# PURPOSE

## This document defines the research that is eligible for using the UW IRB.

# POLICIES

## In general, the use of the UW Institutional Review Boards (IRB) is restricted to human subjects research that is conducted by a UW employee or agent as part of the responsibilities or expectations of the employee or agent’s position. Some important exceptions are described below in Section 5.2.

# DEFINITIONS

## None

# RESPONSIBILITIES

## The Human Subjects Division (HSD) is authorized by the UW Vice Provost for Research to determine whether a specific human subjects research activity is eligible to use the UW IRB.

# PROCEDURES

## Determination of eligibility. The Human Subjects Division (HSD) is authorized by the UW Vice Provost for Research to determine whether a specific human subjects research activity is eligible to use the UW IRB. The determination is a routine part of the pre-review process that occurs when a new application is submitted to the UW IRB. The determination may also be made in response to an investigator’s request prior to submission.

### HSD uses the following criteria when making the determination. All of the criteria must be met. Exceptions are described in Section 5.2.

|  |  |
| --- | --- |
| **Criteria** | |
| Engagement | The UW is engaged in the research, as defined by federal guidance <http://www.hhs.gov/ohrp/policy/engage08.html> . Also see the [**SOP Engagement**](https://www.washington.edu/research/policies/sop-engagement-2/)and [**WORKSHEET: Engagement**](https://www.washington.edu/research/forms-and-templates/worksheet-engagement/) on the Human Subjects Division website. |
| Lead investigator on the UW IRB application  *Note: This includes UW faculty, staff or students who may be collaborating with other institutions. When this collaboration meets the definition of “engaged”, UW IRB review is required.* | The person who will be the lead investigator on the IRB application:   * Has a **UW Institutional Base Salary** **(IBS)** as a UW faculty member or staff person; * Has another **UW** appointment such as resident, fellow, or postdoctoral trainee with an IBS (including appointments for which such individuals receive their paychecks directly from a non-UW entity); * Has a faculty or other UW appointment (e.g., Senior Fellow) with a PDR (Faculty Paid Direct) earn type (e.g., UW faculty paid direct by Howard Hughes Medical Institute); or * Is a matriculated UW student who has a faculty advisor deemed appropriate by HSD and the IRB. The student may be full-time, part-time, or (for graduate students) have On-Leave status as approved by the Graduate School. |
| Reason for doing the research | The research will be performed as part of the responsibilities and expectations of the lead investigator’s UW position, as defined by UW Academic Titles and Ranks.  <http://ap.washington.edu/ahr/academic-titles-ranks/> |
| Institutional conflict of interest | When UW institutional conflict exists with respect to the research as determined by the UW Office of Research, the conflict management plan does not require an external IRB to perform the IRB review and oversight. |

## Exceptions. The UW IRB will conduct the IRB review and oversight in the following circumstances:

### Formal institution-wide agreements between the UW IRB and another institution. The terms of these agreements may allow UW research to be reviewed by another IRB instead of the UW IRB, or non-UW research to be reviewed by the UW IRB, under certain conditions. There are currently agreements with the following institutions.

#### Benaroya Research Institute (Virginia Mason Medical Center)

#### Fred Hutchinson Cancer Center

#### Group Health Cooperative

#### King County – Seattle Public Health Department

#### Northwest Kidney Centers

#### Pacific Northwest National Laboratory (PNNL)

#### Puget Sound Blood Center

#### Seattle Biomedical Research Institute

#### Seattle Children’s Medical Center

#### Swedish Medical Center

#### Washington State IRB

### A study-specific agreement between the UW IRB and another institution may allow the other institution to use the UW IRB, or vice versa. The agreement must be approved and signed in advanced by HSD. Relevant factors include: the nature of the UW’s involvement; the research risks; the nature and resources of the other institution; and which institution is administering the research funding.

### Federal SBIR or STTR grant to a small business. The small business may use the UW IRB when the UW is involved in the research as a significant collaborator or partner, even when the UW involvement does not meet the federal definition of engagement. A study-specific authorization agreement with the small business is required.

### Research conducted by a non-salaried or affiliate UW faculty member (i.e., a faculty member without an IBS) may be reviewed by the UW IRB when the funding for the research has been awarded to the faculty member and is administered through the UW. However, HSD reserves the right to deny on a case-by-case basis the continued use of the UW IRB when a UW faculty member changes the type of UW faculty appointment as part of a move to another institution, depending upon: the location of the new institution, the nature of the research, and compliance history. Research for which the funding is administered through another institution is not eligible to use the UW IRB. If there is no funding, eligibility will be determined on a case-by-case basis by request.

### Research in which both the UW and VA Puget Sound Health Care (VAPSHC) are engaged. Due to current VA policy, this type of research always requires “dual review” – i.e., review by the VAPSHC IRB as well as review by the UW IRB. Because of the close relationship between the UW and the VAPSHC, UW faculty members whose paid employment is at the VAPSHC are eligible to serve as the lead investigator on the UW IRB application.

### Visiting appointments. Visiting faculty members are eligible to use the UW IRB for research conducted as part of their UW appointment. Visiting graduate students or postdoctoral fellows may use the UW IRB if they are directly supervised by an appropriate UW faculty mentor. Visitors should consult with the Human Subjects Division about (1) whether IRB approval from their home institution may also be required; and (2) what to do when their UW appointment is ending but the research is still continuing.

### Other exceptions will be considered by HSD Leadership on a case-by-case basis. To make the request, email hsdinfo@uw.edu. Requests must be approved in advance and in writing.

## Refusal. HSD and the UW IRB reserve the right to not review a project under circumstances other than those described above. Consultation and concurrence must be obtained from the UW Associate Vice Provost for Research Administration and Integrity. A written explanation shall be provided to the lead investigator.

# MATERIALS

## [SOP Engagement](https://www.washington.edu/research/policies/sop-engagement-2/)

## [WORKSHEET: Engagement](https://www.washington.edu/research/forms-and-templates/worksheet-engagement/)

# REFERENCES

## OHRP, “Guidance on Engagement of Institutions in Human Subjects Research”; October 16, 2008.

|  |  |  |  |
| --- | --- | --- | --- |
| **Version Number** | **Posted Date** | **Implementation Date** | **Summary of Changes** |
| 2.3 | 09.27.2022 | 09.27.2022 | Update name of Fred Hutchinson Cancer Center |
| 2.2 | 09.08.2017 | 09.08.2017 | Updated links |
| Previous versions |  |  | Beyond records retention requirements |

# Key words: Engagement; IRB review