PURPOSE and APPLICABILITY

This document provides information about local context considerations relevant to human subjects research conducted by University of Washington employees or agents. For questions about this information, contact the UW Human Subjects Division at hsdrely@uw.edu.

Section 1: Institution and HRPP Information	
Institution Name	University of Washington (UW)
Overview	UW is a large, public flagship research university comprised of: • 3 campuses in Seattle, Tacoma and Bothell WA • UW Medicine (not including affiliated covered entities that are healthcare components considered to be non-UW legal entities)
Federalwide Assurance (FWA)	FWA00006878
FWA Expiration Date	1/13/2027
Institution Name on FWA	U of Washington
Institutional Components on FWA	UW Medicine (does not include affiliated health care entities unless specifically identified here) • UW Medical Center (2 campuses: Montlake and Northwest) • Harborview Medical Center • Airlift Northwest • UW Physicians (UW Neighborhood Clinics) UW Bothell Branch UW Tacoma Branch
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.
AAHRPP Accreditation	No
CTSA	Institute of Translational Health Sciences
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.
HRPP/IRB Contact Information	**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 **IRB Office** Human Subjects Division (HSD) Box 359470, University of Washington Seattle, WA 98195-9470

	IRB Contact for All Externally Reviewed Studies Phone: 206-543-0098; ask for Reliance Team hsdrely@uw.edu **Primary HRPP/IRB Contact (Human Protections Administrator)** Jason Malone, MPA, CIP, Director Phone: 206-543-7246 jmmalone@uw.edu **IRB Contact for Subject Inquiries** Phone: 206-543-0098 hsdinfo@uw.edu
Affiliations and FWA status	Research conducted at UW frequently involves collaboration with regional partners. These regional partners are **not** listed under UW's FWA. UW maintains reliance agreements with some of these partners (indicated with *), however those agreements do not allow for "daisy-chaining" of reliance agreements. Separate authorization must be obtained from these institutions for the conduct of IRB review on their behalf: • Seattle Children's* • Fred Hutch* • Kaiser Permanente of Washington* • Agencies of the State of Washington* • Benaroya Research Institute at Virginia Mason* • Washington State University • Valley Medical Center • VA Puget Sound Healthcare System • Bloodworks Northwest* • Washington Center for Bleeding Disorders* • The Pacific Northwest National Laboratory (PNNL) • Northwest Kidney Centers • Public Health – Seattle and King County*
Community description and attitudes towards research	**Washington State Population** Washington State is home to an estimated 7.9 million people, with over half concentrated in the Seattle-Tacoma-Bellevue metropolitan area, where the University of Washington is located. The state is divided geographically by the Cascade Mountain range. Eastern Washington has roughly twice the land area and one-fourth the population of Western Washington. Communities across Washington vary greatly in age, race, ethnicity, languages spoken, education, and levels of comfort with the research enterprise. According to census data, approximately 20% of Washington residents speak a language other than English at home, with nearly 8% of residents indicating that they speak English less than "very well". In the Eastern Washington counties of Yakima, Franklin, and Adams over half the population self-identifies as Hispanic or Latino. Washington has several active military installations and 29 federally recognized Tribal Nations. Even for research conducted in UW Medicine's Seattle area facilities or targeted to the Seattle area, there may be more than a dozen different languages spoken and diverse considerations depending on the targeted populations for enrollment. Given

