|  |  |
| --- | --- |
| University of Washington Human Subjects DIvision | **WORKSHEET Engagement** |

|  |
| --- |
| **PURPOSE AND APPLICABILITY** |

This worksheet assists researchers and HSD staff in determining whether the UW is engaged in a non-exempt research project. It may also be used to assess whether non-UW institutions or individuals might be engaged in research, however other institutions may have their own policies on engagement. Researchers conducting multi-institutional research should consult with any non-UW institutions involved in the research for their policies. This form does not need to be completed and retained, unless specifically requested by the UW IRB.

For research led by Fred Hutch use the [WORKSHEET UW Engagement for Fred Hutch-led Research](https://www.washington.edu/research/forms-and-templates/engagement-fh/) instead of this worksheet.

|  |
| --- |
| **POLICY** |

Refer to the [UW’s Engagement Guidance](https://www.washington.edu/research/hsd/guidance/engagement/) for a more complete overview of the concept of engagement and how HSD interprets and applies engagement for UW research reviewed by any IRB. When the VA is involved, review [Special considerations about VA appointments and UW engagement](https://www.washington.edu/research/hsd/is-the-uw-irb-the-right-irb/identify-the-correct-irb/research-involving-va/#engagement) on our website.

**HSD uses the following definitions of engagement:**

* **Research funded or supported by a federal agency that has signed onto the Common Rule:** Unless otherwise instructed by the federal funding agency for a specific research project, the UW applies the [definition of engagement provided by OHRP](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html) to all research, regardless of the source of the research funding.
* **All other research:** Unless otherwise instructed by the funding agency for a specific research project (excluding industry funders), UW applies the [definition of engagement provided by OHRP](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html), with the exception that UW is not engaged when it is only the direct recipient of funding.

|  |
| --- |
| **ENGAGEMENT ASSESSMENT** |

Use the tables below to determine whether UW is engaged in human subjects research. These tables were adapted from the [OHRP guidance on engagement](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html).

**Table 1 - Funding**

| **Criterion** | **Met** | **Action** |
| --- | --- | --- |
| * 1. UW is receiving funding through a grant, contract, or cooperative agreement **directly** from a [**federal agency that has signed onto the Common Rule**](https://www.hhs.gov/ohrp/education-and-outreach/revised-common-rule/common-rule-departments-agencies/index.html). It does not matter whether some or all of the activities involving human subjects will be carried out by another organization. |  | **If the box is checked UW is engaged in the research.**  If the box is not checked, proceed to [Table 2](#Table2). |
| **+ NOTE** “Directly” does not include a subcontract, pass-through, or flow-through funds from an organization that is the prime recipient of the federal support. |  |  |

**T****able 2 – Activities that Engage an Organization**

If UW’s [employees/agents](https://www.washington.edu/research/hsd/guidance/engagement/#agent) conduct any of the activities in the table below, that will generally engage UW. If any of these boxes are checked, review [Table 3](#Table3) for possible limited exceptions.

| **Activities** | **Met** | **Action** |
| --- | --- | --- |
| * 1. UW’s employees or agents will intervene for research purposes with subjects by performing invasive or noninvasive procedures.   Examples: drawing blood; administering a drug; administering individual or group counseling or psychotherapy; utilizing measurement procedures. |  | **If the box is checked UW is likely engaged in the research.**  Review potential exceptions in 3.1, 3.2, and 3.3 of [Table 3](#Table3). |
| **+ Examples:**   * Drawing blood; administering a drug; utilizing measurement procedures. |  |  |
| * 1. UW’s employees or agents will intervene for research purposes with subjects by manipulating the environment. |  | **If the box is checked UW is likely engaged in the research.**  Review potential exceptions in 3.1 and 3.3 of [Table 3](#Table3). |
| **+ Examples:**   * Presenting sensory stimuli; orchestrating environmental events or social interactions. |  |  |
| * 1. UW’s employees or agents will interact for research purposes with subjects. |  | **If the box is checked UW is likely engaged in the research.**  Review potential exceptions in 3.1, 3.2, 3.3, and 3.4 of [Table 3](#Table3). |
| **+ Examples:**   * Engaging in research-dictated communication; conducting interviews; administering questionnaires. |  |  |
| * 1. UW’s employees or agents will obtain the informed consent of the subjects. |  | **If the box is checked UW is engaged in the research.**  There are no exceptions. |
| * 1. UW’s employees or agents will **obtain** for research purposes **identifiable private** information or identifiable biological specimens **from any source** for the research, even if the employee or agent does not directly interact or intervene with the subjects. |  | **If the box is checked UW is likely engaged in the research.**  Review potential exceptions in 3.1, 3.2, 3.3, 3.7, 3.8, 3.9, 3.10 of [Table 3](#Table3). |
| **+ Examples:**   * Observing or recording private behavior. * Using, studying, analyzing for research purposes identifiable private information or identifiable specimens provided by another institution. * Using, studying, analyzing for research purposes identifiable private information or identifiable specimens already in the possession of the investigators.   **+ Individually identifiable** means the identify of the subject is or may **readily** be ascertained by the investigator or associated with the information. This includes situations in which the private information or specimens can be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems. |  |  |

