**Key Information about the University of Washington (UW) as a Single IRB**

This document is intended to give UW researchers and researchers at institutions that might rely on the UW IRB a list of *key information* to consider when planning for Single IRB review by the UW IRB. See [HSD’s website](https://www.washington.edu/research/hsd/single-irb/uw-irb-as-a-single-irb/) for a full description of how UW operates as a single IRB. For questions, contact HSD’s Reliance Team at [hsdrely@uw.edu](mailto:hsdrely@uw.edu).

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| Section 1: Institution and HRPP Information | |
| Institution Name on FWA | U of Washington |
| Federalwide Assurance (FWA) | FWA00006878 |
| FWA Expiration Date | 01/13/2027 |
| Registered IRBs | IRB00000241 “U of W – A”  IRB00000242 “U of Washington IRB#2 – B”  IRB00005647 “U of Washington IRB #7 – J”  IRB00000727 “U of Washington IRB#4 – D” |
| HRPP/IRB Contact Information | **IRB Office**  [Human Subjects Division (HSD)](https://www.washington.edu/research/hsd/)  Box 359470, University of Washington  Seattle, WA 98195-9470  **IRB Contact for Single IRB Studies**  Phone: 206-543-0098; ask for Reliance Team  [hsdrely@uw.edu](mailto:hsdrely@uw.edu)  **Institutional Official**  Joe Giffels  Sr. Associate Vice Provost for Research Administration and Integrity  Box 351202, Gerberding Hall G80  Seattle, WA 98195  Phone: 206-616-0804  [jgiffels@uw.edu](mailto:jgiffels@uw.edu)  **Primary HRPP/IRB Contact (Human Protections Administrator)**  Jason Malone, MPA, CIP, Director  Phone: 206-543-7246  [jmmalone@uw.edu](mailto:jmmalone@uw.edu)  **IRB Contact for Subject Inquiries**  Phone: 206-543-0098 (Subjects without means can call collect at 206-221-5940)  [hsdinfo@uw.edu](mailto:hsdinfo@uw.edu) |
| Hours of Operation | 8 a.m. – 5 p.m. (Pacific). HSD is closed on federal holidays |
| IRB schedule, make up and expertise | UW operates 4 IRBs. Each convened IRB [meets every other week](https://www.washington.edu/research/hsd/meeting-schedule-for-the-irbs/). IRB members are drawn from UW faculty and staff as well as community members within the greater Seattle metropolitan area. |
| AAHRPP Accreditation | No. A completed AAHRPP Evaluation Checklist is available upon request. |
| Quality Assurance Attestation | UW’s HSD is routinely inspected by OHRP, FDA, UW internal audit, and others. HSD’s most recent federal inspections conducted by FDA in 2017 and 2023 resulted in no findings. |
| Standing Reliance Agreements | The following organization may rely on the UW IRB through standing reliance agreements:   * Seattle Children’s * Fred Hutch * Kaiser Permanente of Washington * Benaroya Research Institute at Virginia Mason * Public Health – Seattle and King County * Bloodworks Northwest * Washington Institute for Coagulation * Certain studies involving WA State L&I |

