

WSU PRELIMINARY INTAKE FORM (WSU as REVIEWING IRB)

For requesting WSU to be the Reviewing IRB for multi-site studies prior to initial review

Requests for Wayne State University to be the Reviewing IRB/single IRB (sIRB) should be submitted as early in the process as possible by emailing relyirb@wayne.edu.

For single IRB NIH-funded research, the sIRB can be the IRB at the lead site, one of the participating sites, or an independent, fee-based IRB. When WSU IRB is the sIRB named in the proposal, we must have agreed to take on this responsibility in advance. This form is used for the purpose of making that decision ahead of the grant submission.

WSU IRB serves as the Reviewing IRB for an external organization only if WSU is also engaged in the research and/or or has a master agreement in place with the external organization.

A Reliance Agreement (or IRB Authorization Agreement or IAA) is a formal, written document indicating a collaborative arrangement between institutions that allows one or more institutions to cede human subjects research review to another Institutional Review Board (IRB). A reliance agreement describes the responsibilities of the Relying institution and researcher as well as the responsibilities of the Reviewing IRB and its institution. Reliance agreements can be used to avoid having duplicate IRB reviews at multiple sites, and they are also needed for meeting the NIH Single IRB policy for multi-center studies.

Generally, Wayne State University IRB does not enter into Reliance Agreements for the following:

- studies we deem “exempt”;
- international research sites; or
- studies where only some of the sites would rely on WSU and others would do their own review.

For additional information, please refer to the Reliance Agreements page of the website at: <https://research.wayne.edu/irb/reliance-agreements> as well as WSU IRB Policy 04-17 (External Institutional Review Boards & Reliance Agreements for Multi-Site Research) found on this page: <https://research.wayne.edu/irb/policies-human-research>.

NOTE: PLEASE DO NOT COMMUNICATE TO ANOTHER INSTITUTION THAT WSU IRB IS WILLING TO SERVE AS THE IRB OF RECORD UNTIL YOU HAVE SUBMITTED THIS FORM AND RECEIVED CONFIRMATION BACK FROM WSU IRB THAT THEY ARE WILLING AND ABLE TO DO SO.

PLEASE FILL OUT EVERY QUESTION ON THE FORM AND COMPLETE THIS FORM FOR EACH RELYING SITE. THE IRB NEEDS ALL OF THE INFORMATION ON THIS FORM TO MAKE ITS DECISION. DECISIONS ARE MADE ON A CASE-BY-CASE BASIS. IF YOU LEAVE A QUESTION BLANK, THE IRB WILL SEND THE FORM BACK TO YOU AND REQUIRE YOU TO COMPLETE IT BEFORE ISSUING A DETERMINATION. EMAIL THE COMPLETED SET OF FORMS TO RELYIRB@WAYNE.EDU.

1. **Study Title:**

2. **Wayne State:**

PI Name (with Degrees):
Email:
Phone Number:
If applicable, coordinator name and email:

3. **Non-Wayne State - the Relying Institution:**

Institution/Affiliation:
Does this institution (if any) routinely conduct human subjects research? <input type="checkbox"/> Yes <input type="checkbox"/> No
PI Name(s) with Degrees:
Email:
Phone Number:
If applicable, coordinator name and email:

4. **Other Institution's IRB (if applicable):**

IRB Name/Affiliation:
Point of Contact Name and Email:

5. **Is the other institution AAHRPP-accredited?**

6. **Is the study >min. risk (> daily life risk)?**

7. **Funding Information:**

- a. Have you applied for or received funding? Yes No

If Study is Currently Funded or Funding Has Been Applied For:

- i. Specify the source:
- ii. Specify the institution that is prime awardee:
- iii. If NIH-funded, what type of award (e.g. K, R01, etc.)?

8. **How many total sites are engaged in the study (including WSU and Other Institutions)?**

9. **Pick any of the following WSU-affiliated sites which are engaged (Check all that apply):**

- | | |
|------------------------------|--|
| <input type="checkbox"/> DMC | <input type="checkbox"/> Detroit VAMC |
| <input type="checkbox"/> KCI | <input type="checkbox"/> None of these |

10. **Regulatory Information:**

- a. Is the study FDA-regulated?
- b. Does the study qualify as a clinical trial?
- c. Will a study investigator (at WSU or another institution) hold an IND or IDE for the study?

Yes No

If yes, which institution:

11. **Type of research participants? (Check all that apply)**

- | | | |
|---|---|---|
| <input type="checkbox"/> No Subjects | <input type="checkbox"/> Newborns/Infants Under 2 | <input type="checkbox"/> Prisoners |
| <input type="checkbox"/> Healthy Controls | <input type="checkbox"/> Minors 2 and over | <input type="checkbox"/> Non-English speakers |
| <input type="checkbox"/> Adults | <input type="checkbox"/> Pregnant Women | <input type="checkbox"/> Impaired Decision Making |

12. Process History:

- a. How far along in the process is the study?
- b. WSU IRB# (if applicable):

13. Study Summary (~ 5-10 sentences):

Include the overall aim, procedures involving human participants or their data, data source, participant population, location, potential risks, etc. Do not copy and paste the lay summary.

