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| University of Washington Human Subjects DIvision | **WORKSHEET External Reliance, Initial Submission** |

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| **1**  **PURPOSE AND APPLICABILITY** |

This document is intended to be used as an aide for IRB Reliance Administrators on how to review and process the initial request to have UW research reviewed by an external (non-UW) IRB. It lists the issues and criteria that are considered when making the decision about the request, for documenting the decision, for completing an assessment of the study for applicable local context, and for communicating or documenting any local context information to the external IRB. This worksheet describes the process from initial assessment of the application in Zipline, to the action which changes the status in Zipline to “Pending sIRB Review.”

This worksheet can also be used to guide the review of modifications and updates to applications which have already been authorized for review by a non-UW IRB, especially when the changes to the reliance arrangement are extensive (e.g., there is a change of which external IRB will review the research). When using this worksheet to guide those reviews, also refer to the **WORKSHEET External Reliance, Follow-on Submissions**.

Read the entire application and then evaluate it using this worksheet. Issues should usually be evaluated in the order listed, but an experienced reliance administrator may be able to quickly identify key issues “out of order” when reading the application which may eliminate the need for some steps. There is no requirement to complete and retain this worksheet.

Hyperlinks are used sparingly in this document because they are difficult to maintain. Reference documents are bolded and can be found in the [Published Document Library](https://uwnetid.sharepoint.com/sites/OR/HSD/Published%20Document%20Library/Forms/AllItems.aspx). The **Ctrl+F** function is also helpful when searching for specific information.

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| 1. **TRIAGE AND INITIAL ASSESSMENT** |

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| **2.1 Urgency of review**. If the researcher has described time constraints that need to be considered, prioritize as appropriate. |
| **+ Guidance**  Researchers may indicate that they have “Just In Time (JIT)” status and need a quick turnaround. JIT status means the sponsor has allowed them to wait to obtain IRB approval until they receive notice that their score is in a fundable range. *In most cases,* *this does not mean the researcher needs a rush authorization or approval*. Refer researchers to the [**GUIDANCE Just In Time**](https://www.washington.edu/research/hsd/guidance/just-in-time-and-irb-review/) webpage for more detailed information. If the researcher insists there is a tight deadline for IRB approval or reliance agreement execution, request written confirmation from the sponsor. If you receive confirmation that the sponsor does require IRB approval by a certain date, contact the Senior Reliance Administrator or Assistant Director for Reliances for guidance on conducting an expedient authorization or approval. |
| * 1. **Conflict of interest.** Verify that the administrator has no conflict of interest with respect to the item. If there is a conflict of interest, consult with the Senior Reliance Administrator or Assistant Director for Reliances and re-assign the item to another member of the team. (**SOP Reviewer Conflict of Interest**) |
| **2.3 Triage for assignment to an internal review team.** It may be easy to immediately identify some studies that should be routed for internal review rather than authorized for review by a non-UW IRB. This is intended to be a quick assessment. A more thorough assessment is conducted later in this worksheet. These studies are typically:   * Minimal risk oncology studies * Exempt research * Easy to review, non-federally-funded research for which a reliance may be more work (chart reviews, secondary use of identifiable data).   If you are not certain, consult with the Senior Reliance Administrator or the Assistant Director of Reliances. |
| **+ Guidance**  **Internal Review**  When a submission should be handled by a Review Team (because, for example, the study team has responded “Yes” to Basic Information Question 5 in error) follow these steps:   1. Assign the study to the correct review team in Zipline. Review team assignments can be identified by using the [contact locator on the HSD webpage](https://www.washington.edu/research/contact-us/?keyword=508). 2. Assign the TOL for that team as the IRB coordinator in Zipline. 3. Add a comment to the study describing the situation and the reason for transfer to a review team. 4. The TOL will get the notification of the comment and will take it from there. |

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| 1. **AC****CURACY AND COMPLETENESS OF THE APPLICATION** |

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| **3.1. Faculty Advisor.** If a UW student or resident is serving as the UW PI for the research, a faculty advisor’s approval must be obtained before the reliance agreement can be executed. The following determinations may be made without the advisor’s approval: Not Research; Not Human Subjects; Not Engaged. If advisor approval is required, verify that it has been requested and provided using the **Manage Ancillary Review** activity. If the faculty advisor is not a UW employee with a NetID, faculty advisor sign-off can be documented via email and uploaded in Zipline using **Manage Ancillary Review**.  *EXAMPLE LANGUAGE FOR THIS COMMUNICATION IS IN THE RELIANCE TEAM HANDBOOK*  *NOTE: Completion of the IRB 101 online training is not currently required for studies reviewed by a non-UW IRB.* |
| **3.2. Version of REQUEST External IRB Review form**. Verify that the version used by the researcher provides adequate information for the review of this specific study. If not, request an updated version.  The administrator must use their judgement to identify the most efficient and appropriate approach when the submitted **REQUEST** form version is out of date. HSD staff use their discretion regarding whether the information provided in an out-of-date form provides enough information to assess the applicable regulatory and/or policy requirements. |
| **+ Guidance**  Guiding Principles for Judgement Calls   1. The end result should be that the application contains the necessary information to document that the applicable regulatory and/or policy requirements were assessed and satisfied. 2. The method used to obtain missing information should allow future reviewers and auditors to easily find and assess that information (e.g., if you opt to insert information into the existing **REQUEST** form rather than uploading supplementary questions, be sure the location of the information makes sense).   If the **REQUEST** form that was submitted is missing important information, the pre-reviewer should:   1. Request that the researcher submit a replacement **REQUEST** form using the most recent version (this is the preferred option due to the limited length of the **REQUEST** form); or 2. Ask the researcher to provide the information that is needed by inserting it into the older version of the **REQUEST** form they have submitted. |
| **3.3. Completeness of materials.** Verify that all required materials have been provided. For example, make sure there is a CV for the PI if the study will be reviewed by any IRB other than WCG or Advarra. A list of required documents is at the end of the **REQUEST External IRB Review** form. |
| **3.4. Funding Information in the SmartForm.**  **External funding.**   * The external *Funding Organization* is critical for identifying the regulations that apply to a study. It is also important for some issues related to clinical trial registration at ClinicalTrials.gov and reporting in the case of serious or continuing noncompliance. * Information about the funding organization and the route of funding should be provided in as many situations as possible and to the extent it is known by the UW research team. This includes situations in which UW is not receiving any funds but a partner organization (e.g., Fred Hutch) is receiving funds. This may require research teams to be creative about how they provide the information in Zipline. They may need to add explanatory information as a comment or as an attachment. * Funding for the study as a whole should be listed in “Study Funding Sources” section of Zipline. This includes direct awards to the UW that will be used for the overall study (e.g., UW is the primary awardee and will send out sub-awards to other sites) as well as sub-awards to UW from a parent grant that is issued to another organization. This is also where industry funding should be listed. * For non-industry multi-site studies, funding that is given directly from an external agency to the UW for use only by and at UW should be listed in “Additional Local Funding Sources.” Examples of these are K (Career) or T (Training) awards given directly to UW faculty and trainees. These are typically infrequent and, if the situation is unclear, it can be listed in the “Study Funding Sources.” * If the researcher has indicated that the *Route of Funding* is “From the sponsor to another organization….”, then make sure the *Funding Organization*listed is the originating sponsor instead of the “pass through” organization between the sponsor and the UW. * Verify that the *Grants Office ID* (eGC1) has been provided for any external or Royalty Research funding that is being administered through the UW. Researchers may list the eGC1 number as “pending” when they submit the application. Authorization can be issued without an eGC1, but the UW Office of Sponsored Programs has read-only access to Zipline and uses the information in Zipline to check against information in their system. If there is no eGC1 number in Zipline, that makes it challenging for them to do.   **Funding proposal documents:**  **When UW is the prime recipient:** In most cases, the funding application, proposal, scope of work or other description of the funded project provided to the external funder should be uploaded to the application. It is preferential to have the entire grant proposal, rather than just the scope of work because important information related to the reliance request may be in other portions of the funding application. (**Exceptions:**  center grants; some training grants; other funding with no specific human subjects activities described.) Industry sponsored studies are not required to provide a copy of the funding contract/CTA.  **When UW is a subaward**: Copies of information about UW’s role as a subawardee should be uploaded to the application, this is typically very limited information and is something like a scope of work. If the parent grant (which is awarded to another institution) is uploaded, that is also acceptable, but is not required. However, if the Reliance Administrator believes that they need a copy of the parent award in order to process the reliance request, it can be requested. Other institutions may or may not be willing to release this information.  **When the overall study is funded, but UW is not receiving any funding for its role:** Researchers may upload copies of the proposal, however it is not required.When any documents are uploaded, it should be very clear in the application that UW is not the recipient of the funds. |
| **+ Guidance**  Examples of external funding that appear to be internal funding:   * Institute for Translational and Health Sciences (ITHS) – Early Investigator (Catalyst and Voucher) awards are internal, all other awards are federal funding * Alcohol and Drug Abuse Institute (ADAI) – usually Washington State funding * Center for AIDS Research (CFAR) – federal funding * Department for Environmental & Occupational Health Sciences (DEOHS) program called, Professional Training Opportunities Program (PTOP) in Occupational Health & Safety – federal funding   What is a “pass through” situation? The second option listed for **Route of Funding** has many names:   * Pass through funding * Flow through funding * Subcontract * Subaward   All of these names indicate that the research funds are “passing through” from the sponsor to another organization before then coming to the UW. The “in between” organization is called the **prime (or primary) recipient**. This is common for federally-funded research. Failure to correctly identify the sponsor means we may fail to identify the research as federally funded and incorrectly identify the regulations that apply to the research.  *Example*: Duke University has an institute called the Duke Clinical Research Institute. They frequently obtain federal funding for clinical trials (as the prime recipient) and then subcontract the research and the money to individual research sites across the country. Many UW researchers participate in these trials. Instead of selecting the name of the federal funding agency for Funding Organization, many researchers or study staff incorrectly select Duke Clinical Research Institute or Duke University as the Funding Organization.  *NOTE that the grant certification requirement was eliminated in the revised Common Rule however, the grant application continues to be a required part of the Zipline application because it is a valuable source of information.* |
| **3.5. Completeness of answers.** Verify that all required questions have been answered. (Answers indicating “none” or “not applicable” are acceptable.) Ensure that the answers provide sufficient information for the administrator to fully assess the application for the engagement of UW, the need to establish a reliance agreement, and to assess the applicability of local context. |
| **+ Guidance**  **A guiding principle**: Will the next person looking at this application understand what has been done? Edits to the **REQUEST** form require extra work, especially from the researcher. However, numerous uploaded comments and response letters in the study’s history make it very challenging for HSD staff to accurately understand the study when they are reviewing the application in the future. This can lead to serious oversights, overlooked problems or IRB noncompliance. Requiring edits is most appropriate when:   * Any of the following are true: * The situation involves the correction of a factual error or the supplying of information that was inappropriately omitted in the **REQUEST** form; * The study is likely to last a long time; * The application is likely to be viewed by other HSD staff in the future.   Drug and Device Supplements are not required. |
| **3.6. Consistency of application**. The information provided in the application is internally consistent across all parts of the application.  Inconsistencies or inaccuracies on ***Zipline*** SmartForms must typically be corrected because the SmartForms are the data source for metrics and reports. This applies to requests for external reliances as well as IRB review and determinations. |
| **+ Guidance**  The information in the **REQUEST External IRB Review** form should be consistent with other parts of the application. For example, the responses in the **REQUEST** form should cover all aspects of the study which are described in a protocol and are to be completed by UW researchers. This information should also match the information in any funding documents. If the **REQUEST** form does not cover all of these activities, there should be an explanation from the researchers as to why. |
| **3.7. Industry Clinical Trial Billing Information**. HSD charges a fee for the authorization and oversight of certain industry trials. If the application meets all of the following criteria, the research team must provide billing information as requested on the first page of the **REQUEST** form.   * Industry-sponsored-and-initiated, * Clinical trial, * To be reviewed by a non-UW IRB, * A Clinical Trial Agreement (aka the contract) is or will be negotiated through OSP.   If the information is not there, you may begin screening the application, but you must **not** confirm the reliance and issue an authorization letter until the information is provided by the study team. The information should be in the new worktag format (e.g., GRXXXX, CCXXXX, PGXXXX). Old budget formats (e.g., XX-XXXX) should not be accepted. |
| **+ Guidance**   |  |  | | --- | --- | | **Industry-sponsored-and-initiated** | A commercial entity wrote the protocol/initiated the research and is funding the research and/or serving as the sponsor according to the FDA’s definition. Providing only study drug or the device is not sufficient to be considered the sponsor of the study. | | **Clinical Trial** | Use the definition in the **CHECKLIST Clinicaltrials.gov**. Note that there are some industry-initiated studies that are not clinical trials (e.g., survey studies or post-market chart reviews do not typically meet the definition of a clinical trial). | | **Reviewed by a non-UW IRB** | Use of any non-UW IRB meets this criterion, even if the IRB is mandated by the sponsor. | | **Contract negotiated through OSP** | Review the information in the funding section. You may need to identify this by examining the information in SPAERC. If it is unclear, ask additional information from the study team which might mean that you require that they provide the eGC1 number. |   Q: What if the sponsor renegotiates with a new CTA and budget?  A: HSD will only bill once as long as it’s the same protocol regardless of whether or not there is a new CTA and/or budget.  Q: What about extension phases?  A: Extension phases will not be billed separately as long as they are reviewed as part of the same study by the non-UW IRB. If the extension phase is considered a separate study requiring re-authorization by HSD, then the extension phase will be billed as a new study.  Q: What about studies for which the CTA is negotiated by Fred Hutch or another organization?  A: Not billed because there is typically no funding coming to the UW for that research and there may not be an associated budget. Occasionally there is flow down funding to UW, but that funding is usually limited to a partial salary. If HSD wanted to bill for this, significant outreach would be needed to Fred Hutch to communicate that this fee would be charged and to develop a process for invoicing for those fees outside of Workday. |

