|  |  |
| --- | --- |
| University of Washington Human Subjects DIvision | **WORKSHEET Pre-Review, Initial Application** |

**CONTENTS**

[Purpose](#Purpose)

[Procedures](#Procedures)

[Section 1: Triage and Basics](#Basics)

[Section 2: The Regulatory Ladder](#Ladder)

[Section 3: For Items Requiring IRB Review](#Review)

[Related Materials](#related)

**PURPOSE**

This worksheet provides support for HSD staff conducting pre-review of initial applications that have not requested External IRB review (including deferral responses and conditional approval responses) by identifying the issues that should be covered as part of the pre-review.

This worksheet is not intended to be the only resource HSD staff need while reviewing initial applications. Rather, the worksheet: 1) prompts staff to consider the possible regulatory or policy issues that may apply to any particular study; 2) points staff to the resources they might need to reference when reviewing for that regulation or policy; and 3) provides some targeted instruction for how staff should approach review of some complex and/or less common issues.

**PROCEDURES**

Read the entire application and then evaluate it using this worksheet. Issues should usually be evaluated in the order listed, but experienced pre-reviewers may be able to quickly identify key issues “out of order” when reading the application which may eliminate the need for some pre-review 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.

**SECTION 1: Triage and Basics [**[**top**](#Top)**]**

This section addresses these issues:

1. Is there anything about the application that requires it to be assigned a higher-than-usual priority?
2. Should this pre-review be conducted by the assigned pre-reviewer?
3. Is the application ready for “walking up the regulatory ladder”?

|  |
| --- |
| **1.1 Urgency of review**. If the researcher has described time constraints that need to be considered, prioritize as appropriate.  |
| **+ Guidance**Researchers may indicate in the IRB Protocol that they have “Just In Time (JIT)” status and need a quick approval. 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 approval*. Refer researchers to the [GUIDANCE Just In Time](https://www.washington.edu/research/hsd/guidance/just-in-time-and-irb-review/) page for more detailed information. If the researcher insists there is a tight deadline for IRB approval, request written confirmation from the sponsor. If you receive confirmation that the sponsor does require IRB approval by a certain date, contact a TOL, Senior Review Administrator or ADO for guidance on conducting an expedient approval.  |
| **1.2 Conflict of interest.** Verify that the pre-reviewer has no conflict of interest with respect to the item. If there is a conflict of interest, consult with the TOL or SRA and re-assign the item to another member of the team. (**SOP Reviewer Conflict of Interest**)  |
| **1.3 Triage for inappropriate researchers** (*applies only to non-student researchers*). Based on the information already provided in the application, is there anything that strongly suggests that this researcher is not eligible to use the UW IRB? If yes, consult with a TOL, SRA or member of HSD Leadership.  |
| **+ Guidance**The purpose of this question is to identify applications where it is **obvious** that the researcher is not 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 is covered in Section 2.*Example:* A physician with no UW affiliation of any kind wants to do a clinical trial and have it reviewed by the UW IRB. Example: A nonprofit organization with no connection to the UW wants to do a study and have it reviewed by the UW IRB  |
| **1.4 Red Flag PI.** If the lead researcher is on the [Red Flag List](file:///F%3A/Red%20Flag%20List), consult with the Regulatory Affairs Manager (RAM).  |
| **1.5 Triage for assignment to HSD Reliance Team for External Review**. If this is an application that must be reviewed by the Fred Hutch IRB or by an independent commercial IRB, reassign the application to the “Reliance” team in Zipline and send an email to hsdrely@uw.edu alerting the Reliance Team to the study. If you are not certain: Send an email to hsdrely@uw.edu so that the Reliance Team can assess the submission and determine which IRB should do the review. The email should include a brief statement identifying the information in the application that leads you to believe the UW IRB may not be the appropriate IRB and should also include: Zipline study number; study title; and PI name.  |
| **+ Guidance****Applications that must be reviewed by the Fred Hutch IRB:**1. The PI has a Fred Hutch primary appointment as listed in the [Cancer Consortium member directory](https://www.cancerconsortium.org/membership/member-search.html) (the research can be any discipline, but would most likely be cancer-related or infectious disease)
2. The PI has a UW primary appointment as listed in the [Cancer Consortium directory](https://www.cancerconsortium.org/membership/member-search.html), and
	* The research is cancer-related as defined on [HSD’s webpage](https://www.washington.edu/research/hsd/is-the-uw-irb-the-right-irb/identify-the-correct-irb/oncology-related-research/#which), and
	* The research requires review by the convened board either because it is greater than minimal risk or because the IRB must determine the risk level. This also includes research for which the UW IRB does not have the appropriate member expertise to determine the risk.

 **Applications that must be reviewed by an independent commercial IRB** such as WCG IRB, or Advarra meet **all** of the following criteria:1. The study is funded **solely** by industry (e.g., a drug or device company).

*Where to find this information***:** * Look at the funding organization on the SmartForm.
* There may also be information in any documents uploaded with the funding Smartform and (if there is one) a formal Study Protocol document.
1. The study is industry-initiated. This means that the idea for the study came from the industry sponsor.

*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 suggests that the PI is conducting the study on behalf of a company.
 |
| **1.6 Triage for assignment to Team S.** Some applications should be assigned to Team S either for an initial assessment or for Team S to conduct the review These are:1. If the application involves **any non-UW institutions or individuals**, Team S should assess most studies and may conduct the review. Reassign the application to Team S and make a private comment in Zipline noting where you noticed information about other institutions or individuals.

