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| University of Washington Human Subjects DIvision | **SOP IRB Member Standards** **and Responsibilities**  |

**1 PURPOSE and APPLICABILITY**

 Members of the IRB provide an invaluable service to the UW research community and to the volunteer participants in UW research. IRB members have an obligation to maintain the highest standards of judgement relative to their duties as members. This document provides an overview of IRB member standards and responsibilities.

**2 PROCEDURES**

2.1 **Attendance.** Voting members of the IRB establish the IRB quorum. Full-time members are those who attend at least 70% of convened meetings annually. Less than 70% attendance is considered part-time.

Unless sharing a position or other specified arrangement, all members are generally expected to attend at least 50% of convened meetings. Voting members are expected to arrive promptly and to stay at a convened meeting until all IRB business has been completed, whenever possible. The expected duration of meetings is 2 hours maximum, but many meetings are significantly shorter. IRB member meeting availability is requested by the IRB’s Team Lead several months in advance and members are expected to keep their availability current. When availability for any given meeting changes, IRB members must notify the Team Lead with sufficient time in advance of meeting to identify an alternate member and ensure the presence of a quorum and requisite expertise.

2.2 **Conflict of interest disclosure.** All potential conflicts of interest must be disclosed by IRB members. See **SOP Reviewer Conflict of Interest** for detailed information about how member conflict of interest is defined, disclosed, and managed.

2.3 **Meeting preparation, review of materials and in-meeting procedures.**

 **Preparation.** All members attending an IRB meeting are expected to be familiar with all items on the agenda. Members are expected to systematically evaluate each item according to: (1) the three ethical principles outlined in the Belmont Report; (2) the applicable criteria for IRB approval; (3) UW policies and procedures as provided on the UW website; and (4) other requirements as listed on UW IRB checklists and worksheets. These criteria and requirements are provided to each IRB member, posted on the HSD website, and are made available prior to and at the IRB meetings in the **Pre-Review Note** provided by HSD staff for each item on the agenda.

 **Primary reviewer.** The IRB member with the most appropriate expertise for reviewing a specific item is assigned to the role of primary reviewer. The primary reviewer:

* May contact the researcher to obtain additional information that will be helpful to the review. The reviewer must work with HSD staff to ensure that any information gathered from the researcher is disclosed at the IRB meeting and documented in the IRB record.
* Provides a brief summary of the item to the IRB at the meeting.
* Leads a discussion of the criteria for approval with respect to the item, including the identification of any concerns.
* Usually makes the first motion proposing specific IRB actions.
* May assist in writing or reviewing the correspondence to the researcher which communicates the IRB’s decisions, requirements, and questions.
* May assist in verifying that the researcher’s responses to a Conditional Approval decision by the IRB satisfactorily meet the IRB’s conditions.

**Secondary reviewer.** The secondary reviewer is an IRB member who fulfills the same responsibilities as the primary reviewer on a given item, is available for backup purposes, and is chosen to ensure appropriate balance of scientific and/or nonscientific expertise for the item.

 **Convened meeting procedures** are described in the **SOP Convened IRB Meetings**, including the additional in-meeting responsibilities for the IRB Chair/Vice Chair.

 2.4 **Conduct and confidentiality.** IRB members are expected to behave according to professional standards of courtesy and respect in discussions with each other and about researchers. IRB members review documents that may contain personal, confidential and proprietary information. Members are responsible for maintaining all IRB proceedings and documents in strict confidence within the limits of applicable state and federal laws. Such information may not be used for any purpose other than the IRB review and may not be disclosed to anyone outside of the IRB, HSD, and the Office of Research except as allowed by law.

