Human Subjects Research Reliance Request Form

Application Instructions

* Do not delete or re-format any portion of this application.
* Do not leave any repose fields blank. If a response field if not applicable to your research, please respond as “N/A.”
* Please submit to irb@wsu.edu
* Please have the subject line read as “Reliance Request Form for Submission”
* If someone other than the WSU PI is submitting this form or corresponding on behalf of the WSU PI, the WSU PI **must** be Cc’d at their WSU email.
* If you are requesting rush review due to funding disbursements, please indicate this in your submission email so that our office can make the appropriate considerations when reviewing the reliance request.
* If you have questions regarding the form, please contact our office at irb@wsu.edu.

Background about Collaborative Research

* WSU IRB must ensure that all performance sites which are engaged in research (i.e., whose employees are the primary recipient of the research funding, are consenting subjects, are interacting with subjects to collect research data, or are analyzing identifiable data) have a review by an IRB.
* WSU IRB is responsible for providing IRB oversight for research conducted by faculty, employees and students of WSU. If your research engages outside investigators who are employees or students from external sites, then those investigators would need to seek their own IRB review and approval through the institutions that they are affiliated with for their involvement in the research. In some cases, however, if both institutions agree, one institution may serve as the single IRB of record for the project. For example, WSU may review the project for the outside institution, or WSU may cede review to the outside institution’s IRB. This is called a **reliance agreement**, and it is done to prevent unnecessary burden caused by multiple reviews.
* The questions in this form are necessary for WSU IRB to ensure that each **engaged** site on this study has proper IRB oversight. The questions will help to determine whether your WSU human subject research requires WSU IRB review **OR** whether a reliance agreement with another institution/investigator may be appropriate. Your responses determine the route of processing for this request. It is not a guarantee that WSU will or will not rely **OR** serve as the reviewing IRB.

**Details About Reliance**

Reasons for Reliance

Select all that apply. If you are unsure, select “unsure”

[ ]  My project does not involve external collaboration with non-WSU collaborators/sites; **a reliance agreement is not required.**

[ ]  This is a multi-center project where research procedures will be performed at one or more collaborating external sites outside of WSU. WSU is **not** the lead/central site/coordinating site for the multi center project.

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[ ]  My research involves a WA state agency and must be reviewed by WSIRB\*.

[ ]  My research involves Providence St. Joseph Health Care facilities and must be reviewed by Providence St. Joseph Health IRB\*\*

[ ]  My collaborator(s) are independent investigators\*\*\* involved and engaged in human subject research activities and request review by WSU IRB.

[ ]  To comply with Single IRB review requirements for federally supported research where the IRB of record has been specifically designated either in the grant or by the funding agency.

[ ]  The non-federal sponsor has requested the review by WSU IRB (attach the request document).

[ ]  This is an industry sponsored, industry-initiated study which needs to be reviewed by a commercial IRB.

[ ]  I am seeking exceptions for a Single IRB review mandate.

☐ Other

☐ Unsure

*\* The Washington State IRB must conduct the review of your research project because Washington State Agencies (for example, the Washington State Department of Health) are involved in this project. \*\* The Providence St. Joseph Health IRB will conduct the review of your research project if the research is conducted in facilities owned by Providence Health Care or involves use of Providence patients or records. Use this link to apply for Providence St. Joseph Health IRB’s review. External research link for Providence St. Joseph Health is:* [*https://research.providence.org/about/*](https://research.providence.org/about/) *Note that if the project also includes portions that do not involve Providence St. Joseph Health IRB, then you will need to submit a separate application for those portions of the project to WSU IRB. \*\*\* Definition of* ***independent investigator****: An independent investigator is an individual collaborator who is not affiliated with an institution (e.g., former student working after graduation with their faculty mentor, professional in the community with specific expertise, community partners).*

**Investigator/Study Information**

**Study Title**

[insert text]

Research Type

Select the option that best applies for the research.

[ ]  Non-Clinical Research

[ ]  [Clinical Research](https://grants.nih.gov/policy/clinical-trials/definition.htm)

WSU Principal Investigator (PI)

Only **one** WSU faculty member or staff member who has a research requirement associated with their position may serve as the Principal Investigator (PI). The PI is ultimately responsible for the conduct of the proposed research. The PI may delegate research responsibilities to other approved [key personnel](https://irb.wsu.edu/research-terminology/) but must maintain oversight and retain ultimate responsibility for the conduct of those to whom they delegate research responsibilities to. Prospective PIs are advised to review the investigator responsibilities outlined in the [HRPP Manual: Section 12](https://irb.wsu.edu/documents/2022/09/hrpp-manual.pdf) prior to serving in this role.

| **Name** **(First Last)** | **WSU ID #** | **WSU Email** | **WSU Phone #****(###)###-####** | **WSU College/Department Affiliation** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |

**Funding**

**Funding Type**

 Select all that apply.