	this vast spread of demographical variables, the reviewing IRB may need to ask the UW PI additional population-specific information in order to consider: 1. Has the UW PI adequately considered the population of the target region, described it for your review, and designed the research accordingly? 2. Are populations being unjustifiably excluded for convenience (e.g., non-English speaking, Native Americans, etc.)? 3. Are additional steps needed to ensure equitable enrollment for the target region? The overall attitude towards research in the Seattle-Tacoma-Everett-Bellevue Metro area is favorable. Seattle is home to a large number of research institutions. Scientific and medical research is portrayed frequently in a positive light in local news.
Post Approval Monitoring Program	UW Human Subjects Division operates the Post Approval Verification and Education program (PAVE). PAVE auditors *may* be available to audit studies reviewed by external IRBs upon request. PAVE FAQs.
Researcher Training Requirements	UW does not currently have an institutional requirement that researchers complete either Human Subjects Protections (HSP) Training or Good Clinical Practice (GCP) training. UW researchers are instructed to follow the training requirements of any funding agencies, collaborating institutions or reviewing IRBs. **UW researchers maintain their own training records and can provide these to the reviewing IRB upon request.**
Researcher Qualifications	For all studies not reviewed by a commercial IRB, HSD confirms that the UW PI and UW study team members are qualified according to its standard operating procedures as part of assessing the study for reliance. **The reviewing IRB may either rely upon this assessment or may conduct its own assessment according to its policies.**
Public Health Service (PHS) Financial Disclosure Compliance	UW is in compliance with PHS Significant Financial Interest disclosure requirements. **UW researchers maintain documentation of their own financial conflict of interest management plans and must provide these to the reviewing IRB.**
Indemnification of University Personnel	Standing Order Regarding Indemnification of University Personnel
Risk Management Policy	UW is self-insured by a revolving fund authorized and created under WA State law (RCW 28B.20.250). Proof of Insurance and Liability Coverage Terms and Conditions.

Section 2: State and Local Laws and Policies pertaining to Human Subjects Research	
Retention of State Records	Under WA State law (RCW 40.14.050), research records held by the UW are considered public records and must be retained and available for inspection for specified time periods. University and UW Medicine retention periods vary depending on the type of research and document. **The reviewing IRB cannot require that UW records (including identifiers) be destroyed prior to the end of the applicable records retention periods. The UW study team is responsible for identifying applicable retention periods.** UW held research records may also be subject to public records requests. Any requests must be immediately forwarded to the UW Office of Public Records.

Legally Authorized Representatives (LARs)	There are no WA state laws that directly address the use of LARs in research. However, WA State law (RCW 7.70.065) defines who may provide consent for patients in life-threatening or end-of-life situations. Per legal advice, the UW uses this list to identify LARs in the research context. **Order of priority for LARs:** (i) The appointed guardian of the patient, if any; (ii) The individual, if any, to whom the patient has given a durable power of attorney that encompasses the authority to make health care decisions; (iii) The patient's spouse or state registered domestic partner; (iv) Children of the patient who are at least eighteen years of age; (v) Parents of the patient; (vi) Adult siblings of the patient; (vii) Adult grandchildren of the patient who are familiar with the patient; (viii) Adult nieces and nephews of the patient who are familiar with the patient; (ix) Adult aunts and uncles of the patient who are familiar with the patient; and (x) An adult who has exhibited special care and concern for the patient and meets other requirements listed under the law.
Age of Majority	There are no WA State laws that directly address the age of majority for consent to participate in research. However, there are several laws that define the age of majority under specific circumstances or for providing consent for specific types of healthcare. Per legal advice, the UW applies these laws to research involving the specific type of healthcare when defining the age of majority for providing consent. **The age of majority in WA is 18** (RCW 26.28.010) unless the person is: • An emancipated minor as declared by a court or under a petition for relief from domestic violence (**age 16**) (RCW 13.64) (RCW 26.50.020) • A minor married to a person who has reached majority (**any age**) (RCW 26.28.020) • Receiving inpatient treatment for substance abuse or chemical dependency (**any age** if the child meets the definition of a "Child in need of services" at RCW 13.32A.030(5)) (RCW 70.96A.235) • Receiving outpatient treatment for substance abuse or chemical dependency (**age 13**) (RCW 70.96A.095) • Receiving outpatient treatment for mental health services (**age 13**) (RCW 71.34.530) • Receiving inpatient treatment for mental health without parental consent (**age 13**) (RCW 71.34.500) • Receiving treatment for sexually transmitted disease (**age 14**) (RCW 70.24.110) • Choosing or refusing birth control or abortion services (**any age**) (RCW 9.02.100) • Receiving prenatal care services (**any age**) (State V. Koome, 84 Wn 2d 901 (1975))
Use of health care information in WA state for research **with** written consent	Under WA state law (RCW 70.02),the patient or their LAR must explicitly authorize the use of 4 different types of records. These are specifically and separately identified in the UW HIPAA Authorization Template for Research and are: • Sexually transmitted disease • AIDS or HIV • Behavioral or mental health/illness, including psychotherapy notes • Drug or alcohol abuse, diagnosis, or treatment

