| U W  and H S D logo | **REQUEST External IRB Review** |
| --- | --- |
|  |
|  |

# PURPOSE AND INSTRUCTIONS

Use this form to request authorization to obtain IRB review from a non-UW (“external”) IRB instead of the UW IRB.

1. Complete this form.
2. In [Zipline](https://www.washington.edu/research/hsd/zipline/), select the activity called Create New Study. Answer all questions on the Zipline SmartForms. Be sure to answer “yes” to Question 5 (external IRB) on the Basic Study Information SmartForm.
3. Upload this Request form and the other required documents listed at the end of this form on the appropriate SmartForms.
4. Submit the Zipline application to HSD as a Word document (**do not convert to PDF or other format**).

Contact hsdrely@uw.edu for questions, or review the [HSD website](https://www.washington.edu/research/hsd/is-the-uw-irb-the-right-irb/how-to-ask-for-a-non-uw-irb/) for more information.

# BILLING INFORMATION – Industry Clinical Trials Only

HSD charges a one-time fee for the administrative oversight of research which is:

* Industry-initiated-and-sponsored, and
* A clinical trial according to HSD’s definition, and
* UW OSP executed a contract for the research.

This fee is charged through Workday. HSD does not send invoices. If this research meets the criteria above, provide a Worktag (e.g., GR123456) to which HSD should charge the fee. This can be any Worktag of the department’s choice. HSD will not complete its review without a Worktag.

Worktag to charge:

|  |
| --- |
| Click or tap here to enter text. |

Additional billing instructions (optional):

|  |
| --- |
| Click or tap here to enter text. |

# 1. RESEARCHER INFORMATION

## UW Lead Researcher (PI) Information

|  |  |
| --- | --- |
| **Name**: | **Title**: |
| Click or tap here to enter text. | Click or tap here to enter text. |
| **Email**: | **Phone number**: |
| Click or tap here to enter text. | Click or tap here to enter text. |

## UW Study Team Contact Person for Correspondence from HSD (e.g., research coordinator)

|  |  |
| --- | --- |
| **Name**: | **Title**: |
| Click or tap here to enter text. | Click or tap here to enter text. |
| **Email**: | **Phone number**: |
| Click or tap here to enter text. | Click or tap here to enter text. |

For non-industry, multisite studies in which the UW is not the lead site

Overall Study Lead Researcher (PI) Information

|  |  |
| --- | --- |
| **Name**: | **Title**: |
| Click or tap here to enter text. | Click or tap here to enter text. |
| **Email**: | **Phone number**: |
| Click or tap here to enter text. | Click or tap here to enter text. |

Overall Study Team Contact Person for Correspondence from HSD (e.g., research coordinator, project manager)

|  |  |
| --- | --- |
| **Name**: | **Title**: |
| Click or tap here to enter text. | Click or tap here to enter text. |
| **Email**: | **Phone number**: |
| Click or tap here to enter text. | Click or tap here to enter text. |

**1.1. UW Principal Investigator Qualifications.** For studies to be reviewed by any IRB other than WCG IRB or Advarra, upload a recent Curriculum Vitae (CV), Biosketch (as provided to federal funding agencies), or similar document to the Local Site Documents page in Zipline. The purpose of this CV is to address the PI’s qualifications to conduct the proposed research (education, experience, training, certifications, etc.).

*For help with creating a CV, review* [*http://adai.uw.edu/grants/nsf\_biosketch\_template.pdf*](http://adai.uw.edu/grants/nsf_biosketch_template.pdf) *and* [*https://intranet.medicine.uw.edu/academic-hr/curriculum-vitae-cv*](https://intranet.medicine.uw.edu/academic-hr/curriculum-vitae-cv)

[ ]  The CV will be uploaded.

[ ]  The study will be reviewed by WCG IRB or Advarra. No CV is required for HSD.

**1.2. UW Study Team Qualifications.** For studies to be reviewed by any IRB other than WCG IRB or Advarra, describe the qualifications and/or training for each **UW** study team member to fulfill their role on the study and perform study procedures. You may list these individuals by name, however, if you list an individual by name, you may need to modify this application if that individual is replaced. Alternatively, you can describe study **roles** and the qualifications and training the PI or study leadership will require for any individual who might fill that role.

