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| University of Washington Human Subjects DIvision | **SOP IRB Members**  |

**1 PURPOSE and APPLICABILITY**

This document describes the policies and procedures for selecting, appointing, training, and evaluating members of the UW Institutional Review Boards (IRBs), including those who conduct expedited reviews and limited IRB reviews.

**2 POLICY**

**This policy applies to all IRB members, including any Human Subjects Division (HSD) staff who are appointed as IRB members to a University of Washington (UW) IRB.** HSD staff serve according to the same requirements, processes, and expectations as other IRB members (**SOP IRB Member Standards and Responsibilities**) unless otherwise indicated below.The IRB Director and members of the Regulatory Affairs team are prohibited from being appointed to the IRBs. The opportunity to serve as an IRB member is open to all eligible persons regardless of race, sex or other identity.

**3 PROCEDURES**

3.1 **IRB composition.** In accordance with federal and state regulations and UW policy, each UW IRB:

* Consists of at least five members. Overlapping membership between IRBs is permitted.
* Includes at least one [scientist member](#scientist).
* Includes at least one [nonscientist member](#scientist).
* Includes at least one member who is not otherwise [affiliated with the UW](#affiliation) and who is not part of the immediate family of a person who is affiliated with the UW.
* Is sufficiently qualified through the experience and expertise of its members, and the diversity of its members, including considerations of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of subjects.
	+ Participation of a consultant may be sought when the IRB has a need to supplement their expertise on a particular topic (**SOP IRB Consultants**).
	+ Every nondiscriminatory effort will be made to ensure that each IRB is gender inclusive and that qualified persons of any gender will be considered, so long as no selection is made on the basis of gender.
	+ No IRB may consist entirely of members of one profession.
* Is able to ascertain the acceptability of proposed research in terms of institutional commitments (policies and resources), and regulations, applicable law, and standards of professional conduct and practice, when these issues are appropriately part of the UW IRB’s roles and responsibilities.
* Includes one or more members who are knowledgeable about and experienced in working with protected or vulnerable populations (e.g., children, prisoners, pregnant women, mentally disabled persons) when reviewing research involving those populations. Alternatively, the IRB may draw upon an expert consultation for this purpose.

* Ensures compliance with the American Nursing Magnet program by requiring at least one nurse IRB member to votes on nursing-related protocols that are reviewed by the convened IRB.
* May include [alternate IRB members](#alternate) for primary members.

3.2 **Nomination, selection, and appointment.**

3.2.1 **Nomination.** IRB members and IRB Chairs/Vice Chairs may be nominated by various sources including HSD leadership or staff, existing IRB members, Associate/Vice Deans, Department Chairs, Division Chiefs, self-nomination, and other methods.

3.2.2 **Selection.** One or more members of HSD leadership evaluates each nomination for: expertise, training, and experience; membership classification (e.g., scientist/nonscientist; affiliated/unaffiliated); and fit to a specific IRB (e.g., need for nonscientist; expertise fits departments assigned to that IRB). A nomination may be respectfully declined, based on evaluation. In general, to be selected as an IRB Chair, a nominee must be an experienced IRB member.

3.2.3 **Appointment.** Accepted nominations are forwarded to the FWA Signatory Official (Institutional Official) for any additional review and for formal appointment. The nomination packet includes a copy of the nominee’s resume or curriculum vitae and a draft appointment letter for the official’s signature (**TEMPLATE Appointment Letters**; **POLICY Signatures and Attestations**). If the nominee is appointed, the signed letter is returned to HSD leadership for distribution to the new member and official IRB records.

3.2.4 **Delegation of IRB authority.** As allowed by federal regulations, a UW IRB chair may delegate the authority to a **designated reviewer** to conduct expedited IRB review (described in **SOP IRB Review**) and limited IRB Review (**Exempt Research Guidance**) of all qualifying IRB applications and to grant a waiver or alteration of HIPAA authorization.

* Designated reviewers are generally HSD staff members who are also IRB members and who have been provided with delegation of authority from an IRB Chair (**TEMPLATE Delegated IRB Authority Memorandum**) when they are deemed by a member of HSD leadership to be sufficiently trained and experienced.
* Delegation of authority ends automatically when an individual leaves HSD or is hired into an HSD position that is prohibited from being an IRB member. The delegated authority may also be temporarily or permanently suspended by HSD leadership, if necessary.