Notifiable Conditions	The Washington State Department of Health maintains a list of notifiable conditions WA state law and administrative code describes • The permitted and mandatory disclosures (i.e., reporting) for sexually transmitted diseases (RCW 70.02.220) • Rules for notification of partners at risk of human immunodeficiency virus (HIV) infection (WAC 246-100-072). **The reviewing IRB should consider whether information about notification should be shared with participants. It is the responsibility of the UW study team to identify whether information about any conditions identified by the research will be shared with public health authorities.**
Mandated Reporting of Abuse or Neglect	Under WA state law (RCW 26.44.030) and UW Executive Order 56, all UW employees and volunteers who have a reasonable cause to believe that a child has suffered abuse or neglect must immediately report the suspected abuse. Mandatory reporters of abuse or neglect of vulnerable adults is defined in WA state law (RCW 74.34.020), including when and how such abuse should be reported (RCW 74.34.035). **The reviewing IRB should consider whether information about the potential for reporting should be shared with participants and/or their parents or LARs.**
Recording or transmitting of private communications	WA state law (RCW 9.73.030) requires that some type of consent or notification occur for transmission or recording of private communications. Review HSD guidance on this state law. **The reviewing IRB should not approve the recording of private communications in WA state without the prospective consent or notification of all individuals to be recorded.**
Use of eCare/MyChart	Under UW Medicine policy, the UW Medicine's eCare/MyChart system may not be used for research recruitment purposes. **The reviewing IRB should not approve the use of UW Medicine's eCare/MyChart system for research recruitment.**
Use of EPIC Care Everywhere	Under UW Medicine policy, UW Medicine's EPIC Care Everywhere may not be used for research purposes unless the clinical data is necessary for patient/participant safety activities. **The reviewing IRB should not approve the use of UW Medicine's EPIC Care Everywhere unless it determines that it meets the requirement above.**
Use of Amazon's Mechanical Turk	Studies using Amazon's Mechanical Turk (MTurk) must comply with the UW Procurement Services policy that no UW employee, family member, or student directly involved in the research will participate as a subject. The policy requires adding a qualifying question that asks whether the subject is a UW employee or family member, or UW student who is directly involved in the research. If they answer yes, they must be disqualified from MTurk activities. **The reviewing IRB should allow UW researchers to add this qualifying question.**
Administering or handling of cannabis	UW has a robust policy about research that involves the growth, production, procurement, administration, or use of marijuana. This policy does not apply to observational research for which the researcher does not grow, produce, procure, or administer marijuana. **UW's HSD will communicate any limitations on the research directly to the reviewing IRB.**

Financial assistance for research-related injury	The Human Subjects Assistance Program (HSAP) is a discretionary no-fault program that may provide limited medical and other assistance to participants who experience a research-related medical problem. Researchers may choose to provide a HSAP information sheet to research participants. **If the reviewing IRB determines that the study poses greater than minimal risk, the consent form should contain language relevant to HSAP.** Required language is in the document UW Guide to Consent Elements for Externally Reviewed Studies. *Language suggesting a promise or commitment to pay should be avoided.*
UW Required Consent Considerations	**Format:** UW has no institutional requirements for the format of consent materials and strongly supports flexibility for consent format and content. **Elements:** UW has a limited list of institutionally-required consent elements. These are described, and required and sample language is included for each, in the document UW Guide to Consent Elements for Externally Reviewed Studies. **The reviewing IRB should ensure that these elements are present as applicable to the study and may approve alternative language for each element unless otherwise indicated.** **Use of short forms:** UW is subject to RCW 69.78 which mandates that UW adopt a policy concerning the identification and recruitment of persons who are members of underrepresented demographic groups to participate in clinical trials. This policy must use methods recognized by the United States FDA to identify and recruit such persons. UW therefore requires that its investigators adhere to FDA guidance about the use of short form consent, and specifically requires the following: When agents or employees of UW will be obtaining consent using the short form consent method for any research, **it is UW policy that**: 1. **An appropriately qualified interpreter will be available to the subject** throughout their participation in the research. 2. **For research that involves more than minimal risk and/or FDA regulated studies:** ▪ After the use of a short form process, researchers must provide study participants with a translated consent form in a language understandable to them. This form must be provided to the reviewing IRB for approval **within 30 days** of using the short form consent process and the IRB-approved translated consent form must be provided to the participant **within 2 weeks** of IRB approval. UW does not specify the method by which the form is provided (e.g., email vs. paper) and does not require that the form is signed. 3. UW researchers may use the short forms of the reviewing IRB's institution, or those provided by HSD. **The reviewing IRB may apply more conservative requirements for the use of the short form consent method, but it may not waive the UW policy requirement.** **Electronic Signatures:** WA State has adopted the Uniform Electronic Transactions Act, effective June 11, 2020. This law describes the conditions which must be met for an electronic signature to be legally effective. Due to the complexities of the legal conditions and the