*Describe: the role (or name of person), the study activities they will perform, and the qualifications or training that are relevant to performing those study activities.*

|  |
| --- |
| Examples: **Research Study Coordinator:** Obtain consent, administer surveys, blood draw. Will have previous experience coordinating clinical research and be a certified phlebotomist in WA.**Undergraduate Research Assistant:** Obtain consent, perform all study procedures. Will have had coursework in research methods, complete an orientation to human subjects protections given by the department, and will receive training from the PI or the graduate student project lead on obtaining consent and debriefing subjects.**Acupuncturist:** Perform acupuncture procedures and administer surveys. Must be licensed with WA State DoH and complete training in administering surveys given by the project director, and experienced survey researcher.**Co-Investigator:** Supervise MRI and CT scan procedures and data interpretation, obtain consent. MD, specialty in interventional radiology and body imaging. 5-years clinical research experience.  |

|  |
| --- |
| Click or tap here to enter text. |

**1.3** **Financial Conflict of Interest.** Does any member of the UW team have ownership or other Significant Financial Interest (SFI) with this research as defined by [UW policy GIM 10](https://www.washington.edu/research/policies/gim-10/)?

[ ]  **No**

[ ]  **Yes** **→** Has the Office of Research made a determination regarding this SFI as it pertains to the proposed research?

[ ]  **Yes →** Reminder, the UW study team is responsible for providing information about any SFI management plans to the reviewing IRB and information about the management plan must be included in consent materials for subjects. Review HSD’s [GUIDANCE Consent Language for External Studies](https://www.washington.edu/research/policies/guidance-consent-elements-externally-reviewed-studies/) for consent language.

[ ]  **No** **→** Contact the Office of Research (206.616.0804, research@uw.edu) for guidance on how to obtain the determination.

#  2. IRB RELIANCE INFORMATION

**2.1.** Why are you requesting reliance on another IRB? Check all that apply.

[ ]  **2.1.a.** This is an industry-sponsored, industry-initiated study that qualifies for review by a commercial IRB

[ ]  **2.1.b.** This is a study related to cancer that qualifies for review by the Fred Hutch IRB

[ ]  **2.1.c.** In order to comply with single IRB requirements for federally-supported research

[ ]  **2.1.d.** The non-federal sponsor has requested it (upload in Zipline documentation of the sponsor’s request)

[ ]  **2.1.e.** It has been requested by another institution involved in the research (upload in Zipline documentation of the institution’s request)

[ ]  **Other →** Please briefly explain:

|  |
| --- |
| Click or tap here to enter text. |

**2.2.** If you have checked any boxes aside from **2.1.a.**, or **2.1.b.** in item **2.1.** above, has the external IRB already agreed that it can conduct review on behalf of the UW?

*If you do not have confirmation that the external IRB can review on behalf of the UW, HSD strongly recommends you seek that confirmation before you submit this application. If the external IRB cannot review on behalf of UW, you will need to complete an application for review by the UW IRB.*

[ ]  **No**

[ ]  **Yes** **→** Provide contact information for the external IRB’s staff person assisting with the reliance:

|  |  |
| --- | --- |
| **Name**: | **Title**: |
| Click or tap here to enter text. | Click or tap here to enter text. |
| **Email**: | **Phone number**: |
| Click or tap here to enter text. | Click or tap here to enter text. |

**2.3. Consultation history**. Has there been any consultation with someone at UW HSD, the Fred Hutch IRO or the Seattle Children’s IRB about this study?

*It is not necessary to obtain advance consultation. However, if advance consultation was obtained, answering this question will help ensure that HSD is aware of and considers the advice and guidance provided in that consultation.*

[ ]  **No**

[ ]  **Yes** **→** Briefly describe the consultation or upload a copy of any communications (e.g., emails, letters of support, etc.)

|  |
| --- |
| Click or tap here to enter text. |

**2.4. Combination site:** Will UW be part of a combined site with other institution(s)? For example, study procedures will be conducted by Fred Hutch and UW employees and both Fred Hutch and UW are part of a single combined site being submitted to the reviewing IRB under one PI.

