External IRB Modification Worksheet

NON ePROTOCOL SUBMISSIONS

This worksheet is used for modifications to any study being conducted at WSU or one of our affiliate institutions that is under the oversight of an external IRB. An external IRB is any IRB that is not the WSU IRB. Please submit this completed worksheet along with the required attachments as instructed.

Modifications include (for example):

• Change in PI & Key Personnel changes	• Changes to the reliance agreement: (e.g., transfer of the study to another outside IRB)
• Local context changes include HIPAA Authorization and/or Waiver	• Changes to the protocol or consent documents that affect the local context of the study
• Changes to the injury language in the consent form	

The IRB office will notify the PI and designated personnel via email when the modification is authorized.

This form must be opened and saved using Adobe or software that allows for electronic signature.

Non-eProtocol studies submit this modification request to the appropriate External IRB email box:

NCI CIRB: cirb@wayne.edu	**WCG IRB: wirb@wayne.edu**
All others: relyirb@wayne.edu	

For eProtocol SUBMISSIONS STOP
Do Not Use or Submit this form. Use the eProtocol Amendment Form instead.

Section A: Study Details

1. WSU IRB#/Reference#	**Date Completed:**
Study Title:	
PI's Name: **PI's Email Address**	**Status of Principal Investigator** (*check all that apply*) ☐ WSU Faculty ☐ WSU Student ☐ DMC Staff ☐ KCI Staff ☐ Other (specify):
Submission Completed by: ☐ submission completed by the WSU PI	**Title:** **Email:**
Principal Investigator's Signature of Attestation for this Modification Submission **Signature & Date:** _____	

2. Sponsor/Select the External IRB that is used for this study:

Sponsor Contact Information	
Sponsor's Name:	Phone:
Contact Name:	Title:

☐ **WCG IRB**	☐ **National Cancer Institute CIRB**
☐ **Advarra**	☐ **Other Reviewing IRB (insert Name & contact below)**

Institution's Name:

IRB Point of contact (POC)Name:

Email: **Phone #:**

Please select all that apply and complete the applicable sections.

Section B: Unanticipated Problem/Event Reporting

If Not Applicable, Select N/A and go to next section ☐ **N/A**

Unanticipated Problem (UP)/Adverse Event/Protocol Violation Instructions

Protocol Violations/Deviations submitted to the Reviewing IRB:
Include with **this** submission all documents that are provided to the reviewing IRB (i.e., reporting form, UP communications)
Is this an:

- ☐ Initial Report
- ☐ Follow-Up Report
- ☐ External/Reviewing IRB's Determination

Local Context Protocol Violations/Deviations:
This includes HIPAA, key personnel, and breach of confidentiality are submitted to the WSU IRB

- **STOP - DO NOT SUBMIT THIS MODIFICATION FORM**
- Please submit the Unanticipated Problems & Event Reporting Form available on the WSU IRB's website.

Section C: WSU Local Key Personnel Changes

If Not Applicable, Select N/A and go to next section ☐ **N/A**

Study personnel: persons engaged in the collection of data or have access to data through intervention or interaction with the participant, including the consent process, or have access to the participant's identifiable private information. This may include collaborators, fellows, residents, research assistants, etc.

Note: Do not list/add key personnel from other sites outside of WSU and local affiliates.

- If a financial conflict of interest exists, a Financial Conflict of Interest Detailed Disclosure form must be completed then submitted to the WSU Financial Conflict of Interest Committee. The FCOI disclosure form can be found at http://research.wayne.edu/coi/index.php.
- All key personnel are required to take the CITI training program found at www.citiprogram.org.

Key Personnel Research Role and Obligations:

(I) Complete and maintain required human participant research training and update every three years.
(II) Follow the direction of the Principal Investigator to adhere to the IRB approved study protocol, institutional policies, and research regulations.

Does this submission include key personnel changes? ☐ **Yes** ☐ **No**

Select the personnel change type: ☐ **Deletion** ☐ **Addition**

Key Personnel Additions: complete the **Additional Key Personnel/Change Request Form** and include with this submission

Key Personnel Deletion: State the name and role of individuals being deleted in the box below.

Section D: Local Context Changes & HIPAA Documents

If Not Applicable, select N/A and go to next section ☐ **N/A**

Please select all that apply and attach a highlighted or tracked changes copy of consent/assents form(s) along with the most recent version of the IRB approved consent form.

1. ☐ Changes to HIPAA Summary Form (including waiver) and/or HIPAA Authorization:
- ***Please submit updated HIPAA Summary Form with PI signature(s) and updated consent with HIPAA Authorization revisions***.