[ ]  N/A – This project is not funded

[ ]  Federal funding

[ ]  Non-Federal funding

**Funding Details**

Insert additional rows to table below if needed.

| **Funding Agency Name** | **Grant Title** | **PI listed on Grant** | **Funding/ORSO # for Grant** | **Institution who is primary awardee on grant** | **Institution who is subaward on grant** |
| --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |

*If applicable, include a copy of* *all grant/contract applications or awards.*

**Type of Reliance Requested**

*Please specify what type of reliance is requested for the collaborative project.*

[ ]  I am requesting that WSU relies on another IRB for the project’s review

[ ]  I am requesting that WSU reviews for another IRB or collaborator for the project’s review

**Research Approval**

*Please indicate whether the research has already been approved by an IRB (either WSU IRB or an external IRB).*

[ ]  The research has already been approved by an IRB

[ ]  The research has not been approved by an IRB

*Please include the approval date and the IRB number for the protocol.*

[insert text]

Study/Reliance Overview

Research Questions/Objectives

List all research questions/objectives this study aims to address.

[insert text]

Research Purpose (e.g.,)

Briefly provide a summary of the rationale and justification for conducting this research as it applies to any anticipated contributions to generalizable knowledge. Readers not familiar with the subject area must be able to readily understand the research purpose. Use lay language and avoid the use of undefined acronyms and technical terminology.

[insert text]

Reason for Reliance Request

Please describe why the reliance is being requested (ex: study already has external IRB approval from non-WSU institution and WSU personnel are being added to the project)

[insert text]

**Research Engagement**

**Sites/Investigators Involved in Research for Which Reliance is Requested**

Please list out all of the research sites/institutions that will be involved in the project below. **Please also include WSU as a site!**

Insert additional rows to table for each institution/independent investigator involved.

| **Institution Name (If independent investigator, list N/A)** | **Contact Information for IRB (If independent investigator, list N/A)** | **Activities Performed (list all activities performed. Ex: recruitment, consent, administering surveys, analysis of identifiable data, etc.)** | **Name of investigator responsible for activity at this site** | **Relevant training of investigator (CITI, previous research experience, etc.)** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |

**Sites Not Engaged**

List below the name of external sites that will not be under IRB review because they are not engaged in the research.\* Justify the reason. \*Note: All research sites under this study must be under IRB oversight (either WSU or their own IRB) unless they are not engaged in the research (for example, if they are only obtaining de-identified data that has already been collected and will not be interacting with human subjects). Check with WSU IRB or the external IRB for guidance on engagement in research if you are unsure.

Insert additional rows to table below if needed.

| **Site Name** | **Justification for Reliance not needed** |
| --- | --- |
|  |  |

Sites Conducting Separate IRB Review

Some sites may conduct their own IRB review without reliance, such as tribal IRBs that are independent sovereign entities. Please include all sites who will be conducting their own IRB review and not engaging in reliance.

Insert additional rows to table below if needed.

| **Site Name** | **Justification for Separate Review** |
| --- | --- |
|  |  |

**If WSU is relying on another IRB, please complete below (if not, list N/A)**

Please indicate if you have consulted with someone at WSU HRPP/IRB about the reliance.

Select one.

[ ]  Yes

[ ]  No

[ ]  N/A

**Has the external IRB already agreed to conduct review on behalf of the WSU researchers on this project?**

Select one.

[ ]  Yes

[ ]  No

[ ]  N/A

Local Context Review Details

Please provide any local context review details (institutional requirements, local laws, age of majority, assent and consent requirements, cultural aspects of the population, human subjects training requirements):

[insert text]

Vulnerable Subject Populations

If any vulnerable populations are the priority population or specifically being excluded from the research, please include these below (ex: children, prisoners, pregnant people).

[insert text]

Reportable Activities

Are there/could there be any reportable activities in the research, such as abuse/neglect of children or vulnerable adults? Please explain below.

[insert text]

CITI Training

If WSU is relying on another IRB’s review, the WSU IRB will be responsible for verifying that the WSU investigator has appropriate CITI training completed. The WSU investigator will be responsible for ensuring that all WSU key personnel on the project have completed training as appropriate. Please review the CITI training requirements for WSU investigators here: <https://irb.wsu.edu/training/>

☐ I acknowledge that I am aware of the training requirements and understand the responsibilities regarding required trainings.

If applicable, attach documentation of correspondence about the reliance request (from WSU IRB/HRPP or non-WSU IRB/HRPP).

**If WSU is reviewing, please complete below:**

Training Requirements

If the relying institution has training requirements separate from WSU’s CITI requirements, please describe these requirements below:

[insert text]

Local Context Forms

If the relying institution has institutional or local context forms that they require, please name them below and attach them to this request form (list N/A if none)

[insert text]

**CITI Training**

*If WSU is reviewing for external collaborators, the non-WSU investigators and key personnel will be required to have CITI training completed prior to being added to the project. Please review the CITI training requirements for non-WSU investigators here:* [*https://irb.wsu.edu/training/*](https://irb.wsu.edu/training/)

☐ I acknowledge that I am aware of the training requirements and understand the responsibilities regarding required trainings.

If applicable, attach documentation of correspondence about the reliance request, and/or any additional training certificates or local context forms from the external institution.