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

1. **PURPOSE**

This document describes the policies and procedures for deciding whether reliance on an external (non-UW operated) IRB is required and/or allowable, and, if it is, for executing reliance agreements and documenting the reliance arrangement.

1. **CONTEXT**
	1. Institutions and individuals may work cooperatively and be engaged in a research project involving human subjects. Often under these cooperative arrangements, multiple institutions and individuals can be engaged in the research. It may be advantageous, or required, to obtain IRB review from only one IRB for some or all of the engaged institutions or individuals rather than seeking IRB review from all engaged parties. This arrangement is referred to as single IRB (sIRB) review.
* **2018 Common Rule requirement**. Effective January 20, 2020, all of the domestic institutions that are engaged in a federally-supported, non-exempt, cooperative research project must rely upon approval by a single IRB. Health and Human Services (HHS) supported research does not have to comply with the requirement if at least one IRB has approved the research before January 20, 2020.
* **NIH multi-site policy**. For most NIH applications submitted on or after January 25, 2018, NIH requires the use of a single IRB for all domestic sites participating in multi-site non-exempt human subjects research.
* **Other research**. For research not subject to the 2018 Common Rule, the NIH policy or another sponsor’s requirement to use a single IRB, it may be advantageous to the research to obtain IRB review from the same IRB for many or all engaged institutions or individuals rather than seeking IRB review from multiple IRBs.
	1. Federal regulations require that an institution’s reliance on an external IRB be documented along with the responsibilities that each entity will undertake to ensure compliance with the regulations.
1. **POLICY**
	1. **Studies eligible for review by an external IRB.** UW can rely on external IRBs for review of non-exempt, human subjects research. UW does not typically rely on the determinations made by a non-UW institution that a project is not research with human subjects or is exempt but will do so in very limited circumstances. In those circumstances, UW will not use the SMART IRB Agreement and requires a separate reliance agreement be drafted and used. The conditions under which UW will rely on an external IRB are described on [HSD’s website](https://www.washington.edu/research/hsd/is-the-uw-irb-the-right-irb/general-information/#which) and in the **[WORKSHEET External](https://www.washington.edu/research/forms-and-templates/worksheet-human-subjects-research/) Reliance, Initial Submissions.**
	2. **Qualifications of the external IRB.** HSD assesses the qualifications of the proposed external IRB as part of the process by which a reliance agreement is executed or reliance is documented under the terms of an umbrella agreement (such as the SMART IRB Agreement). This assessment is accomplished in a variety of ways determined and directed by HSD Management. It includes consideration of the scope of the agreement and the type of research to be reviewed. The assessment may include identification of the IRB institution’s Federalwide Assurance or other federally issued assurance, and accreditation status; a review of the external IRB’s standard operating procedures, registrations status, member roster, and audit history, site visits; and the collection of other information about the IRB’s performance.
	3. **Research not eligible for review by an external IRB.** It is possible that a study may not qualify for review by an external IRB. For example, if the external IRB selected by the sponsor or researchers does not meet IRB quality standards when assessed by HSD staff. In these situations, HSD staff will work closely with the UW researcher, as described below, to pursue other options for IRB review.
	4. **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.
	5. **Reliance agreement options**. In order to support flexibility and tailor the terms of reliance agreements to the regulatory requirements for individual studies, UW makes use of and accepts a variety of reliance agreement templates and structures. These include, but are not limited to, UW’s own reliance agreement templates (**TEMPLATE Study Specific Reliance Agreement Full (SSRA)**, **TEMPLATE Study Specific Reliance Plan (SSRP)**, **TEMPLATE Study Specific Reliance Agreement Basic (B-SSRA)**).
	6. **Research not subject to federal requirements.** When relying on external IRB for research not subject to federal regulations, UW will execute a reliance agreement. UW considers it best practice for documenting roles and responsibilities and to avoid disruption to the research if it becomes subject to federal regulations.
	7. **Local context information.** When an external IRB reviews UW research, in order to comply with federal regulations its members must be able to ascertain the acceptability of the proposed research in terms of institutional commitments and regulations, applicable law, and standards or professional conduct and practice. This means that the IRB must consider locally relevant information such as state laws and local policies that apply to the research, community attitudes, institutionally required consent information and the qualifications of research staff. Additionally, it is UW policy that the external IRB must agree to consider any stipulations in UW financial conflict of interest reviews and may consider the impact of any UW ancillary reviews on the conduct of research at UW.
		1. **Information HSD can provide.**
* Information about the UW Human Research Protections Program (HRPP) such as FWA status.
* Information about the institution such as institutional training requirements and locale such as community attitudes toward research.
* Analysis of applicability of state laws.
* Analysis of applicability of local policies regarding protected health information and compensation for injury.
* Institutional consent requirements.
* A confirmation that the PI and study team members are qualified to carry out the research according to UW institutional policies. When providing this confirmation for studies reviewed by a non-UW IRB, HSD follows the standards described in SOP Research Team for studies reviewed by the UW IRB.
	+ 1. **Information the UW researcher must typically provide.**
* Information about how the study will be carried out at/by UW, e.g., site specific recruitment, procedures, etc. This includes information about the adequacy of any resources for carrying out the study.
* UW specific consent materials that include UW required elements.
* Confirmation and documentation of any training (Human Subjects Protections, Good Clinical Practice, etc.) for UW team members.
* Information about any conflicts of interest for UW team members.
* Specific information about credentialing for UW team members.