Indications that the study may involve non-UW institutions or individuals can be found in any part of the application (e.g., IRB Protocol, Study Protocol, grant application, SmartForms).TOLs and Sr. Administrators (SrA) will screen for this when assigning work, but all reviewers should keep this assessment in mind, particularly while doing the first high level, big picture read through the application.Review the **INSTRUCTIONS Team S Routing** for additional details about what studies should be routed to Team S and check in with your TOL or SrA with questions. b) If the application is a **transfer of IRB oversight** for an ongoing study from a non-UW IRB to the UW IRB. Transfers of IRB oversight have special considerations and often require reliance agreements which will be assessed by Team S. Team S may keep the study or return it to you and provide instructions for how to review the research after it has completed the assessment. You do not need to screen applications to identify whether or not they are transfers. Referral to Team S is only required if the application explicitly states that the study was previously reviewed by another IRB or you have strong reason to believe that it has been. |
| **1.7 Washington State IRB.** The involvement of certain Washington State agencies requires approval from the WSIRB and may also require UW IRB approval for some or all procedures. When reviewers identify the involvement of these agencies, they should direct the PI to contact WSIRB about their requirements. The UW review is not contingent upon the outcome of the WSIRB review so the reviewer may proceed with the UW review and approval. Review the HSD webpage on [Research Involving Washington State Agencies](https://www.washington.edu/research/hsd/is-the-uw-irb-the-right-irb/identify-the-correct-irb/research-involving-washington-state-agencies/).Some studies may require the execution of a “split agreement”, which is a unique agreement specific to WSIRB. WSIRB will tell the research team whether a split agreement is required. UW does not have to identify the need for a split agreement. WSIRB will prepare the agreement and send to the investigators to complete. If the application contains a partially executed split agreement, send to the Reliance Team. If there is no split agreement, proceed with the review. It can be executed if needed after review is complete. |
| **1.8 Appropriate UW IRB and HSD team**. Verify that the item has been assigned to the appropriate UW IRB and HSD team. If the item has been inappropriately assigned or it there is some other reason why it should be assigned to a different HSD team, consult with a TOL, SRA or member of HSD Leadership. (**F:\Department Distribution**) *Note that for collaborative research studies, an individual identified as the Site PI for a relying site can be selected as a Study PI on the Basic Information page.* ***Only UW agents should be selected as the Study PI.*** |
| **1.9 Faculty Advisor and IRB 101 Tutorial.** If the researcher is a student or resident, the faculty advisor’s approval must be obtained and the certificate documenting that the student/resident has completed the IRB 101 tutorial must be uploaded before exempt status or IRB approval (unconditional) can be granted. The following determinations may be made without the advisor’s approval or IRB 101 certificate: 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.  |
| **1.10 UW Office of the Youth Protection Coordinator.** If the project involves interaction (in-person or remotely) with individuals under the age of 18, the researchers must comply with [UW Administrative Policy Statement 10.13](https://www.washington.edu/youth/policy/protecting-youth-at-uw-aps-10-13/). Researchers are alerted to this policy in the SmartForms and Section 6 of the IRB Protocol but **there are no actions for the pre-reviewer** to take.  |
| **1.11 UW Medicine Security Review**The project must undergo review if it involves use of UW Medicine patient health information (identifiable or de-identified) for machine learning outside UW IT Systems. IRB approval cannot be granted until the researcher uploads documentation that the security review has been completed. |
| **1.12 Applicable regulations.** Identify the applicable laws and regulations that the UW is required to apply to this study (e.g., because it is a condition of the funding agency or sponsor, and/or because of applicable laws). Review HSD content for those agencies (e.g., guidance, SOPs, worksheets), this pre-review worksheet, and the **GUIDANCE Human Subjects Regulations**.The Department of Defense (DoD) applies the FDA regulations more broadly than does the UW. Review the [DoD guidance about FDA regulated research](https://www.washington.edu/research/hsd/guidance/specific-agencies/dod/#5). If the DoD research involves a drug, device or biologic, consult with a TOL or member of HSD Leadership. A “Yes” response to Study Scope #3 is usually an indication that a study is FDA regulated. Consult with your TOL if the study appears to be FDA regulated but the researcher doesn’t want to revise the response to this question, or the appropriate response seems inconsistent with the determination about the applicability of FDA regulations. Any discrepancy (such as a letter from the FDA applying FDA regulations when they are not planning to submit data to the FDA) should be explained in a Note in the Submit Pre-Review activity.* If the research will occur outside of Washington State, check for applicable local context issues in the research location. Review the “Non-UW Research Setting” section of **IRB Protocol** for anything of note and check with a TOL, SRA or member of HSD Leadership if you’re unsure how to incorporate local context into your review.

PCORI, while not a signatory to the Common Rule, must be reviewed according to the Common Rule.  |
| **1.13** **Version of IRB Protocol form**. Verify that the version used by the researcher provides adequate information for the review of this specific study. The pre-reviewer must use their judgement to identify the most efficient and appropriate approach when the submitted IRB Protocol version is out of date. HSD staff use their discretion to ensure the application contains all the necessary information to document that the applicable regulatory and policy requirements were assessed and satisfied.  |
| **+ Guidance**Methods for incorporating missing information include but are not limited to: asking the researcher to paste the missing question/information into the IRB Protocol they’ve provided; asking the researcher to upload a separate document containing the missing question/information; get the information during screening and have the researcher incorporate the missing information into another question in the IRB Protocol; if the missing information is extensive, require the researcher to resubmit on the current version of the IRB Protocol.Brief summary of significant changes (full change notes can be found in the ‘Previous Version’ Archive Document Library).

|  |  |  |  |
| --- | --- | --- | --- |
| **IRB Protocol Section** | **Question** | **Change Notes** | **Version It Changed** |
| Risk/Benefit Assessment | Use of gadolinium | Updated information for subjects and additional risk language  | IRB P, v5.5 |
| Privacy and Confidentiality | Data Security Protections | Major revisions to question, especially to risk levels | IRB P, v5.5IRB P-NC, v4.0 |
| Participants | Number of Subjects | Updated to ask about subject enrollment instead of completion | IRB P, v 5.5IRB P-NC, v4.0 |
| Consent of Adults | Use of Short Form Consent | New question | IRB P, v5.2 |
| Procedures | Machine learning. | New question | IRB P, v4.6IRB P-NC, v3.4 |
| Risk/Benefit Assessment | Anticipated Risks | Revised to add reference to reasonably foreseeable risks guidance | IRB P, v4.3 |
| Procedures | Study procedures. | Revised to add link to reasonably foreseeable risks guidance | IRB P, v4.3 |
| Overview | Subject Matter Expertise | New question | IRB P, v4.1 |
| Procedures | Cannabis, hemp, related compounds. | New question | IRB P, v 3.7 |
| Non-UW Settings | If the PI is a student: Does the research involve travelling outside the U.S. | New question | IRB P, v3.5IRB P-NC, v2.3 |
| Procedures | MRI scans. | Revised to move gadolinium info from MRI procedures to MRI risks section | IRB P, v3.0 |
| Consent of Adults | Electronic presentation of consent information. | Revised to add sub-question – “communication of significant findings” | IRB P, v3.0 |
| Risk/Benefit Assessment | MRI risk management. | Revised to move gadolinium info from MRI procedures to MRI risks section | IRB P, v3.0 |
| Recruiting/Screening | Payment to participants. | Revised to list info researchers should include per new Payment Guidance | IRB P, v2.8 |
| Consent of Adults | Written Documentation of Consent – Electronic Consent Signature | Revised to list REDCap and Docusign as options | IRB P, v2.7 |
| Consent of Adults | Research use of human fetal tissue obtained from elective abortion. | New question | IRB P, v2.2 |
| Consent of Adults | Recordings. | New question | IRB P, v2.1 |
| Consent of Adults | Deception. | Revised to include RCR verbiage | IRB P, v2.0 |
| Risk/Benefit Assessment | Return of individual results. | New question | IRB P, v2.0IRB P-NC, v2.1 |
| Consent of Adults | Consent process and characteristics – Information is tailored to the needs of the subject population. | New sub-question  | IRB P, v1.9 |

