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

**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 modification applications 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 modifications. 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’ll need to reference to review 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**

Evaluate the modification using this worksheet. Issues should usually be evaluated in the order listed, but experienced pre-reviewers will often 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.

To fully and accurately identify what is being modified in a Zipline application:

* Read the Modification Summary in the SmartForm
* Identify any revised documents such as the IRB Protocol form and the consent form – by looking at the *Documents* tab
* Use the *Compare* functionality in Zipline and *Compare* and *Tracked Changes* features in Word
* Check the footers on uploaded documents to see if they have changed

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

This section addresses these issues:

1. Is there anything about the modification 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 their modification to add funding 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 Reliance Administrator (SRA) or member of HSD Leadership 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/SRA and re-assign the item to another member of the team. (**SOP Reviewer Conflict of Interest**)  |
| **1.3 Triage for assignment to Team S.** If the application involves the addition of any non-UW institutions or individuals, Team S and the Reliance Team should assess the modification and may conduct the review. Reassign the application to Team S and make a private comment in Zipline noting where you noticed information about the institutions or individuals. Indications that there may be more than one institution or individual may be found in any part of the application (e.g., IRB Protocol, study protocol, grant application, SmartForms).TOLs and Sr. Administrators will screen for this when assigning work but all staff should keep this assessment in mind, particularly while doing the first high level, big picture read through the modification.Review the **INSTRUCTIONS Team S Routing** document (F:\! HSD INTERNAL DOCS TEMPORARY FOLDER) for additional details and check in with your TOL, SRA, or the Reliance Team with questions. |
| **1.4 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/) for more details. 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. |
| **1.5 UW Office for the Youth Protection Coordinator.** If the modification includes adding 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. |
| **1.6 UW Medicine Security Review**The project must undergo the 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. |
| **1.7 Applicable regulations. Begin every modification review by looking at the “Reviews” tab in Zipline.** This will help you quickly 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) including protected populations (e.g., prisoners). This requires identifying the regulations that apply to the study prior to the modification and then determining whether the modification affects which regulations apply. Use the 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. Defer to DoD’s opinion about the applicability of FDA regulations. If you don’t know the DoD’s interpretation for a specific DoD-involved study, consult with a 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 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 the **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.  |
| **1.8 Version of Supplements.** The most recent version of the supplements should be used however, HSD staff may use their discretion to determine whether the version submitted by the researcher provides adequate information.  |
| **1.9 Completeness of materials.** Verify thatall required materials have been provided, including appropriate supplements. Reviewing this Pre-Review Worksheet and the resources it references will help you determine what the required materials are. The pre-reviewer must use judgement to identify the most efficient and appropriate approach when the application materials, including an older version of the IRB Protocol, are missing information. 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 existing IRB Protocol; 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.If the modification is for a determination and the modification will not change the status of the determination, the pre-reviewer uses judgement about whether the missing materials are needed or if the information can be obtained through screening correspondence instead. (**SOP Pre-Review**; **GUIDANCE Pre-Review**)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** |
| Procedures | Machine learning | Removal of this question, now in AI SUPPLEMENT | IRB P, v5.6IRB P-NC, v4.1 |
| Overview | Supplements | Added Artificial Intelligence Systems and the SUPPLEMENT Artificial Intelligence (School of Medicine Only) | IRB P, v5.6IRB P-NC, v4.1 |
| 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  | Electronic Consent Signature | Removed checkbox about ensuring REDCap is set up to be Part 11 compliant if the study is FDA regulated | IRB P, v5.4 |
| Consent of Adults | Electronic Consent Signature | Removed subquestion about if the electronic consent method is legally valid in the jurisdiction where the research will occur | IRB P, v5.3 |
| Risk/Benefit Assessment | Return of individual research results | Revisions to question to be more relevant for no contact study designs | IRB-NC, v3.9 |
| Consent of Adults | Use of Short Form Consent | New question | IRB P, v5.2 |
| Overview | Supplements | Added new Participants at Risk of Suicide SUPPLEMENT | IRB P, v5.0 |
| Procedures | Recordings | Question moved from the Procedures section to the Consent of Adults section | IRB P, v4.7 |
| Procedures | Machine learning. | New question | IRB P, v4.6IRB P-NC, v3.4 |
| Overview | COVID | Removed COVID question | IRB P, v4.4 |
| 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 |
| Participants | UW Medicine and UW Dentistry residents and fellows | New question | IRB P, v3.8 |
| 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 |

