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

**PURPOSE**

This worksheet provides support for HSD staff conducting pre-review of continuing review 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 continuing review 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 continuing review and then evaluate it using this worksheet. Issues are usually 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**

This section addresses these issues:

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

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| **1.1 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 Team Operations Lead (TOL) or Senior Reliance Administrator (SRA) and re-assign the item to another member of the team (See **SOP Reviewer Conflict of Interest**). |
| **1.2 Eligibility for closure**. Determine whether the research requires continuing review or whether it can be closed. (See **SOP IRB Review**) In general, the study can be closed if all of these criteria are met:* Research-related interactions and interventions with human subjects are complete.
* All collection of identifiable specimens or data has been completed.
* Analyses of identifiable private information/biospecimens described in the IRB application are complete.

In ZIPLINE, the criteria for closure are considered to be met when the top four research milestones listed on the Continuing Review SmartForm have been met. Request clarification from the researcher if other information in the submission indicates the milestones have been incorrectly checked.**If the study is eligible for closure, review the sections on *Data and Safety Monitoring*, *New Information*, and *Institutions Relying on UW Review* in this Worksheet. All other sections may be skipped.****NOTE: a study should not be closed if there are unresolved RNIs.**  |
|  **1.3 Expiration of IRB approval and urgency of review**. If IRB approval has already expired, see **SOP IRB Review and SOP Administrative Actions** for details. The researcher will likely already have received a notice that approval is lapsed and all human subjects activities must cease except those activities meeting very specific criteria described in the **SOP IRB Review**. If IRB approval is so close to expiration that continuing review cannot be completed before expiration, inform the researcher that all research involving human subjects must stop upon expiration, except those activities that meet very specific criteria described in the **SOP IRB Review**. Make it a top priority to do the review.  |
| **1.4 Version of Status Report form**. The most recent versions of the status report forms should be used however, HSD staff may use their discretion to determine whether the version submitted by the researcher provides adequate information for the continuing review of the study.  |
| **1.5 Completeness of answers**. Verify that all required questions have been answered. (Answers indicating “none” or “not applicable” are acceptable.) The pre-reviewer uses judgement to assess whether the answers provide sufficient information to fully understand the study status and any new information about risks, consenting, and the experience of the subjects. |
| **+ Guidance**Would the missing answers provide information relevant to the criteria for determinations and/or IRB approval?Will the next person looking at the application understand the status of the study at this point and understand what is being approved? |
| **1.6 Completeness of materials**. Verify that all required materials have been provided. Obtain missing items from the researcher.Generally, this is just the status report, but other items may be provided. Some of those other items may be more appropriately submitted as an RNI including data and safety monitoring reports (see Section 2) and any other materials that contain information that meets reporting requirements in the [Reporting Table](https://www.washington.edu/research/hsd/study-activities/report-events-and-new-information/guide-to-reporting-new-information/).  |
| **1.7 Consistency of application**. The information provided in the application is internally consistent across all parts of the application, and with information in the last Continuing Review.  |

**Section 2: Issues to Clarify Before Review (as needed)**

The purpose of this section is to address issues that should be clarified (i.e., additional information obtained) before the review is conducted.