[ ]  **No**

[ ]  **Yes** **→** Please list the combined site PI’s name. The local UW PI and the combined site PI may be the same or different people.

|  |
| --- |
| Click or tap here to enter text. |

# 3. OVERALL STUDY INFORMATION

**3.1.** Study sponsor name:

|  |
| --- |
| Click or tap here to enter text. |

Sponsor protocol or grant number:

|  |
| --- |
| Click or tap here to enter text. |

**3.2.** Who is the author of the protocol or research plan?

[ ]  **Sponsor**

[ ]  **Lead Researcher**

[ ]  **Other** **→** Please briefly describe:

|  |
| --- |
| Click or tap here to enter text. |

**3.3**. Is the UW the only site, or a lead participating site in a multi-site study?

*UW is the lead site if it is the primary recipient of a funding award and/or the UW PI is responsible for the overall conduct of the study.*

[ ]  **Only site**

[ ]  **Lead site of multi-site study**

[ ]  **Participating site of multi-site study**

[ ]  **Other** **→** Please briefly explain:

|  |
| --- |
| Click or tap here to enter text. |

# 4. STUDY ACTIVITIES CONDUCTED BY UW RESEARCH TEAM

**4.1.** Which of the following activities will be conducted by the UW research team? Check all that apply:

[ ]  **Obtain consent and/or assent**

[ ]  **Perform research procedures**

[ ]  **Administer study interventions being tested**

[ ]  **Obtain, use, or analyze identifiable data and/or specimens**

[ ]  **Other responsibilities or roles** **→** Please briefly explain:

|  |
| --- |
| Click or tap here to enter text. |

**4.2.** Identify any of these populations from which you will deliberately recruit:

[ ]  **Children**

[ ]  **Pregnant women/fetuses**

[ ]  **Prisoners**

[ ]  **Neonates of nonviable or uncertain viability**

[ ]  **Native Americans/Alaska Natives**

[ ]  **Cognitively impaired adults**

[ ]  **Other unique populations** **→** Please briefly explain:

|  |
| --- |
| Click or tap here to enter text. |

**4.3.** Will you be collecting, obtaining or using fetal tissue for this study?

[ ]  **No**

[ ]  **Yes →** Review HSD’s [GUIDANCE Consent Elements for Externally Reviewed Studies](https://www.washington.edu/research/policies/guidance-consent-elements-externally-reviewed-studies/) for required consent language.

**4.4.** Is it reasonably foreseeable that you may obtain information from subjects about abuse or neglect of children and/or vulnerable adults?

[ ]  **No**

[ ]  **Yes** **→** Briefly explain:

|  |
| --- |
| Click or tap here to enter text. |

**4.5.** If you will access any UW-held records that are healthcare related, indicate by checking the box if you will access those records **with** or **without** (or both) the written permission (e.g., consent, HIPAA Authorization) of the individuals who the records are about. If you will not access records from the locations listed, leave the boxes blank.

| **Location of Records** | **Without written permission** | **With written permission** |
| --- | --- | --- |
| **UW Medical Center (Montlake and/or Northwest)** |[ ] [ ]
| **UW Medicine Neighborhood Clinics** |[ ] [ ]
| **Hall Health Center** |[ ] [ ]
| **Airlift Northwest** |[ ] [ ]
| **Harborview Medical Center** |[ ] [ ]
| **Department of Pediatrics Molecular Development Lab** |[ ] [ ]
| **School of Dentistry Clinics and Family Practice Plan** |[ ] [ ]
| **Autism Center at CHDD** |[ ] [ ]
| **Psychology Clinics in the College of Arts & Sciences** |[ ] [ ]
| **Rubenstein Pharmacy in the School of Pharmacy (aka Hall Health Pharmacy)**  |[ ] [ ]

**4.6.** Which of the following Data and Safety Monitoring activities will apply to the UW Parts of this study:

[ ]  **Local DSMB**

[ ]  **Non-local DSMB**

[ ]  **Study Monitoring Committee (multicenter)**

[ ]  **Sponsor Site Monitoring**

[ ]  **Independent Medical Monitor**

[ ]  **Non-local PI**

[ ]  **Local PI or study team only**

[ ]  **None of the above (DSMP not required)**

[ ]  **Other** **→** Please briefly explain:

|  |
| --- |
| Click or tap here to enter text. |

**4.7.** Are subjects in your study likely to earn $600 or more in subject payments for UW research during the calendar year?