 |
| **1.14 Version of Supplements.** The most recent version of these supplements should be used however, HSD Staff may use their discretion to determine whether the version submitted by the researcher provides adequate information.* Department of Defense
* Drug, Biologic, Botanical, Supplement
* Device
* Genomic Data Sharing
 |
| **1.15 Completeness of materials.** Verify that all required materials have been provided, including appropriate supplements.For example, if consent is being presented electronically, make sure all content has been provided in the IRB application (e.g., a Word document with text for a website or video). Reviewing this Pre-Review Worksheet and the resources it references will help you determine what the required materials are. |
| **+ Guidance**If the application will receive a determination rather than undergo IRB review, the pre-reviewer uses judgement about whether the missing materials are needed or whether the information can be obtained through screening correspondence instead. (**SOP Pre-Review**; **GUIDANCE Pre-Review**)  |
| **1.16 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.
* 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.

**Funding proposal.** 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. (**Exceptions:**  center grants; some training grants; other funding with no specific human subjects activities described.)  |
| **+ 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.  |
| **1.17 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 pre-reviewer to fully understand the research procedures, subject population, risks, and nature of the experience for subjects.  |
| **+ Guidance****A guiding principle**: Will the next person looking at this application understand what is approved? Edits to the protocol 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 and IRB members to accurately understand the study when they are reviewing future modifications, continuing review applications, or Reports of New Information. This can lead to serious oversights, overlooked problems or IRB noncompliance. Requiring edits is most appropriate when:* The application requires IRB review (because it is non-exempt human subjects research);
* 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 IRB Protocol;
* The study is likely to last a long time;
* The study is likely to involve many modifications
 |
| **1.18 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 always be corrected because the SmartForms are the data source for metrics and reports. This applies to requests for determinations as well as IRB approvals. |
| **+ Guidance**The information in consent, assent, and parental permission forms should be consistent with other parts of the application. For example, there should be no inaccurate or misleading information in the consent form (unless deception is a planned part of the research). It is especially important to identify and address discrepancies when risks are described across multiple documents. For example, in a clinical drug trial the risks may be described in a study protocol, investigator brochure, and drug package insert, in addition to the IRB Protocol and consent forms. For full board studies, discrepancies should be called out in the Pre-review Note.Consistency between IRB application and grant application: Review **SOP Grant Review and Certification** and **GUIDANCE Reading a Grant Application** for information about which inconsistencies to clarify. *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 IRB application because it is a valuable source of information.* |

**SECTION 2: The Regulatory Ladder [**[**top**](#Top)**]**

The purpose of this section is to “walk up the regulatory ladder”, to the point where it is clear that UW IRB review is required.

|  |
| --- |
| **2.1 Delayed Onset Human Research (DOHR) determination.** The TOL or Sr. Administrator are responsible for reviewing DOHR determinations and should refer to the webpage **GUIDANCE Delayed Onset Human Research**, the researcher instructions in the **APPLICATION Determination, Delayed Onset Human Research**, and **INSTRUCTIONS Zipline for Staff**. |
| **+ Guidance**Criteria for granting DOHR status include:1. The investigator has provided documentation from the Sponsor that DOHR status is required;
2. The work described in the grant application falls into one of the three categories described in the guidance;
3. When the reason for the DOHR status is the need for significant pre-human subjects development activities, the pre-reviewer verifies that those activities are described in the grant application and that they would require significant time (e.g., animal studies; purification of compounds, assay development; development of study instruments; other significant and lengthy development work).
 |
| **2.2** **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, no further pre-review is required. (Review **GUIDANCE Is it Research?**; **WORKSHEET Human Subjects Research Determination**; **GUIDANCE Case Reports, IRB Review, and HIPAA**)* If the study appears to qualify for the Common Rule exclusion of public health surveillance activities from research, consult with a member of HSD Leadership.
 |
| **+ Guidance****Scope of clinical research**. Sometimes researchers describe procedures that the subjects would experience regardless of whether they participate in the proposed activity. This is especially common in descriptions of clinical research. Remember that the IRB is approving what is described in the application. While it may be valuable for researchers to describe the non-research procedures as context, it is important that the application clearly distinguish between what is clinical care versus what is research. TIP: Specific procedures that subjects will undergo regardless of whether they participate in the study are likely to be clinical care rather than research.**Revised Common Rule**. There is a one-word change in the definition of “research” but the meaning and interpretation has not changed. However, 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?** **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?** |
| **2.3 Human subjects.** Determine which individuals, records, or specimens (if any) meet the applicable definition of “human subject”, as defined by the regulations that apply to the study. (Review **WORKSHEET Human Subjects Research Determination**)If the research does not involve human subjects, review the information in Section 2 of this Worksheet on GDS certification but then no further pre-review is required.  |
| **+ 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 Leadership 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 a member of 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. **HIPAA waivers for NHS.** If a researcher’s activities do not meet the Common Rule definition of human subjects research but they do need a HIPAA wavier to access UW PHI, this is accomplished by having the researcher submit for a not human subjects determination that specifically notes the application is being submitted in order to obtain the HIPAA waiver. This process should only be used for granting waivers for UW PHI. Review **SOP HIPAA** for more information. |
| **2.4 GDS certification**. Look in the IRB Protocol and grant application to identify whether the application involves sending genomic data to a NIH or other national database to comply with the NIH Genomic Data Sharing (GDS) policies. (**GUIDANCE Genomic Data Sharing**) **If you are not familiar with GDS certification, you will need to be trained on the identification of this requirement and process so check with your supervisor before reviewing a GDS request.** The TOL or Sr Administrator are generally assigned all items requiring GDS certification. The TOL/SRA may delegate this responsibility to an administrator under the circumstances described in the **SOP Genomic Data Sharing Certification – HSD Procedures**. **The certification process:** * When the UW is the only site and unless otherwise indicated in the application, the UW must provide an institutional certification even if the activity does not require IRB review.
* If the UW is involved in a multi-site or collaborative project, the responsibilities of the GDS certification requirement will be determined by the Reliance Team as part of drawing up a Reliance Agreement.
* If UW is providing the certification, the **SUPPLEMENT Genomic Data Sharing** must be uploaded to the application. (**SOP Request for Genomic Data Sharing Certification – Investigators**)
* For applications that require UW IRB review and certification, the certification process is conducted in combination with the IRB review. For applications that do not require IRB review, refer the application to a TOL, SRA or member of HSD Leadership for the certification process. (**SOP Genomic Data Sharing Certification - HSD Procedures**)
 |
| **2.5 Study Risk level**. Determine whether the study risks meet the applicable definition of minimal risk. Consider risks associated with local context (e.g., special local sensitivities about HIV infection) and check with a TOL, SRA or member of HSD Leadership if you’re unsure how to incorporate local context into your review. Keep in mind that it is critical to first be sure that you have clearly distinguished the research procedures from any non-research procedures that are described in the application.  |
| **+ Guidance**Identify which definition of minimal risk to use:* Standard Common Rule and FDA definition (**WORKSHEET Expedited Review**)
* Definition for prisoners (**GUIDANCE Prisoners**)