2. ☐ Consent: Changes to research related injury language

3. ☐ Consent: Changes to local contact info (includes for WSU PI change)

4. ☐ Consent: Changes to study cost

5. ☐ Consent: Changes to study title
New Study Title:

6. ☐ Change in key personnel member's conflict of interest status (please provide conflict of interest plan if applicable)

7. ☐ Other Changes:

Describe proposed changes and the rationale: **PLEASE NOTE: If this description is not completed the submission will be returned.**

Section E: Ancillary Reviews

If Not Applicable, select N/A and go to next section ☐ N/A

Ancillary Reviews Do the changes require any of the following approvals? If ***Yes***, must provide approval letter with this submission	
Embryonic Stem Cell Research Oversight Committee (ESCRO)	☐ No ☐ Yes (*If "**Yes**" provide letter*)
Institutional Biosafety Committee (IBC)	☐ No ☐ Yes (*If "**Yes**" provide letter*)
Radiation Safety Committee (RSC)	☐ No ☐ Yes (*If "**Yes**" provide letter*)
WSU FCOI Committee (required when key personnel indicate a COI for the submission)	☐ No ☐ Yes (*If "**Yes**" please provide FCOI management plan*
Karmanos Cancer Institute Protocol Review & Monitoring Committee (PRMC)	☐ No ☐ Yes (*If "**Yes**" provide letter*)
McLaren Health Care review	☐ No ☐ Yes (*If "**Yes**" provide letter*)
Veterans Administration-CIC Approval	☐ No ☐ Yes (*If "**Yes**" provide letter*)
Department of Psychiatry	☐ No ☐ Yes (*If "**Yes**" provide letter*)
Detroit Medical Center (DMC) Review https://www.dmc.org/for-health-professionals/clinical-translation-research-office **Note:** Research occurring at DMC must copy mmontie@dmc.org on ALL communications with WSU IRB.	☐ No ☐ Yes *If "**Yes**" DMC Approval can be gained concurrently, but is required for IRB Administrative* authorization.

Section F: WSU PI Change

If Not Applicable, STOP THIS FORM IS COMPLETE

Changing the PI requires electronic signatures from the new PI, current PI, and the Department Chair. If the current PI is not available, questions, 2 (c) & (d) must be completed.		
1.	**The Current Principal Investigator Name & Signature must be provided for page 1 of this form.**	
2.	a. Should the current PI be:	☐ Removed from the study. ☐ Added as key personnel in the research role of:
	b. Is the current PI available to provide an original signature on this form?	☐ Yes **– go directly to Q#3** ☐ No **– answer sub-questions below (2c & 2d) and obtain a signature from the Department Chair, Dean, or Signatory Official authorizing the PI change**
	c. State why the current PI is unable to provide an original signature (include details regarding attempts to obtain a signature):	
	d. Include documentation (e.g. e-mail) from the current PI acknowledging that a PI change is appropriate, or explain why it is not possible to obtain documentation:	☐ Documentation from the current PI is being submitted.

3. Information for the proposed new Principal Investigator	Name of new PI:		☐ **The proposed PI's bio-sketch or CV is attached to this modification request.**
	Department		
	Address	Pager	
		E-Mail	
		Telephone	
Reason for the change in PI:			
Please describe the proposed PI's professional and/or educational qualifications for being the PI on this study:			

New Principal Investigator's CITI Training

PI must have completed the CITI training program at https://www.citiprogram.org/Default.asp
Further directions and a listing of the training are available at: http://irb.wayne.edu/mandatory-training.php
The new PI must affiliate with Wayne State University for their CITI profile.

eProtocol submissions NOTE: For eProtocol submissions, the new PI must include their WSU Access ID for their CITI profile. Note, CITI information updates in eProtocol each business morning.

a) Have you taken: ☐ HIPS ☐ RCR & ☐ Basic/Refresher Course for Human Subjects?

☐ Yes ☐ No - STOP: do not submit this modification request until are required CITI training is complete.

b) If CITI training was taken under a former name (e.g., maiden),

What is that name?

Is the Principal Investigator's CITI Training up to date? ☐ Yes ☐ No

Section G: WSU New Principal Investigator Attestation & Authorized Signatory

Open and save form using Adobe or software that allows for electronic signature.

Principal Investigator's Signature and Attestation

FCOI Statement: Do you, your spouse or domestic partner, and/or dependent children have a potential and/or real financial conflict of interest with the sponsor of this project (including all secondary sources)?

☐ NO

☐ YES (*if yes, please include WSU Memo of Understanding/Agreement to FCOI Management Plan*)

In signing as the Principal Investigator, I attest/agree to:

1. Attest to the accuracy of the information provided in this submission.
2. Agrees to accept primary responsibility for the scientific and ethical conduct of the research, as approved by the IRB.
3. Agrees to abide by the IRB's policies and procedures.
4. Agrees to submit unanticipated problem/adverse event reports in a timely manner.
5. Agrees to abide by the investigator responsibilities in the reliance/institutional authorization agreement.

_____ _____

New Principal Investigator's Signature & Date **Title**

Certification for Change in PI by the Dean/Chair/Authorized Signatory

Name of the Dean/Chair/authorized signatory **Title**

Name of College/Department/Institute/Center

Is authorized signatory's CITI training up to date? ☐ Yes ☐ No

FCOI Statement: Do you, your spouse or domestic partner, and/or dependent children have a potential and/or real financial conflict of interest with the sponsor of this project (including all secondary sources)?

☐ NO

☐ YES (*if yes, please include WSU Memo of Understanding/Agreement to FCOI Management Plan*)

In signing for submission of this research project: I attest that I am the authorized signatory for the Department Chairperson, Dean, and Institute/Center Director for the above noted College/Department/Institute/Center.

I certify that:
(a) appropriate support will be provided for the research project including adequate facilities and staff.
(b) appropriate scientific and ethical oversight has been and will be provided; and
(c) the research uses procedures consistent with sound research design.
(d) the research design is sound enough to yield the expected knowledge.

Signature of Chair/Dean/Authorized signatory **Date**