[ ]  **No**

[ ]  **Yes →** Briefly explain and review HSD’S [GUIDANCE Consent Elements for Externally Reviewed Studies](https://www.washington.edu/research/policies/guidance-consent-elements-externally-reviewed-studies/) for required language:

|  |
| --- |
| Click or tap here to enter text. |

**4.8. Costs to subjects**. For clinical trials that involve the use of clinical services, items, or tests through UW Medicine or UW Physicians (UWP), will there be any research-related costs for which subjects and/or their health insurance may be responsible (examples might include: CT scan required for research eligibility screening; co-pays; surgical costs when a subject is randomized to a specific procedure; cost of a device;)?

[ ]  **No or not applicable** (e.g. not a clinical trial)

[ ]  **Yes →** Review HSD’s [GUIDANCE Consent Elements for Externally Reviewed Studies](https://www.washington.edu/research/policies/guidance-consent-elements-externally-reviewed-studies/) and ensure appropriate language about costs is included in the consent form.

**4.9.** Is there a plan to deposit genomic information in an external database (such as the NIH dbGaP database) for sharing with other researchers?

[ ]  **No**

[ ]  **Yes** **→** Briefly explain:

|  |
| --- |
| Click or tap here to enter text. |

**4.9.a. If yes, will UW be asked to provide NIH required certification for the submission?**

[ ]  **No**

[ ]  **Yes →** Review HSD’s [Genomic Data Sharing Guidance](https://www.washington.edu/research/hsd/guidance/ancillary/gds/) which includes HSD’s required consent elements for certification.

**4.10.** **Recordings.** When an audio recording will capture a private communication or conversation between two or more individuals where at least one participant in the conversation is in Washington State, Washington State law requires that consent must be obtained from all individuals who will be recorded.

**4.10.a. Does the research involve creating audio recordings (including video recordings that capture audio) in Washington State?**

*Refer to* [*Washington State law on Consent for Audio Recording guidance*](https://www.washington.edu/research/hsd/guidance/consent/#audio) *for more details.*

[ ]  **No →** Go to question **4.11.**

[ ]  **Yes →** Consent for audio recordings must be obtained using one of these methods:

* Subjects will provide written consent either as part of the research consent or as a separate audio recording consent.
* Recording of verbal consent with the communication or an announcement that the conversation is being recorded. **Check box to confirm that** **consent for audio recording will be obtained.**

[ ]  **Confirmed**

**4.10.b. Will audio recordings take place in a UW Medicine clinical setting?**

[ ]  **No →** Go to question **4.11.**

[ ]  **Yes →** [UW Medicine policy](https://depts.washington.edu/comply/audio-recordings/) requires approval from the applicable UW Medicine entity’s Chief Executive Officer or Executive Director when audio recordings will be made for research purposes in a UW Medicine clinical setting. **Check the box to confirm that this approval has been obtained.** Documentation of the approval must be available upon request from the IRB.

[ ]  **Confirmed**

**4.11.** For studies in which documentation of consent or HIPAA authorization will be obtained: will subjects use an electronic method to provide their consent or authorization signature? NOTE: Use of e-signatures requires advance approval of the reviewing IRB **and** advance concurrence from HSD.

