|  |  |
| --- | --- |
| University of Washington Human Subjects DIvision | **CHECKLIST External IRB for UW Researchers** |

|  |  |
| --- | --- |
|  |  |

Use this checklist after HSD has authorized you to use an external IRB to assist you in obtaining approval from an external IRB and understanding your responsibilities for reporting during the life of the study. This checklist applies to studies led by a UW researcher as well as studies led by a non-UW researcher for which UW is relying on a non-UW IRB.

|  |
| --- |
| **Steps for obtaining initial IRB approval from the external IRB** |
| [ ]  | **Obtain authorization for the external IRB review from other institutions as needed.** The authorization for external review provided by HSD is only for the involvement of UW staff, faculty and students. When employees or agents of other organizations are involved in the research, such as obtaining consent, interacting with subjects, or analyzing identifiable specimens or data, their institutions must also typically authorize the external IRB to conduct review on their behalf. This includes organizations such as Seattle Children’s, Fred Hutch, and any other regional research partners. Follow the procedures of each of the involved institutions to obtain their authorization to use the external IRB. |
| [ ]  | **Begin obtaining any required UW ancillary reviews and approvals** if you have not already done so. *You will need to provide the results of some of these reviews to the reviewing IRB.* HSD does not initiate or facilitate these reviews with the exception of Genomic Data Sharing (GDS) certification (if the UW researcher requests certification). If other institutions, such as Fred Hutch or Seattle Children’s, are involved in the research, you may be required to obtain other ancillary reviews at those institutions. Work with the other institutions involved to understand their requirements.

|  |  |  |
| --- | --- | --- |
| UW Ancillary Review | When required? | Provide results to external IRB? |
| [Financial Conflict of Interest Disclosure](https://www.washington.edu/research/compliance/financial-conflicts-of-interest-fcoi/) | Any UW investigator has a conflict as defined in [GIM 10](https://www.washington.edu/research/policies/gim-10/). | Yes, mandatory under UW policy |
| [Human Subjects Radiation Approval Committee (HSRAC)](https://www.ehs.washington.edu/radiation/use-radiation-human-subjects-research) | Radiation exposure (procedures or materials) to subjects | Yes, if requested by the external IRB |
| [Institutional Biosafety Committee (IBC)](https://www.ehs.washington.edu/biological/institutional-biosafety-committee-ibc) | Use of recombinant/synthetic DNA/RNA, human gene transfer and other biohazardous agents | Yes, if requested by the external IRB |
| Radioactive Drug Research Committee (RDRC)Contact James W. Vélez (jvelez@uw.edu) | Investigational radioactive drugs being used without an IND for basic science research | Yes, if requested by the external IRB |
| [Embryonic Stem Cell Research Oversight Committee (ESCRO)](https://www.washington.edu/research/embryonic-stem-cell-research-oversight-escro/) | Use of human embryonic stem cells (hESC) | Yes, if requested by the external IRB |
| [Office of the Youth Protection Coordinator Registration](https://www.washington.edu/youth/policy/protecting-youth-at-uw-aps-10-13/aps-10-13-info-for-researchers/) | The research involves in-person or virtual interactions with subjects under 18. | Yes, if requested by the external IRB |
| [Material Transfer Agreements (MTA) and Data Use Agreements (DUA).](https://www.washington.edu/research/myresearch-lifecycle/setup/collaborations/agreement-types/)  | Data and/or specimens are shared amongst institutions. | Yes, if requested by the external IRB |
| [Cancer Consortium Scientific Review Committee](https://www.cancerconsortium.org/en/support/study-management/study-start-up/committee-reviews/src.html) | Cancer-related intervention studies. | Yes, if requested by the external IRB |
| UW Medicine Security Review for Machine LearningContact Sally Beahan (sbeahan@uw.edu) | The research involves the use of UW Medicine patient data (whether identified or de-identified) for machine learning outside of UW IT systems. | Yes, if requested by the external IRB |
| Approval from the relevant CEO or Executive Director for [Audio Recordings In The Clinical Setting For Research, Education Or Quality Improvement Purposes](https://depts.washington.edu/comply/audio-recordings/) | Audio recordings will be made for research purposes in a UW Medicine clinical setting. | No |
| UW HR Labor Relations Contact Jennifer Mallahan (mallaj@uw.edu) | UW Medicine and UW Dentistry residents and fellows are study subjects. | No |
| [Genomic Data Sharing Certification](https://www.washington.edu/research/hsd/guidance/ancillary/gds/)  | Genetic information will be submitted to certain NIH repositories. This certification is typically done after the study has been approved by the IRB. | No |
| [Clinical Research Budget and Billing (CRBB)](https://depts.washington.edu/crbb/) | Clinical services, items or tests that are provided as part of a research study by UW Physicians or UW Medicine hospitals or clinics. | No |