**T****able 3 – Limited Exceptions**

UW would be considered **not engaged** if the involvement of UW employees/agents is **limited to** one or more of the following activities.

| **Activities** | **Met** |
| --- | --- |
| * 1. UW’s employee or agents will perform commercial or other services for investigators provided that **all** of the following conditions are also met: * the services performed do not merit professional recognition or publication privileges; * the services are typically performed by those institutions for non-research purposes; **and** * the employees or agents will not administer any study intervention being tested or evaluated by the research |  |
| **+ Examples:**   * An appropriately qualified laboratory whose employees perform routine serum chemistry analyses of blood samples for investigators as a commercial service. * A transcription company whose employees transcribe research interviews as a commercial service. * A hospital whose employees obtain blood through a blood draw or collect urine and provide such specimens to investigators as a service. * A radiology clinic whose employees perform chest x-rays and send results to investigators as a service. |  |
| * 1. UW is not considered a "study site" for the research, but its employees or agents will provide clinical trial-related medical services that are dictated by the research protocol and would typically be performed as part of routine clinical monitoring and/or follow-up of subjects enrolled at a study site by clinical trial investigators (e.g., medical history, physical exam, assessment of adverse events, blood test, CT scan) provided that **all** of the following conditions also are met: * the employees or agents do not administer the study interventions being tested or evaluated; * the clinical trial-related medical services are typically provided by UW for clinical purposes; * the employees or agents do not enroll subjects or obtain the informed consent of any subject for participation in the research; **and** * when appropriate, investigators from an institution engaged in the research retain responsibility for: **(1)** overseeing research-related activities; **and (2)** ensuring appropriate arrangements are made for reporting research-related data to investigators at an engaged institution, including the reporting of safety monitoring data and adverse events as required by the IRB-approved research. |  |
| * 1. UW is not considered a "study site" for the research, but its employees or agents will administer the study interventions being tested or evaluated, limited to a one-time or short-term basis (e.g., an oncologist at a clinic administers chemotherapy to a subject as part of a clinical trial because the subject unexpectedly goes out of town, or is unexpectedly hospitalized), provided that **all** of the following conditions are also met: * an investigator from a non-UW institution engaged in the research determines that it would be in the subject's best interest to receive the study interventions being tested or evaluated; * UW’s employees or agents do not enroll subjects or obtain the informed consent of any subjects for participation in the research; * investigators from the non-UW institution engaged in the research retain responsibility for:   + overseeing research-related activities;   + ensuring the study interventions are administered in accordance with the IRB-approved procedures; **and**   + ensuring appropriate arrangements are made for reporting protocol-related data to investigators at the engaged institution, including the reporting of safety monitoring data and adverse events as required by the IRB-approved research; **and**   + an IRB designated on the non-UW institution's FWA is informed that study interventions being tested or evaluated have been administered at an institution **not** selected as a research site. |  |
| * 1. UW’s employees or agents will: * inform prospective subjects about the availability of the research; * provide prospective subjects with information about the research (which may include a copy of the informed consent document and other IRB approved materials) but do not obtain subjects' consent for the research or act as representatives of the investigators; * provide prospective subjects with information about contacting investigators for information or enrollment; **and/or** * seek or obtain the prospective subjects' permission for investigators to contact them. |  |
| * 1. UW is permitting the use of its facilities for intervention or interaction with subjects by investigators from another institution. |  |
| **+ Examples:**   * Investigators from another institution conduct or distribute a research survey in the classroom. * Permitting investigators from another institution to recruit research subjects. * Permitting investigators from another institution to draw a blood sample at the organization for research purposes. |  |
| * 1. UW’s employees or agents **release** to investigators at another institution identifiable private information or identifiable biological specimens pertaining to the research subjects. |  |
| **+ NOTE** While the UW may not be engaged in human subjects research, a HIPAA authorization or a waiver is still required when PHI is being used or accessed. Ensure the institution you are releasing to has either of these before providing the data/specimens. |  |
| * 1. UW’s employees or agents: * Obtain coded private information or human biological specimens from another institution involved in the research that retains a link to individually identifying information, **and** * Are unable to readily ascertain the identity of the subjects to whom the coded information or specimens pertain because, for example:   + they have entered into an agreement with the holder of the links (or code key) prohibiting the release of the links/key to the organization's employees or agents under any circumstances;   + the releasing institution has IRB-approved written policies and operating procedures applicable to the research project that prohibit the release of the links/key to the organization's employees or agents under any circumstances; **or**   + there are other legal requirements prohibiting the release of the links/key to the organization's employees or agents. |  |
| **+ NOTE** Other members of the research team may be located at other institutions. It includes anyone involved in conducting the research. Individuals who provide coded information or specimens and who also collaborate on other activities related to the conduct of the research with the investigators who receive the information/ specimens are considered to be involved in conducting the research. Examples of such additional activities include but are not limited to: **(1)** the study, interpretation, or analysis of the data resulting from the coded information or specimens; **and (2)** authorship of presentations or manuscripts related to the research.  **+ Coded** means:   * identifying information that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol, and/or combination thereof (i.e., the code); **and** * a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.   **+ NOTE** This set of circumstances related to engagement should be considered only after it has already been determined whether research involving coded private information or specimens is or is not research involving human subjects. |  |
| * 1. UW’s employees or agents will access or utilize individually identifiable private information **only** while visiting another institution (which is engaged in the research), provided their research activities are overseen by the IRB of the institution that is engaged in the research. |  |
| * 1. UW’s employees or agents will access or review identifiable private information for purposes of study auditing. |  |
| * 1. UW’s employees or agents will receive identifiable private information for purposes of satisfying U.S. Food and Drug Administration reporting requirements. |  |
| * 1. UW’s employees or agents will author a paper, journal article, or presentation describing the study. |  |