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| 1. **ASSESSING THE UW STUDY TEAM** |

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| **4.1. Red Flag PI.** If the UW lead researcher is on the [Red Flag List](file://file.oris.washington.edu/Shared-HS/Red%20Flag%20List/2021.02.17_Red%20Flag%20List.docx), consult with the Sr. Reliance Administrator or Assistant Director of Reliances. |
| * 1. **UW PI.** Based on the information already provided in the application, assess whether there is anything that suggests that the PI is not acting as an employee or agent of UW for the purposes of the proposed research. If they are not acting as an agent of UW, the UW may not be the appropriate institution to establish a reliance agreement on behalf of the PI for this research. |
| **+ Guidance**  The purpose of this question is to identify applications where it is obvious that the PI is not acting as a UW employee or agent, with the goal of preventing unnecessary work for HSD staff. A detailed analysis of whether the researcher is a UW employee or agent and the UW is engaged is covered in further sections.  *Example:* A UW physician with their own company is conducting a research study to test the effectiveness and safety of a device owned by the company. No UW resources will be used and the activity is not related to their role at UW.  *Example:* A UW affiliate faculty member who has their own private practice is contributing to a research project at another university. No funds are coming to UW, no UW resources will be used and the activities will not be related to UW in any way.  In some extenuating circumstances, it may be appropriate for a non-UW PI to be listed on the application, e.g., in cases where UW is engaged but there is not a UW affiliated PI for the research. The most common situations would likely involve Fred Hutch or Seattle Children’s. |
| **4.3. Qualifications of UW Study Team.** For all studies reviewed by an IRB other than a commercial IRB such as WCG or Advarra, assess the qualifications of the UW PI to serve as the PI for the proposed study and the qualifications of the study team members. Refer to the **SOP Study Team** for guidance on assessing qualifications. |
| **+ Guidance**  **Key Questions:**   * Does the PI’s educational, professional or other training indicate a background in the topic of the research? * Do the study roles look like they encompass the key activities for the study?   **Examples of Red Flags:**   * Someone who does not have a medical background who is serving as the PI on a clinical trial. For example, they may have a Ph.D., but not an M.D. This may be acceptable as long as they have an M.D. co-investigator or other arrangements are in place. * EFIC studies when the investigator has no prior experience with EFIC research and does not have a mentor or co-investigator who has prior experience. * Greater than minimal risk studies whose risks come from unique community considerations when the researcher has no prior experience with the community.   *NOTE: HSD and UW do not have an institutional Human Subjects training requirement. Investigators are required to follow the training requirements of any funding agency or other compliance units, but HSD does not maintain these records. Investigators must provide copies of these if requested by the non-UW IRB.* |
| **4.4. Financial Conflict of Interest (FCOI).** Note whether or not any members of the study team have an FCOI. If there is one, you should indicate that in the Authorization Letter. You do not need to collect any of the FCOI management plans. |

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| 1. **ASSESSING THE ACTIVITIES FOR RELIANCE** |