Resources for assessing and understanding risk include:* [**GUIDANCE Consent** *Identifying and Describing Reasonably Foreseeable Risks in Research*](https://www.washington.edu/research/hsd/guidance/consent/#r)
* [“Risk Assessment: A Foundational Concept”](http://www.washington.edu/research/learning/online/index.php/lessons/risk-assessment-a-foundational-concept/) video tutorial
* Consultation with HSD Leadership, IRB members, or with others (**SOP IRB Consultants**).
* Obtaining additional information from the researcher.
 |
| **2.6** **Exempt.** Determine whether the research qualifies for exempt status and if yes, in which category(s). (**GUIDANCE Exempt Research**)If the research qualifies for exempt status, the only remaining pre-review items to assess are in section 3:* Limited IRB Review
* Assessing Subject Confidentiality and Privacy Protections (if LIRB is used)
* Destruction of Identifiers
* Certificate of Confidentiality or Privacy Certificate
* Reliance Agreements
* Financial Conflict of Interest
 |
| **+ Guidance****Consent and exemptions:** * Although HSD provides researchers with a TEMPLATE for designing exempt consent, the **GUIDANCE Exempt Research** clearly states that: **(1)** HSD does not review and approve consent plans and consent materials for exempt research and **(2)** researchers are responsible for providing subjects with the particular information listed in the guidance.
* HSD advises researchers *not* to submit consent materials for exemptions. However, if consent materials are submitted with an exempt application, the reviewer should treat this document as another piece of information about the research and ask the researcher about information that is inconsistent with the exempt determination (e.g., study procedures not listed in the IRB Protocol Form that would disqualify the study from exempt status, information that might mean the difference between having to do a limited IRB review or not, etc.). Instead of asking the researcher to revise the consent materials to correct any inconsistencies, it is generally advisable to ask the researcher to remove these and to let them know that HSD does not review and approve consent plans and materials.
* **Exempt category 3 requirements.** The regulations require that for research conducted under exempt category 3, subjects must *prospectively agree to participating in an intervention*. HSD policy requires that for some exempt category 3 research, *subjects must agree to be deceived*. The reviewer has discretion to determine the best way to document these requirements. It could be in the IRB Protocol, in a comment, or in any consent materials that the researcher uploads, but it does not require the researcher to upload consent materials.
 |
| **2.7 Engagement**. Determine whether the UW is engaged in the research. If non-UW institutions or individuals are involved, Team S and the Reliance team will assess those other institutions/individuals for engagement. (**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 investigator(s) conducting non-exempt human subjects research is a UW employee/agent (or is an employee/agent of [an institution for which the UW is the IRB of record](https://www.washington.edu/research/hsd/is-the-uw-irb-the-right-irb/identify-the-correct-irb/)), then the UW is engaged and analysis of engagement is complete.

**HIPAA waivers for NED.** If a researcher’s activities do not engage the UW in the Common Rule definition of human subjects research but they do need a HIPAA wavier to access UW PHI, this is accomplished by having the researcher submit for a not engaged determination that specifically notes the application is being submitted in order to obtain the HIPAA waiver. This process should only be used for granting waivers for UW PHI. Review **SOP HIPAA** for more information. |

**SECTION 3: For Items Requiring IRB Review [**[**top**](#Top)**]**

The purpose of this section is to ensure the:

1. Appropriate level of IRB review
2. Identification of any special requirements and/or criteria for the IRB review
3. Identification of all determinations that the IRB must make
4. Identification of any other issues that need to be brought to the IRB’s attention

|  |
| --- |
| **3.1 Limited IRB Review**. If the study requires LIRB, follow procedures in the **GUIDANCE Exempt Research**.  |
| **3.2 Assessing Subject Confidentiality and Privacy Protections.** The Pre-reviewer should use the **GUIDANCE Data Security Protections** and the information the researcher has provided in their application including subject risk, identifiability of the data, and the data security level the researchers have chosen to assess whether the data security protections are adequate to protect the privacy of subjects and to maintain the confidentiality of the data. UW ITHS REDCap is commonly used by UW researchers to gather and store data. For detailed information about how REDCap works and the ways in which is interacts with the **GUIDANCE Data Security Protections**, review this [presentation from the February 3, 2020 staff meeting.](file://FILE.oris.washington.edu/shared-hs/Staff%20Meeting%20Materials/%21%202020/02.03.2020/REDCap%20HSD%20Staff%20Mtg.%20PPT%202020.02.03.pdf) |
| **3.3 Expedited review.** Determine whether the item qualifies for expedited IRB review and, if yes, in which category(s) (**WORKSHEET Expedited Review**). If the investigator wishes, the pre-reviewer can work with them to make revisions to the study that would allow it to qualify for expedited review, but if the pre-reviewer and investigator cannot agree on changes, the item will be reviewed by the convened IRB.  |
| **+ Guidance**Expedited categories do not need to be identified and recorded when review is conducted by the full board and the study is determined to be of no greater than minimal risk. However, if a study includes category 9 procedures, it is **HSD** **policy** ([following OHRP Guidance](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/2018-requirements-faqs/index.html)) that continuing review should be conducted at the same frequency as required in the Old Common Rule (i.e., at intervals appropriate to their degree of risk but not less than once per year). For studies that include category 9 procedures:1. Inform the convened IRB in the Pre-Review Memo that if they determine the study is no greater than minimal risk, it will require continuing review;
2. Be sure to record the justification for requiring continuing review when completing the **Submit Committee Review** activity.
 |
| **3.4 Clinical Trials.** The *Zipline* **CTgov Data Entry** activity must be completed by the Regulatory Affairs (RA) team before an expedited or full board application can be approved, unless all procedures fall into expedited category 5 in which case there is no need to wait for the CTgov assessment. * If **the study is not a clinical trial**, there are no additional requirements.
* If **the study is a clinical trial but is not an applicable clinical trial**, the consent statement (**SOP Consent**) is not required but a DSMP is required by **HSD policy**. Check for a **Private Comment** from the RA team listing any missing requirements.
* If **the study is an applicable clinical trial**, the consent statement and a DSMP are required. Check for a **Private Comment** from the RA team listing any missing requirements.
 |
| **+ Guidance**The Regulatory Affairs Team conducts assessments once a week on Fridays for submissions that were submitted one week prior. If you cannot wait until the next assessment date and need an immediate assessment, email hsdreprt@uw.edu to request it.  |
| **3.5 Recruitment.** **Cold Contact Recruitment.** Researchers often obtain the names and contact information of possible research participants (e.g., from medical records) and then send them a “cold contact” letter or email to ask if they are interested in a study.  HSD receives many complaints about these letters, especially when they contain sensitive information.  Additionally, confidentiality breaches involving these letters have increased. Review [GUIDANCE Cold Contact Recruitment](https://www.washington.edu/research/hsd/guidance/recruitment/cold-contact-recruitment/) on the HSD website for the **HSD policy** statement on this issue and example letters for what is and is not approvable per the policy. The IRB Protocol instructs researchers to upload the actual cold contact recruitment materials rather than a description of materials so that staff can assess them for adherence to HSD policy. **eCare/MyChart:** Per UW Medicine policy, the UW Medicine eCare/MyChart system may **not** be used for research recruitment purposes. UW Medicine Research IT may approve exceptions to this policy on a case-by-case basis. HSD staff should ask the researchers to provide documentation of the exception. Researchers seeking an exception should be referred to Mark Todd, Assistant Director, Research IT Services at marktodd@uw.edu. **Care Everywhere:** Per UW Medicine policy, researchers may not use EPIC Care Everywhere data for research purposes **unless** the clinical data is necessary for patient/participant safety activities.  |
| **3.6 Paying Research Subjects.**Use the framework in [GUIDANCE Subject Payment](https://www.washington.edu/research/hsd/guidance/subject-payment/)to evaluate subject payment proposals described in the IRB Protocol and/or consent form(s). The IRB Protocol informs researchers that they may reference the consent form(s) rather than describing payment plans in the IRB Protocol. HSD staff have the discretion to determine whether a description of the payment should also be listed in the IRB Protocol, particularly if the IRB has requested a rationale for the proposed payment.* **Social Security Number.** The IRB Protocol directs researchers to the UW Financial Management website to determine when SSNs must be collected and when research payments must be reported to the UW Tax Office. If total payments are likely to meet or exceed $600 in a calendar year, the consent process/form must inform subjects that the UW will report this as Miscellaneous Income to the IRS.