* *Review our guidance on* [*Documentation of Consent*](https://www.washington.edu/research/hsd/guidance/consent/#10) *and instructions for* [***UW E-Signature Tools***](https://www.washington.edu/research/hsd/guidance/consent/econsent/)*for information about options (including REDCap e-signature and the DocuSign system) and any associated requirements.*
* *FDA-regulated studies must use a system that complies with the FDA’s 21 CFR Part 11 requirements about electronic systems and records. Note that the UW ITHS REDCap and the UW-IT supported DocuSign e-signature systems do not meet this requirement.*
* *Having subjects check a box at the beginning of an emailed or web-based questionnaire is not considered legally effective documentation of consent.*

[ ]  **No**

[ ]  **Yes** **→** Indicate which methodology will be used:

[ ]  **UW ITHS REDCap** (excludes REDCap Mobile application, which is a separate software application for use with a mobile device for consent when internet service is absent or unreliable)

[ ]  **Other REDCap Installation →** Please name the institutional version you will be using (e.g., Vanderbilt, Univ. of Cincinnati) in the field below and provide a completed supplement, [**Other REDCap Installation**](https://www.washington.edu/research/forms-and-templates/supplement-other-redcap-installation/) with your submission.

[ ]  **UW DocuSign**

[ ]  **Other →** Please describe in the field below and provide a signed [**Other E-signature Attestation Letter**](https://www.washington.edu/research/forms-and-templates/template-other-esignature-attestation-letter/) with your Zipline submission.

|  |
| --- |
| Click or tap here to enter text. |

**4.12. Use of Short Form Consent.** Does the study involve use of a drug, biologic, botanical, nutritional supplement and/or is the study otherwise considered to be greater than minimal risk to subjects?

[ ]  **No→** Skip this question.

[ ]  **Yes** **→** If you anticipate using the short form consent for the infrequent and unanticipated enrollment of individuals with non-English language preference when the consent form has not been translated into the subject’s language, check the confirmation boxes below.

[ ]  **Confirm** that an interpreter will be available to the subjects for the duration of their participation in the study.

[ ]  **Confirm** that you will provide a translated consent form as a modification to the reviewing IRB **within 30 days** of using the short form consent process and provide subjects with an IRB-approved translated consent form **within 2 weeks** of IRB approval.

**4.13. Cannabis (marijuana), hemp, and related compounds.** These questions are about: cannabis (any part of the plant, in any form), hemp, cannabidiol (CBD), delta-8-THC, any product derived from cannabis or hemp, and related synthesized compounds. All UW research must comply with federal laws about cannabis because of conditions associated with the federal money that UW receives. Answer the questions below so that HSD can determine whether the federal laws apply to your specific situation. Review the UW [Guidance on Research Involving Marijuana](https://www.washington.edu/research/policies/guidance-on-research-involving-marijuana/) for additional information.

**4.13.a**. Does your research involve any of the following? Check all that apply.

[ ]  Study staff will obtain or handle any of the above items

[ ]  Study will provide money to the study participants to obtain any of the above items

[ ]  Study participants will use or consume any of the above items on campus or in any UW-owned or leased facility

[ ]  None of the above

**4.13.b.** If you checked any box except “None of the above”, provide the following information about each cannabis and related item your research will involve: Name of the item, how you will obtain it, the source, and whether it contains ≥0.3% THC (tetrahydrocannabinol).

|  |
| --- |
| Click or tap here to enter text. |

# 5. ADVISORY POINTS – NO RESPONSE REQUIRED

**5.1.** **UW Office of the Youth Protection Officer.** If the project involves interaction (in-person or remotely) with individuals under the age of 18, researchers must comply with the **UW Administrative Policy Statement 10.13** and the requirements listed at [this website](https://www.washington.edu/youth/policy/protecting-youth-at-uw-aps-10-13/). This includes activities that are deemed to be Not Research or Exempt. It applies only to the UW site (i.e., it does not apply to research conducted by a non-UW PI). [Information and FAQs](https://www.washington.edu/youth/policy/protecting-youth-at-uw-aps-10-13/youth-program-faqs/#researchers) for researchers are available.

**5.2.** **Use of Amazon’s Mechanical Turk (mTurk).** If your study involves the use of MTurk, you must comply with the [UW Procurement Services policy](https://finance.uw.edu/ps/amt/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.