If the modification is for a determination and the modification will not change the status of the determination, the pre-reviewer uses judgement about whether the missing materials are needed or if the information can be obtained through screening correspondence instead. (**SOP Pre-Review**; **GUIDANCE Pre-Review**) |
| **1.10 Information about new funding 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 UW.

**Funding proposal.** In most cases the application, proposal, scope of work or other description of the funded project should be uploaded to the application. (**Exceptions:** center grants; some training grants; other funding with no specific human subjects activities described.) 1. **CTgov assessment.** With any new federal funding source, consider whether a new CTgov assessment should be made by the Regulatory Affairs Team. Internal review staff are not expected to be able to make this assessment on their own, but can refer to the basics on the [HSD Clinical Trials webpage](https://www.washington.edu/research/hsd/clinical-trials/) to get a sense of whether the changes in the modification may qualify the application as an ‘applicable’ clinical trial. Staff should also look at the **CTgov Data Entry** to see whether the study was previously determined to be a clinical trial but not an applicable trial in which case the addition of federal funding may make the study an applicable clinical trial.If a new assessment is needed, email hsdreprt@uw.edu to request it.
2. **OCR studies with 3-year approvals.** If federal funding is added with a modification, the study is no longer eligible for a Flexible approval period. Review the section on *Duration of Approval* in the **SOP IRB Review** for information about how to proceed.
 |
| **+ 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.  |
| **1.11 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 what is being modified, how, and when.  |
| **+ 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 for 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, and
* 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
 |
| **1.12 Consistency of application**. The information provided in the modification is internally consistent. Inconsistencies or inaccuracies on ***Zipline*** SmartForms must always be corrected because the SmartForms are the data source for metrics and reports. This applies to modifications to determinations as well as IRB approved applications.  |
| **+ 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 false 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: 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** **Research vs. non-research.** Determine whether any procedures and activities being added with the modification are “research”, as defined by the regulations that apply to the study. Also, consider whether the modification makes the entire study “not research”. (**INSTRUCTIONS Zipline for Staff – Changing Determinations at the Time of a Modification**)If the modification is not research, no further pre-review is required. (**GUIDANCE Is it Research?**; **WORKSHEET Human Subjects Research Determination**; **GUIDANCE Case Reports, IRB Review, and HIPAA**)* If the modification activities appear 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 whatever is described in the application. 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 provide 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 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 the **GUIDANCE Is It Research?** |
| **2.2 Human subjects.** Determine whether any new individuals, records, or specimens meet the applicable definition of “human subject”, as defined by the regulations that apply to the study. It is also possible that the modification could make the entire study “not human subjects”. [**WORKSHEET Human Subjects Research Determination**; **INSTRUCTIONS Zipline for Staff – Changing Determinations at the Time of a Modification** -and- **Not Human Subjects Modification for IRB Reviewed Studies (No Change in Study Review Level**)]If the modification 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 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 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 modification involves the addition of 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. |
| **2.3 GDS certification**. Look in the IRB Protocol, any new grant applications, and modification summary to identify whether the modification involves sending genomic data to a NIH 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 process so check with your supervisor.** The TOL and Senior Administrator are generally assigned items requiring GDS certification. The TOL/SRA may delegate this responsibility to a Review 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 or modifying 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 modifications that require UW IRB review and certification, the certification process is conducted in combination with the IRB review. For modifications 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**)
 |
| **2.4 Study Risk level**. Determine whether the proposed modification changes the study risk level using the applicable definition of minimal risk. Consider the 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.  |
| **+ 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 management, IRB members, or with others (**SOP IRB Consultants**).
* Obtaining additional information from the researcher.
 |
| **2.5 Exempt.**Modifications to exempt studies that do not change the determination can be processed as described in **INSTRUCTIONS Zipline for Staff**. For modifications that will require transitioning from an exempt category under the Original Common Rule to an exempt category under the Revised Common Rule, refer to **GUIDANCE Exempt Research** for instructions.If a modification to an exempt study will require the study to change from a determination to an IRB approval, refer to **INSTRUCTIONS Zipline for Staff – Changing Determinations at the Time of a Modification**.  |
| **2.6 Engagement**. Determine whether the UW is engaged in the proposed modification to the research. If non-UW institutions or individuals are being added, 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 New application or modification**. Determine whether the application is most appropriate as a new application or as a modification. For example, if the study was not previously identified by HSD as a clinical trial but this modification will add procedures that make it a clinical trial, it likely more appropriate for the modification to be submitted as a new application.If it is more appropriate to submit a new application, communicate the determination and rationale to the researcher. When you ask the researcher to withdraw the modification and submit a new application be sure to inform them about the **Copy Submission** activity.  |
| **+ Guidance**This is a judgement call for which the following factors should be considered: the degree of overlap with the already-approved study; expectations about the future modification activities of the study based on past experience with the study and the investigator; and the impact of the modification on the complexity of the application and the IRB’s subsequent ability to adequately track and oversee the study activities.  In general, a modification should be submitted as a new application instead if:* It takes the study in an entirely new direction
* It is a really big sub-study or a registry or repository