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| * 1. **Delayed Onset Human Research (DOHR) determination.** HSD does not rely on non-UW IRBs or institutions for DOHR determinations. The researchers may be requesting this if an **APPLICATION Determination, Delayed Onset Human Research** is uploaded in Zipline. The TOL or Sr. Administrator for the appropriate internal review team are responsible for reviewing DOHR determinations. |
| **+ Guidance**  **Internal Review**  When a submission should be handled by a Review Team follow these steps:   1. Assign the study to the correct review team in Zipline. Review team assignments can be identified by using the [contact locator on the HSD webpage](https://www.washington.edu/research/contact-us/?keyword=508). 2. Assign the TOL for that team as the IRB coordinator in Zipline. 3. Add a comment to the study describing the situation and the reason for transfer to a review team. 4. The TOL will get the notification of the comment and will take it from there. |
| * 1. **Single Patient Expanded Access.** HSD does not rely on non-UW IRBs or institutions for Single Patient Expanded Access of a drug or device. The researchers may be requesting this if an **APPLICATION Notification of Emergency Use, Drug or Biologic** is uploaded in Zipline. Single Patient Expanded Access has special handling instructions. Consult with the Sr. Reliance Administrator or Assistant Director of Reliances. |
| * 1. **Research vs. non-research.** Determine whether some or all of the described procedures and activities are “research”, as defined by the regulations that apply to the study. If all of the procedures described in the application are not research, a reliance agreement is not necessary. (**GUIDANCE Is it Research?**; **WORKSHEET Human Subjects Research Determination**; **GUIDANCE Case Reports, IRB Review, and HIPAA**).   ***NOTE ABOUT EXPANDED ACCESS and HUMANITARIAN USE DEVICES:*** UW will rely on non-UW IRBs for expanded access for more than one patient and clinical use of an HUD, which is not considered research under either OHRP or FDA definitions but **does** require IRB review. Researchers are instructed to submit to the IRB that would review the activity if it was research (e.g., Fred Hutch for oncology, UW for non-oncology, WCG or Advarra if industry wrote the protocol, etc.). Review Section 12 of this worksheet for how to process expanded access protocols and clinical HUD requests. |
| **+ Guidance**  **Scope of research**. A project, especially one involving multiple institutions, may contain some aspects that are research and some that are not. UW faculty, staff and students may be participating in the non-research portion, the research portion, or both. UW only needs to rely on the external IRB for the portion of the activities that are research. For some studies this is difficult to disentangle, and it may be most expeditious to rely for the whole project, however for some, disentangling the research from the non-research aspects is important to understanding whether or not a reliance is needed.  **Revised Common Rule.** The revised Common Rule provides specific clarification about (1) scholarly and journalistic activities, such as oral history, and (2) public health surveillance activities that are specifically considered “not research”. These clarifications are generally consistent with long-standing HSD interpretation and practice. They are incorporated into the **GUIDANCE Is It Research?** If the study appears to qualify for the Common Rule exclusion of public health surveillance activities from research, consult with the Sr. Reliance Administrator or Assistant Director of Reliances.  **Quality improvement.** These activities are challenging. HSD’s definition and guidance about how to identify quality improvement activities that are not also research continues to evolve and are described in **GUIDANCE Is It Research?**  **Making the determination.** When a Reliance Administrator determines that a request does not require reliance because the activity is not research, the determination can be completed by the Reliance Administrator.   1. If a study team does not require a formal determination: 2. Add a comment to the study in Zipline describing the determination of not research. 3. Request Clarification in Zipline instructing the study team to discard the study. 4. If a study team requires a formal determination (or the Reliance Administrator believes formal documentation is advantageous): 5. Request Clarification so the item can be re-routed to the internal pathway. This request should include several instructions:  * Instruct the study team to save a copy of documents relevant to making the determination. These may include:   + The **REQUEST External IRB Review** form attached on the External IRB page.   + Documents attached to the Study-Related Documents page. * Instruct the study team to change the Basic Study Information Question 5 response to “No”. Answering “No” will remove the External IRB page, which is why it is important for researchers to save documents. * If the study is listed under item 4 as “Multi-site”, instruct the study team to change the new Basic Study Information Question 6 about having UW be the IRB for other sites to “No.” Answering “No” will remove the Study-Related Documents page. * Instruct the study team to upload a completed IRB Protocol to the appropriate item (8 or 9) on Basic Study Information . In some cases, the **REQUEST External IRB Review** form may be used if it has enough information to make the determination instead of the IRB Protocol. * Instruct the study team to upload any documents from the Study-Related Documents page that are relevant to support the IRB determination to the appropriate location in Zipline. * Ensure that the documentation within the submission is sufficient to support the determination. This may include comments/clarification provided on the History tab. If the documentation is not sufficient request additional information as needed. * Instruct the study team to re-submit.   While waiting for a response, the item can remain assigned to “Reliance” as the Team and the Reliance Administrator as the Coordinator.  When the study team has responded, complete the determination as described in the **INSTRUCTIONS Zipline for Staff** and **re-assign the application from “Reliance” to “Team S.”** |
| * 1. **Human subjects.** Determine whether the involvement of individuals, records, or specimens (if any) meet the definition of “human subject”, as defined by the regulations that apply to the study. (**WORKSHEET Human Subjects Research Determination**)   If the research does not involve human subjects a reliance agreement is not necessary. |
| **+ Guidance**  **Revised Common Rule.**   * The wording of the definition of “human subject” has changed slightly but the meaning of the definition has not changed. * *Newborn dried bloodspots.* Effective January 21, 2019, the research use of de-identified or anonymous newborn dried bloodspots is no longer considered to involve human subjects.   **Large national datasets.** Many large and widely available national datasets have been assessed by HSD management to determine whether they involve “human subjects”. Check the **GUIDANCE Data Sets Not Requiring HSD or IRB Review** to see if the dataset has already been determined to be “Not Human Subjects”. If it is not on the list, ask HSD leadership to consider adding it to HSD’s list in the Guidance. For example, many federally-managed data sets are likely candidates to add to the list.  **Coordinating Center, Data Center, or Core Facility**.If the application involves one of these as part or all of the proposed activities, carefully consider whether human subjects are involved in the Coordinating Center, Data Center, or Core Facility activities. This gets at the scope of what is being reviewed and approved in the application. Remember that if the project involves non-UW institutions or individuals, the application should be assigned to Team S for an initial assessment.  **PHI of deceased individuals.** Deceased individuals are not considered human subjects. In addition, there are no HIPAA related responsibilities for HSD staff or the IRB to fulfill.  **Making the determination.** When a Reliance Administrator determines that a request does not require reliance because the activity is not human subjects, the determination can be completed by the Reliance Administrator.   1. If a study team does not require a formal determination: 2. Add a comment to the study in Zipline describing the determination of not research. 3. Request Clarification in Zipline instructing the study team to discard the study. 4. If a study team requires a formal determination (or the Reliance Administrator believes formal documentation is advantageous): 5. Request Clarification so the item can be re-routed to the internal pathway. This request should include several instructions:  * Instruct the study team to save a copy of documents relevant to making the determination. These may include:   + The **REQUEST External IRB Review** form attached on the External IRB page.   + Documents attached to the Study-Related Documents page. * Instruct the study team to change the Basic Study Information Question 5 response to “No”. Answering “No” will remove the External IRB page, which is why it is important for researchers to save documents. * If the study is listed under item 4 as “Multi-site”, instruct the study team to change the new Basic Study Information Question 6 about having UW be the IRB for other sites to “No.” Answering “No” will remove the Study-Related Documents page. * Instruct the study team to upload a completed IRB Protocol to the appropriate item (8 or 9) on Basic Study Information. In some cases, the **REQUEST External IRB Review** form may be used if it has enough information to make the determination instead of the IRB Protocol. * Instruct the study team to upload any documents from the Study-Related Documents page that are relevant to support the IRB determination to the appropriate location in Zipline. * Ensure that the documentation within the submission is sufficient to support the determination. This may include comments/clarification provided on the History tab. If the documentation is not sufficient request additional information as needed. * Instruct the study team to re-submit.   While waiting for a response, the item can remain assigned to “Reliance” as the Team and the Reliance Administrator as the Coordinator.  When the study team has responded, complete the determination as described in the **INSTRUCTIONS Zipline for Staff** and **re-assign the application from “Reliance” to “Team S.”** |
| * 1. **Exempt.** Determine whether the research qualifies for exempt status. If the research qualifies for exempt status a reliance agreement is not necessary. The UW does not typically accept or rely on the exemption determinations of non-UW institutions. (**WORKSHEET Exempt Determination; GUIDANCE Exempt Research**)   In rare circumstances, UW can enact a reliance on another institution’s exemption determination. Work with the Senior Reliance Administrator or the Assistant Director of Reliances if you believe that accepting or relying on the exemption determination of another institution may be warranted. In these circumstances, UW cannot use the SMART IRB Agreement, and a study specific agreement tailored to exempt research may need to be drafted. |
