External IRB Modification Worksheet

This worksheet is used for subsequent submissions for 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.

Subsequent submission modifications include (for example):

• Change in PI & Key Personnel changes	• Changes to the reliance agreement: (i.e 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.

Note: Unanticipated Problems/Adverse Events are submitted on the Unanticipated Problem Form available on the WSU IRB's Forms and Submission Requirements website.

This form must be opened and saved using Adobe or software that allows for digital 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	

eProtocol SUBMISSION INSTRUCTIONS:

- Only studies where the initial submission was authorized via eProtocol can submit this modification request via eProtocol.
- Log into eProtocol at: https://ksprodweb.ovpr.wayne.edu
- Please select "Start an Amendment" and attach this completed form for the Protocol Information Attachments section.
- If you wish to transition a study to eProtocol, please see the Initial External IRB Worksheet and Guide.

Section A: Study Details

WSU IRB#/Reference#	**eProtocol#** ☐ **N/A**, this is not an eProtocol submission
Principal Investigator's (PI) Name: **PI's Email Address:**	**Submission Completed by:** ☐ submission completed by the WSU PI **Email Address:**
Status of Principal Investigator (*check all that apply*) ☐ WSU Faculty ☐ WSU Student ☐ DMC Staff ☐ KCI Staff ☐ Other (specify):	
Study Title:	

Please select the External IRB that is utilized:

☐ **WCG IRB**	☐ **Advarra**

☐ **National Cancer Institute CIRB**

Please select all NCI CIRB sites that apply:

☐ WSU / Karmanos Cancer Institute (CIRB Signatory) MI020	☐ Detroit Medical Center-HCC (CIRB Affiliate) MI053
☐ Huron Valley-Sinai Hospital (CIRB Affiliate) MI127	☐ Weisberg Cancer Treatment Center (CIRB Component) MI220

☐ **NCI CIRB McLaren Site(s) select all that apply:**

☐ McLaren Cancer Institute-Bay City (MI037)	☐ Karmanos Cancer Institute at McLaren Greater Lansing (MI140)
☐ McLaren Cancer Institute-Bloomfield (MI343)	☐ McLaren Cancer Institute-Owosso (MI298)
☐ McLaren Cancer Institute-Central Michigan (MI214)	☐ McLaren Cancer Institute-West Branch (MI322)
☐ McLaren Cancer Institute-Clarkston (MI285)	☐ McLaren Oakland Medical Center (MI318)
☐ McLaren Cancer Institute-Flint (MI060)	☐ McLaren-Port Huron (MI082)
☐ McLaren Cancer Institute-Lapeer Region (MI263)	☐ Mid-Michigan Physicians-Lansing (MI092)
☐ McLaren Cancer Institute-Macomb (MI066)	☐ Singh and Arora Hematology Oncology PC (MI262)
☐ McLaren Cancer Institute-Northern Michigan (MI081)	☐ Other Name: Other Site Number:
☐ McLaren Cancer Institute-Owosso (MI298)	

☐ **Other Reviewing IRB Commercial, Academic, or Hospital IRB (if selected state the Institution's Name)**	**Institution's Name:** **IRB Point of contact (POC):** **Name:** **Email:** **Phone #:**

Sponsor Contact Information

Sponsor's Name:	Phone:
Contact Name:	Title:
Is this study supported by a Common Rule agency? https://research.wayne.edu/irb/04_2015_forms/common_rule_agencies_guidance_toolrev.pdf	☐ Yes ☐ No

If study has NIH funding, please check all that apply:
☐ Study exempt from Federal regulations ☐ Training applicants ☐ Career development applicants
☐ Fellowship applicants

Additional entities/contacts that require notification of completed authorization	
Name/Title:	Email Address:
Name/Title:	Email Address:
Name/Title:	Email Address:

Section B: Modification Submission Details

Please select all that apply and complete the applicable sections.	
Local Key Personnel Change	☐ Complete Section C
Health Precaution for In-Person Research Activities	☐ Complete Section D
IRB of Record Change	☐ Complete Section E
WSU Study Lead Site/Coordinating Center Change	☐ Complete Section F
Local Context Change to Consent Form/HIPAA Authorization, & Ancillary Reviews	☐ Complete Section G
WSU PI Change	☐ Complete Section I
PI Attestation – **Digital signature is required on this form** **eProtocol Submissions: Signature is not required on this form. Please follow instructions at the end of this form.**	☐ Complete Section J

☐ **Unanticipated Problem(UP)/Adverse Event/Protocol Violation**
Submit the UP form available on the IRB's website and follow instructions for the Unanticipated Problems & Event Reporting Form

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.