It is the IRB’s responsibility to determine whether the consent process/form should include a statement that SSN will be collected. This decision is based on the specific subject population and whether the inclusion of that information is likely to influence their decision about whether to participate.  |
| **3.7 Nursing research.** *(Applies only to full board reviews)* If the PI meets one of the criteria below, consult with a TOL, SRA or member of HSD Leadership to arrange for a nurse IRB member to be present for the review. This is a requirement because of UW’s nationally-certified status as a Nursing Magnet Program. * Member of the faculty or a student in any of the UW nursing programs (i.e., main campus, Tacoma, Bothell), or
* A nurse employee/manager at any UW Medicine clinical care facility.
 |
| **+ Guidance*** All three branches of the UW have nursing programs and they are separate/independent of each other: UW, UW Bothell, and UW Tacoma.
* UW main campus School of Nursing departments are: (1) Biobehavioral Nursing and Health Informatics; (2) Family and Child; and (3) Psychosocial and Community Health.
* UW Tacoma nursing program is called Nursing & Healthcare Leadership.
* UW Bothell nursing program is called the School of Nursing & Health Studies.
* If the researcher is a nurse employee, it should be evident from their entry in the UW Directory.
 |
| **3.8 Cannabis (marijuana), hemp, and related compounds.** Review the researcher’s response to the cannabis question in the IRB Protocol (full and no contact). If they have checked anything *except* “None of the above”, consult with a member of HSD Leadership. |
| **3.9 International research.** [GUIDANCE International Research](https://www.washington.edu/research/hsd/guidance/international-research/). |
| **3.10 Translation.** **HSD policy** requires the IRB to review the *method of translations* (i.e., *how* translations will be obtained and the *qualifications* of the translators). Researchers are required to submit all consent materials that will be provided to subjects in written or electronic form, but the IRB is not responsible for reviewing the translated documents. This means HSD staff **are** expected to confirm that the translated forms have been uploaded but **are not** expected to check footers, count lines, or use Google translate to verify the accuracy of translated documents. Staff should use their judgement and follow up with the researcher if there is something about a translated document that seems obviously wrong. **HSD policy** requires researchers to submit the **TEMPLATE Translation Attestation** with their translated consent forms for greater than minimal risk studies. Review **SOP Consent** for procedural details. |
| **3.11 Consent.** **General considerations.** Use **SOP Consent**, **GUIDANCE Consent**, **GUIDANCE Designing the Consent Process**,and **WORKSHEET Consent Requirements and Waivers** to assess consent requirements. The **WORKSHEET Consent Review for IRB Members** provides a summary of the main topics in GUIDANCE Consent. **Consent form clinical trials registration statement.** The **CTgov Data Entry** activity must be completed before an expedited or full board application can be approved (EXCEPTION: if all procedures fall into expedited category 5, there is no need to wait for the CTgov assessment).  |
| **3.12 Waivers or alterations**. Identify any consent/parental permission/assent/HIPAA authorization waivers or alternations and any waivers of documentation of consent/parental permission/assent that the IRB will need to consider or that the researcher has requested. Evaluate whether there is sufficient information for the IRB to grant the waiver or make an enforcement discretion determination.**WORKSHEET Consent Requirements and Waivers**, **CHECKLIST Waiver or Alteration of HIPAA Authorization**, **GUIDANCE Designing the Consent Process** **Note – t**he Office for Civil Rights oversees HIPAA regulations. |
| **3.13 Emergency Exception from Informed Consent (EFIC).** **If you are not familiar with EFIC research, you will need to be trained. Check with your supervisor.** Note that to grant this exception, a physician must be present (in-person or by phone) and participate in the review by the convened IRB. Review **WORKSHEET Exception from Informed Consent** *currently in draft form;* and[FDA EFIC Guidance](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/exception-informed-consent-requirements-emergency-research).Include **Note to File** in Zipline application about **exception to Short Form policy** **for EFIC studies submitted before January 1, 2026**. After sending out the approval letter, paste Note to File into comment and check box to issue e-mail notification to PI/PI Proxy/Primary Contact. Leave blank the check box in Staff Data Entry Q.11 about IRB approval for use of the short form consent process.**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
* The study does not have the option to exclude participants with a non-English language preference.