| **+ Guidance**  **Federal regulatory opinion:** When different institutions are conducting portions of a single research study: the entire study must fit into one or more of the exemption categories in order for the exemption to apply to the portion of the study occurring at a single institution. This applies even when the components of the study are being conducted by different institutions under subcontracts. (IRB Forum, January 20, 2013, Communication from Edward Bartlett, Office of Human Research Protections. “Review of protocols for tasks done by a subcontractor”).  The federal single IRB requirements only apply to non-exempt research. Enacting a reliance agreement for exempt research is typically slower than simply making an exemption determination. In addition, it establishes obligations between institutions for reporting requirements and information sharing that may encumber the research with more regulatory burden than is necessary to protect subjects.  **Making the determination.** When a Reliance Administrator determines that a request does not require reliance because the activity is exempt, the determination can be completed by the Reliance Administrator.   1. Exemptions always require a formal determination: 2. Request Clarification so the item can be re-routed to the internal pathway. This request should include several instructions:  * Instruct the study team to save a copy of documents relevant to making the determination. These may include:   + The **REQUEST External IRB Review** form attached on the External IRB page.   + Documents attached to the Study-Related Documents page. * Instruct the study team to change the Basic Study Information Question 5 response to “No”. Answering “No” will remove the External IRB page, which is why it is important for researchers to save documents. * If the study is listed under item 4 as “Multi-site”, instruct the study team to change the new Basic Study Information Question 6 about having UW be the IRB for other sites to “No.” Answering “No” will remove the Study-Related Documents page. * Instruct the study team to upload a completed IRB Protocol to the appropriate item (8 or 9) on Basic Study Information. In some cases, the **REQUEST External IRB Review** form may be used if it has enough information to make the determination instead of the IRB Protocol. * Instruct the study team to upload any documents from the Study-Related Documents page that are relevant to support the IRB determination to the appropriate location in Zipline. * Ensure that the documentation within the submission is sufficient to support the determination. This may include comments/clarification provided on the History tab. If the documentation is not sufficient request additional information as needed. * Instruct the study team to re-submit.   While waiting for a response, the item can remain assigned to “Reliance” as the Team and the Reliance Administrator as the Coordinator.  When the study team has responded, complete the determination as described in the **INSTRUCTIONS Zipline for Staff** and **re-assign the application from “Reliance” to “Team S.”** |
| * 1. **Engagement**. Determine whether the UW is engaged in the research. If the UW is not engaged in the research, a reliance agreement is not necessary. (**WORKSHEET Engagement**; **GUIDANCE Engagement**) |
| **+ Guidance**  **Quick engagement assessment triage:**   * If there is external funding for the research, check the **Route of Funding** to determine whether UW is the primary recipient. If yes, the UW is engaged and the analysis of engagement is complete. * If the study team members conducting non-exempt human subjects research is a UW employee/agent, then the UW is engaged and analysis of engagement is complete.   **Making the determination.** When a Reliance Administrator determines that a request does not require reliance because the UW is not engaged, the determination can be completed by the Reliance Administrator.   1. If a study team does not require a formal determination: 2. Add a comment to the study in Zipline describing the determination of UW not engaged. 3. Request Clarification in Zipline instructing the study team to discard the study. 4. If a study team requires a formal determination (or the Reliance Administrator believes formal documentation is advantageous): 5. Request Clarification so the item can be re-routed to the internal pathway. This request should include several instructions:  * Instruct the study team to save a copy of documents relevant to making the determination. These may include:   + The **REQUEST External IRB Review** form attached on the External IRB page.   + Documents attached to the Study-Related Documents page. * Instruct the study team to change the Basic Study Information Question 5 response to “No”. Answering “No” will remove the External IRB page, which is why it is important for researchers to save documents. * If the study is listed under item 4 as “Multi-site”, instruct the study team to change the new Basic Study Information Question 6 about having UW be the IRB for other sites to “No.” Answering “No” will remove the Study-Related Documents page. * Instruct the study team to upload a completed IRB Protocol to the appropriate item (8 or 9) on Basic Study Information. In some cases, the **REQUEST External IRB Review** form may be used if it has enough information to make the determination instead of the IRB Protocol. * Instruct the study team to upload any documents from the Study-Related Documents page that are relevant to support the IRB determination to the appropriate location in Zipline. * Ensure that the documentation within the submission is sufficient to support the determination. This may include comments/clarification provided on the History tab. If the documentation is not sufficient request additional information as needed. * Instruct the study team to re-submit.   While waiting for a response, the item can remain assigned to “Reliance” as the Team and the Reliance Administrator as the Coordinator.  When the study team has responded, complete the determination as described in the **INSTRUCTIONS Zipline for Staff** and **re-assign the application from “Reliance” to “Team S.”** |
| * 1. **Mandated reliance due to regulations, funder, or another organization involved in the research.** Assess whether the study is required to be reviewed by a single IRB for any of the following reasons:  1. **Research is federally funded, supported or federal employees involved.** Reliance on another IRB is usually required in order to meet the single IRB requirements of the Revised Common Rule and/or the NIH single IRB policy. 2. **Non-federal funder requirement**. The funder requires external IRB review as a condition of support. 3. **Requirement of another institution engaged with UW in a collaborative study.** The other institution may require the UW to rely upon its IRB or another IRB that it specifies. |
| **+ Guidance**  **Federal Single IRB Mandates:**  **NIH Single IRB Policy** requires that a single IRB review on behalf of all domestic institutions engaged in “multi-site” NIH-funded or supported research where sites are conducting the same research protocol for *competing* *grants and contracts* submitted to NIH on or after January 25, 2018. Exceptions:   * Non-competing renewals * There is only one domestic institution engaged in the research * K and T awards * NIH has issued a study-specific exception   **Common Rule Single IRB section** requires that a single IRB review on behalf of all domestic institutions engaged in a cooperative research project. This requirement applies for all agencies who have signed onto the Common Rule. Exceptions:   * If the funder has issued a study-specific exception * Projects reviewed and approved by any IRB prior to January 21, 2020.   More information is on [HSD’s webpage.](https://www.washington.edu/research/hsd/single-irb/) If you are uncertain, consult with the Sr. Reliance Administrator or Assistant Director of Reliances. |
| * 1. **UW Mandated Reliance.** Assess whether single IRB review or reliance on the external IRB is required due to UW policy or under the terms of a cooperative agreement.  1. **Industry study**. Must have all of the following characteristics:    * Industry-sponsored and industry-initiated. 2. **Cancer Related Full Board study**. Must have **all** of the following characteristics:    * The person who would be the PI on the Fred Hutch IRB application is a member of the Cancer Consortium (verify membership on the [Cancer Consortium Site](https://www.cancerconsortium.org/membership/member-search.html)), (NOTE: Fred Hutch does not allow students to be the PI on their IRB applications, in the case of student-led research, their advisor would serve as the PI on the Hutch application);    * Study is Cancer Related (review guidance below for definition);    * The study requires full, convened IRB review either because it is greater than minimal risk or because the convened IRB must confirm the risk level;    * Another IRB has not already been selected as the single IRB in order to comply with the federal single IRB mandate. 3. **Terms of an existing cooperative or central IRB reliance agreement**. The terms of an existing cooperative agreement or central IRB agreement specify that the study should be reviewed by another IRB. Refer to the information on the [HSD webpage](https://www.washington.edu/research/hsd/is-the-uw-irb-the-right-irb/identify-the-correct-irb/) and, if needed, the terms of the original agreements which are stored in the [Reliance Team electronic folders](file://FILE.oris.washington.edu/reg%20affairs/Reliances/7%20-%20Cooperative%20Partner%20Agreements). |
| **+ Guidance**  **Explanation of terms:**  **Industry-sponsored-and-initiated:** A for-profit entity is serving as the sponsor under the FDA’s definition of “sponsor” and/or funding the research and the for-profit entity wrote and/or owns the protocol. This is in contrast to investigator-initiated studies and investigator-sponsor studies which may be funded or otherwise supported by the for-profit entity, but for which someone else wrote the protocol (typically the UW investigator or another investigator at a non-profit institution). For-profit entities are often pharma/device companies but can include any for-profit entity. Industry research is almost always research that is conducted solely in support of the for-profit entity’s desire to market and sell their product.  *Where to find this information*:   * A formal Study Protocol has been uploaded and it is clear from the title page and introduction that the company is the author; and/or * There may be a contract or letter uploaded with the funding information that suggests that the PI is conducting the study on behalf of a company.   **Cancer-Related:** This definition has been established by the UW/Fred Hutch/Seattle Children’s Cancer Consortium:   * Funded by National Cancer Institute (NCI); or ​ * Directly involves cancer patient research; or * The study cohort will include both patients with a cancer diagnosis and others without a cancer diagnosis **AND** includes a primary or secondary analysis of the portion of the cohort with a cancer diagnosis; or ​ * Research of secondary conditions related to cancer treatment in patients with a cancer diagnosis who have received that treatment; or​ * Cancer prevention studies that specifically include a primary outcome of cancer diagnosis ​ * Regardless of the above, the primary site of a multi-site trial has classified the study as cancer or cancer-related; or​ * Bone marrow transplants even if not related to cancer treatment​. |
| * 1. **Optional reliance is not administratively burdensome.** Assess whether establishing and maintaining the reliance on an external IRB will be less administratively burdensome for HSD and the UW investigators than UW conducting its own review. For example, because:  1. Another institution is conducting most of the research, especially procedures involving any subject contact. 2. There is very little or no UW local context information to communicate to the external IRB. 3. The study is related to an existing study or series of studies reviewed by the external IRB. 4. The external IRB has greater IRB member expertise than the UW IRB.   In other words, if review by an external IRB is **not** required by the single IRB mandates, the sponsor, or under UW policy and cooperative agreements, is the study *poorly suited to* external IRB review because review of the study would be better accomplished (e.g., faster, more flexibly, lower level of review) by a UW IRB? For example, UW IRB review might be appropriate when there are significant local context considerations and ancillary review results to be communicated to the reviewing IRB, or the reviewing IRB will not take the UW’s local context information into account. |
| * 1. **Study characteristics indicating required consultation prior to authorization.** Some types of research may have special considerations that should be addressed by HSD leadership. Assess whether the study involves any of the following: * Exception from Informed Consent/Emergency Medicine Research that is not part of the SIREN Network -> this may require additional community consultation involvement. * Research targeting Native American/Alaska Natives that is \*not\* being reviewed by a tribal IRB or an Indian Health Service IRB -> the appropriateness of relying on a non-tribal IRB for this research may need to be evaluated.   Consult with the Sr. Reliance Administrator or the Assistant Director of Reliances if any of these are identified. |