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| Section 2: Single IRB Review Policies and Processes | |
| UW as a Single IRB | UW typically only serves as a single IRB for federally-funded, UW-led research as described on [HSD’s website](https://www.washington.edu/research/hsd/single-irb/uw-irb-as-a-single-irb/#when). |
| Review Fees | In general, UW does not charge for single IRB review, except in some circumstances such as large or highly complex studies. Any charges will be negotiated directly with the UW PI. |
| Online Application System | UW uses an online, Huron-based application system called [Zipline](https://www.washington.edu/research/hsd/zipline/) which can only be accessed by UW faculty, staff and students. Access cannot be granted by HSD to non-UW investigators or administrators. *The UW study team is responsible for providing required study and site information to HSD in Zipline and for delivering all IRB communications and approved materials to relying sites.* |
| Dedicated Single IRB Team | Most single IRB studies are handled by a specialized team of reviewers and reliance administrators within HSD’s Reliance Team. Expedited reviews are completed by trained staff designated by the chair(s). Full board reviews are completed by one of UW’s 4 IRBs. |
| SMART Master Reliance Agreement | UW is a SMART signatory and may make use of the SMART Master Reliance Agreement depending on the nature of the study and the relying sites. Relying sites do not have to be a SMART signatory in order to rely on the UW IRB. |
| Applicability of federal regulations to non-federally supported research | UW has **not** elected on its FWA to apply federal regulations to non-federally funded research. In general, UW follows federal regulations in the review of non-federally funded research; however it encourages flexibility in certain situations under its [Flexibility Policy](https://www.washington.edu/research/policies/guidance-authority-and-responsibilities-of-hsd-and-uw-irb/). The UW IRB may apply flexibility to the review of Single IRB studies when the terms of the relying sites’ FWAs allow. |
| Post Approval Monitoring and Auditing | UW IRBs have the authority to require for-cause audits of any studies they review. In the case that the UW IRB requires an audit of a study for which there are relying institutions, it is the responsibility of the relying institution (or the lead/coordinating center) to provide adequate resources to complete the required audit activities for their institution.  UW HSD operates a [Post-Approval Verification and Education (PAVE)](https://www.washington.edu/research/policies/sop-pave-evaluation/) program. Under this program, it may perform a not-for-cause audit of any study reviewed by the UW IRBs. |
| Researcher Training and Qualification Requirements | The UW IRB does not generally require that researchers provide documentation of training such either Human Subjects Protections (HSP) training or Good Clinical Practice (GCP).  Investigators at relying sites are expected to follow their institution’s policies regarding training. Relying sites must attest that their investigators are trained and qualified according to the relying institution’s policies. Relying sites are only required to provide the name and contact information of the site PI. Names, titles and contact information of other site study staff are not required. |
| Consent | The UW IRBs typically allow significant flexibility for consent materials and plans. UW’s template consent form is **not** required.  Studies under 5 sites may opt to use a study-specific template with limited customization for each site or allow sites to develop their own consent documents.  For studies with a large number of sites (5+), a template with limited customization may be required. |
| Public Health Service (PHS) Financial Disclosure Compliance | For studies with PHS financial disclosure requirements, UW Is not able to provide conflict of interest and management plans for non-UW investigators.  Relying institutions and investigators must provide for their own conflict of interest assessment and management plans. If a relying site is not able to provide for this, UW IRB may not be able to review on behalf of the site. |
| HIPAA Authorization Language | The UW IRB allows relying sites to use either HIPAA language embedded within a consent form or standalone HIPAA Authorization forms. The UW IRB will **not** vet HIPAA authorization language for compliance with the HIPAA privacy rule. Sites must vet and use their own language or forms. If the site does not have its own standalone form or language, the site will be directed to use [UW’s standalone form](https://www.washington.edu/research/forms-and-templates/template-hipaa-authorization/) which has been vetted by UW Medicine Compliance for compliance with the HIPAA privacy rule and other WA state requirements.  The UW IRB does not require that standalone HIPAA Authorization forms used by relying sites be submitted for review. |
| HIPAA Waivers | Unless instructed otherwise, the UW IRB will consider and issue waivers or alterations of HIPAA as required in order to carry out the research. Institutions who wish to consider and issue their own waivers can choose to do so instead. |
| Genomic Data Sharing (GDS) Certification | UW IRB can provide the required IRB certification for single IRB studies it reviews. However, it cannot provide the institutional certification unless it is the organization submitting the information to the genomic repository on behalf of all sites. |

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| **Version Number** | **Posted Date** | **Implementation Date** | **Summary of Changes** |
| 1.5 | 01.10.2024 | 01.10.2024 | Add reference to most recent FDA inspection |
| 1.4 | 06.29.2023 | 06.29.2023 | Update QA Attestation to match revisions to UW Compliance Statement |
| 1.3 | 06.30.2022 | 06.30.2022 | Update FWA information; minor wordsmithing |
| 1.2 | 10.20.2021 | 10.20.2021 | Revise sections on standing reliance agreements, auditing, researcher qualifications, HIPAA, contacts, minor wordsmithing |
| 1.1 | 12.30.2020 | 12.30.2020 | Minor wordsmithing |
| Previous versions |  |  | For older versions: HSD staff refer to the SharePoint Document Library; Others – contact [hsdinfo@uw.edu](mailto:hsdinfo@uw.edu). |

**Keywords:** FWA; Internal reliance; Multi-site/collaborative research; Single IRB