provided/read to participants: | ☐ **document attached** |
| | II. Provide justification for waiver of written documentation of consent. | |

| | | |
|---|---|---|
| 17. | **HIPAA**<br>Does this amendment include changes related to Health Insurance Portability and Accountability Act (HIPAA) documents? | ☐ Yes<br>☐ No **– go directly to Q#18** |
| | a. Select the HIPAA documents being added or changed: | ☐ HIPAA Summary Form<br>☐ HIPAA Authorization Form(s) |
| | b. Is a Waiver of HIPAA documentation now being requested? | ☐ Yes<br>☐ No, this is not needed for this study<br>☐ No, the IRB already granted this previously |
| | c. Describe the proposed changes and provide justification: | |

| | | |
|---|---|---|
| 18. | **Investigator's Brochure/Package Inserts**<br>Does this amendment include changes to a drug brochure or package insert? | ☐ Yes<br>☐ No **– go directly to Q#19** |

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|---|---|---|
| | a. Select the document that will be changed:<br>NOTE: Only administrative or editorial changes are allowed for expedited review. | ☐ Investigator's Drug Brochure<br>☐ Drug Package Insert |
| | b. List the name and describe the changes to the Drug Brochure/Package Insert:<br>This section must be completed by providing a brief **summary** of the changes. | |
| | c. Will the proposed changes affect previously enrolled participants? | ☐ Yes<br>☐ No |
| | d. Will currently enrolled participants be notified of this change? | ☐ Yes<br>☐ No – State why participants will not be notified: |

**Investigator Brochure/Package Insert Changes continued**

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 for on-hold:

☐ Other:

**b.** Describe the proposed other changes selected and provide justification:

## 20. Updating Appendices

☐ N/A **– An appendix is not being added or revised**

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