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| 1. **ASSESSING THE EXTERNAL IRB** |

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| * 1. **Prohibited IRBs.** There are some IRBs that UW cannot rely on for the review of any activities. This is typically because the external IRB does not allow UW to rely on its review, or there may be other regulatory and administrative considerations which make reliance on the external IRB unfeasible. The UW IRB cannot rely on any of the following: * IRBs operated by any location of the U.S. Department of Veterans Affairs, including VAPSHCS or the VA Central IRB, * An IRB operated by an institution located outside of the U.S. such as the University of British Columbia or the KEMRI IRB.   In order to prevent researchers from submitting requests to rely on these IRBs, HSD does not generally make these IRBs selectable in Zipline. Requests to add these IRBs are likely to come in via email as researchers are preparing an application. If researchers request reliances on these IRBs, tell them that UW does not rely on these IRBs, which may mean that they need to submit an application for review by the UW IRB. |
| **6.2. Required IRBs**. HSD policy sometimes specifies which external IRB *must* be used. If the study falls into any of the categories below, confirm that the appropriate external IRB has been selected in Zipline.   |  |  | | --- | --- | | **Type of study** | **Required external IRB** | | Industry-sponsored-and-initiated | WCG IRB or Advarra | | Cancer Related | Review UW’s webpage on [Cancer-Related Research](https://www.washington.edu/research/hsd/is-the-uw-irb-the-right-irb/identify-the-correct-irb/oncology-related-research/) to identify the correct IRB. This may be one of several depending on the circumstances of the research.  *Quick Reference:* If there is no other IRB serving as the sIRB, and the study requires full board review, Fred Hutch should be the IRB even if UW is the only institution engaged. | | UW has an existing cooperative or master reliance agreement that specifies an IRB. Refer to the information on the [HSD webpage](https://www.washington.edu/research/hsd/is-the-uw-irb-the-right-irb/identify-the-correct-irb/) and, if needed, the terms of the original agreements which are stored in the [Reliance Team electronic folders](file://FILE.oris.washington.edu/reg%20affairs/Reliances/7%20-%20Cooperative%20Partner%20Agreements). | The IRB specified in the agreement. If it is not clear from the agreement which IRB should conduct the review, consult with the Senior Reliance Administrator or the Assistant Director of Reliances. | |
| **6.3. IRBs allowed without consultation.** HSD policy allows reliance on many different IRBs. The following IRBs have already been determined to meet HSD’s quality standards and authorization on them can be completed by the Reliance Administrator without consultation.   |  | | --- | | **One of these large, accredited independent IRBs**:   * Advarra * WCG IRB * BRANY * Salus IRB * Sterling IRB | | **The IRB of a Comprehensive Cancer Center** (designated by the National Cancer Institute).   * Use the [NCI website](https://www.cancer.gov/research/nci-role/cancer-centers/find) to find out whether an IRB is part of a Comprehensive Cancer Center. Note that Comprehensive Cancer Centers are a *subset* of NCI-designated Cancer Centers. * Examples   + Memorial Sloan Kettering   + Dana Farber | | **An IRB established by the federal government**. Examples:   * Centers for Disease Control (CDC) IRB * National Institutes of Health (NIH) IRB * National Cancer Institute (NCI) Central IRB * National Aeronautics and Space Administration (NASA) IRB | | **The IRB of any research university classified as R1: Doctoral University** (Highest Research Activity) in the Carnegie Classification of Institutions of Higher Education Flagship research university.  [The current list, in alphabetical order](https://en.wikipedia.org/wiki/List_of_research_universities_in_the_United_States). | |
| **6.4. IRBs requiring consultation.** HSD may agree to rely on IRBs not listed in section 6.3 above on a case-by-case basis if, in the estimation of the Sr. Reliance Administrator, the Assistant Director of Reliances or any member of the HSD leadership team, the IRB meets HSD’s quality standards.  The following factors will be considered in order to reach a decision about whether the proposed IRB is acceptable:   * The existence of and contents of any IRB restrictions imposed by the FDA, listed on the [FDA website](https://www.fda.gov/science-research/clinical-investigations-compliance-enforcement/institutional-review-boards-restrictions-imposed-letters-and-disqualification-proceedings); * The existence of and contents of any IRB related determination letters issued by OHRP, listed on the [OHRP website;](https://www.hhs.gov/ohrp/compliance-and-reporting/determination-letters/2022/index.html) * The IRB’s accreditation status; * Carnegie Classification of the IRB’s institution (if relevant); * HSD’s experience (if any) with the IRB or its institution; * The risks associated with the research; * The experience of the IRB and the institution with the specific type of research, or specific risks; * Other IRB quality indicators (e.g., meeting frequency; IRB member roster & expertise, a review of the IRB’s SOPs); * FWA status, other federally issued assurance status, and registration status of the IRB; * Whether there appears to be possible conflict of interest on the part of the IRB.   Consult with the Sr. Reliance Administrator or the Assistant Director of Reliances if the proposed IRB falls into this category. They will let you know what, if any, additional information is required in order to confirm the acceptability of the IRB. To expedite the process, you may start to obtain the information needed to address the consideration factors, e.g., by looking on the internet for the IRB’s roster, FWA status, SOPs, etc. |

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| 1. **NEGOTIATING AND DOCUMENTING THE RELIANCE AGREEMENT** |

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| **7.1. IRBs for which there is no study-specific negotiation required.** Some external IRBs already have a standing reliance agreement with UW for all or some research, meaning that a study-specific reliance agreement does not have to be negotiated with those IRBs unless they specifically request it. If the study will be reviewed by any of these IRBs for the research indicated, the rest of this section does not need to be completed unless the IRB has provided reliance-related documents. HSD’s acknowledgement letter serves as documentation that UW will rely on their review under the terms of existing agreements.   * WCG IRB (all research) * Advarra (all research) * Fred Hutch IRB (all research) * Seattle Children’s IRB (all research) * Kaiser Permanente interregional IRB (all research) * Benaroya Research Institute at Virginia Mason IRB (all research) * WA State DSHS IRB (all research) * NCI CIRB (all research) (review Section 9 for additional HIPAA waiver instruction) * NMDP IRB (for BMT CTN studies) (review Section 9 for additional HIPAA waiver instruction) * Jaeb IRB (all research) * Mass General Brigham IRB (for NEALS Consortium, ALL ALS, or NeuroNEXT studies) * Vanderbilt IRB (for PETAL Network studies) (review Section 9 for additional HIPAA waiver instruction) * University of Cincinnati IRB (for StrokeNet studies) |
| **7.2. Identify what reliance agreement structure the reviewing IRB prefers to use.** External IRBs have a wide variety of preferences as to which reliance agreement structure they prefer to use, the timing of the execution of the reliance agreement, and how they wish to receive this information. In general, the Reliance Administrator should follow the lead of the external IRB unless there is significant conflict with other HSD policies and processes. If this information has not already been provided by the researchers in Zipline or received in another way, you should reach out to the IRB to request information such as:   * Whether or not they plan to use the SMART Reliance Agreement or another type of agreement. * Whether they plan to use any online platforms, such as IREx or the SMART IRB Online Reliance System.   Identify the appropriate IRB/HRPP/Research Regulatory contact at the relying institution. Sources of this include:   * 1. The SMART IRB Point of Contact listed on the SMART IRB website.   2. Someone identified on the institution’s IRB website as having responsibility for reliances or the generic email address for the office.   3. Someone identified by the study team in Zipline (i.e., under item 2.2 in the **REQUEST** form) or other communications.   Send an email to the relying institution IRB/HRPP/Research Regulatory contact (if available) and study team requesting the reliance.  Once you have identified the reliance structure, choose one of the two sections below to guide your review of the reliance agreement.  *EXAMPLE LANGUAGE FOR THIS COMMUNICATION IS IN THE RELIANCE TEAM HANDBOOK* |
| **7.3. When the IRB wishes to use the SMART IRB Reliance Agreement.** UW is a signatory to the SMART IRB Agreement, and, in general, it is the preferred agreement when both institutions are already signatories to the agreement.  **IMPORTANT NOTE:** There are several versions of the SMART Reliance Agreement. UW is currently signed onto Version 3.0. The other institution must also be a signatory to version 3.0 in order to enact a new reliance using SMART. Make sure to verify:   * That the other institution is signed onto SMART, which may require reviewing the list of signatories on the SMART website, and * That the materials used to document the reliance adhere to the current terms of SMART 3.0 and not terms of previous versions. It is ideal, but not required, that the materials specifically reference SMART 3.0.  |  |  |  | | --- | --- | --- | | **Flexible terms in the SMART Agreement** | | | | **Flexible Term** | **UW’s preference or requirements** | **Explanatory Notes** | | Which SOPs will be used. | **Preference:** None. This should be the SOPs of the reviewing IRB and/or the SMART SOPs. This should never be the UW IRB SOPs. | None | | Use of PHI without authorization | **Preference:** UW strongly prefers that the reviewing institution assumes this responsibility.  **Acceptable:** The reviewing institution will not assume this responsibility, but only if they have a legal or policy statement to that effect. | When the reviewing institution will not assume this responsibility, the UW IRB must consider and issue the waiver itself, which poses additional work and introduces room for noncompliance.  If the reviewing institution will not consider and issue waivers that are required for the research, review section 9 for additional waiver instructions. | | Use of PHI with authorization | **Required:** Relying Institution (UW) provides its own form or language. | The Standalone UW Template HIPAA Authorization must be used. HSD cannot vet or provide any other language. | | Consideration of Financial Conflict of Interest (FCOI) | **Required:** Relying institution provides its own analysis and any FCOI plans will be considered by the reviewing IRB. | UW should always be responsible for performing its own FCOI analysis and the reviewing IRB should always consider any UW FCOI management plans in its review.  The reviewing IRB may perform additional analysis and require additional steps be taken by the researcher to mitigate the conflict, however the conditions of UW’s FCOI management plan are the floor. | | Notifications of IRB actions | **Requirement:** UW requires that the reviewing IRB notify HSD directly of any continuing or serious noncompliance or suspension of the research.  HSD does not require any other notifications directly from the reviewing IRB. | UW may have reporting responsibilities to other UW units, funding agencies, and other regulatory agencies. These reporting responsibilities often require timely reporting. This requirement is unlikely to be met if the IRB uses the study team as a pass-through for these notifications. | | Reporting to Regulatory Agencies | **Preference:**  *Either*:  Reviewing IRB may draft and send reports and provide relying institution opportunity to review and comment.  *Or:*  Reviewing IRB may draft and send reports without involvement of relying institution.  **Not Allowed:** The relying institution will draft and send the reports. | UW prefers that the reviewing organization draft and submit all reports with limited involvement of UW. UW should never be *required* to draft and submit reports. | | Auditing | **Preference:** Whatever term provides the most flexibility for accomplishing this responsibility.  As much as possible, avoid full responsibility for providing an audit to fall to HSD specifically. | HSD would like to reserve the most flexibility for accomplishing this task when applicable, so it is best to leave this section as allowing both reviewing IRB and relying institution to conduct audits. PAVE auditors \*may\* be available in some circumstances, however they may not and it would be best to allow flexibility to sort this out as the situation warrants. | | Insurance | **Not Allowed:** Several items. | Refer to the **SOP Reliance Insurance and Indemnification** for guidance and instructions | | Indemnification | **Not Allowed:** Several items. | Refer to the **SOP Reliance Insurance and Indemnification** for guidance and instructions. |  |  |  |  | | --- | --- | --- | | **Other Responsibilities not described in the SMART Agreement** | | | | There are a few responsibilities that are not described in the agreement and are commonly left out of many flexible terms, but which must still be addressed if applicable to the study. Assess the study to see if any of these situations are present. If they are applicable to the research, you should add them to the flexible terms or contact the external IRB to discuss the terms. If none apply, you can skip this table. | | | | **Flexible Term** | **UW’s preference or requirements** | **Explanatory Notes** | | Required OHRP Prisoner Certification | **When federally-funded**: Reviewing institution will assume.  **When not federally-funded:** Not required. | Because the UW has chosen not to apply the federal regulations to non-federally-funded research, it has opted \*not\* to obtain prisoner certification when the study does not have federal funding. However, when federally funded, some institutions must obtain this certification on behalf of all engaged institutions. It is HSD’s preference that that is the institution of the reviewing IRB.  If the reviewing IRB will not assume this responsibility, alert the Sr. Reliance Administrator or Assistant Director of Reliances. | | CoC or DoJ Certificate | **Default**: Reviewing institution will assume. | * Requiring UW to take on this responsibility would mean that HSD has to perform additional reviews of the consent forms. | | NIH Genomic Data Sharing Responsibilities | **Preference:** Can be negotiated. Review explanatory notes. | See Section 10 for special instructions. | |
| **7.4. When the IRB wishes to use another agreement.** IRBs may opt to use another reliance template to document the terms of the agreement. In these cases, consult with the Sr. Reliance Administrator or the Assistant Director of Reliances for guidance. |