 |
| [ ]  | **Before submitting to the reviewing IRB, understand your responsibility for any IRB review fees.** External IRBs may charge fees for review. HSD will **not** pay fees associated with IRB review by any external IRB. All fees must be paid from the study budget or other study resources. For multi-site studies, these fees are frequently paid by the lead site or sponsor. If you are not sure who will pay the fees, check with the lead site and/or sponsor. |
| [ ]  | **Submit to the reviewing IRB**1. **Follow the instructions of the reviewing IRB to apply.** Use their forms and processes. If this is a multi-site study, the lead PI’s team, a coordinating center or the industry sponsor may facilitate this process.
2. **When submitting to the reviewing IRB, make sure to include the following:**
	1. **A copy of the “Acknowledgement of Reliance on an External IRB” letter provided by HSD** (available in the documents tab for the study in [Zipline](https://www.washington.edu/research/hsd/zipline/))**.** If you do not include this with your submission to the reviewing IRB, approval of your application may be delayed.
	2. **UW Required Consent Information.** If consent will be obtained from subjects or their representatives, reviewthe  [GUIDANCE Consent Elements for Externally Reviewed Studies](https://www.washington.edu/research/policies/guidance-consent-elements-externally-reviewed-studies/) to identify whether consent materials must contain UW-specific required information. If so, you are responsible for ensuring that this information is included in the consent materials reviewed by the external IRB.
	3. **For industry-sponsored studies, make sure that the compensation for injury language in the consent form is consistent with the Clinical Trial Agreement (CTA) and UW’s required language is used.** HSD routinely audits consent forms **after** they have been approved by an external IRB to confirm consistency with the CTA and HSD’s consent form language requirements. Discrepancies may result in the need for consent revisions, IRB re-review at the sponsor’s expense, and re-consenting of subjects.
	4. **Financial Conflict of Interest Information**.
		1. If the [Office of Research](https://www.washington.edu/research/compliance/financial-conflicts-of-interest-fcoi/) has issued a Conflict Management Plan for any UW research team members, **you must provide these plans to the reviewing IRB.** If Significant Financial Interest (SFI) has been disclosed to the Office of Research and you have not yet received a plan, indicate in your application to the reviewing IRB that it is pending and send it to the reviewing IRB when you receive it.
		2. The reviewing IRB may have a lower monetary threshold for conflicts of interest than the UW. You are required to follow the reviewing IRB’s financial conflict of interest disclosure requirements. This may mean that you have to make additional disclosures to the reviewing IRB that you did not have to disclose to the UW. Follow the reviewing IRBs instructions for these additional disclosures.