Therefore, EFIC studies submitted to the UW IRB before January 1, 2026, may continue to operate under the previous short form policy until their completion.That means that this study is not required to obtain advance approval from the IRB to use the short form consent method, and it is not required to report its use to the IRB or provide participants with a translated long form consent after obtaining consent using the short form method. Clinical trials (including EFIC studies) submitted to HSD 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/). |
| **3.14 Destruction of identifiers.** Verify that the researcher checked the box on this question in the IRB Protocol confirming that identifiers and links between identifiers and codes will not be destroyed or, if they will be, that destruction will not occur until after the end of the applicable state records retention requirement. Verify that the consent form language accurately reflects their plan for identifier storage and, if applicable, destruction.  |
| **3.15 Regulatory requirements related to subject population.** Identify population-specific requirements and determinations. Evaluate whether there is sufficient information for the IRB to assess the requirements and make the determinations.  |
|  | **3.15a** Children. (**WORKSHEET Children; GUIDANCE Involvement of Children in Research;** and **GUIDANCE Human Subjects Regulations** for a list of Washington State laws that determine age of majority for research.)If the research will occur outside of Washington State, remember to check for the age of majority in the research location.Consult a TOL or SRA if the category of child research appears to be 407 “Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.” |
| **3.15b** Prisoners. (**WORKSHEET Prisoners**; **SOP Prisoners**; **GUIDANCE Prisoners**)The definition of “prisoner” is complex and multi-faceted. Review the full description and multiple examples in the Definitions section of **GUIDANCE Prisoners**.Decide whether to recommend that the IRB review for the involvement of incidental prisoners, based on the issues discussed about incidental prisoners in **SOP Prisoners**. Use the **GUIDANCE** to identify the applicable regulations. The **WORKSHEET** summarizes, and the **SOP** describes in more detail, the prisoner-specific processes that must be followed under various regulations (or lack of regulations). If certification to OHRP is required, inform a TOL or SRA so that they can begin the certification process as described in the **SOP**. If there will be interaction with prisoners, the initial review of their involvement must receive full board review with a prisoner advocate present. **All** prisoner research must undergo continuing review at least once, annually.  |
| **+Guidance.** * **Minimal risk.** Remember that the 45 CFR 46 definition of minimal risk is slightly different for prisoners.
* **Exempt status or expedited review.** Review the **GUIDANCE Exempt Research** and **WORKSHEET Expedited Review** for limitations on which prisoner research can be exempt or can be reviewed by the expedited process. Staff are encouraged to consult with a prisoner advocate if their expertise would be helpful.
* **Expedited review of research governed by Subpart C** must comply with all the Subpart C requirements (including OHRP certification) except for the prisoner advocate requirement and the requirement to inform prisoners about the lack of impact on pardon or parole.
* **Certification and multi-institutional research.** Review **SOP Prisoners** for what to do if the research is governed by Subpart C AND is being reviewed by another IRB in addition to the UW IRB.
 |
| **3.15c** Pregnant women and fetuses. (**WORKSHEET Pregnant Women**) The Revised Common Rule no longer includes pregnant women as an example of a population that is potentially vulnerable to coercion or undue influence however, Subpart B has not been revised or deleted.Refer to the two sections on fetal tissue below if the research includes collection/use of fetal tissue. |
| **3.15d** Neonates (unviable, or of uncertain viability). (**WORKSHEET Neonates**) UW research involving this population is very rare. If a specific study appears to involve this population, consult with a TOL, SRA or member of HSD Leadership for a consensus.  |
| **3.15e** Transplantation of fetal tissue. (**CHECKLIST Transplantation of Fetal Tissue**) UW research involving this procedure is extremely rare. If a specific study appears to involve this procedure, consult with a TOL, SRA or member of HSD Leadership to ensure that all regulatory requirements are identified and addressed.  |
| **3.16 Specific federal agency requirements and/or approval criteria**. Identify requirements and determinations that are specific to any federal agencies that are involved in the research. Review **GUIDANCE Human Subjects Regulations** for a list of agencies with specific requirements.Use the HSD content for those agencies (e.g., guidance, SOPs, worksheets)to determine whether any of those requirements apply to a specific study. |
|  | **3.16a** FDA and the IDE requirement.If the FDA regulated application involves the use of an investigational device, use the **WORKSHEET FDA Devices and the IDE Requirement** to assess whether the device qualifies for an IDE exemption, an Abbreviated IDE, or whether it needs/has an IDE from the FDA. **If you are not familiar with FDA regulated investigational devices, you will need to be trained on the process so check with your supervisor.** (**SOP FDA Regulated Research**; **WEBPAGE FDA Regulated Research Guidance**) |
|  | **3.16b** FDA device risk determination.If the FDA regulated application requires a device risk determination, verify that the application provides sufficient information for the determination. In most cases the researchers should submit the **SUPPLEMENT Devices**. **If you are not familiar with FDA regulated investigational devices, you will need to be trained on the process so check with your supervisor.** (**SOP FDA Regulated Research**; **WEBPAGE FDA Regulated Research**; **WORKSHEET FDA Devices and the IDE Requirement**) |
| **+ Guidance**Note that the FDA considers this determination to be part of the IRB’s responsibilities for conducting its initial review of a [investigational] device study. This is not the same as the study risk determination that is made by the IRB for FDA regulated devices. How are the two risk determinations different?

|  |  |  |
| --- | --- | --- |
| Issue | Study Risk Determination | Device Risk Determination |
| What risk is being assessed? | All types of risks (physical, social, legal, etc.) of all of the research procedures.  | The physical (medical) risk of using a specific device with a specific population, in a specific manner, and for a specific purpose.  |
| Who makes the determination? | The HSD pre-reviewer and (if the item goes to the full board) the IRB | The full convened IRB, unless the FDA has already made a determination. |
| If there is a difference of opinion, whose determination is the final one? | The IRB’s | The FDA’s |
| How is the risk categorized | Minimal risk OR more than minimal risk | Not Significant risk OR Significant risk |