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| 1. **ASSESSING AND COMMUNICATING LOCAL CONTEXT INFORMATION** |

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| **8.1. IRBs for whom study-specific local context information is not required.** Some external IRBs keep UW’s local context information on file for reference across studies, meaning that study-specific local context information does not have to be communicated to those IRBs unless specifically requested. If the study will be reviewed by any of these IRBs, the rest of this section does not need to be completed.   * WCG IRB * Advarra * NCI CIRB (see Section 9 for HIPAA waiver instructions) * NMDP IRB (see Section 9 for HIPAA waiver instructions) * Jaeb IRB * Fred Hutch IRB * Kaiser Permanente interregional IRB * Benaroya Research Institute at Virginia Mason |
| **8.2. IRBs that require limited local context information.**  These IRBs require limited study-specific local context information when it is applicable. This information is communicated via the Acknowledgement letter when completing the “Confirm Reliance” activity. You do not need to provide a copy of the **INFORMATION SHEET UW General Local Context Profile** or **GUIDANCE Consent Elements for Externally Reviewed Studies.**  **Limited Local Context Information.**   * Seattle Children’s 🡪 Seattle Children’s keeps the **INFORMATION SHEET UW General Local Context Profile** on file, however it has requested assistance with some items. These are addressed by completing the Acknowledgement letter which already contains these items. * WA State IRB at DSHS 🡪 assess the study against the **INFORMATION SHEET UW General Local Context Profile** . If there are any local context requirements, include them in the body of the Acknowledgement letter. It is unlikely that there will be any since most reliances on WSIRB review will involve only analysis of data or will take place within WA State Facilities. |
| **8.3. All other IRBs.** All study-specific local context information should be communicated to these IRBs. HSD’s preference is that this information is provided at the same time that the reliance agreement is executed. However, due to the policies and processes of other IRBs, it may need to happen before or after the execution of the reliance agreement. Regardless, the administrator should not complete the “Confirm Reliance” activity in Zipline until this step has been completed.  **Step 1:** Identify if there is local context information applicable to UW’s involvement in the study by comparing the content of the Zipline Application against the **INFORMATION SHEET UW General Local Context Profile**. If it is unclear whether any of the local context applies, obtain additional information from the study team.  **Step 2**: Identify how the external IRB wishes to collect local context information. IRBs use a variety of methods such as online system like IREx, emailed word documents called local context surveys, or granting HSD access to their application system. You may need to email them directly to obtain this information. Existing team logins for some systems like IREx and the SMART IRB Exchange are in the Reliance Team Handbook. If you need to create a new login in a system in order to communicate the information, make sure to add or update the information in the handbook.  **Step 3:** Communicate the information.   * **If there is** applicable UW local context information, using the study information provided in Zipline, work with the UW researcher to complete any local context forms, surveys, questionnaires, etc. required by the reviewing IRB according to its instructions. Review the **SOP External Reliance Agreements** for a description of HSD’s local context responsibilities and the UW researcher’s local context responsibilities. This will likely be a collaborative effort and can take place via email. It may be most efficient for you to first complete the information that you can, and to indicate to the researchers using comments or highlighting the areas they need to complete.   If appropriate to the way the local context is being collected, include the **INFORMATION SHEET UW General Local Context Profile**. Use it (and the **GUIDANCE Consent Elements for Externally Reviewed Studies**) as a reference document for any of the local context materials.  If the reviewing IRB does not have a preferred method for obtaining local context information, provide the **INFORMATION SHEET UW General Local Context Profile** and the **GUIDANCE Consent Elements for Externally Reviewed Studies** via email to the reviewing IRB.   * **If there isn’t** applicable UW local context information and the external IRB does not have a plan to collect local context information, communicate the lack of local context to the IRB and send them the **INFORMATION SHEET UW General Local Context Profile** as an informational reference document. |
| **+ Guidance**  A guide for assessing applicable local context can be found as an addendum in the Reliance Team Handbook. |
| **8.4. Special Local Context.** If the researchers indicate that any of the following will occur in the research, consult with the Sr. Reliance Administrator or the Assistant Director of Reliances:   * Audio or video recording in WA State without notification or consent of subjects * Administration or study of marijuana or derivatives meeting the Office of Research’s definition. |
| **8.4. Documenting the Local Context Information in Zipline.** Add a final copy of whatever local context information was provided to the external IRB (e.g., a copy of the questionnaire, a printout of the survey, a screenshot of the information in the system, a copy of the completed **INFORMATION SHEET UW General Local Context Profile**) along with any correspondence with the external IRB to the study in Zipline following the “Upload Shared Regulatory Documents” section in the **INSTRUCTIONS Zipline for Staff**. This can be done at any time. |

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| 1. **SPECIAL LOCAL CONTEXT: HIPAA WAIVERS** |

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| * 1. **Identify the need.** Some external IRBs will not grant HIPAA waivers, either in full or in part, for research for which UW is relying on that IRB. This is typically due to the logistical or legal limitations of the external IRB. Because all HSD staff are also IRB members, the assigned Reliance Administrator can complete the HIPAA Waiver. The following IRBs do not consider or issue HIPAA waivers on behalf of relying institutions: * Vanderbilt University Medical Center (VUMC) IRB 🡪 will issue full waivers, but not partial; e.g., for screening * University of California San Francisco (UCSF) IRB * National Marrow Donor Program (NMDP) IRB * National Cancer Institute (NCI) CIRB   There may be other IRBs that do not consider and grant HIPAA waivers. When enacting study-specific reliance agreements, pay attention to the terms of agreements and whether or not the IRB/institution will consider and grant HIPAA waivers. For any studies for which the external IRB will not consider and grant HIPAA waivers, you should consider and grant the waiver.  You should identify what portion of the research the waiver will apply to. For example, consider whether the waiver will apply only to recruitment or to the entire study. |
| * 1. **Collect Additional Information**. If the external IRB will not consider and grant waivers, you must collect additional information about the proposed use of PHI. Request that the study team complete and return a **SUPPLEMENT External Reliance, HIPAA Waiver Request**. The document should be uploaded to the Local Site Documents section of the Zipline SmartForms. |
| * 1. **Review the waiver.** Using the **SOP HIPAA, the GUIDANCE HIPAA**, and the information provided in the **SUPPLEMENT** along with other information about the study in Zipline assess whether the use of PHI meets the criteria for a waiver. If additional information is needed in order to make the determination, request that information from the study team.   Pay special attention to the following activities and request additional information from the study team if the External IRB application and supplemental documentation does not provide sufficient information:   * Data sharing and security * Storage and secondary use of the data   If you believe that the waiver criteria are not met, consult with the Sr. Reliance Administrator or the Assistant Director of Reliances. |
| * 1. **Complete Documentation of the Waiver.**  1. Complete the **CHECKLIST Waiver of HIPAA Authorization** and upload to the Supporting Documents section on the External Staff Data Entry activity. 2. Document the waiver under the “UW IRB and/or HSD actions” question on the External Staff Data Entry activity. 3. Waivers should be conveyed to the study team and the external IRB on the External IRB authorization letter. Use the template language on the letter.   If the waiver cannot be granted, work with the Sr. Reliance Administrator or the Assistant Director of Reliance on how to document this. |