|  |
| --- |
| Special Instructions for specific IRBs |
| WCG IRB | On the WCG IRB submission form, under this question: *Will this research be conducted through an organization that has a contract or Master Services Agreement (MSA) to use WCG IRB for IRB services?*Answer: **Yes** Name of the organization: **University of Washington** (Unless the site PI has a primary appointment at another institution such as Fred Hutch. In those cases, select the name of that organization.)WCG IRB Institution # **55014** |
| Advarra | When registering for an account in CIRBI, Advarra’s online system, make sure to list your institutional affiliation as “**University of Washington**” unless you have a primary appointment at another institution such as Fred Hutch. In those cases, select the name of that organization. |

 |
| [ ]  | **Respond to any requests for local context from the reviewing IRB.** As part of the process of allowing the external IRB to review the study, HSD may have already provided the reviewing IRB with information about state and local laws, policies and other context. However, the reviewing IRB may request additional information from you during the life of the study. The **study team** is responsible for providing the reviewing IRB with:* Information about how the study will specifically be carried out at/by UW, e.g., site specific recruitment, procedures, etc.
* Final consent materials that contain any UW-specific required information as described in the [*UW Guide to Consent Elements for Externally Reviewed Studies*](https://www.washington.edu/research/policies/guidance-consent-elements-externally-reviewed-studies/)
* Confirmation and documentation of any training (Human Subjects Protections, GCP, etc.) for your team members
* The status of, and information about, any conflicts of interest
* The status of, and documentation of, any required, local ancillary reviews (Radiation Safety, IBC, etc.)

Contact **HSD** (hsdrely@uw.edu) if the reviewing IRB requests information about: * State or local laws impacting the research
* Institutional information such as FWA numbers and the status of audits
* Confirmation from an institutional representative that the study team is qualified to perform the research
* If you need additional guidance or the reviewing IRB has additional requests for information from HSD, the local IRB or HRPP
 |
| **What to do when you have obtained approval from the external IRB** |
| [ ]  | Tell HSD that the reviewing IRB has approved the study. When you have received documentation of the external IRB’s approval for UW, send the approval documentation to HSD (hsdrely@uw.edu). This assists HSD in understanding that the study has been approved. HSD will upload approval documents to the study record in Zipline and change the study status to “Active”. As long as you have secured all of the other required approvals for the study, you do not need to wait until the study status is “Active” in Zipline in order to begin recruitment or study procedures. However, until HSD receives these documents, the status of the study in Zipline will be “Pending sIRB Review” and the PI will receive a reminder every 6 months that approval documents have not been received.*NOTE: You do not usually need to send approval documents from WCG IRB or Advarra to HSD. WCG IRB and Advarra automatically send approval documents to HSD.* |
| [ ]  | Be prepared to respond to HSD’s post-approval consent audit. For initial reviews of the protocol or UW investigator, HSD performs a 100% audit of all consent forms for the following studies: * All studies reviewed by Advarra
* All studies reviewed by WCG IRB
* All industry sponsored and initiated clinical trials reviewed by any other non-UW IRB (except Jaeb IRB and Fred Hutch IRB).

