WSU Initial External IRB Worksheet and Guide

Initial External IRB submissions are now accepted via eProtocol at
https://ksprodweb.ovpr.wayne.edu/

To request review by an external IRB please complete the eProtocol Application and submit this completed worksheet along with the required attachments as instructed.

"REQUEST TO RELY ON ANOTHER IRB" IRB MUST BE SELECTED FOR THE eProtocol-Protocol Checklist

- **CITI training must be completed by the Principal Investigator and all Key Personnel before submitting to the Authorized Signatory (Dean/Chair)**
- **PLEASE NOTE**: Prisoner research or planned emergency research **will not** be considered for relying on an External IRB
- **Please contact the IRB Administration Office if you have any questions along the way. Phone (313) 577-1628, Email: WSUIRBInfo@wayne.edu**

Section A: Study Details

1. Preliminary Study Details

WSU IRB eProtocol#	**Submission Completed by:** ☐ submission completed by the WSU PI
Principal Investigator's (PI) Name:	**PI's Email address**

Status of Principal Investigator (*check all that apply*)
☐ WSU Faculty ☐ WSU Student ☐ DMC Staff ☐ KCI Staff ☐ Other (specify):

Is this prisoner research (enrolling incarcerated individuals) or planned emergency research?	☐ Yes ☐ No If yes, **STOP.** **The WSU IRB does not consider prisoner research or planned emergency research for reliance on an External IRB. A complete eProtocol application must be submitted for WSU IRB review.**

Is the study supported by a common rule agency? ☐ Yes ☐ No

https://research.wayne.edu/irb/04_2015_forms/common_rule_agencies_guidance_toolrev.pdf
https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html

Does this study have federal funding?	☐ Yes ☐ No

Is this study an exempt submission? ☐ Yes ☐ No

If Yes, the WSU IRB will determine whether a reliance agreement is appropriate for an exempt submission. For exempt submissions it standard procedure for each individual IRB to maintain oversight and not rely on an outside IRB. For the WSU IRB, this would require submission of an Exempt application via eProtocol.

2. Please select the External IRB you wish to utilize:

☐ **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:
☐ McLaren Cancer Institute-Owosso (MI298)	Other Site Number:

☐ **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 #:**

Please <u>select all that apply</u> to your Commercial, Academic, or Hospital IRB

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

☐ Smart IRB** Participating Institution (see https://smartirb.org/) ☐ IRB Reliance Exchange (IREx) Institution (see https://www.irbexchange.org/p/) ☐ Other Master Agreement already signed (such as a consortium agreement), Please provide name of consortium:	☐ New Agreement Needed – Not Using SMART IRB or Other Existing Agreement ☐ External IRB is AAHRPP accredited ☐ External IRB provided a Local Context Worksheet to be completed

3. Transfer Oversight from WSU IRB to an External IRB **If Not Applicable, Select N/A and go to next section ☐ N/A**	
Is this study being transferred from the WSU IRB to an External IRB? ☐ Yes ☐ No **Note:** If the WSU IRB has tabled, deferred, disapproved, or terminated this research study in the past, WSU IRB oversight cannot be transferred to an external IRB.	
Please provide the current WSU IRB#	
Are there participants enrolled in the study?	☐ Yes If yes, how many ☐ No
Is the study currently open to enrollment?	☐ Yes ☐ No
Note: If you are transferring IRB oversight from WSU to WCG IRB, you will need to complete the transfer form posted at www.wcgirb.com	

Section B: Previously Authorized Studies

4. Request to Transition Previously Authorized Submissions from Paper-Based to eProtocol **If Not Applicable, Select N/A and go to next section ☐ N/A**	
Are you transitioning a previously authorized external IRB submission to eProtocol? ☐ No ☐ Yes *If "**Yes**", provide the previously approved IRB#* *If "**Yes**" complete the following steps below*	
✓ Create an eProtocol Initial Submission ✓ Select Request to Rely on an External IRB ✓ Complete this entire worksheet and follow instructions indicated for the worksheet	✓ Attach this Initial External IRB Worksheet to eProtocol's Protocol Information Attachments section ✓ Add all WSU and WSU affiliate key personnel to the Personnel Information section ✓ The previously approved study must remain open until External IRB Authorization is provided by the WSU IRB
Questions? Email: IRBQuestions@wayne.edu	

