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| University of Washington Human Subjects DIvision | **SOP Internal Reliance Agreements**  |

**1 PURPOSE and APPLICABILITY**

This document describes the policies and procedures for deciding whether it is appropriate for another institution or individual to rely on the UW IRB and for executing reliance agreements and documenting the reliance arrangement.

**2 CONTEXT**

Federal regulations require that an institution or individual’s reliance on an IRB be documented along with the responsibilities that each entity will undertake to ensure compliance with the regulations. This is accomplished through reliance agreements.

**3 POLICY**

**Studies eligible for reliance on the UW IRB.** HSD allows reliance on its IRBs for the review of non-exempt, human subjects research. In rare circumstances, HSD may also enter into agreements with other institutions or individuals who wish to rely on HSD’s determination that an activity is not human subjects research or is exempt. In those circumstances, UW will not use the SMART IRB Agreement and requires a separate reliance agreement be drafted and used.

**Institutions and individuals eligible for reliance on the UW IRB.** U.S.-based institutions or individuals must be engaged in a non-exempt, human subjects research project that is eligible for the use of the UW IRB as described in the **Engagement Guidance**. HSD will not generally allow reliance on the UW IRB when the non-UW institution or individual cannot demonstrate that their activities constitute engagement in the research, when IRB review is required by that institution solely in order to meet its unique institutional policies, or when the institution is not based in the U.S.

**Who makes the decision.** The UW’s Vice Provost for Research has delegated decision-making authority, including the negotiation and execution of reliance agreements, to UW’s Institutional Official (IO) and specific HSD staff. HSD staff who do not have this delegated authority are, however, allowed to determine that a non-UW institution may rely on the UW IRB for certain classes of studies addressed under an existing reliance agreement with that institution as described in the [**WORKSHEET Internal Rel**](https://www.washington.edu/research/forms-and-templates/worksheet-human-subjects-research/)**iance Agreements**, **WORKSHEET Non-UW Investigator Agreements**, and **WORKSHEET Non-Assured Institution Agreements.**

**Reliance agreement options**. In order to support flexibility and tailor the terms of reliance agreements to the circumstances of individual studies, UW makes use of and accepts a variety of reliance agreement templates and structures. These include UW’s own reliance agreement templates (the **TEMPLATE Study Specific Reliance Agreement, Full** the **TEMPLATE Study Specific Reliance Agreement, Basic**, the **TEMPLATE Non-UW Investigator Agreement**,and the **TEMPLATE Non-Assured Institution Agreement**), the *SMART IRB Master Reliance Agreement*, as well as other templates and formats. If another institution will rely on the UW for an exempt determination that includes limited IRB review , the reliance must be documented in writing, including the responsibilities of each entity, in the standard way for any other reliance on the IRB’s review.

**Research not subject to federal requirements.** When a non-UW institution or individual will rely on the UW IRB for research not subject to federal regulations and/or guidance, UW will execute a reliance agreement. Although a formal, written agreement is not required in these situations, HSD considers it best practice for documenting roles and responsibilities related to IRB review.

**4 PROCEDURES**

* 1. **Researcher request for review by the UW IRB**. UW researchers request permission for a non-UW institution or individual to rely on the UW IRB for a specific study by answering the appropriate questions in their Zipline IRB application and uploading a completed **SUPPLEMENT Multi-site and Collaborative Research** and/or **SUPPLEMENT Non-UW Individual Investigators**. This request can be part of an initial IRB application or a modification application for a study already approved by the UW IRB.
	2. **Decision by HSD**. HSD staff use the **WORKSHEET Team S Engagement Assessment** to assess the provided materials and information. Additional information or materials may be requested if needed to assess the request. A member of the HSD Leadership Team or the Sr. Reliance Administrator makes the final decision about the acceptability of the proposed reliance.
	3. **Confirming the reliance arrangement and negotiating the reliance terms.** When a request is granted, HSD staff use the [**WORKSHEET Internal Rel**](https://www.washington.edu/research/forms-and-templates/worksheet-human-subjects-research/)**iance Request**, the **SOP Reliance Insurance and Indemnification**,and/orthe **WORKSHEET Non-UW Investigator Agreements** to assess whether the proposed reliance falls under the terms of an existing reliance agreement, confirm that the other institution or individual is willing to rely on the UW IRB, negotiate a new agreement if needed, and to clarify study specific responsibilities for any flexible terms of agreements or for responsibilities not covered by the agreement. Staff may use the **TEMPLATE** **Study Specific Reliance Plan (SSRP)** or another method to document flexible terms.
	4. **Transfers of ongoing research.** When the request for reliance means that a study currently reviewed and approved by a non-UW IRB will be transferred to the UW IRB, HSD staff responsible for executing the reliance complete additional activities in the **WORKSHEET Team S Engagement Assessment** to accomplish the transfer in an orderly way that assures continuous IRB oversight with no lapse in either IRB approval or the protection of human subjects, and with minimal disruption of research activities. HSD staff use the form **TEMPLATE Transfer Plan UW and Non-UW IRB**, a form provided by the receiving institution, or another written method to document information about the transfer. The **TEMPLATE Transfer Plan UW and Non-UW IRB** may also be used in rare circumstances when a study is transferred and the transferring institution will not rely on the UW IRB, for example, because the transferring institution’s engagement has concluded.
		1. When the transfer is complete, HSD staff ensure that all transfer-related documentation has been placed in the study file and any records requested from the transferring IRB have been provided.
	5. **Documenting the reliance decision and arrangement.** All decisions about reliances, documentation of the decision, and the terms of the reliance arrangement are considered HSD records and are appropriately recorded in the Zipline system.
	6. **Withdrawal of reliance.** In rare circumstances, it may be necessary for UW or the relying institution to withdraw from the reliance arrangement. In these circumstances, HSD will:
		+ Review and comply with the terms of the reliance agreement in regard to timelines and requirements for written notification to other parties,
		+ Assess whether the circumstances require reporting to any funders or other oversight agencies, and prepare and submit any required reports according to HSD’s policies and procedures,
		+ To the extent feasible, assist the other institution with the transfer of oversight to the new IRB.