Wayne State University's Role in the Research:

Please check all that apply and give further detail. Must check at least one.

ACTIVITY	DETAILS
<input type="checkbox"/> Lead site (Overall PI and lead study team are here)	<i>If checked, please attach a copy of the protocol to your email when you submit this request.</i>
<input type="checkbox"/> Prime awardee <input type="checkbox"/> Prime awardee/direct grant recipient BUT WSU-affiliated investigators are NOT conducting <u>any</u> other procedures under the protocol	<i>If checked, please attach a copy of the grant/award to your email when you submit this request.</i>
<input type="checkbox"/> <u>WSU has received</u> a subcontract	
<input type="checkbox"/> Conducting the full protocol here (enrolling, analyzing data, and administering study interventions or procedures)	A. Number of subjects enrolled here: B. Type of study interventions HERE? <input type="checkbox"/> Biomedical research interventions/procedures <input type="checkbox"/> Collection of identifiable biospecimens <input type="checkbox"/> Sociobehavioral or educational interactions (surveys, questionnaires, etc.) <input type="checkbox"/> Other:
<input type="checkbox"/> Only conducting some part(s) of the protocol Choose all that apply: <input type="checkbox"/> Enrollment/Consenting Subjects <input type="checkbox"/> Access to Identifiable Data <input type="checkbox"/> Access to De-identified Data <input type="checkbox"/> Data Analysis <input type="checkbox"/> Data Storage/Banking <input type="checkbox"/> Administering Study Interventions/Procedures/Interactions <input type="checkbox"/> Medical records review only	
<input type="checkbox"/> WSU-affiliated researchers solely participating in the protocol on-site at the other institution or assisting the other institution with their protocol How?	A. How many researchers? B. If WSU students, are they getting paid or receiving academic credit at WSU? <input type="checkbox"/> Payment <input type="checkbox"/> Academic/internship credit <input type="checkbox"/> Neither
<input type="checkbox"/> Investigator from another institution has now begun employment at WSU and is bringing research with him/her	A. What is investigator's role NOW? <input type="checkbox"/> Data analysis <input type="checkbox"/> Assistance with manuscripts <input type="checkbox"/> Other: B. Will funding be transferred to WSU? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not funded

Relying Institution/Individual's Role in the Research:

Please check all that apply and give further detail. Must check one or more.

ACTIVITY	DETAILS
<input type="checkbox"/> Lead site (Overall PI and lead study team are there)	<i>If checked, please attach a copy of the protocol to your email when you submit this request.</i>
<input type="checkbox"/> Prime awardee <input type="checkbox"/> Prime awardee/direct grant recipient BUT procedures are being conducted ONLY at WSU by WSU researchers-NOT at the Other Institution or with the Other Institution's researchers	<i>If checked, please attach a copy of the grant/award to your email when you submit this request.</i>
<input type="checkbox"/> Other Institution <u>has received</u> a subcontract	
<input type="checkbox"/> Conducting the full protocol there (enrolling, analyzing data, and administering study interventions or procedures)	A. Number of subjects enrolled there: B. Type of study interventions THERE? <input type="checkbox"/> Biomedical research interventions/procedures <input type="checkbox"/> Collection of identifiable biospecimens <input type="checkbox"/> Sociobehavioral or educational interactions (surveys, questionnaires, etc.) <input type="checkbox"/> Other:
<input type="checkbox"/> Only conducting some part(s) of the protocol Choose all that apply: <input type="checkbox"/> Enrollment/Consenting Subjects <input type="checkbox"/> Access to Identifiable Data <input type="checkbox"/> Access to De-identified Data <input type="checkbox"/> Data Analysis <input type="checkbox"/> Data Storage/Banking <input type="checkbox"/> Administering Study Interventions/Procedures/Interactions <input type="checkbox"/> Medical records review only	
<input type="checkbox"/> Other Institution's researchers coming to WSU to assist on-site with our protocol How?	A. How many researchers? B. If students, are they getting paid or receiving academic credit at their institution? <input type="checkbox"/> Payment <input type="checkbox"/> Academic/internship credit <input type="checkbox"/> Neither
<input type="checkbox"/> Former WSU Investigator is moving institutions and taking research with him/her	A. What is investigator's role NOW? <input type="checkbox"/> Data analysis <input type="checkbox"/> Assistance with manuscripts <input type="checkbox"/> Other: B. Will funding be transferred from WSU? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not funded