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| **2.1 Delayed Onset Human Research (DOHR).** When reviewing a request for renewal of DOHR status, the TOL or a Sr. Administrator 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**TOLs are responsible for tracking expiring DOHR determinations using an automated report that is delivered to their email. One month ahead of expiration, the TOL or Sr. Administrator uses the **Add Comment** activity to provide the following notice (or something similar):DOHR status for this project will expire on XX/XX/XXXX. If DOHR status is no longer required because you have obtained IRB approval or an exempt determination for this project, please confirm that is the case using the **Add Comment** activity and HSD will administratively close this application. If the Sponsor requires renewal of DOHR status for continued access to funding, use the Instructions in the **APPLICATION Determination, Delayed Onset Human Research** to submit a renewal request. |
| **2.2 Data and Safety Monitoring**. *Assess this even if the study is eligible for closure*.If the study has external monitoring (as described in a Data and Safety Monitoring Plan), identify whether any monitoring reports have been submitted to HSD during the current approval period. * A description of external monitoring is most likely to be found in the DSMP question in the IRB Protocol, in a Study Protocol, and/or in a stand-alone monitoring plan.
* If there is monitoring, check previous RNI submissions for the study to determine whether a report has been submitted according to the reporting schedule described in the DSMP.
* *If there is monitoring and a report for the current period has not been submitted*, ask the research to confirm that no reports have been issued or to provide a copy of issued reports as an RNI submission. Contact hsdreprt@uw.edu to inform them of the situation so the Regulatory Affairs Team can assess the matter for researcher noncompliance. The continuing review should not be approved until the pre-reviewer confirms the RNI has been submitted.
* When reviewing a report in conjunction with a continuing review, consider whether it affects the appropriateness of expedited review for the application or the appropriateness of closing the study (if requested by the researcher).
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| **2.3 New information**. *Assess this even if the study is eligible for closure.* If there is new information in the Continuing Review application that suggests an **increased risk, decreased benefits, or that the study may no longer meet the applicable criteria for approval, or that alters prior determinations,** obtain more information, as necessary, from the researcher. Consult with a TOL/SRA, the Regulatory Affairs Team, or a member of HSD Leadership about the possibility that the new information indicates noncompliance or an unanticipated problem that the researcher needs to report. (See [Reporting Table](https://www.washington.edu/research/hsd/study-activities/report-events-and-new-information/guide-to-reporting-new-information/)) |
| **2.4 Subject numbers**. *This applies only to studies involving more than minimal risk or studies where the IRB approved a specific number of subjects before continuing review instead of a fixed approval period.* Identify whether over-enrollment has occurred or is likely to occur during the coming year. You may need to ask the researcher about the number of withdrawals, so that those can be subtracted from the total number of enrollments. * If over-enrollment is likely during the coming year, bring this to the attention of the researcher and include it in the Pre-Review Note.
* If over-enrollment has occurred, inform the Regulatory Affairs team. The RA team will provide you guidance on how this may (or may not) intersect with the continuing review.
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| **2.5 Funding**. If a funding source is listed that has not already been approved by the IRB, ask the researcher to submit a modification to add the funding to the study. If a funding source has expired, ask the researcher to submit a modification to remove the funding. This does not delay the continuing review or its approval.  |
| **2.6 Financial Conflict of Interest**. If there is a new Financial Conflict of Interest (FCOI), a Management letter must be provided and reviewed by the IRB with the Status Report before approval can be granted.  |

**Section 3: Regulatory and Compliance Issues Affecting the Review**

The purpose of this section is to identify the regulatory and compliance issues that influence the nature of the review and what conditions must be fulfilled in order to obtain approval.