**5.3.** **School of Medicine research involving** [**Artificial Intelligence**](https://depts.washington.edu/comply/docs/308_G1.pdf). A security review of the research is required by UW Medicine for human subjects research involving the use of AI when **all** of the following criteria are met:

1. The research is led by **School of Medicine Principal Investigators (PIs);**
2. The research involves either the targeted enrollment of **UW Medicine patients, OR,** use of[**UW Medicine Data**](https://depts.washington.edu/comply/docs/308_G1.pdf)**; and**
3. The research involves the **use of AI outside of a secure [UW Medicine environment](https://depts.washington.edu/comply/docs/308_G1.pdf).**

For information about how to obtain a security review, refer to the [UW Medicine Information Security Risk Management Program website.](https://depts.washington.edu/uwmedsec/restricted/services/risk-management/) For questions about this process, contact uwmed-security@uw.edu

**5.4.** **Use of UW Medicine’s eCare/MyChart and 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. Additionally, the UW Medicine’s eCare/MyChart system may not be used for research recruitment purposes.

**5.5.** **UW Medicine and UW dentistry residents and fellows as study subjects.** You must inform the UW HR Labor Relations representative who negotiates with the resident’s union about the study before beginning it. This is currently Jennifer Mallahan mallaj@uw.edu.

**5.6. Use of the OnCore Clinical Trial Management System (CTMS).** The [OnCore CTMS](https://www.seattlectms.org/) serves as a centralized resource to support oncology and non-oncology clinical research conducted within or across the Fred Hutch/UW/Seattle Children’s Consortium. The amount of information entered into the CMS will vary depending on the type of study. For more information, review the [CTMS Program Office website](https://www.iths.org/ctms/) or send questions to CTMS@fredhutch.org.

**5.7.** C**ancer-related intervention research protocols.** You must obtain scientific review from the [Cancer Consortium Scientific Review Committee](https://www.cancerconsortium.org/research-support/clinical-research-support/study-start-up/scientific-review-committee.html) before the external IRB reviews the research. This is required regardless of funding or location of the research. For questions contact PRMS@fredhutch.org.

**5.8.** **Other Responsibilities.** You must follow the responsibilities of UW PIs for research reviewed by non-UW IRBs which are described in the checklist, [External IRB for UW Researchers](https://www.washington.edu/research/forms-and-templates/checklist-external-irb-uw-researchers/).

# 6. REQUIRED ATTACHMENTS

Upload the following documents to the appropriate **Zipline** SmartForms.

| **Document** | **Required?** | **Zipline SmartForm** |
| --- | --- | --- |
| REQUEST External IRB Review (this document) | Yes | External IRB |
| Any funding proposals supporting the research | Yes, unless this is an industry-sponsored, industry-initiated study | Study Funding Sources or Local Funding Sources |
| Draft or Template Consent Form(s) | Yes, if they are available from the sponsor, coordinating center, lead site, or the external IRB at the time of your External IRB Request submission to Zipline. | Local Site Documents |
| CV for UW PI | Yes | Local Site Documents |
| A document that provides a detailed description of the research*Examples: study protocol, research plan, grant application, dissertation proposal* | Yes  | Study-Related Documents (Local Site Documents for single site research) |
| Any materials you have received from the external IRB that you have been directed to give to the HRPP/IRB office or the institution*Examples: instructions to the HRPP/IRB office, documents to be signed or completed by the HRPP/IRB, documents that collect local context information, letters of indemnification, attestations to be signed by a UW institutional official* | Yes, these materials will most likely come from IRBs at other academic medical centers or from NIH designated central IRBs (e.g., Vanderbilt, Johns Hopkins, the NCI central IRB) rather than from commercial IRBs | Study-Related Documents (Local Site Documents for single site research) |
| Documentation of the sponsor or other institution’s requirement for external IRB review*Review item 2.1 above for explanation. This documentation may already be in a funding proposal or other materials received from the reviewing IRB* | Yes, if you are seeking external IRB review due to the requirement of a sponsor or another institution.  | Study-Related Documents (Local Site Documents for single site research) |
| SUPPLEMENT Other REDCap Installation or Other E-Signature Attestation Letter | Yes, if some or all participants will use electronic signatures to provide consent and/or HIPAA authorization, and the e-signature system is a non-UW REDCap system or other non-UW system | Local Site Documents  |