|  |
| --- |
| **RELATED MATERIALS & REFERENCES** |

OHRP, [Common Rule Departments and Agencies](https://www.hhs.gov/ohrp/education-and-outreach/revised-common-rule/common-rule-departments-agencies/index.html)

OHRP, [Engagement of Institutions in Human Subjects Research (2008)](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html)

[WEBPAGE Engagement Guidance](https://www.washington.edu/research/hsd/guidance/engagement/)

|  |  |  |  |
| --- | --- | --- | --- |
| **Version Number** | **Posted Date** | **Implementation Date** | **Summary of Changes** |
| 2.0 | 03.27.2025 | 03.27.2025 | Convert from PDF to Word; moderate reorganization of information and word smithing |
| 1.9 | 05.27.2021 | 05.27.2021 | Remove references to paper process |
| 1.8 | 01.03.2020 | 01.03.2020 | Removed link to retired document |
| 1.7 | 08.31.2018 | 08.31.2018 | Remove link to retired document |
| 1.6 | 05.12.2017 | 05.12.2017 | Update links and committee drop-down list |
| Previous versions |  |  | For older versions: HSD Staff – refer to the SharePoint Document Library; Others - contact [hsdinfo@uw.edu](mailto:hsdinfo@uw.edu). |

**Keywords:** Engagement