 |
| **3.16c** FDA and the IND requirement.If the FDA regulated application requires an IND, written verification of the IND from the sponsor, FDA, multi-site coordinating center or Contract Research Organization must be uploaded to the application. The application cannot be approved or conditionally approved until written verification of the IND is uploaded. **If you are not familiar with FDA regulated investigational drugs, you will need to be trained on the process so check with your supervisor.** When a study team provides an IND Exempt letter from the FDA, HSD considers the study to be FDA regulated, even if the study team has no plans to submit data to the FDA. This is because such letters indicate that certain FDA regulations apply.The researchers should upload the **SUPPLEMENT Drugs, Biologics, Botanicals, Supplements** and the Investigator Brochure and/or Package Insert for the investigational drug. (**SOP FDA Regulated Research**; **WEBPAGE FDA Regulated Research Guidance**; **WORKSHEET FDA Drugs and the IND Requirement**) |
| **3.16d** Humanitarian Use Device. If the proposed activity involves a Humanitarian Use Device (HUD), identify whether the proposed use of the HUD is research, clinical practice, or both. Inform the IRB in the Pre-Review Note that the study involves a HUD, the purpose for which it is being used (clinical care, research, or both), and provide the IRB with the appropriate criteria for approval (listed in Appendix A of the **GUIDANCE Humanitarian Use Device**). If you are not familiar with HUDs, you will need to be trained on the process so check with your supervisor.  |
| **+ Guidance*** HUDs are listed on the Devices SmartForm which will also note the unique Humanitarian Device Exemption (HDE) number assigned to it by the FDA.
* For a list of all HUDs currently approved for clinical use at the UW, review [this webpage](https://www.washington.edu/research/hsd/guidance/hud/approved-huds/).
 |
| **3.16e** Department of Defense. Verify that the application includes the **SUPPLEMENT Department of Defense**. Reviewers use the **WORKSHEET Department of Defense** to ensure that the researcher and the IRB meet the relevant DoD requirements. These may include requirements related to consent waivers, consent content, subject payment, recruiting methods, and the enrollment of children or prisoners. The SUPPLEMENT may contain some information that reviewers need to verify items in the WORKSHEET, but it is intended to both provide the IRB with info it needs **and** to ensure that researchers are aware of the requirements. Reviewers are not expected to check the IRB application to ensure that researcher “confirmations” in the SUPPLEMENT are accurate.  |
| **3.16f** Department of Justice. Verify that the application provides sufficient information for the IRB to determine whether the study meets the DOJ (and when applicable, Bureau of Prisons) criteria for approval (**GUIDANCE Department of Justice Research**; **WORKSHEET Department of Justice**). If you do not have experience reviewing to DOJ regulations, check with your supervisor before approving the study. A Privacy Certificate is a confidentiality protection that is required for all studies that are supported by the National Institute of Justice (NIJ) and several other DOJ agencies. It is similar to a Certificate of Confidentiality in that it makes individually identifiable data about research participants immune from legal action. It is HSD policy to require the researcher to submit the Privacy Certificate with their application materials so the IRB can verify that the confidentiality protections described in the Certificate match what is described in the application materials. When the study is ready to be approved, the IRB Chair must sign the certificate. Review the NIJ Privacy Certificate Guidance [here](https://nij.ojp.gov/funding/privacy-certificate-guidance) and [here](https://nij.ojp.gov/funding/confidentiality-and-privacy-protections) for additional information. The NIJ site has far less information than the NIH CoC site so if you’re unsure about how to proceed, talk with a TOL, SRA or member of HSD Leadership who may identify the need to contact NIJ, or ask the researcher to contact NIJ, directly.If a study is initially funded by an agency that issued an automatic Certificate of Confidentiality (CoC) and then obtains DOJ funding which requires a Privacy Certificate, the protections of the Privacy Certificate supersede the CoC. All consent materials should describe the Privacy Certificate protections rather those of the CoC.  |
| **3.16g** Environmental Protection Agency. Verify that the application provides sufficient information for the IRB to determine whether the study meets the EPA criteria for approval. (**SOP Environmental Protection Agency Research**; **WORKSHEET Environmental Protection Agency**) |
| **3.16h** Department of Energy**.** Verify that the application provides sufficient information for the IRB to determine whether the study meets the DOE criteria for approval. (**GUIDANCE Department of Energy Research**; **SUPPLEMENT Department of Energy**) |
| **3.17 Certificate of Confidentiality (CoC)**. (**GUIDANCE Certificate of Confidentiality**; [NIH CoC webpage](https://grants.nih.gov/policy/humansubjects/coc.htm)) Identify whether a Certificate of Confidentiality:* Has been automatically granted to the study because of federal funding (**GUIDANCE Certificate of Confidentiality** for limited exceptions to NIH auto-CoC policy);
* Hasn’t been automatically granted and but is being requested by the researcher; or
* Hasn’t been automatically granted and the researcher hasn’t mentioned obtaining one, but the IRB should be advised to require one.

**If there is (or will be) a CoC:** * Examine the consent form to make sure that the required CoC language is present. This includes a requirement to inform subjects that the CoC expires when the funding expires. Refer to, **GUIDANCE Designing the Consent Process** for preferred language.
* Include the CoC bullet(s) in the Zipline letter.

**If the researcher needs to request a CoC:** Advise the PI to get the process started ASAP. (Refer them to: **GUIDANCE Certificate of Confidentiality** *How do I apply for a CoC if I don’t have an automatic CoC with my funding?*; [NIH CoC webpage](https://grants.nih.gov/policy/humansubjects/coc.htm))**Expiration date.** Auto-CoCs expire when the funding expires. CoCs issued via the NIH application process prior to 1/12/21 list an expiration date on the certificate. CoCs issued via the NIH application process on or after 1/12/21 expire when the study is complete. For CoCs that expire at the end of the study, use 1/2/3456 as the expiration date in Staff Data Entry. |
| **3.18 NIH Data Management and Sharing (DMS) Policy. (**[NIH Data Management and Sharing Policy Overview](https://sharing.nih.gov/data-management-and-sharing-policy/about-data-management-and-sharing-policies/data-management-and-sharing-policy-overview) and [NIH Policy Supplement: Protecting Privacy When Sharing Human Research Participant Data](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-213.html)**)****Identify whether the DMS policy applies, and data will be shared:*** The policy applies to all research funded by NIH funding applications submitted on or after January 25, 2023, that will result in the generation of scientific data.
* Researchers must share data through an established repository **unless** there is a reasonable justification for not sharing the data.
* In circumstances when the NIH Genomic Data Sharingpolicy also applies, follow the process and requirements for Genomic Data Sharing Certification instead.