Review the HSD **Clinical Trials** webpage for information about how “clinical trial” is defined.Consult with a TOL, SRA, or member of HSD Leadership as desired.  |
| **3.2 Limited IRB Review**. If the modification requires adding LIRB, follow procedures in the **GUIDANCE Exempt Research**.  |
| **3.3 Assessing Subject Confidentiality and Privacy Protections.** The Pre-reviewer should use the **GUIDANCE Data Security Protections** and the information the researcher has provided in the modification 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, given the proposed modifications to the study. 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) |
| **3.4 Artificial Intelligence.** The **GUIDANCE School of Medicine Research using AI** applies to UW reviewed human subjects research involving the use of [**Artificial Intelligence Systems (AI)**](https://depts.washington.edu/comply/docs/308_G1.pdf)**when**:1. It is led by **School of Medicine Principal Investigators** (PIs); **AND**,
2. It involves either the targeted enrollment of **UW Medicine patients, OR** use of [**UW Medicine Data**](https://depts.washington.edu/comply/docs/308_G1.pdf). Note that UW Medicine Data is NOT limited to clinical records and includes many types of data stored in any UW Medicine system or application.

The guidance does not apply to studies approved before the 9/1/2025 effective date unless the modification adds a new use of AI. Studies that meet these criteria should be referred to your Team Lead. |
| **3.5 Expedited review.** Determine whether the modification 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. **Minimal risk studies:** Does the modification fit within the expedited category(s) used for the initial review? If not, does it fit into one of the other first seven categories? If not, does it qualify as a [**minor change**](https://www.washington.edu/research/glossary/minor-change/)? If the answer is NO to all of these, the modification must be reviewed by the full convened board. **Full board studies**: Does the modification meet the definition of a “minor change”? If yes, it can be reviewed by the expedited process. If no, it must be reviewed by the full board. **Minor change:** Examples of minor changes can be found in the **WORKSHEET Expedited Review**.  |
| **3.6 Consent form clinical trials registration statement.** This item applies to Zipline modifications to an ‘applicable’ clinical trial that are adding a new consent form or to studies that were previously not an ‘applicable’ clinical trial but with the modification, now meet the definition of an ‘applicable’ clinical trial. Review the “Information about new funding in the SmartForm” section of this worksheet for information about how to proceed if you think a modification might change the study to an ‘applicable’ clinical trial. * 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.
 |
| **3.7 Recruitment.****Cold Contact Recruitment.** Researchers often obtain the names and contact information of possible research participants (say, 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 the [**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.  |
| **3.8 Paying research subjects**. Use the framework in [**GUIDANCE Subject Payment**](https://www.washington.edu/research/hsd/guidance/subject-payment/)to evaluate any new or modified subject payment proposals described in the IRB Protocol and/or the 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 but 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.  |
| **3.9 Nursing research.** (*Applies only to full board reviews*)If a new 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 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.
 |
| **3.10 Cannabis (marijuana), hemp, and related compounds.** Review any changes in 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. |
| **3.11 International research.** Review [**GUIDANCE International Research**](https://www.washington.edu/research/hsd/guidance/international-research/)and the section on “translation”below. |
| **3.12 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 new or modified translated consent forms for greater than minimal risk studies. Review **SOP Consent** for procedural details. |
