WSU Initial External IRB Worksheet and Guide

Initial External IRB submissions are now accepted via eProtocol at
https://ksprodweb.ovpr.wayne.edu/
Complete the eProtocol Application and submit this completed worksheet and attachments.

- **SELECT "REQUEST TO RELY ON ANOTHER IRB" for the eProtocol-Protocol Checklist to deter the user completing sections of the eProtocol application that are not required for external IRB submissions.**
- **Select all applicable boxes for the Protocol Checklist, Study Location, and Participant Population**
- **Attach Consents using the appropriate consent templates.**
- **Attach Assents for the Assent Information section.**
- **CITI training, Obligations, & COI statement completion is required for the Principal Investigator and all Key Personnel.**
- **Contact the IRB Administration Office if you have any questions at (313) 577-1628 or irbquestions@wayne.edu**

Section A: Study Details

1. Preliminary Study Details

WSU IRB eProtocol#	**Submission Completed by:** ***The individual completing the submission must be included for eProtocol Personnel Information section.*** ☐ select if submission completed by the WSU PI
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.**
Does this study have federal funding?	☐ Yes ☐ No

Is this study an exempt submission? ☐ Yes ☐ No

For exempt submissions it is 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. External IRB Contact Information

Is this a submission to Advarra, WCG IRB or NCI CIRB? ☐ Yes ☐ No

If No, provide the name and contact information for the External IRB below and select the agreement type.

Name of IRB & Institution:

IRB Point of contact (POC) Information: Name:

Email: **Phone #:**

Agreement Type: **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/)

☐ 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

☐ Other Master Agreement already signed (such as a consortium agreement)

Name of Consortium:

Section B: Health Precautions for In-Person Research Activities

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

Does the research site and/or study include procedures/precautions for a health pandemic?

☐ **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 C: Drugs & Device Details

4. 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, enter the drug's name & IND for eProtocol Drugs and Devices section.
(b) Does this study involve an IDE?	☐ No ☐ Yes If yes, enter the device's name & IDE for eProtocol Drugs and Devices section.
(c) Does this study involve an HDE?	☐ No ☐ Yes If yes, enter the HDE for eProtocol Drugs and Devices section
(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 D: Attachments & Ancillary Reviews/Approvals

Attachments

The following documents must be provided with the eProtocol application for local context review.

Protocol Information Consent & Assent Information sections attach:

- Completed Consent Forms attached for the Protocol Information Consent Information section.
- Completed Assent Forms attached for the Protocol Information Assent Information section.
- Indicate "N/A" for all questions for the consent and assent sections.

Protocol Information Attachments section:

- Initial External IRB Worksheet (this form)
- PI's CV/Resume
- Research Protocol/Research Proposal
- Reviewing IRB Local Context Form (if applicable)
- Reviewing IRB Reliance Agreement or Smart IRB Acknowledgement (if applicable)
- NCI CIRB HIPAA Authorization Form (if applicable)

Ancillary Reviews/Approvals

DMC Approval	PRMC Approval
FCOI	VA CIC Approval
Institutional Biosafety Committee (IBC)	Radiation Safety
McLaren Approval Letter & Supporting Document(s)	