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

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

Non eProtocol submissions: If an addition, complete the **Additional Key Personnel/Change Request Form** and include with this submission. ☐ **Additional Key Personnel/Change Request Form is attached.**

eProtocol submissions NOTE: Complete the Personnel Information section to add key personnel. The Additional Key Personnel/Change Request Form is not required.

If a deleting key personnel, see the Key Personnel Deletion section below.

Note: Key personnel from other sites outside of WSU and local affiliates should not be listed on the key personnel form/eProtocol submission.

- 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.

☐ **Key Personnel Deletion**

State the name and role of individuals being deleted in the box below.

eProtocol submissions NOTE: For eProtocol submissions please also delete the individual(s) from the Personnel Information.

Section D: Health Precautions for In-Person Research Activities

Health Pandemic Precautions (i.e. COVID-19)

a. Does the research include any in-person activities (i.e. in-person recruiting, in- person data collection, in-person treatments or interventions)? ☐ Yes ☐ No

b. 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 ☐ N/A

If No, please provide a justification to omit mitigation procedures:

*Mitigation procedures include:

I. A means to inform participants/patients, staff and visitors about the health pandemic 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.

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

Section E: IRB of Record Change

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

IRB of Record Change	
New IRB of Record Requested:	Phone:
Contact Name & Title:	E-mail:
Please select all that apply to the new Commercial, Academic, or Hospital IRB.	
☐ Smart IRB** Participating Institution (see https://smartirb.org/)	☐ New Agreement Needed – Not Using SMART IRB or Other Existing Agreement
☐ External IRB provided a Local Context Worksheet to be completed	☐ External IRB is AAHRPP accredited
Are there participants enrolled in this study?	☐ Yes If yes, how many: ☐ No
Is the study currently open to enrollment?	☐ Yes ☐ No

Section F: WSU Lead Site/Coordinating Center Change

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

WSU Lead Site/Coordinating Center Change	
Current lead site:	Phone:
Lead Study Site PI:	E-mail:
Contact Name & Title:	E-mail:
New Lead study site requested:	Phone:
Contact Name & Title:	E-mail:

Section G: 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.

eProtocol Submission Note: Attach the updated/revised consent(s) in the Consent Information. section. Attach updated/revised Assents in the Assent Information section.

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***.
   - **eProtocol submissions NOTE:** ***eProtocol Submissions complete the eProtocol HIPAA Section***.
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
   eProtocol submissions NOTE: To change the study title for eProtocol open the submission in edit mode and make the revision under the Summary & Purpose section.
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 H: 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 **For eProtocol Submissions please see the Protocol Checklist section and select all that apply**	
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*)
Materials Transfer Agreement (MTA)	☐ No ☐ Yes (*If "**Yes**" please contact mtainfo@wayne.edu*)
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	☐ 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 I: WSU PI Change

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

Changing the PI requires an electronic signature from the new PI, current PI, and the Department Chair.
If the current PI is not available questions, 3 (c) & (d) must be completed.

For eProtocol submissions follow the instructions below

1.	Name of current PI	
2.	**Current PI' digital SIGNATURE**	
3.	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? • **eProtocol Submissions the new PI must be changed for the Personnel Information section**	☐ Yes **– go directly to Q#4** ☐ No **– answer sub-questions below (3c & 3d) 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): • **eProtocol Submission NOTE: The new PI must be changed for the Personnel Information section**	
	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

4. 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:				

What are the proposed PI's professional and/or educational qualifications for being the PI on this study?
For eProtocol submissions STOP Do Not Complete. Update the Participant Population section for eProtocol.

New PI'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 is 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?

eProtocol Submission Instructions:

- For eProtocol submissions, a digital signature is not required.
- The new PI must be changed for the eProtocol Personnel Information section.
- The new PI's expertise must be provided for the Protocol Information Participant Population section
- The new PI must complete the Obligations and COI sections.
- Attach the New PI's CV/Resume for the Protocol Information Attachments section.
- Upon selecting "**Submit Form**" the amendment application will route to the authorized signatory for Change in PI sign-off.

For eProtocol SUBMISSIONS STOP THIS FORM IS COMPLETE.

For Non-eProtocol submissions - certifications on the following pages are required. Please continue to next page.

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

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

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

_____ _____

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

_____

Name of College/Department/Institute/Center

Is 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 with this submission*)

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 of the WSU Faculty or authorized signatory **Date**

Section J: WSU PI Attestation for Submission of this External Modification Request
PI Signature is required
If this is a PI Change, the new PI signs this section.

Principal Investigator's Signature and Attestation

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

_____ _____

Principal Investigator's Name **Title**

Is the Principal Investigator'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 with this submission*)

In signing the description of this research project, the PI:

1. Attests 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 adverse event reports in a timely manner.
5. Agrees to abide by the investigator responsibilities in the reliance/institutional authorization agreement.

_____ _____

Signature of Principal Investigator **Date**