**5 DEFINITIONS**

In this document, the term *reliance agreement* refers to the actual reliance agreement as well as any attachments, addenda, exhibits, and other materials such as a letter of indemnification or letter or acknowledgement to rely associated with the reliance agreement.

**6 RELATED MATERIALS**

SOP Reliance Insurance and Indemnification

[SUPPLEMENT Multi-site and Collaborative Research](https://www.washington.edu/research/forms-and-templates/supplement-multi-site-or-collaborative-research/)

[SUPPLEMENT Non-UW Individual Investigators](https://www.washington.edu/research/forms-and-templates/supplement-non-uw-individual-investigators/)

TEMPLATE Non-Assured Institution Agreement

TEMPLATE Non-UW Investigator Agreement

TEMPLATE Study Specific Reliance Agreement Full

TEMPLATE Study Specific Reliance Agreement Basic

TEMPLATE Study Specific Reliance Plan (SSRP)

TEMPLATE Transfer Plan UW and Non-UW IRB

[WEBPAGE Engagement Guidance](https://www.washington.edu/research/hsd/guidance/engagement/)

WORKSHEET Internal Reliance Agreements

WORKSHEET Non-UW Investigator Agreements

WORKSHEET Non-Assured Institution Agreements

WORKSHEET Team S Engagement Assessment

**7 REGULATORY REFERENCES**

FDA Guidance: Using a Centralized IRB Review Process in Multicenter Clinical Trials https://www.fda.gov/regulatoryinformation/guidances/ucm127004.htm

TITLE 45 CODE OF FEDERAL REGULATIONS Part 46, 2018 Requirement (The Common Rule)

SACHRP Guidance, Attachment A: Initial Considerations for Single IRB Review: Points to Consider https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-a-november-2-2016-letter/index.html

OHRP sample authorization agreement https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/forms/irb-authorization-agreement/index.html

OHRP, “Consideration in Transferring a Previously-Approved Research Project to a New IRB or Research Institution”, draft guidance; May 23, 2012. https://www.hhs.gov/ohrp/regulations-and-policy/requests-for-comments/draft-transfer-document/index.html

FDA, “Guidance for IRBs, Clinical Investigators, and Sponsors: Considerations When Transferring Clinical Investigation Oversight to Another IRB”, May 2014. https://www.fda.gov/downloads/regulatoryinformation/guidances/ucm307779.pdf

OHRP, Determination of Exception for Certain HHS-Conducted or -Supported Cooperative Research Activities Subject to the 2018 Requirements. <https://www.hhs.gov/ohrp/regulations-and-policy/single-irb-requirement/114b-exception1/index.html>

Vice Provost for Research Delegation of Authority for Establishing Reliance Agreements Memo, April 4, 2023

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|  **Version Number** | **Posted Date** | **Implementation Date** | **Summary of Changes** |
| 2.5 | 08.29.2025 | 08.29.2025 | Add information about withdrawal of reliance and use of SMART for exemptions. |
| 2.4 | 11.26.2024 | 11.26.2024 | Update reference for retired SOP Use of the UW IRB |
| 2.3 | 09.26.2024 | 09.26.2024 | Add information about SOP Reliance Insurance and Indemnification |
| 2.2 | 11.02.2023 | 11.02.2023 | Revise information about transfers |
| 2.1 | 07.27.2023 | 07.27.2023 | Add statement that when another institution relies of UW IRB for LIRB, the reliance must be documented in the standard way |
| Previous versions |  |  | For older versions: HSD staff see the SharePoint Document Library; Others – contact hsdinfo@uw.edu.  |

**Keywords:** Internal reliance, Multi-site; Single IRB; Transfers