Section C: eProtocol Submission Details

5. eProtocol Submission

Complete the following sections for the eProtocol Application

Use Firefox or Safari web browser and enable pop-ups

☐ **Personnel Information** section completed with **COI** and **Obligations**

☐ **Participant Checklist**	☐ **Study Location** State location of research activities **Study Location:** Complete items 1 & 2 responses must state "Yes"
☐ **Funding**	☐ **VAMC Checklist** (If applicable)

☐ **Protocol Checklist**: **Select "Request to Rely on Another IRB-External IRB Submission"** and all other applicable boxes.
If "Request to Rely on Another IRB-External IRB Submission" is not selected the user will be prompted to complete sections of the eProtocol application that are not required for external IRB submissions.

☐ **Study Details**: **drop down menu**

- Select: "External IRB"
- Select the Review Type: Full Board, Expedited, or Exempt
  - Exempt submissions may not be accepted and each IRB will need to complete their own IRB review
  - If unsure regarding the review type please contact the reviewing IRB for assistance.

eProtocol- Protocol Information sections

☐ **Summary & Purpose**: Provide the estimated start and end date **Note:** This is the section where you can make changes to the study title, if needed.	☐ **Participant Population:** Complete the PI's experience question. If enrolling Non-English speaking individuals, please state
☐ **Consent Information**: Attach the Consent(s) ONLY State N/A for all other items requested for eProtocol	☐ **Assent Information**: Attach the Assents (s) ONLY State N/A for all other items requested for eProtocol
☐ **HIPAA** (if applicable): If PHI will be collected attach the HIPAA Authorization with the Consent. For NCI CIRB submissions the HIPAA Authorization is a separate document	☐ **Drugs and Devices** (if applicable): The appropriate boxes must have been selected for the Protocol Checklist (i.e. investigational drug, commercially available drug, investigational medical device, chemotherapeutic drug, etc)

☐ **Attachments:**

Attach the following documents to the Protocol Information Attachments section:

- ☐ Initial External IRB Worksheet (this form)
- ☐ PI's CV/Resume
- ☐ Research Protocol/Research Proposal
- ☐ Letter(s) of approval from review committees (i.e. PRMC, DMC, CIC, IBC, etc) (if applicable)
- ☐ McLaren Approval and McLaren Authorization Form for McLaren sties
- ☐ Reviewing IRB Local Context Form (if applicable)
- ☐ Reviewing IRB Reliance Agreement or Smart IRB Acknowledgement (if applicable)
- ☐ NCI CIRB HIPAA Authorization Form (if applicable)

Section D: Health Precautions for In-Person Research Activities

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

Does the research site and/or study include procedures/precautions with:
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.

☐ **Yes** ☐ **No** ☐ **N/A**

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

See the WSU IRB COVID-19 website for information regarding precautions and considerations to protect participants during in-person research activities https://research.wayne.edu/irb/coronavirus

Section E: Drugs & Device Details

7. Investigational New Drug (IND), Investigational Device Exemption (IDE), Humanitarian Device Exemption (HDE)

Complete the Drugs and Devices section for eProtocol and answer all questions below.

PSF Appendix F is not required.

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

(a) Does this study involve an IND application?	☐ No ☐ Yes If yes, IND#
(b) Does this study involve an IDE?	☐ No ☐ Yes If yes, IDE#
(c) Does this study involve an HDE?	☐ No ☐ Yes If yes, HDE#
(d) Specify the name of the organization or individual who holds the IND/IDE/HDE, or select "Not Applicable":	Name/Organization/Individual holding IND/IDE/HDE: Not Applicable ☐

(e) If the study does not yet have an IND/IDE number, please explain the FDA application status: ☐ **N/A**

(f) Describe the drug and/or device accountability plan that includes receiving, storing, securing, dispensing, final disposition and accountability of the drug and/or device.
Note: For devices, the PI is required to oversee the maintenance of the device, including dates and use by participants, and disposal.