	diversity of possible e-signature systems, **HSD must concur with the e-signature system for obtaining consent and/or HIPAA authorization prior to its use**. **DocuSign and UW ITHS REDCap.** UW eSignatures (UW's DocuSign application) and the UW ITHS installation of REDCap are the only tools that have been pre-confirmed by UW to be compliant with WA State law. Both are available to UW researchers. Equivalent, non-UW REDCap installations or other e-consent systems may also be used if authorized by HSD. Note that these two systems are not considered to meet the Part 11 requirements necessary for FDA regulated research. UW eSignatures is not Part 11 compliant. For the use of UW eSignatures, the UW researcher must apply to use it through the UW-IT office. **Non-UW Installations of REDCap.** Researchers may request concurrence from HSD by asking the owner of the REDCap Installation to complete the SUPPLEMENT Other REDCap Installation and submitting it to HSD. **Other e-Consent Platforms.** Researchers may request concurrence from HSD by asking the Chief Information Officer, Chief Information Security Officer, or other individual with sufficient authority and subject matter expertise to complete the TEMPLATE Other eSignature Attestation Letter and submitting it to HSD. **Specific information about the e-signatures must be provided in writing to participants, preferably in the consent form.** Required language is in the document UW Guide to Consent Elements for Externally Reviewed Studies. See below for limitations on the use of e-platforms for obtaining documentation of HIPAA authorization.

Section 3: HIPAA Compliance and other considerations for access to protected health information	
Overview	UW is a hybrid covered entity. This means that some, but not all, components of the UW provide health care and are therefore subject to HIPAA and related WA state laws. The UW covered entity is a complex set of components, described in UW Medicine's Policy COMP.101 and 101.G1 UW HIPAA Designation. *In general*, research data is not considered subject to HIPAA once it is removed from the UW Medicine electronic systems. For example: • A researcher from the School of Medicine (SoM, which is not part of the UW covered entity) reviews UW Medicine medical records and abstracts identifiable information and stores that information on SoM servers. The initial use of the medical records is subject to HIPAA, but once the information is held by the researcher outside of the medical records, it is no longer subject to HIPAA for any secondary disclosures. • A School of Dentistry researcher conducts a survey of patients in a clinic waiting room. The survey data is not entered into the patients' clinical dental records and is stored on the researcher's computer. The survey data is never subject to HIPAA.