 2.5 **Knowledge and adherence to federal regulations and UW policies and procedures.** HSD staff participate in all IRB meetings to provide regulatory guidance and expertise and provide a Pre-Review Note for each agenda item. IRB members should feel free to draw upon that expertise during a review. However, IRB members are expected to have an adequate working knowledge of, and adherence to applicable regulations, ethical principles and UW policies and procedures. Therefore, IRB members are expected to:

* Participate in initial orientation and training.
* Participate in ongoing training as provided at regular IRB meetings.
* Understand the three basic principles of the Belmont Report (respect for persons; beneficence; justice).
* Use or have a working knowledge of the **WORKSHEET Criteria for IRB Approval** and use the resources provided by HSD in the **Pre-Review Note** for each agenda item.
* Be familiar with the HSD website.
* Read communications from HSD, including the regularly published e-Newsletter.
* Participate, as interest and time allows, in training opportunities outside of the IRB meetings.

 2.5 **Consultation service.** IRB members may be asked to provide consultation for HSD staff on a specific item for any of the UW IRBs and are expected to do so whenever possible. This does not typically require attendance at an IRB meeting, review of an entire protocol, or even a written review. IRBs and HSD staff are respectful of IRB members’ time and will ask for consultation only when necessary. See **SOP IRB Consultants** for more information.

 2.6 **Mentorship of new members.** Newly recruited IRB members shadow an experienced member as part of the onboarding process (**SOP IRB Members**). Generally, the Chair serves in this role but mentorship may be undertaken by any experienced member of the IRB. This mentorship includes making sure the new member’s concerns and questions are based in the IRB criteria for approval and helping the new member understand how to use the primary reviewer tools.

 2.7 **The IRB Chair** has additional responsibilities including:

* Leading IRB meetings as described in **SOP Convened IRB Meetings**
* Participating in the Chair Council
* Expected to provide significant consultation on Reports of New Information and expedited review submissions.
* Assisting with the periodic assessment of IRB members
* Providing ongoing guidance and mentorship to new and established members
* Reviewing single patient emergency and non-emergency use of investigational drugs/biologics/devices

2.8 The IRB Vice-Chair provides immediate back-up to the IRB Chair when they are unavailable. Their responsibilities include:

* Lead IRB meetings in the absence of the IRB Chair
* Participate in the Chair Council
* Expected to provide significant consultation on Reports of New Information and expedited review submissions.
* Providing ongoing guidance and mentorship to new and established members
* Reviewing single patient emergency and non-emergency use of investigational drugs/biologics/devices.

2.9 **Expedited and limited IRB reviews.** IRB members who have delegated authority from an IRB Chair to conduct limited IRB reviews and reviews using the expedited process are expected to demonstrate a thorough understanding of human subjects regulations and ethical issues. Their communications with researchers must be clear, concise, and as free as possible of regulatory jargon.

**3 RELATED MATERIALS**

 [SOP Convened IRB Meetings](https://www.washington.edu/research/policies/sop-convened-irb-meetings/)

 [SOP IRB Consultants](https://www.washington.edu/research/policies/sop-irb-consultants/)

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

 [WORKSHEET Criteria for IRB Approval](https://www.washington.edu/research/forms-and-templates/worksheet-criteria-for-irb-approval/)

**4 REGULATORY REFERENCES**

 None

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| **Version Number** | **Posted Date** | **Implementation Date** | **Summary of Changes** |
| 2.4 | 06.26.2025 | 06.26.2025 | Add review of single patient non-emergency use of investigational drugs/biologics/devices as a responsibility of the IRB Chair and IRB Vice-Chair |
| 2.3 | 02.01.2024 | 02.01.2024 | Add role of Vice Chair |
| 2.2 | 06.01.2023 | 06.01.2023 | Clarify attendance requirements, remove optional secondary reviewer component; other minor modifications |
| 2.1 | 02/25/2021 | 02/25/2021 | New information about expedited & limited IRB review  |
| 2.0 | 12/09/2020 | 12/09/2020 | Significant reorganization of, and minor updates to content |
| 1.2 | 05/26/2017 | 05/26/2017 | Updated links |
| Previous versions |  |  | For older versions: HSD staff refer to the SharePoint Document Library; Others – contact hsdinfo@uw.edu. |

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