Section F: Ancillary Reviews & Approvals

8. Ancillary Reviews

See eProtocol's-Protocol Checklist section, select all applicable ancillary reviews

If Not Applicable, Select N/A ☐ N/A

- Attach Ancillary Review/Approvals for the Protocol Information Attachment section
- DMC Review and Approval can be conducted concurrently with the WSU IRB Submission
- If McLaren, the McLaren Approval Letter & External Authorization form both must be submitted

Section G: Additional eProtocol & Submission Guidance

9. Sections that are NOT required for eProtocol

- **Summary & Purpose (start and end date are required only)**
- **Background, Rationale, Data Analysis, and Procedures**
- **Participant Population (only PI's Expertise required)**
- **Recruitment Process, Participant Compensation, and Costs section**
- **Risks**
- **Data Safety Monitoring**
- **All Addendums**
- **Recruitment Materials: see section Advertisement Policy below**

10. eProtocol Review Process Information

- ☐ Upon receipt of your submission in the WSU IRB Office you will receive email notifications during the review process up until final authorization (emails are sent to the WSU email address)
- ☐ If the IRB Administrator request revisions
  - Revision requests are forwarded via eProtocol to the PI & Study Coordinators' WSU email account
    - To make changes to the sections indicated per the revision request complete the following:
      - Open the application in edit mode
      - Attach the highlighted/track changes revised documents to the applicable sections
        - Consent & Assent Information section
        - Attachments section
        - Label the documents as revised with the revision date
      - Corrections should be made to the sections indicated per the comments request.
      - Indicate that revisions have been made in the comments section by addressing each comment.
      - Select "Submit to IRB" to return the revisions back to IRB
- ☐ Revisions are reviewed, if no additional requests or pending ancillary reviews, authorization will be provided.
- ☐ Authorization will be provided in the form of an email to the PI and coordinators WSU email account
- ☐ The WSU IRB will copy additional contacts noted on the worksheet

Note: Studies requiring DMC Review:

- DMC review can occur concurrently with IRB review. Please contact the DMC Clinical & Translation Research Office for DMC submission instructions.
- DMC personnel may be added to the IRB application for DMC reviewer view access.
- To forward a copy of your IRB Application to the DMC Clinical & Translation Research Office
  - Select Print View tab:
    - Select applicable sections of the eProtocol form
    - Save form as a PDF to provide for DMC Review
    - Consent & Assents and other participant documents will need to be saved separately and forward to DMC for review.

To inquire about WSU IRB submission status email: irbstatus@wayne.edu

11. Additional Guidance: WSU Advertisement Policy

Advertisements include the following: Flyers, Advertisements, Recruitment Materials, Brochures, and scripts.

Do not submit advertisement materials with the eProtocol Application.
Submit documents to the Reviewing IRB.

Advertisement criteria

- Advertisements may not imply a certainty of favorable outcome or benefits beyond what is outlined in the informed consent.
- No claims should be made that the drug, biologic or device is safe or effective for the purposes under investigation, or that the test article is known to be equivalent or superior to any other drug, biologic or device.
- The terms "new treatment", "new medication" or "new drug" should not be used without explaining that the test article is investigational.
- Advertisements should not promise "free treatment", when the intent is only to say that participants will not be charged for taking part in the investigation.
- Advertisements may state that the participants will be paid, but should not emphasize the payment or the amount to be paid, by such means as larger or bold type. See the IRB policy on "Compensation for Research Participants" for guidelines on compensation
- Advertisements should state that it is for a research study.
- Advertisements may not be coercive or imply undue pressure.
- Advertisements may be limited to the information the prospective participants need to determine their eligibility and interest.
- Advertisements may not include exculpatory language

These items below may be included, however are not required

- The name and address of the clinical investigator and the identity of the research facility.
- The condition under study and/or the purpose of the research.
- The criteria, in summary form, that will be used to determine eligibility for the study.
- A brief list of the benefits or incentives of participation, if any.
- The time or other commitment required of the participants.
- The name of the person or office to contact for further information.