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| **3.1 Applicable regulations.** Identify the applicable laws and regulations that the UW is required to apply to this study. It is especially important to determine which version of the Common Rule should be applied to this review. * In Zipline, “Regulatory Authority” is listed at the top of the CR Workspace and under “Regulatory Oversight” in the **Reviews** tab. Possibilities include:
	+ Pre-2018 Requirements; 2018 Requirements; 2018 Requirements + FDA; 2018 Requirements + DOJ; 2018 Requirements + FDA + DOJ.
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| **3.2 Level of review.** Determine whether the item qualifies for expedited IRB review and, if yes, in which category(s). This should include the evaluation of any new information relevant to risks and benefits that is provided (such as a DSMB report) – to assist in determining whether the research involves minimal risk (**SOP IRB Review**; **WORKSHEET Expedited Review**). |
| **+ Guidance**There are some restrictions on the use of expedited review when the research involves prisoners. See **WORKSHEET Expedited Review**. |
| **3.3 Nursing research**. (*Applies only to full board reviews*) If the PI meets one of the criteria below, consult with a TOL, SRA, or a member of HSD Leadership to arrange for a nurse IRB member to be present for the review. This is a requirement because of the 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
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| **+ 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.
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| **3.4 EFIC research and requirement for physician IRB member.** If the research involves the Emergency Exception to Informed Consent (EFIC), a licensed physician who is a member or consultant to the IRB and who is not otherwise participating in the study must be a part of the IRB’s review or provide concurrence with the IRB’s review.EFIC studies are designated in Staff Data Entry in Zipline. If you are not familiar with EFIC research you will need to be trained; check with your supervisor. |
| **3.5 Clinical Trials registration**. Status Reports for clinical trials cannot be fully approved if the UW PI is required to register the study at ClinicalTrials.gov and registration is not complete. * Look at the **CTgov Data Entry** to determine whether: 1) the study is a clinical trial that must be registered, 2) the UW is responsible for monitoring registration and results reporting; and 3) whether the study has been registered.
* If the study has been registered, you are done with this pre-review item.
* If the study has **not** been registered, look at the “History” tab for a comment to see whether the PI has been notified that registration is required before continuing review can be completed.
	+ If there is a comment, the review can begin but cannot be completed until the study is registered. If there is no comment, contact hsdreprt@uw.edu for guidance. A MRSA can be used if the approval will expire before registration is completed. If the registration deadline has passed, inform the RA team that the PI should be placed on the Red Flag list and all IRB review should stop.
	+ When the PI confirms registration is complete and provides the NCT registration number, inform hsdreprt@uw.edu and you are done with this pre-review item.
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| **3.6 Certificate of Confidentiality, Privacy Certificate**. For studies with a Certificate of Confidentiality or a Privacy Certificate, determine whether the Certificate has expired or will expire in the coming year. Automatic-CoCs expire on the same date as the federal funding expires. CoCs issued via the NIH application process *on or after 1/12/21* expire when the study is complete and will have 1/2/3456 as the expiration date in Staff Data Entry. The expiration date for CoCs granted via the NIH application process *prior to 1/12/21* is printed on the Certificate. (See **GUIDANCE Certificate of Confidentiality**)* If the Certificate will expire determine whether a Certificate is required for the study to meet the Criteria for Approval (see **Staff Data Entry**). If it is required, inform the researcher that an extension must be requested (unless the research will be completed before the expiration date). Conditional Approval can be granted until the extension has been received. If it is not required, the researchers may opt to extend the Certificate or remove the CoC language from the consent forms.
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| **3.7 Radiation Safety**. If Radiation Safety approval is required for the study, determine whether a current UW or Fred Hutch Human Subjects Radiation Approval Committee (HSRAC) approval is on file (i.e., that the approval has not expired; they are good for one year) (see **Upload** **Shared Regulatory Documents**)* If HSRAC approval is required and it has expired, remind the researcher that current Radiation Safety approval is required. Conditional approval may be granted with the condition that current radiation approval must be obtained.
* If the exposure occurs at a non-UW or non-Fred Hutch facility, check with a TOL, SRA, or member of HSD leadership for guidance.
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| **3.8 Institutions relying on UW review.**  *This should be completed even if the study is eligible for closure.* View staff data entry questions 9 and 10 and the Sites tab (if there is one) in the study application to identify whether there are any non-UW institutions or individuals actively relying on the UW IRB’s review. If there are: * Information in the SmartForms and the **APPLICATION Status Report, Renew or Close** should reflect any information applicable to all institutions and individuals relying on the UW IRB’s review.
* The Huron product upon which Zipline is based contains functionality which is designed to allow the study team to compile information from relying sites reported to them into one report for the IRB. HSD does **not** use this functionality because the necessary technological components are not installed. You can ignore any information that appears due to this functionality (this looks like “(Confirmed sites: 0 of 1. Total enrollment for pSites with completed reports: 0),” and any information about site reports which appears on the Sites tab.
* The continuing review approval letter automatically lists any active relying sites which are in the Sites tab. You should double check that this section is accurate in the letter. If processing a MODCR, include the names of the active relying sites from the Sites tab in the letter. You do **not** need to manually add any institutions or individuals who are not in the Sites tab but who are listed in the staff data entry questions.
* If closing the application in Zipline, any active relying sites in the Sites tab must be closed prior to closing the overall application. **See INSTRUCTIONS Zipline for Staff**, Part VI: Study Closure, for specific instructions. No additional site-specific information is required for this step.
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| **3.10 Need for expiration date and future continuing review**. Determine whether the research requires continuing review in the future (i.e., is an expiration date necessary). This is determined by which version of the Common Rule applies to the study and by whether it meets the revised Common Rule criteria for no continuing review. (See **WORKSHEET Primary Reviewer, Continuing Review and Modification**)* Original Common Rule: An expiration date and future continuing review is required.
* Revised Common Rule: An expiration date and future continuing review may or may not be required.

When an expedited continuing review application does require continuing review, Zipline will require you to enter a justification for why you’ve entered an expiration date (e.g., “This study was approved under expedited category 9 and UW policy requires that it undergo continuing review.”). *Note that FDA- and DOJ-supported research and research that includes prisoner populations require continuing review to occur in intervals of no less than one year.* |
| **3.11 Complete the pre-review process.** If the continuing review must be conducted by the full board, prepare the **Pre-Review Note** that is provided to the IRB. (See **SOP Pre-Review**; **GUIDANCE Pre-Review**; **INSTRUCTIONS Zipline for Staff**)If the pre-reviewer will also serve as the designated reviewer, see **WORKSHEET Primary Reviewer, CR and Mod** for support in identifying IRB review considerations.  |

**RELATED MATERIALS**

* INSTRUCTIONS Zipline for Staff
* GUIDANCE Pre-Review
* SOP Pre-Review
* TEMPLATE Pre-Review Letter
* WORKSHEET Primary Reviewer, CR and Mod

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|  **Version Number** | **Posted Date** | **Implementation Date** |
| 3.0 | 02.27.2025 | Update ct.gov section regarding registration deadlines, MRSA, and expiration of approval |
| 2.9 | 01.30.2025 | Add note that expired funding should be removed with a modification |
| 2.8 | 12.23.2024 | Clarify that confirmation of radiation safety approval is only required for studies with UW or Fred Hutch HSRAC approval |
| 2.7 | 03.02.2023 | Add information about reviewing when institutions are relying on UW’s review  |
| 2.6 | 10.27.2022 | Clarify NIH CoC expiration date information |
| Older versions |  | For older versions: HSD Staff – refer to the SharePoint Document Library; Others - contact hsdinfo@uw.edu. |

**Keywords:** Closure; Continuing review; Pre-review