

As described in University of Washington (UW) <u>Executive Order Number 24</u>, and UW's Federalwide Assurance (FWA) the UW and its IRBs are guided by the ethical principles in the Belmont Report.

In addition, the UW Human Subjects Division (HSD) and the UW IRBs draw upon a variety of ethical codes, such as the Declaration of Helsinki, the Council for International Organizations of Medical Sciences (CIOMS) and the International Council for Harmonization (ICH) when developing policies.

The UW IRBs operate in accordance with applicable laws, regulations, and guidance in the United States (U.S.) and other countries, including but not limited to, the U.S. Department of Health and Human Services (DHHS) (45 CFR 46) and U.S. Food and Drug Administration (FDA) (21 CFR 50 and 56). All human subjects research conducted or supported by DHHS will comply with all subparts at 45 CFR 46 (Subparts A, B, C, D, E).

The UW will ensure that its organizations and investigators engaged in its U.S. federally supported human subjects research will operate under an appropriate OHRP (Office for Human Research Protections) or other federally-approved Assurance for the protection of human subjects. Independent investigators who are not employees or agents of UW may be covered under the UW FWA only in accordance with a formal, written agreement of commitment to relevant human subject protection policies and UW IRB oversight.

The UW IRBs are registered with OHRP and FDA and its FWA is approved by OHRP and applies to all of UW's IRBs. The UW FWA information can be found below and also on the OHRP website.

Institution: U of Washington FWA #: FWA00006878
IRB Organization (IORG) #: IORG0000143

IRB A: IRB00000241 IRB D: IRB00000727
IRB B: IRB00000242 IRB J: IRB00005647

Expiration Date: 01.13.2027

The UW and its IRBs are not accredited with the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP). A completed AAHRPP Evaluation Checklist can be provided upon request.

UW's HSD is routinely audited by OHRP, FDA, UW internal audit, and others. Our most recent federal audit conducted by FDA in 2023 resulted in no findings.