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| 1. **SPECIAL LOCAL CONTEXT: GDS CERTIFICATION** |

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| **10.1. Identify the need for Genomic Data Sharing (GDS) Certification.** GDS Certification is required for submission of genomic data to NIH databanks. This is likely if researchers indicate that they plan to do this in the **REQUEST External IRB Review** form or elsewhere in the Zipline application. Refer to the **SOP Genomic Data Sharing Certification** for more information.  If there is no indication that they plan to submit data, you can skip this section. Otherwise, proceed with the next steps of this section. |
| **10.2. Confirm the plan for GDS Certification**. If the IRB is any of the following, consult with the Sr. Reliance Administrator or the Assistant Director for Reliances. The genomic data sharing certification plan may have been worked out as part of negotiating standing cooperative agreements:   * Fred Hutch * Seattle Children’s * KPiIRB (for KPWA studies) * Benaroya/Viginia Mason   For all other IRBs, reach out to the study team and/or the external IRB to determine whether or not other institutions will perform any or all aspects of GDS certification. Based on past experience it is possible that we are the first institution to request clarity about this. Your correspondence should emphasize both the IRB responsibilities in the certification requirements as well as the institutional attestation requirements. |

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| **+ Guidance**  A plan for how to accomplish institutional certification for Genomic Data Sharing (GDS) in NIH databanks is often left out of Reliance Agreements and addenda. Certification is a two-part process: the IRB must review and be able to attest to certain activities, then the Institution (typically the primary awardee or the institution that is submitting the data to NIH) must certify that several items have been met. Sometimes this can be accomplished in one step such as under HSD’s policy, however in multi-site research, especially when the IRB review is not done by the submitting institution, this process can be complex.  There are no nationwide best practices for coordinating responsibilities for GDS certification for single IRB situations. This is challenging because certification requires an assessment of consent information against institutionally required standards. In a single IRB situation, the institution that must certify often does not have control over the consent form. To address this, HSD tries to identify as part of the reliance process which institution will perform the certification of consent materials, and, if it is UW, to provide the researchers with information about HSD’s certification requirements as part of authorizing the study for review by the external IRB. |

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| **10.3. Document the plan.** Ensure that the submission clearly documents which institution will perform the GDS certification (documentation can be any combination of SSRP, Request Clarification, uploaded correspondence, and/or comment to the study).  If the external IRB or another institution will perform all parts of the GDS certification then there is nothing further the administrator needs to do.  If UW will or may perform a role in the certification, ensure that this information is in the authorization letter to researchers and documented in External Staff Data entry. |

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| 1. **SPECIAL SITUATIONS: TRANSFERS** |

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| **11.1. Identify that it is a transfer and that the transfer is acceptable.** A transfer means that another IRB other than the proposed external IRB has previously reviewed the research. This could be the UW IRB or another external IRB. This will typically be evident from the application itself or from prior communication you have had with the study team. You do not need to screen for this unless there is evidence in the Zipline application that leads you to believe this may be a transfer.  Transfers are acceptable when the study will be reviewed by the external IRB under any of the circumstances in Section 5 above. Common scenarios include:   * transitioning study to sIRB structure under a new IRB. * UW PI is leaving UW but UW continues to be engaged and the other IRB will assume oversight.   1. If the transfer is between two non-UW IRBs, you may proceed with establishing any reliance agreements and providing local context requested by the new IRB. You do **not** need to obtain approval from the Assistant Director of Reliances or complete any of the other steps in this section of the worksheet.   2. If the transfer is from the UW IRB to a non-UW IRB, , consult with the Assistant Director of Reliances. The Assistant Director of Reliances or another member of the leadership team must approve the transfer. |
| **11.2. Assess whether or not a reliance is required.** In most transfer situations, a reliance agreement is required. This is typically because:   * UW will continue to be engaged in the research. In this case an external reliance is warranted, there must be an external request to document the reliance. * UW will not continue to be engaged in the research, but it may take some time for the receiving IRB to review and approve the activities and assume oversight. A temporary reliance on UW’s existing review of the study may be put in place. This reliance should be added to the existing IRB application rather than the external reliance request. In these cases, work with the Sr. Reliance Administrator or the Assistant Director of Reliances.   Transfers of studies previously reviewed by the UW IRB in which a reliance is required because the UW will remain engaged require a separate External Reliance Application in Zipline. Do not convert the existing Zipline application to an external reliance request.  Transfers of studies between two non-UW IRBs should be handled within the existing Zipline external reliance submission via a modification and/or study update.  In situations in which there is no reliance required, the following steps must be followed, but no external reliance submission is required in Zipline. All documentation related to the transfer is added to the UW IRB’s review application in Zipline. |
| **11.3. Communicate the transfer to other HSD Teams.** Other teams may need to take certain actions or put a hold on submissions that might be in process before the transfer is complete:  **When the study was reviewed by the UW IRB:**  Email the TOL of the team that is assigned to the application to let them know about the pending transfer. The email should also include the instruction to assign the final closure request for the study to you. If there are any pending submissions, such as modifications or RNI, for the study, you may need to consult with them and the study team to determine if the submission should be completed before the transfer is accomplished, or if the submission should be withdrawn and addressed by the receiving IRB after the transfer is complete. If you are unsure of what to do, consult with the Sr. Reliance Administrator or the Assistant Director of Reliances.  **When the study is an applicable clinical trial and the UW PI is the responsible party:**  Email the regulatory affairs team at [hsdreprt@uw.edu](mailto:hsdreprt@uw.edu) to let them know about the pending transfer. They will likely need to reassess whether or not the UW PI should remain the responsible party or if the ct.gov registration should be handled by another institution. The IRB transfer process can continue separately from the regulatory affairs team process.  *REFER TO THE RELIANCE TEAM HANDBOOK FOR TEMPLATE EMAIL LANGUAGE FOR THIS STEP* |
| **11.4. Reach an agreement with the other institution about transfer terms.** Work with the other institution to develop an agreement about the terms and timing of the transfer. The appropriate person is typically also the person who would sign reliance agreements but may be another contact such as a client representative from a commercial IRB.  The agreement must include:   1. The timing of the transfer of IRB oversight. This typically occurs at the time that the receiving IRB approves the research. However, in the case of multi-institutional research, care must be taken that any institutions relying on UW IRB review are also approved by the receiving IRB at the time of oversight transfer to avoid lapses in approval. 2. The retention of the transferring IRB’s review records. These may either be retained by the transferring IRB or delivered to the receiving IRB.   **IMPORTANT NOTE:**  When UW is the transferring IRB, UW can retain the records of its review within the terms of its applicable records retention policies. If the receiving institution anticipates wanting to access the record of UW IRB’s review for longer than that, the receiving institution should be provided with copies of the records that they anticipate wanting to access.  Use the **TEMPLATE Transfer Plan UW and non-UW IRB,** or the receiving institution’s form or another type of written agreement to document the plan.  *REFER TO THE RELIANCE TEAM HANDBOOK FOR TEMPLATE EMAIL LANGUAGE FOR THIS STEP* |
| **11.5. Set up records for delivery and/or retention.** If the receiving institution has requested copies of any materials, identify the materials to be delivered and prepare and send them according to the receiving institution’s instructions. This may require scanning paper-based materials. |
| **11.6. Confirm with PI next steps.** Instruct the PI to:   * Notify relevant parties, including the funder and any relying institutions if they will be the party responsible for this as identified in the transfer plan, and * Submit a final status report requesting closure of the existing internal review Zipline application.   Once the final status report has been received, the Zipline application can be closed according to the “Study Closure” section of the **INSTRUCTIONS Zipline for Staff**. Add a comment that the study has been transferred along with the Zipline Number for the External Application for the study. |

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| 1. **SPECIAL SITUATIONS: EXPANDED ACCESS OR HUD** |

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| **12.1. Identify that the activity is expanded access or clinical use of a humanitarian use device.** The protocol or information in the Zipline application will likely indicate that the activity is expanded access or clinical use of an HUD. Refer to HSD’s webpages [Humanitarian Use Guidance](https://www.washington.edu/research/hsd/guidance/hud/) or [Expanded Access Guidance](https://www.washington.edu/research/hsd/guidance/expanded-access/) for more information about these topics. If the activity meets one of these definitions **and** includes a research aspect, treat it as a regular research protocol and follow all of the other instructions in this document. If the activity is only expanded access or clinical use of an HUD, go to the next section. |
| **12.2. Special processing instructions.** Because this is not a research activity:   * There is no local context that needs to be sent to the external IRB; * Some of the regular research consent elements may not apply; * Investigators/treating physicians should not use the HSD HIPAA Authorization form but should instead use regular clinical HIPAA Authorizations.   Use the **TEMPLATE External IRB Acknowledgement Letter, Expanded Access or HUD** instead of the standard authorization letter.  In some circumstances, the external IRB may have established unique reliance processes for these activities. In these cases, consult with the Sr. Reliance Administrator or the Assistant Director of Reliances. |