HSD performs this review in order to ensure that the consent forms adhere to UW’s consent form requirements described in the  [GUIDANCE Consent Elements for Externally Reviewed Studies](https://www.washington.edu/research/policies/guidance-consent-elements-externally-reviewed-studies/). This includes ensuring that consent language is consistent with the terms of the CTA or MCTA and that UW’s required consent language for compensation for injury is used. HSD will complete its initial review within 5 business days, or faster for most studies.**For studies reviewed by Advarra or WCG IRB:** Advarra and WCG IRB will automatically contact HSD to initiate this review prior to releasing approval documents to study teams and sponsors. After HSD has concluded its review, it will communicate to Advarra or WCG IRB that the consent forms are acceptable or that revisions are required. HSD will include the study team in this communication. Recruitment and enrollment of subjects is not allowed until the study team has received the final approved documents from WCG or Advarra. |
| [ ]  | **For funded studies, provide documentation of the external IRB’s approval to the Office of Sponsored Programs (OSP).** OSP will need documentation that the external IRB has approved the study before it can release funds. When you provide this documentation, it may be helpful to also provide the Zipline number associated with the study. For some, but not all, studies, HSD receives a copy of the initial approval letter directly from the external IRB. In these cases, HSD will upload the approval letter in Zipline to facilitate communication with OSP. |
| **Plan for the life of the study** |
| [ ]  | Understand the UW study team’s roles and responsibilities. These responsibilities may be described across several documents such as a communication plan generated by the lead team or coordinating center, instructions given by the reviewing IRB, and materials uploaded by HSD to the study in [Zipline](https://www.washington.edu/research/hsd/zipline/). Make sure that team members who are responsible for regulatory management and reporting have access to these materials and develop a plan for meeting these responsibilities. If you have questions about your responsibilities, contact HSD (hsdrely@uw.edu) or the reviewing IRB. |
| [ ]  | **Develop a plan for maintaining IRB records.** External IRBs will give you access to their approval documents in a variety of ways (on paper, online systems, via email, etc.). The UW PI is responsible for maintaining IRB records for UW research for the life of the study and until any [records retention periods are over](https://www.washington.edu/research/myresearch-lifecycle/closeout/records-retention/). The UW study team is also responsible for making sure documentation of IRB reviews and approvals are available for inspection by study monitors and auditors (e.g., by HSD’s PAVE program, the FDA, or UW’s Internal Audit). If IRB documents are maintained in an online system, you may need to know how to grant auditors access or develop a plan for downloading and storing relevant documents. |
| [ ]  | **Understand what and when to report to the reviewing IRB.** The UW PI is responsible for following the external IRB’s policy for reporting new information about the study, such as unanticipated problems, serious or continuing noncompliance, study suspensions or terminations to the reviewing IRB. Reporting requirements, such as time deadlines for reporting incidents and what types of information must be reported, vary by IRB. Make sure that you and your team are familiar with and follow those reporting requirements throughout the life of the study. These requirements can be found in the reviewing IRB’s website, policy documents, or may be listed on approval documents. |
| [ ]  | **Understand when to contact HSD**. HSD does not require that you obtain reauthorization for review of any parts of the study unless the reviewing IRB requires it. You do not typically need to submit any additional information to HSD regarding continuing review, modifications, etc. However, you should contact HSD in the following situations.**Submit a** [**Study Update**](https://www.washington.edu/research/hsd/training/zipline-online-help-library/researcher-submission-guide/study-modifications/changing-external-irb-studies/) **in Zipline when:** * There is a change in the UW Principal Investigator.
* There is a change in the study team members who require access to the study in Zipline.
* There is a proposal to change which IRB is reviewing the study.
* There is a new plan to implement eConsent.
* The study is a platform protocol and a new intervention/treatment arm/regimen specific appendix is added.
* The study has been closed at the reviewing IRB.

**Contact HSD via email at** **hsdrely@uw.edu** **when:*** You have received documentation of the reviewing IRB’s initial approval (WCG IRB and Advarra reviewed studies are exempt from this requirement)
* The study activities at UW are suspended or terminated by the reviewing IRB.
* The reviewing IRB requests local context information (for example, applicable state and local laws) and you are unsure how to respond.

You **do not** need to send to HSD: * Most modifications, continuing review reports, reports of new information that will be sent to the reviewing IRB, or approval documents for these activities.
* Any other updated documents, for example protocols, investigators brochures, consent materials.
 |
| [ ]  | **Know what and when to report to other UW offices**. When a study is reviewed by the UW IRB, as a courtesy HSD makes other compliance offices aware of any unanticipated problems or noncompliance you report to the UW IRB that is relevant to those offices. ***In contrast, for externally reviewed studies, the UW PI is responsible for notifying these offices.*** When there is a breach of privacy involving information from any UW sources, you will need to report to the appropriate office and may **also** need to report to the reviewing IRB depending on their policies for reporting. The [UW Privacy Office website](https://privacy.uw.edu/report/) describes where and how to report different types of unforeseen events, incidents, and potential or confirmed data breaches. |

**Keywords:** External reliance; Multi-site