3.3 **Documentation of membership.**

3.3.1 **Federal IRB registration.** HSD leadership, usually the Associate Director of Operations (ADO), is responsible for filing and maintaining IRB registrations with OHRP. Per OHRP policy, the IRB registration, including the roster, must be renewed every three years. In addition, a roster update or renewal must be submitted to OHRP within 90 days after any changes occur regarding (1) the contact person who provides the IRB registration information or 2) an IRB Chair. Copies of the modified IRB registration and acknowledgement are retained by HSD as an official HSD record.

3.3.2 **IRB member qualifications and classification.** HSD leadership, usually the ADO, is responsible for obtaining and maintaining a record for each current IRB member who is not also a member of HSD staff, including: resume or curriculum vitae (collected at the time of initial appointment, and for any relevant updates solicited as part of the periodic evaluation) and Notes to File (as needed) concerning the member’s scientist/nonscientist status, affiliated/unaffiliated status, and other relevant information.

 HSD staff IRB member qualifications are initially assessed at the time of hire and reviewed annually as part of performance evaluations (refer to the **GUIDANCE Evaluation for IRB & Reliance Administrator** and **Senior IRB Administrator)**.

3.3.3 **IRB member roster.** HSD uses the **TEMPLATE IRB Roster** to develop and maintain IRB member rosters as official HSD records that include:

* A list of IRB members by name
* Earned degrees
* Scientist/nonscientist status
* Affiliated/unaffiliated status (if affiliated, includes a brief description of the nature of the affiliation)
* Protected population representative capacity (e.g., children, prisoners)
* Indications of experience such as board certifications, licenses, etc., sufficient to describe each member’s chief anticipated contributions to IRB discussions
* Status as a primary or alternate member and identification of primary members for whom each individual is an alternate

3.3.4 **Prisoner Advocates** are listed on the IRB membership roster and federal registrations as voting members but with the stipulation in the “Comments” section of the meeting minutes that the advocate will only count towards quorum when they are in attendance and reviewing prisoner research studies unless they have also been appointed as a standard IRB member.

3.3.5 **Designated reviewers**. The signed **Delegated IRB Authority Memorandum** is kept with the IRB rosters.

3.4 **Term of service.** IRB members and IRB Chair/Vice Chair appointments do not have an end date. These appointments remain in effect until the appointment is terminated by the Institutional Official. No annual reminder letter or other type of re-appointment letter is provided.

* **HSD staff.** HSD staff remain IRB members until they separate from HSD or move to an HSD position that is not eligible for IRB membership.

3.5 **Training and continuing education.**

 3.5.1 **New member onboarding.** Onboarding of new members is generally completed by the ADO or Team Operations Lead (TOL). New members must complete the HSD online tutorials on *Risk Assessment*, *The* *Criteria for Approval*, *Follow-on Submissions, Reviewing Informed Consent and the PAUSE Framework*. The new member is also provided with the following foundational tools: **WORKSHEET Primary Reviewer, Initial**; **WORKSHEET Primary Reviewer, Continuing Review and Modification; WORKSHEET Primary Reviewer, RNI.** Once tutorials are completed, the new member is added to the roster. The TOL and/or ADO identify an experienced reviewer, often the Chair, that the new member will shadow for approximately two meetings. Next, the new member is assigned as a secondary reviewer for approximately four meetings, using the Primary Reviewer Worksheets to prepare and receive guidance and feedback from the TOL, ADO, and/or Chair before during and after the reviews. The TOL and/or ADO determines that the member is ready to serve as a primary reviewer when their secondary reviews have demonstrated that they: 1) are familiar with the IRB application materials; 2) understand how to apply the IRB criteria for approval; and 3) know how to use the primary reviewer tools.

 3.5.2 **Continuing education.** IRB members are provided with continuing education in response to new or revised regulations or policy, the need for introduction to (or a refresher about) special topics (e.g., GDS certification, Zipline upgrades), requests for training from IRB members, or any other needs. Training is typically delivered at an IRB meeting by the ADO or TOL but may be delivered by other HSD staff members, IRB members, IRB Chairs or other individuals with expertise on a particular topic. In addition, IRB members may be invited to view topical webinars to which HSD subscribes from IRB professional organizations such as PRIM&R and AAHRPP. Finally, all IRB members are subscribed to the HSD eNewsletter which is published approximately once a month.

3.6 **Expectations.** All members are expected to adequately fulfill the responsibilities outlined in the document **IRB Member Standards and Responsibilities** and to manage conflicts of interest as described in the **SOP Reviewer Conflict of Interest**.

