WSU Initial External IRB Worksheet

SMART IRB & NEW Reliance Agreement Requests
Submit New External IRB Requests via eProtocol
https://ksprodweb.ovpr.wayne.edu/
EXCEPTION - DO NOT SUBMIT this worksheet for WCG, Advarra, and NCI-CIRB.

EXTERNAL IRB SUBMISSION INSTRUCTIONS:

- SELECT "REQUEST TO RELY ON ANOTHER IRB" for the eProtocol-Protocol Checklist.
  - There are sections of the eProtocol application that ARE NOT required for external IRB submissions. Please see guidance document for additional information.
- Select all applicable boxes for the Protocol Checklist, Study Location, and Participant Population sections.
- Attach Consents for the Consent Information section using the appropriate consent templates.
- Attach Assents for the Assent Information section.
- Attach additional supporting documents for the Attachments section of eProtocol
- 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
- For updates on review status, you may contact: irbstatus@wayne.edu
- Is this a submission to Advarra, WCG IRB or NCI CIRB? ☐ Yes ☐ No
  - If yes, STOP! This form is not required with the external IRB submission.

Section A: Study Details

1. Preliminary Study Details

WSU IRB eProtocol# ☐ *eProtocol Personnel Information section – Enter the Principal Investigator's "Investigator Role" Faculty, Staff, affiliate*	**Submission Completed by:** ☐ *The individual completing the submission must be included in the eProtocol Personnel Information section. IRB Communications will be forwarded to this individual.* ☐ Select if submission completed by the WSU PI
Is this prisoner research (enrolling incarcerated individuals) or planned emergency research?	☐ Yes ☐ No If yes, for prisoner studies, review will need to be conducted by a WSU IRB prisoner representative.
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 instead of this form.

2. External IRB Contact Information REQUIRED

Name of IRB & Institution:

IRB Point of contact (POC) Information: Name:
Email: **Phone #:**

Is the External IRB AAHRPP accredited? ☐ Yes ☐ No

Agreement Type/Information:

☐ Smart IRB** Participating Institution (see https://smartirb.org/)
Attach the Smart IRB acknowledgement letter for the eProtocol attachments section.
☐ IRB Reliance Exchange (IREx) Institution (see https://www.irbexchange.org/p/)

☐ New Agreement Needed – **Not** Using SMART IRB or an Other Existing Agreement

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

Name of Consortium:

Does the external (reviewing) IRB require completion of a local context form/document? ☐ Yes ☐ No

If yes, please fill out and attach this form for the eProtocol Attachments section.

Section B: Drugs & Devices Details

3. 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 this form is complete. ☐ **N/A**

(a) Does this study involve an IND, IDE, HDE application?	☐ No ☐ Yes **If yes,** **Provide the drug and/or Device name for eProtocol.** **Provide the IND, IDE, or HDE number for eProtocol and the study's phase.**

Section C: Attachments & Ancillary Reviews/Approvals

Attachments

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

Protocol Information Consent Information & 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). Note this worksheet is not required for WCG, Advarra, and NCI-CIRB.
- WSU 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)
- **APPENDICES ARE NOT REQUIRED for External IRB Submissions.**

If applicable, the following Ancillary Reviews/Approvals Required:

- DMC Approval
- PRMC Approval
- WSU FCOI Committee (required when key personnel indicate a COI for the submission)
- VA-CIC Approval
- Institutional Biosafety Committee (IBC)
- Radiation Safety Committee
- McLaren Approval Letter & Supporting Document(s)
- Embryonic Stem Cell Research Oversight Committee (ESCRO)