| **3.13 Consent.****General considerations.** Use **SOP Consent**, **GUIDANCE Consent**, **GUIDANCE Designing the Consent Process**,and **WORKSHEET Consent Requirements and Waivers** to assess consent requirements related to the modification. The **WORKSHEET Consent Review for IRB Members** provides a summary of the main topics on 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).  |
| **3.14 Waivers**. 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.**WORKSHEET Consent Requirements and Waivers**, **WORKSHEET Children**, **GUIDANCE HIPAA**, **CHECKLIST Waiver or Alteration of HIPAA Authorization**, **GUIDANCE Designing the Consent Process** **Note – t**he Office for Civil Rights oversees HIPAA regulations. |
| **3.15 Destruction of identifiers.** Verify that any changes to the application (including consent forms) do not indicate that identifiers and links between identifiers and codes 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.  |
| **3.16 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.  |
|  | **3.16a** 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/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.” |
| **3.16b** 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/SRA so that they can begin the certification process as described in the **SOP**. Modifications that add a prisoner population and that include interaction/intervention/direct observations of prisoners must be reviewed by the convened IRB, with the participation of a prisoner advocate. Modifications to procedures involving prisoner populations may be reviewed by the expedited process if: 1) there is no interaction, intervention, or direct observation of prisoners; or 2) the convened IRB has determined that the study is no greater than minimal risk (using prisoner definition of minimal risk) and may be reviewed by the expedited process; or 3) the modification is a minor change that does not change the IRB’s assessment of the prisoner-related criteria for approval and that (for Subpart C-regulated research) does not change the category of permissible research. |
| **+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 modifications to 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. |
| **3.16c** 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.Review the two sections on fetal tissue below if the research includes collection/use of fetal tissue.  |
| **3.16d** 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. |
| **3.16e** Transplantation of fetal tissue. (**CHECKLIST Transplantation of Fetal Tissue**) UW research involving this procedure is very 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.f** Use of human fetal tissue (HFT) from elective abortions.(**WORKSHEET Consent Requirements and Waivers; GUIDANCE Designing the Consent Process**)This type of research requires specific language in the consent form. The requirements come from an NIH policy but UW Policy requires that the consent language be included in the consent form for all research involving HFT from elective abortions which is approved on or after 9/25/2019. UW research involving this type of tissue is rare. If a specific study appears to involve this procedure, you and your TOL/SRA will need to consult with the HSD Director.  |
| **3.17 Specific federal agency requirements and/or approval criteria**. Identify requirements and determinations that are specific to federal agencies who are involved in the modification. 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. |
|  | **3.17a** FDA and the IDE requirement.If the FDA regulated modification involves the adding 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 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**) |
|  | **3.17b** FDA device risk determination. If the FDA regulated modification requires a device risk determination, verify that the modification provides sufficient information for the determination. In most cases the researcher 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 Guidance**; **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 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 |