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| 1. **COMPLETING DOCUMENTATION IN ZIPLINE AND OTHER SYSTEMS** |

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| **13.1. Complete documentation in other systems.** If not already done as part of completing the tasks in the previous sections, complete documentation in the systems required by the external IRB. This may be IREx, the SMART IRB Online Reliance System, or another system used by the external IRB. As part of this, you may need to take screenshots or download information in order to complete the tasks below. |
| **13.2. Upload all documents to the correct location in Zipline.** This includes but is not limited to:   * Any newly completed reliance agreements and addenda such as a letter of indemnification, SMART letter of acknowledgement, or study-specific reliance plans required by the external IRB. * Any local context information specific to the study provided to the external IRB (note: this may be online and screenshots will need to be taken about what was answered). * The version of the **INFORMATION SHEET UW General Local Context Profile** sent to the reviewing IRB. * A completed **CHECKLIST ClincalTrials.gov** if applicable (see item 13.5. below).   **NOTE:** HIPAA Waiver Checklists completed as part of Section 9 above should be uploaded to the External Staff Data Entry rather than Shared Regulatory Documents. |
| **13.3. Prepare the Authorization Letter and Complete the “Confirm Reliance” Activity.** Aside from completing data entry, this should be the concluding activity of executing the authorization to rely on the external IRB.This step should only be completed when you believe that you have completed all of the tasks related to the reliance and local context analysis, provided them to the reviewing IRB and received any executed documents (aside from IRB approval) back from the external IRB.  Follow the INSTRUCTIONS Zipline for Staff to use the “Prepare Letter” function to generate the study-specific letter. Follow the instructions in the letter to complete each section and upload the final version to the Prepare Letter function. Once the letter is prepared, use the “Send Letter” function to send the letter.. Be sure to open the .pdf in the “Send Letter” function to ensure that the correct version has been uploaded prior to sending.  Then, complete the “Confirm Reliance” activity as described in the corresponding section of the **INSTRUCTIONS Zipline for Staff**. |
| **13.4. Complete External IRB Staff Data Entry.** Follow the “External Staff Data Entry” section of the **INSTRUCTIONS Zipline for Staff** and use the following tips to complete the data entry:  **Section 1:** Checkboxes should be checked based on the overall study, not necessarily what’s being done at UW. ICH, GCP and GDPR should never be checked. Refer to the **WORKSHEET Pre-Review Initial Application** for guidance on which regulations apply.  **Section 2:** The 70.02 checkbox should be checked if Study Scope page question 5 was marked “Yes.”  **Section 5, 6, and 7:** This is based on information in the **REQUEST External IRB Review** form.  **For section 12**, if a HIPAA waiver for the study was granted by UW as part of Section 9 above, check the checkboxes for “HIPAA waiver(s) have been granted” and “WA state law(s) compliance confirmed.”  **For section 13**, mark this as “No” unless it’s clear what international sites are being used. |
| **13.5.** **Complete the ClinicalTrials.gov Staff Data Entry**. Using the **CHECKLIST ClinicalTrials.gov** as a guide, assess whether the activity is an applicable clinical trial and if UW is the Responsible Party, then complete the clinicaltrials.gov data entry.  1) If the activity is not an applicable clinical trial and/or UW is not the Responsible Party:   * Complete the data entry following the “CT.gov Data Entry” section of the **INSTRUCTIONS Zipline for Staff**. * You do not need to upload the completed **CHECKLIST ClinicalTrials.gov**.   2) **For studies not reviewed by Fred Hutch:** When the activity is an applicable clinical trial and UW is the Responsible Party:   * Complete the data entry following the “CT.gov Data Entry” section of the **INSTRUCTIONS Zipline for Staff**. * Contact the Regulatory Affairs Team at [hsdreprt@uw.edu](mailto:hsdreprt@uw.edu) to alert them to the study. * Upload a completed **CHECKLIST ClinicalTrials.gov** under Shared Regulatory Documents.   3) **For studies reviewed by Fred Hutch:** When the activity is or may be an applicable clinical trial whose CT.gov obligations are managed by FH Clinical Research Support:   * Questions 1, 2, 3, and 4 of the CT.gov data entry form as applicable, should be completed at the time the CT assessment is initially completed. * The Regulatory Affairs team will go back later and populate the remaining data entry fields once the information has been entered in CT.gov. |
| **+ Guidance**  While clinicaltrials.gov assessment for internally reviewed studies is handled entirely by the Regulatory Affairs Team, clinicaltrials.gov assessment for externally reviewed studies is handled primarily by the Reliance Team. For the vast majority of externally reviewed studies, UW is not the Responsible Party.  Additional guidance on conducting the clinicaltrials.gov assessment is available in the Reliance Team Handbook. If you are ever unsure of your assessment or if the assessment is complex, consult with the Regulatory Affairs team at [hsdrprt@uw.edu](mailto:hsdrprt@uw.edu) for guidance. |
| **13.6. Complete the External Consent Audit Data Entry.** HSD performs a 100% audit of consent materials for the following studies after they have been approved by the external IRB.:   1. All studies reviewed by WCG IRB or Advarra that have consent forms (excluding expanded access protocols). 2. All industry-sponsored and initiated clinical trials with a contract negotiated through OSP reviewed by any external IRB except Jaeb IRB and Fred Hutch IRB.   To facilitate this process, enter the following in the External Consent Audit function for the study in Zipline:   * For all studies that meet the criteria above: no data entry required. * For all other studies: Mark “No Audit Required” for Question 1 “Consent Audit Complete.” |
| **13.7.** **Complete Industry Clinical Trials Billing Data Entry**. HSD charges a fee for work done to authorize and oversee certain industry-initiated studies. See the **SOP HSD Review Fees** for full details. HSD must communicate to the Office of Research the billing information for studies to be charged the fee. If a study has met the criteria in section 3.7, transfer the study and billing information to the appropriate industry billing spreadsheet in the Reliance Team Handbook Folder. |
| **13.8 Add Note to File for Exception to Short Form policy** **for studies conducted under an Emergency Exception to the Informed Consent requirement (EFIC) studies submitted before January 1, 2026**. **Complete this step for EFIC studies only.** After issuing the Authorization Letter and Completing the Confirm Reliance activity, paste Note to File into comment and check box to issue e-mail notification to PI/PI Proxy/Primary Contact.  **HSD Note to File:** The purpose of this note is to document that HSD has issued an exception to this study from the requirements of the revised UW policy for use of the short form consent method that went into effect on January 1, 2025.  HSD recognizes that this policy presents unique challenges for research conducted under an emergency exception to the informed consent requirement (EFIC) because it is generally not possible to know the language preference of the participant or the participant’s legally authorized representative at the time or enrollment, the study could not have anticipated the costs associated with the new translation requirement and does not have the option to exclude participants with a non-English language preference. Therefore, EFIC studies submitted to the IRB before January 1, 2026, may continue to operate under the previous policy until their completion.  That means that this study is not required by UW to provide participants with a translated consent form after obtaining consent using the short form method. **However,** the reviewing IRB may apply more conservative requirements for use of the short form consent method.  Clinical trials submitted after January 1, 2026, will be expected to have appropriately planned and budgeted to comply the [current short form policy](https://www.washington.edu/research/hsd/guidance/consent/#8b1) and the [requirements for diversity in clinical trials](https://www.washington.edu/research/hsd/guidance/dct/). |

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| 1. **RELATED MATERIALS** |

APPLICATION Determination, Delayed Onset Human Research

APPLICATION Notification of Emergency Use, Drug or Biologic

CHECKLIST ClinicalTrials.gov

CHECKLIST External IRB for UW Researchers

CHECKLIST Waiver of HIPAA Authorization

GUIDANCE Case Reports, IRB Review, and HIPAA

GUIDANCE Consent Elements for Externally Reviewed Research

GUIDANCE Data Sets Not Requiring HSD or IRB Review

GUIDANCE Exempt Research

GUIDANCE HIPAA

GUIDANCE Is it Research?

GUIDANCE Just in Time

INFORMATION SHEET UW General Local Context Profile

[INSTRUCTIONS Zipline for Staff](https://www.washington.edu/research/forms-and-templates/instructions-zipline-for-staff/)

REQUEST External IRB Review

SOP External Reliance Agreements

SOP Genomic Data Sharing Certification

SOP HIPAA

SOP HSD Review Fees

SOP Reviewer Conflict of Interest

SOP Reliance Insurance and Indemnification

SOP Study Team

SUPPLEMENT External Reliance, HIPAA Waiver Request

TEMPLATE External IRB Acknowledgement Letter

TEMPLATE External IRB Acknowledgement Letter Expanded Access or HUD

TEMPLATE Transfer Plan UW and non-UW IRB

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

WORKSHEET Engagement

WORKSHEET Exempt Determination

WORKSHEET External Reliance, Follow-on Submissions

WORKSHEET Human Subjects Research Determination

WORKSHEET PAVE Consent Audit

WORKSHEET Pre-Review, Initial Applications

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| **Version Number** | **Posted Date** | **Implementation Date** | **Summary of Changes** |
| 2.0 | 08.29.2025 | 08.29.2025 | Minor updates for SMART 3.0 Implementation and edits to PAVE consent audit. |
| 1.9 | 05.01.2025 | 05.01.2025 | Remove reference to UW Medicine Compliance vetting embedded HIPAA language. |
| 1.8 | 03.27.2025 | 03.27.2025 | Clarify that HSD does not rely on non-UW IRBs for single patient expanded access. |
| 1.7 | 01.30.2025 | 01.30.2025 | Insert Note To File language for EFIC short form exception |
| 1.6 | 11.26.2024 | 11.26.2024 | Update reference from SOP Engagement to GUIDANCE Engagement |
| Previous versions |  |  | For older versions: HSD staff refer to the SharePoint Document Library; Others – contact [hsdinfo@uw.edu](mailto:hsdinfo@uw.edu). |

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