| University of Washington Human Subjects DIvision |  | **SOP Pre-Review** |
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**1 PURPOSE**

This document describes the process by which Human Subjects Division (HSD) staff conduct pre-review of:

* Initial applications for UW IRB review
* Modification applications
* Continuing Review or Status Report applications
* Responses to conditional approval (MRSA) letters or deferral letters

**2 CONTEXT**

2.1 **Rationale**. Pre-review is the initial assessment of an application. The purpose of pre-review is to:

* Ensure that the application is eligible for review by HSD or the UW IRB
* Identify the applicable regulations
* Determine whether the application requires IRB review
* Identify the type of review that is required and appropriate
* Promote compliance, consistency, and efficiency of HSD and IRB reviews
* For researcher responses: Ensure that responses do not change previous pre-review assessments
* Provide the IRBs with assurance that (1) applicable regulatory requirements and determinations have been identified, and (2) the provided materials and information are ready for review
* Allow the IRB to focus on the criteria for approval, ethical principles, and required determinations

2.2 **Required**. Pre-review is required. However, it may be abbreviated when IRB review is urgently required. In such cases, staff are expected to conduct the pre-review assessment at the same time as the IRB does its review, to ensure that no regulatory requirements and determinations are overlooked or undocumented.

2.3 **Who does pre-review**. Pre-review is generally conducted by the HSD staff person assigned to the application at initial intake. However, any of the following HSD staff may perform the pre-review: members of the IRB support teams; members of the HSD management team; any other HSD staff who have significant experience at HSD with shepherding initial IRB applications through the review process.

2.4 **Relationship with expedited review**. Pre-review evaluates the eligibility of initial, modification, and continuing review applications for expedited review. If an application is eligible, the pre-reviewer may combine the pre-review and the expedited review processes (that is, perform both) – if and only if the pre-reviewer is an IRB member authorized to conduct expedited review and has the expertise to conduct the review.

**3 PROCEDURES**

3.1 **Conflict of interest**. Staff do not perform pre-review of an application when they have a conflict of interest with respect to the application being pre-reviewed (**SOP Reviewer Conflict of Interest**).

3.2 **Doing the pre-review**

3.2.1 Read and evaluate the provided information, using the appropriate Worksheet and taking any actions specified by the Worksheet.

* **WORKSHEET Pre-review, Initial**
* **WORKSHEET Pre-review, Modification**
* **WORKSHEET Pre-review, Continuing Review**

3.2.2 Communicate with the researcher and primary contact person as needed to obtain clarification or additional information and materials.

* *Communication to the researcher.* This should almost always be done within Zipline, using the activity **Request Pre-Review Clarification**. Questions and requests can be sent in the activity text box or as an attached Pre-review Letter. Refer to **GUIDANCE Pre-Review** for more detailed information about communicating with researchers and composing review correspondence.

*Researcher response*. All clarifications and new information must be documented as (1) uploaded response letters, other materials, or Comments and/or (2) edits to the application materials and SmartForms.

3.3 **Relationship with expedited review**. The pre-review assessment may indicate that the study requires IRB review and that it qualifies for expedited review. In these cases, the pre-reviewer almost always combines the expedited review with the pre-review, if the pre-reviewer is an IRB member with appropriate expertise. This is assumed in this document. The IRB member conducting the expedited review should use the appropriate Worksheet listed below.

* **WORKSHEET Primary Reviewer Initial Application**
* **WORKSHEET Primary Reviewer CR and Mod**

3.4 **Documenting the pre-review outcomes**

3.4.1 Initial applications. Use the Zipline activity **Submit Pre-review**. This activity interacts with several other Zipline activities. See [**INSTRUCTIONS Zipline for Staff**](https://www.washington.edu/research/forms-and-templates/instructions-zipline-for-staff/), for details about how to submit the pre-review for each type of outcome (i.e., Not Research, Not Human Subjects, Not Engaged, decision that expedited review is required, decision that full board review is required).

3.4.2 All other applications.

* The Submit Pre-review SmartForm is pre-populated for these applications. It is read-only for Continuing Review applications and for Study Team Modifications.
* Follow the appropriate sections of the **INSTRUCTIONS Submit Expedited Review** or **INSTRUCTIONS Submit Pre-Review** (for Full Board Items).
* If the pre-review indicates that the information in the existing Submit Pre-review SmartForm is no longer accurate, follow the **INSTRUCTIONS Edit Pre-Review** to document the changes.

3.5 **Pre-Review Note (or Memo)**

3.5.1 Purpose

* Identify for the IRB the regulatory determinations that must be made (e.g., meeting the criteria for approval, determining the approval period, granting a waiver of consent)
* Provide a brief overview of the study, to frame the IRB members’ reading of the application
* Draw to the IRB’s attention any issues likely to require discussion or to be controverted

3.5.2 Content

* IRB meeting date
* Zipline # and/or DORA #
* Type of item (for example, initial application)
* PI name
* Long application title
* Brief summary of the study (subject populations, study groups, procedures, purpose)
* List of regulatory considerations and determinations that must be made
* Other issues that may be of particular interest to the IRB (e.g. possible consent form revisions, issues that might require Conditional Approval such as confirmation of ancillary review approvals or receipt of a Certificate of Confidentiality).

3.6 **Changing a pre-review assessment**. See the **INSTRUCTIONS Edit Pre-review**.

**4 RELATED MATERIALS**

GUIDANCE Pre-Review

[INSTRUCTIONS Zipline for Staff](https://www.washington.edu/research/hsd/training/zipline-online-help-library/hsd-staff-guide/)

[SOP Reviewer Conflict of Interest](https://www.washington.edu/research/policies/sop-reviewer-conflict-of-interest/)

WORKSHEET Pre-Review, Continuing Review

WORKSHEET Pre-Review, Initial Applications

WORKSHEET Pre-Review, Modifications

WORKSHEET Primary Reviewer, Initial Application

WORKSHEET Primary Reviewer, CR and Mod

**5 REGULATORY REFERENCES**

None

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| **Version Number** | **Posted Date** | **Implementation Date** | **Summary of Changes** |
| 1.2 | 05/27/2021 | 05/27/2021 | Remove references to paper process; update links; transfer to current document template |
| 1.1 | 01/03/2020 | 01/03/2020 | Revised to reference the new document GUIDANCE Pre-Review |
| 1.0 | 08/31/2018 | 08/31/2018 | Document newly implemented |

**Key Words:** Pre-review