 |
| **3.17c** FDA and the IND requirement. If the FDA regulated modification adds a drug that 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 modification 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.**The researchers should upload the **SUPPLEMENT Drugs, Biologics, Botanicals, Supplements** and the Investigator Brochure(s) and/or Package Insert(s) for the investigational drug(s). (**SOP FDA Regulated Research**; **WEBPAGE FDA Regulated Research Guidance**; **WORKSHEET FDA Drugs and the IND Requirement**) |
| **3.17d** Humanitarian Use Device. If the proposed modification 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 HUDs that are currently approved for clinical use at UW, review [this webpage](https://www.washington.edu/research/hsd/guidance/hud/approved-huds/).
 |
| **3.17e** Department of Defense. Verify that the modification includes the **SUPPLEMENT Department of Defense**. Use the **WORKSHEET Department of Defense** to ensure that the researchers and the IRB meet the relevant DoD requirements. This may include requirements related to 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 the 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.  |
| **3.17f** Department of Justice. Verify that the modification 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**; **WORKSHEET Department of Justice**). If you do not have experience reviewing 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 they 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 than those of the CoC.  |
| **3.17g** Environmental Protection Agency.Verify that the modification 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**) |
| **3.17h** Department of Energy.Verify that the modification 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**)  |
| **3.18 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 new federal funding (**GUIDANCE CoC** for limited exceptions to NIH auto-CoC policy);
* Hasn’t been automatically granted but is being requested by the researcher in connection with this modification; or
* Hasn’t been automatically granted and the researcher hasn’t mentioned obtaining one, but the IRB should be advised to require one in connection with this modification.

**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 the **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. |
| **3.19 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 the **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.
 |
| **3.20 Reliance Agreements**. Applications that engage non-UW institutions or individuals are initially assessed by Team S and the Reliance Team 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. |
| **3.21 Participants at Risk for Suicide.** If the modification is adding: (1) procedures screening for suicide risk; (2) instruments or procedures that ask about suicide; and/or (3) participant groups 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 needed. |
| **3.222 Return of results to subjects.** If the modification proposes to return individual results to subjects, or if the modification suggests that the study might now result in clinically actionable urgent information, the designated reviewer or the full board use **GUIDANCE Return of Results** to review the researcher plan as described in the IRB Protocol.  |
| **3.23 Reassessing the requirement for continuing review and duration of approval period.** * If the modification is adding a dataset of 10,000 records or more, consider whether the study is currently undergoing continuing review and if not, whether it should be required, 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.
* If a modification to a study reviewed under the Original Common Rule adds federal support, the approval period will need to be changed. Refer to **Changing Approval Period When Adding Federal Funding** in **INSTRUCTIONS Zipline for Staff**.
 |
| **3.24 Other regulatory approvals required before IRB approval**. Identify whether any are 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 the modification requires 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 |  |

 |
| **3.22b** Financial Conflict of Interest.Identify whether the researcher has identified a Financial Conflict of Interest for any member of the research team, as part of the modification. (**SOP Financial Conflict of Interest**)If there is a conflict, determine whether the FCoI Management Plan [a letter] has been provided with the modification. If there is an 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, it is usually appropriate to consider whether subjects should be re-consented if the modification involves new procedures, time commitments, risks, etc.  |
| **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, CR and Mod** 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, CR and Mod

|  |  |  |
| --- | --- | --- |
| **Version Number** | **Revision Date** | **Summary of Changes** |
| 4.8 | 09.25.2025 | Added major IRB protocol changes, updated information about School of Medicine AI review |
| 4.7 | 06.26.2025 | Added major IRB protocol changes  |
| 4.6 | 01.30.2025 | Add table listing significant IRB Protocol updates |
| 4.5 | 10.31.2024 | Add guidance for granting HIPAA waivers for UW PHI for NHS or NED applications |
| 4.4 | 09.26.2024 | Add references to new suicide risk suite of materials |
| 4.3 | 08.31.2023 | Revise UW Medicine policy on using eCare/MyChart for research recruitment; update references to revised FDA suite |
| 4.2 | 07.27.2023 | Remove reference to retired SOP LIRB and WORKSHEET Identifying the Applicable Regulations; revise instructions for FDA question in Study Scope SmartForm |
| Previous versions |  | For older versions: HSD Staff – refer to the SharePoint Document Library; Others - contact hsdinfo@uw.edu |

**Keywords:** Modification; Pre-review