3.7 **IRB Member Evaluation Process.** At least one member of HSD leadership, relevant IRB TOL, and the IRB Chair will assess the IRB members and IRB Vice Chairs yearly as described below. Additionally, HSD leadership will annually assess IRB Chairs.

* + The membership and composition of each IRB is evaluated to ensure all regulatory and policy requirements are met. If requirements are not met, adjustments are made.
	+ Each IRB member and IRB Chair/Vice Chair is evaluated for acceptable adherence to the **SOP IRB Member Standards and Responsibilities** using the TEMPLATE IRB Member Evaluation. The evaluations are kept in the IRB member files. IRB members who are meeting expectations are sent a yearly email thanking them for their participation and for their adherence to the SOP IRB Member Standards and Responsibilities. When an IRB member is assessed as not adequately fulfilling standards and responsibilities, HSD leadership and/or the IRB chair will communicate the issues to the IRB member using the template as a guide. HSD leadership team, in consultation with the IRB Chair, will determine how to address the issue(s). Possibilities include: (1) development of new or better guidance about problematic issues; (2) provide the member with feedback and/or additional training; or (3) as a last resort, request appointment termination from the IO.

3.8 **Liability coverage.** The UW Compliance and Risk Services provides defense and indemnification with respect to claims resulting from the acts or omissions of University employees or agents when acting in the course and scope of University employment or agency, except where the individual acted or failed to act because of fraud, corruption, or actual malice. This applies to IRB members, including unaffiliated members. The HSD Director acts as the initial contact and communication go-between, as needed, for the IRB member(s) and UW Compliance and Risk Services.

3.9 **IRB membership and Zipline role**. The Zipline role of “IRB Member” (including listings on the Committee Member List and the Designated Reviewer List) is not an official record of who is on an IRB roster or who has received delegated authority from an IRB Chair to do expedited reviews.

* The Zipline IRB member role is assigned for training purposes to new staff in certain HSD positions, so that they can fully participate in supervised and mentored training activities.
* Close supervision during training, combined with the process for assigning responsibility to specific applications, ensures that these individuals do not use the IRB member role inappropriately.

**4 DEFINITIONS**

4.1 **UW Affiliation.** All IRB members are categorized as “affiliated” or “unaffiliated”. An employee, student, or agent of the UW or any components of UW Medicine is considered affiliated, as are members of their immediate family.

Affiliated IRB members may include, but are not limited to:

 Full-time or part-time employees; current students; members of any governing panel or board of the UW; paid or unpaid consultants to the UW; health care providers holding credentials to practice at UW Medicine; volunteers working at the UW on business unrelated to the IRB.

Unaffiliated IRB members have no affiliation with the UW, other than as an IRB member. Unaffiliated members may include individuals whose only association with the UW is that of a patient, subject, or former student at the UW. Paying unaffiliated members a reasonable market rate for their IRB services does not make them affiliated nor does it cause them to have a conflict of interest.

4.2 **Alternate IRB member.** Alternate IRB members may be designated for members of the IRB. Each alternate member must have experience, expertise, background, professional competence, and knowledge comparable to that of the primary IRB member whom the alternate would replace. Representatives of the same department may share a membership to represent scientific expertise. However, it is not required that the two members (primary, alternate) be in the same specific scientific discipline or healthcare specialty within the department. Scientists can be alternates for non-scientists, and vice versa, so long as they have comparable expertise and knowledge that they bring to the IRB. See **SOP Convened IRB Meetings** for the procedures by which an alternate member participates in an IRB meeting.

4.3 **Scientist vs. nonscientist IRB member.** All IRB members are categorized as “scientist” or “nonscientist”. The Food and Drug Administration (FDA) and the federal Office of Human Research Protections (OHRP) offer somewhat different guidance about defining these categories. In developing the definitions below, the UW drew up on the agencies’ stated intent of the distinction between “scientist” and “nonscientist” and upon the analysis and recommendations of a national advisory group appointed by OHRP. The definitions below are based on the following principles:

* The intent is to distinguish between IRB members who are included to view research primarily from the viewpoint of a scientist versus a non-scientist. The UW believes this approach is consistent with federal guidance about “primary concerns” but provides a more useful operational framework for classification.
* The UW allows reasonable flexibility in the interpretation of “inclined to view” or “primary concerns”.
* When the rational for the categorization is not apparent based on occupation or training, or is less well-defined but justifiable, HSD maintains written documentation of the reason for the categorization.
* The presence or absence of advanced professional or scientific training is not a required criterion for “scientist” or “nonscientist”. Instead, the totality of an individual’s background, professional, and personal experience is considered when categorizing them. For example, a long-time elementary school teacher may have obtained a PhD in Experimental Psychology but might be most appropriately classified as a nonscientist. In another example, an attorney specializing in biomedical regulatory affairs or intellectual property might be most appropriately classified as a scientist.
* Scientists are not limited to individuals who are behavioral and biomedical scientists. Scientists in other fields, such as geology or statistics, should be considered scientists for the purposes of IRB membership.
* The same criteria for “scientist” and “nonscientist” are applied to all members, regardless of whether they are reviewing biomedical or socio-behavioral research.
* Although biomedical health professionals are most likely to be appropriately classified as scientists, there may be extenuating circumstances that would make them more appropriately classified as nonscientists.

**Scientist.** Members will be considered “scientists” when the totality of their training, professional experience (type, duration) and personal experience would incline them to view scientific activities from the viewpoint of a scientist.

**Nonscientist.** Members will be considered “nonscientists” when the totality of their training, professional experience (type, duration) and personal experience would incline them to view scientific activities from the viewpoint of a nonscientist.

 4.4 **IRB Chair and Vice Chair**. The Chair is a voting member of the IRB and assumes all the responsibilities of an IRB member as well as oversight the IRB meetings to ensure reviews and approvals consider the relevant regulatory requirements, state laws and university and HSD policies. When the Chair is unable to attend or fully chair the IRB meeting, the Vice Chair (or another member acting as Chair Pro Tempore) may take over the chair responsibilities for conducting the meeting as outlined in the [**SOP**](https://www.washington.edu/research/policies/sop-irb-member-standards-and-responsibilities/) **Convened IRB Meetings**.

**5 RELATED MATERIALS**

POLICY Signatures and Attestations

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

[SOP IRB Consultants](https://www.washington.edu/research/policies/sop-irb-consultants-2/)

SOP IRB Membership Compensation

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

[SOP IRB Member Standards and Responsibilities](https://www.washington.edu/research/policies/sop-irb-member-standards-and-responsibilities/)

TEMPLATE IRB Roster

TEMPLATE Appointment Letter, Chair New

TEMPLATE Appointment Letter, Chair Renewal

TEMPLATE Appointment Letter, Member New

TEMPLATE Appointment Letter, Member Renewal

TEMPLATE Appointment Letter, PA [prisoner advocate]

TEMPLATE Delegated Authority IRB Memorandum

TEMPLATE IRB Member Evaluation

TUTORIAL Risk Assessment

TUTORIAL Criteria for Approval

[WEBPAGE Exempt Research Guidance – Limited IRB Review](https://www.washington.edu/research/hsd/guidance/exempt/lirb)

**6 REGULATORY REFERENCES**

 45 CFR 46.107 [pre-2018 and 2018 requirements]

 21 CFR 56.107

OHRP Guidance, “IRB Registration Process FAQs”, FAQ #12

 OHRP website, “Update/Renew the Registration of an Institutional Review Board (IRB) Previously Registered by an Institution or Organization (IORG); view date 5/1/2015

 FDA Information Sheet Guidance, “Institutional Review Boards Frequently Asked Questions”

 SACHRP Letter to the Secretary; January 24, 2011, Attachment B: Comment and Recommendation Regarding IRB Membership and Definition of Scientist and Non-scientist under 45 CFR 46 and 21 CFR 56

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|  **Version Number** | **Posted Date** | **Implementation Date** | **Summary of Changes** |
| 2.9 | 05.01.2025 | 05.01.2025 | Added statement that the opportunity to serve as an IRB member is open to all  |
| 2.8 | 09.26.2024 | 09.26.2024 | Add Informed Consent tutorial and PAUSE Framework to new member training requirements |
| 2.7 | 06.25.2024 | 06.25.2024 | Add details about IRB member evaluations |
| 2.6 | 02.01.2024 | 02.01.2024 | Inclusion of IRB Chair definition and Vice Chair role |
| 2.5 | 07.27.2023 | 07.27.2023 | Revise reference to information about Limited IRB Review from retiring SOP to Exempt Guidance |
| 2.4 | 04.27.2023 | 04.27.2023 | Minor clarifications and word-smithing throughout; remove description of member compensation and refer to SOP IRB Member Compensation instead |
| Previous versions |  |  | For older versions: HSD staff see the SharePoint Document Library; Others – contact hsdinfo@uw.edu. |

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