**If the DMS Policy applies:*** Data sharing plans must be described in the IRB Protocol form (unless Genomic Data Sharing applies – see above).
* Examine the consent form to ensure that data sharing plans have been described and are consistent with the information provided in the IRB Protocol, including information about possible uses, limitations on uses, the ability to withdraw information etc. Refer to **GUIDANCE Designing the Consent Process** for preferred language.
* If data will be shared through unrestricted (public) access repositories, explicit consent must be obtained.
* If **identifiable** data will be shared, review data sharing plans to the applicable criteria for IRB approval. Consider the risks associated with broad sharing of data through repositories, the nature of the information that will be shared, and the protections that the repository will have in place. When considering these protections, note that **Certificate of Confidentiality** protections extend to copies of protected data shared through a repository.
 |
| **3.19 Reliance Agreements**. Applications that engage non-UW institutions or individuals are initially assessed by Team S for the need for reliance agreements. The agreements are negotiated by the Reliance Team. Review the **INSTRUCTIONS Team S Routing** document (F:\! HSD INTERNAL DOCS TEMPORARY FOLDER) for actions to take if the application has been assigned back to you after the Team S assessment. |
| **3.20 Data and Safety Monitoring Plan (DSMP).** It is HSD IRB policy to require a DSMP for all clinical trials that are being reviewed by the UW IRB, independently of whether the research funding source requires it (**WORKSHEET Primary Reviewer, Initial Application** for policy statement). Neither IRB approval nor MRSA status can be granted until the DSMP is provided. (Refer to the “Clinical Trials” section in this Worksheet for info on identifying CT status.)If the study is a clinical trial but doesn’t have a DSMP: Ask the researcher to provide it (but refer to the Guidance below for an exception). It can be provided as an answer to the DSMP question on the IRB Protocol form, as a supporting document, or embedded within some other document such as a Study Protocol document. The researcher can be referred to guidance on the [ITHS website](https://www.iths.org/investigators/services/dsm/data-and-safety-monitoring-plans/).  |
| **+ Guidance****EXCEPTION:** A DSMP is not required for the IRB application for a clinical trial when:* An external IRB is reviewing most of the clinical trial procedures, AND
* The UW IRB is reviewing only one procedure or a small part of the clinical trial, AND
* The component(s) of the trial being reviewed by the UW does not involve the study intervention or a procedure involving more than minimal risk.

*Example:* A clinical trial is occurring at the VA but the participants are coming to a UW clinic for an MRI scan. The UW IRB is reviewing just the MRI procedure. In this example, the VA IRB is responsible for receiving and reviewing the DSMP.  |
| **3.21 Participants at Risk for Suicide.** If: (1) people will be excluded if they are at risk for suicide; (2) the instruments ask about suicide; and/or (3) they are enrolling participants who may be at risk for suicide, use the table in “Identifying the Need for a Suicide Risk Mitigation Plan” of the GUIDANCE Participants at Risk for Suicide to determine whether a Suicide Risk Mitigation Plan is required. |
| **3.22 Return of results to subjects.** If the researcher plans to return individual results to subjects, or if the application suggests that the study procedures might result in clinically actionable information, the designated reviewer or the full board use **GUIDANCE Return of Individual Results** to review the researcher plan as described in the IRB Protocol.  |
| **3.23 Requirement for continuing review and duration of approval period.** The IRB may be required to specify the duration of the approval period depending on the regulations that govern the study. This determines the date of the next continuing review (if required). Review **WORKSHEET Primary Reviewer, Initial Application** for details about regulatory requirements for frequency and duration of continuing review. Briefly, most RCR minimal risk research (except categories 8b and 9) do not require continuing review. FDA and DOJ studies require continuing review on at least an annual basis. *NOTE that for datasets 10,000 records or larger, consider whether continuing review should be required even if the applicable regulations do not require it, particularly if a repository or registry is being created. As with any records review, also consider: direct and indirect identifiability and sensitivity of the data; the amount and type of variables; and the data security level and protections researchers have described.*  |
| **3.24 Other regulatory approvals required before IRB approval**. Identify whether there are any required and whether the researcher has provided documentation of these approvals. Ensure that the researcher is aware that the IRB approval cannot be finalized until these approvals are received by HSD.  |
|  | **3.24a** Radiation Safety**.** Identify whether any research procedures require subjects to be exposed to radiation. If the exposure will occur at a UW or Fred Hutch facility, confirmation of approval by the Human Subjects Radiation Approval Committee (HSRAC) must be uploaded to *Zipline* before the application can be fully approved by the IRB. If the exposure will occur at some other facility, check with a TOL, SRA or member of HSD Leadership for guidance. |
| **+ Guidance** **Where to find this information**. Look at the Additional Study Scope SmartForm and the IRB Protocol (Sections: Procedures; Risk/Benefit).Procedures involving radiation include (but are not limited to):

|  |  |
| --- | --- |
| X-rays | CT scans |
| PET scans | DEXA scans |
| Delivery of substances tagged with a radio-isotope | Radio-immunotherapy |
| Radiation (e.g., cancer treatment) | Nuclear medicine scans |
| Brachytherapy | External bean radiation therapy (EBRT) |
| Fluoroscopy |  |

 |
| **3.24b** Financial Conflict of Interest.Identify whether the researcher has identified a Financial Conflict of Interest for any member of the research team. (**SOP Financial Conflict of Interest**)If there is a conflict, determine whether the FCoI Management Plan [a letter] has been provided with the application. If there is a FCOI but no Management Plan, IRB approval cannot be granted until it is provided.  |
|  **3.25 Other issues**. Identify any other issues that should be addressed during the designated review or brought to the convened IRB’s attention, based on ethical issues, the population, etc. For example, consider the Belmont principles while reading the IRB Protocol and consent form, how much subjects are being paid, etc. In general, you should consult with a TOL, SRA or member of HSD Leadership before communicating about them with the researcher.  |
| **3.26 Complete the pre-review process**. Follow the appropriate instructions in Zipline and, if the item will be reviewed by the full board, prepare the Pre-Review Note. (**SOP Pre-Review**; **GUIDANCE Pre-Review**; **INSTRUCTIONS Zipline for Staff**)If the pre-reviewer will also serve as the designated reviewer, review **WORKSHEET Primary Reviewer, Initial Application** for support in identifying IRB review considerations.  |

**RELATED MATERIALS [**[**top**](#Top)**]**

* INSTRUCTIONS Zipline for Staff
* GUIDANCE Pre-Review
* SOP Pre-Review
* TEMPLATE Pre-Review Letter
* WORKSHEET Primary Reviewer, Initial Application

|  |  |  |
| --- | --- | --- |
| **Version Number** | **Revision Date** | **Summary of Changes** |
| 5.2 | 06.26.2025 | Added major IRB protocol changes  |
| 5.1 | 01.30.2025 | Insert Note To File language for EFIC short form exception; revise day of the week RA team conducts ct.gov assessments; add table listing significant IRB Protocol updates |
| 5.0 | 10.31.2024 | Add guidance for granting HIPAA waivers for UW PHI for NHS or NED applications |
| 4.9 | 09.26.2024 | Add reference to new suicide risk suite of materials |
| 4.8 | 05.30.2024 | Add clarifying statements related to situations when the FDA issues an IND Exempt letter |
| 4.7 | 11.02.2023 | Add link to information about cancer-related and Fred Hutch primary PIs; add information about transfers process |
| Previous versions |  | For older versions: HSD Staff – refer to the SharePoint Document Library; Others - contact hsdinfo@uw.edu. |

**Keywords:** Pre-review