Preparatory to Research Activities Not Allowed for Recruitment Activities	While the preparatory to research provision applies in theory to research conducted at UW, **in practice it is almost always impossible for UW research teams to make the attestations required under the Preparatory to Research requirements at 45 CFR 164.512(i)(1)(ii)** because: • the research study staff who are accessing the PHI are not members of the workforce of the covered entity, but rather of the non-covered components (e.g., an academic unit), and/or • PHI accessed for recruitment purposes will be removed from the covered entity to servers that are owned by the non-covered components (e.g., the academic units) **For access to UW Medicine PHI without authorization for recruitment purposes, the reviewing IRB should consider a partial or full waiver of HIPAA Authorization rather than determining that the activities fall under the Preparatory to Research provision.**
Obtaining HIPAA Authorization for UW Medicine Records	Researchers accessing UW Medicine and/or Fred Hutch records with patient permission are advised to use a separate HIPAA Authorization form maintained by HSD and vetted by UW Medicine and Fred Hutch compliance. This is because of the Washington State law requiring explicit "opt in" language for release of certain types of health care information as well as other state law requirements. UW HIPAA Authorization template UW HIPAA Authorization template for pregnancy Language in these templates cannot be modified. **The reviewing IRB should not approve consent materials that contain HIPAA Authorization language for the purposes of accessing UW health care records. The UW's Standalone HIPAA Authorization Form must be used.** **Electronic Authorization**. Use of electronic signatures to obtain a HIPAA authorization to access UW PHI for research purposes is permitted using any of the approvable methods for obtaining electronic signatures outlined in HSD's Consent Guidance. For authorization to obtain/access PHI at any other HIPAA-covered institution, consult that institution's privacy and/or health records information office. **HSD Policy Reference:** GUIDANCE HIPAA GUIDANCE Consent INSTRUCTIONS UW E-Signature Tools

Section 4: Possible Ancillary Reviews	
UW researchers are responsible for identifying the need for, obtaining and maintaining any required ancillary reviews and approvals, and communicating relevant information to the reviewing IRB. HSD does not maintain this information.	
Any UW investigator has a conflict as defined in GIM 10.	Financial Conflict of Interest Disclosure
Radiation exposure (procedures or materials)	Human Subjects Radiation Approval Committee (HSRAC)

Recombinant/synthetic DNA/RNA, human gene transfer and other biohazardous agents	Institutional Biosafety Committee (IBC)
Radioactive drugs being used without an IND for basic science research	Radioactive Drug Research Committee (RDRC) Contact James W. Vélez (jvelez@uw.edu)
Human embryonic stem cells (hESC)	Embryonic Stem Cell Research Oversight Committee (ESCRO)
Genomic Data Sharing Certification	UW HSD can perform certification upon request
Research involving in-person or virtual interactions with participants under 18	Office of the Youth Protection Coordinator Registration
Cancer-related intervention studies	Cancer Consortium Scientific Review Committee
The research involves the use of UW Medicine patient data (whether identified or de-identified) for machine learning outside of UW IT systems.	UW Medicine Security Review for Machine Learning Contact Sally Beahan (sbeahan@uw.edu)
UW Medicine and UW Dentistry residents and fellows are study participants.	UW HR Labor Relations Contact Jennifer Mallahan (mallaj@uw.edu)
Clinical services, items or tests that are provided as part of a research study by UW Physicians, UW Medicine hospitals or clinics	Clinical Research Budget and Billing (CRBB)
Material Transfer Agreements (MTA) and Data Use Agreements (DUA)	MTAs are issued by two UW offices, CoMotion and the Office of Sponsored Programs (OSP). DUAs associated with grant activities may be negotiated by the Office of Sponsored Programs or by the investigator's academic department.
Audio recordings made for research purposes in a UW Medicine clinical setting require prior approval from the relevant CEO or Executive Director	UW Medicine Compliance: Audio Recordings In The Clinical Setting For Research, Education Or Quality Improvement Purposes

Version Number	Posted Date	Implementation Date	Summary of Changes
2.5	07.31.2025	07.31.2025	Update information about community and attitudes.
2.4	06.26.2025	06.26.2025	Update information about acceptable eSignature platforms for HIPAA.
2.3	05.01.2025	05.01.2025	Update information about HIPAA forms. Remove references to SCCA.
2.2	03.27.2025	03.27.2025	Update FDA Part 11 compliance statement for UW ITHS REDCap
2.1	12.23.2024	12.23.2024	Update FDA Part 11 compliance statement for UW ITHS REDCap; revise policy information about short form consent
Previous versions			For older versions: HSD staff refer to the SharePoint Document Library; Others – contact hsdinfo@uw.edu.

Keywords: External reliance; FWA; Multi-site; Single IRB