* The status of and documentation related to any required, local ancillary reviews (Radiation Safety, Institutional Biosafety Committee, etc.) that may impact the IRB’s considerations.
* Analysis of applicability of any department/academic unit level policies.
1. **PROCEDURES**
	1. **Preliminary, pre-award requests.** In order to meet the requirements of some funding agencies including NIH, researchers may need to obtain a preliminary decision about HSD’s willingness to rely on an external IRB before a funding proposal is submitted or awarded by the agency. HSD also strongly recommends that researchers obtain a preliminary decision for all research, regardless of funding. To obtain a preliminary decision, researchers follow [instructions on HSD’s website](https://www.washington.edu/research/hsd/single-irb/uw-lead-coordinating-site/letters-support-single-irb/). HSD typically documents its preliminary decision in a letter of support issued to the researcher. When the funding is awarded by the agency, researchers must follow the instructions for requesting formal authorization described below.
	2. **Researcher request for authorization by HSD**. Researchers submit an application for authorization by HSD through the Zipline e-IRB system by completing a **REQUEST External IRB Review** and following the [instructions on the HSD website](https://www.washington.edu/research/hsd/is-the-uw-irb-the-right-irb/how-to-ask-for-a-non-uw-irb/). The [External IRB Initial Review Process Diagram](https://www.washington.edu/research/policies/external-irb-initial-review-process-diagram-2/) illustrates the process.
	3. **Decision by HSD**. HSD staff use the [**WORKSHEET External**](https://www.washington.edu/research/forms-and-templates/worksheet-human-subjects-research/) **Reliance, Initial Submission** to assess the researcher’s request. Additional information or materials may be requested by HSD staff if needed to make the determination.
		1. If HSD staff decide that the activity does not qualify for review by *any* external IRB, the researcher may modify the application to be routed for the appropriate internal review as determined by HSD staff rather than preparing an entirely new application. For example, if the UW is not engaged in the activity, the application can be modified and resubmitted so that HSD staff can issue a determination that the UW is not engaged.
		2. If HSD staff decide that the activity does not qualify for review by *the proposed* external IRB, they will work with the UW researcher to pursue other options for obtaining IRB review, including identifying another IRB or obtaining review from the UW IRB. If this involves pursuing an exception to the single IRB review requirement of a sponsor or coordinating center, HSD staff can work with the UW researcher to prepare an exception request.
	4. **Confirming the reliance arrangement and negotiating the reliance terms.** HSD staffuse the [**WORKSHEET External**](https://www.washington.edu/research/forms-and-templates/worksheet-human-subjects-research/) **Reliance, Initial Submission** and the **SOP Reliance Insurance and Indemnification** to assess whether the proposed reliance falls under the terms of an existing reliance agreement, confirm that the external IRB is willing to review the study, 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.
	5. **Local context assessment and the applicability of other regulatory issues.** HSD staffuse the [**WORKSHEET External**](https://www.washington.edu/research/forms-and-templates/worksheet-human-subjects-research/) **Reliance, Initial Submission** to assess the need to provide study specific local context information to the reviewing IRB. HSD will communicate local context information to the external IRB in the format requested by the reviewing IRB. This may include providing a copy of the **INFORMATION SHEET UW General Local Context Profile** and the **GUIDANCE Consent Elements for Externally Reviewed Studies.**
		1. For situations in which the external IRB will not assume responsibility for certain regulatory oversight (for example, considering and issuing waivers of HIPAA Authorization), HSD staff will identify the need for HSD or the UW IRB to assume this regulatory oversight and will use the **WORKSHEET External Reliance Request** to perform any necessary action.
	6. **Transfers of ongoing research.** When the request for review by an external IRB means that a study currently reviewed and approved by the UW IRB will be transferred to an external IRB, HSD staff complete additional activities as indicated in the **WORKSHEET External Reliance Request** 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**, the **TEMPLATE Study Specific Reliance Plan (SSRP),** 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 UW will not rely on the other IRB, for example, because UW’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, any records requested by the external IRB have been provided, and, if HSD will retain a record of the study on behalf of the receiving IRB, will make arrangements for the storage of records.
	7. **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. A formal determination letter is provided to the researcher through the Zipline system.
	8. **UW researcher responsibilities.** UW researchers’ responsibilities for externally reviewed studies are described in the **CHECKLIST** [**External IRB for UW Researchers**.](https://www.washington.edu/research/forms-and-templates/checklist-external-irb-uw-researchers/)
	9. **Receipt of approval documents from external IRB.** HSD requests that researchers provide a copy of initial approval documents received from the external IRB. In limited circumstances, HSD may receive initial approval documents directly from the external IRB. These documents are uploaded to the study record in Zipline.
	10. **Post-Approval Audit.** As part of HSD’s Post Approval Verification and Education (PAVE) program, HSD may audit consent materials approved by the external IRB at initial review to ensure that:
* UW required elements (as outlined in the **GUIDANCE Consent Elements for Externally Reviewed Studies)** are present.
* Any compensation for injury language is consistent with the applicable Master Clinical Trial Agreement (MCTA), study-specific Clinical Trial Agreement (CTA) or any other documents that address financial coverage for research-related injuries and that the language is not in violation of the Medicare Secondary Payer (MSP) rule.
	+ - * HSD staff use the **WORKSHEET PAVE Consent Audit** and the **CHECKLIST PAVE Consent Audit** to assess the materials. If consent materials are not consistent with these requirements, HSD will contact the UW research team and/or the reviewing IRB to describe the inconsistencies. Inconsistent consent materials may need to be re-reviewed by the external IRB at the sponsor and/or PI’s expense, and subjects who have already been enrolled in the study may need to be provided with any new or revised information.
	1. **Changes to or new information about the reliance agreement.** Researchers are responsible for providing the following new information to HSD:

There is a change in the UW Principal Investigator

There is a proposal to change which IRB is reviewing the study

There is a change in the study team members who require access to the study in Zipline

There is a change to the information about study team member qualifications provided in the **REQUEST External IRB Review**

There is a new plan to implement eConsent that has not already been authorized by HSD

Any additional, study-specific changes communicated to the study team in the formal determination letter for the research

The study has been closed at the external IRB

* + 1. Researchers follow the instructions on the HSD website to submit the changes in Zipline. HSD staff use the **WORKSHEET External Reliance, Follow on Submissions** to assess the new information. Additional information or materials may be requested by HSD staff if needed to make the determination.
	1. **Withdrawal of reliance.** In rare circumstances, it may be necessary for UW or the reviewing IRB 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,
		+ Assist the study team with identifying a new IRB, if needed,
		+ To the extent feasible, assist the other institution with the transfer of oversight to the new IRB.
1. **RELATED MATERIALS**

[CHECKLIST External IRB for UW Researchers](https://www.washington.edu/research/forms-and-templates/checklist-external-irb-uw-researchers/)

[INFORMATION SHEET UW General Local Context Profile](https://www.washington.edu/research/forms-and-templates/local-context-profile/)

[GUIDANCE Consent Elements for Externally Reviewed Studies](https://www.washington.edu/research/policies/guidance-consent-elements-externally-reviewed-studies/)

REQUEST External IRB Review

SOP Reliance Insurance and Indemnification

TEMPLATE Study Specific Reliance Agreement Basic (B-SSRA) [internal HSD document]

TEMPLATE Study Specific Reliance Agreement Full (SSRA) [internal HSD document]

TEMPLATE Study Specific Reliance Plan (SSRP) [internal HSD document]

TEMPLATE Transfer Plan UW and Non-UW IRB [internal HSD document]

[WEBPAGE External IRB Process Diagram](https://www.washington.edu/research/policies/external-irb-initial-review-process-diagram-2/)

[WEBPAGE How to Ask for a Non-UW IRB](https://www.washington.edu/research/hsd/is-the-uw-irb-the-right-irb/how-to-ask-for-a-non-uw-irb/)

[WEBPAGE Is UW the Right IRB? General Information](https://www.washington.edu/research/hsd/is-the-uw-irb-the-right-irb/general-information/)

[WEBPAGE Letters of Support for a Single IRB](https://www.washington.edu/research/hsd/single-irb/uw-lead-coordinating-site/letters-support-single-irb/)

WORKSHEET External Reliance, Follow-On Submissions [internal HSD document]

[WORKSHEET External](https://www.washington.edu/research/forms-and-templates/worksheet-human-subjects-research/) Reliance, Initial Submission [internal HSD document]

WORKSHEET PAVE Consent Audit internal HSD document]

CHECKLIST PAVE Consent Audit internal HSD document]

**6 REFERENCES**

45 CFR 46, 2018 Common Rule Requirement

FDA Guidance, “[Using a Centralized IRB Review Process in Multicenter Clinical Trials](https://www.fda.gov/regulatoryinformation/guidances/ucm127004.htm)”

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

NIH, “[Final Policy on the Use of a Single Institutional Review Board for Multi-Site Research](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-094.html)”

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)”

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](https://www.hhs.gov/ohrp/regulations-and-policy/requests-for-comments/draft-transfer-document/index.html)”, draft guidance; May 23, 2012

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)”

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|  **Version Number** | **Posted Date** | **Implementation Date** | **Summary of Changes** |
| 1.3 | 08.29.2025 | 08.29.2025 | Add information about withdrawal of reliance, use of SMART for exemptions, and update information about consent audit. |
| 1.2 | 09.26.2024 | 09.26.2024 | Add information about SOP Reliance Insurance and Indemnification |
| 1.1 | 02.29.2024 | 02.29.2024 | Add note that researchers must communicate to HSD any study-specific changes described in the formal determination letter |
| 1.0 | 06.29.2023 | 06.29.2023 | Newly posted SOP; previous versions were drafts and can be found in the Reliance Team shared drive |

**Keywords:** External reliance; Multi-site