|  |  |
| --- | --- |
| University of Washington Human Subjects DIvision | **SOP Convened IRB Meetings** |

**1 PURPOSE and APPLICABILITY**

This document describes the procedures for conducting a meeting of the convened UW Institutional Review Board (IRB).

**2 CONTEXT**

Meetings of the convened IRB may be attended in person or virtually via phone or video conferencing. IRB meetings are led by the IRB Chair. IRB Chair, in this document, can also include the Vice Chair or another member acting as Chair Pro- Tempore.

**3 PROCEDURES**

3.1 **Meeting requirements.** The IRB Chair coordinates with HSD staff to ensure the following requirements are met prior to calling the meeting to order. No vote can be taken, nor determinations made on an item, if these requirements are not met. The fulfillment of the requirements is documented in the meeting minutes (**SOP Convened IRB Meeting Administration**).

3.1.1 **A quorum**, consisting of a simple majority of members and including at least one non-

scientist, must be present for all reviews. Absent or recused members do not count toward

quorum. HSD staff monitor quorum throughout the meeting and identify designated alternate

voting members should quorum be lost. If quorum cannot be maintained, remaining agenda

items will be tabled.

3.1.2 Members in attendance must have **sufficient expertise** to determine whether the applicable

criteria for approval have been met. This includes, when relevant, expertise with any vulnerable

population involved in the research. The HSD staff team verify the fulfillment of this requirement when preparing the meeting agenda.

3.1.3 IRB member **conflicts of interest** are identified prior to, and during the meetingas described in

the **SOP Reviewer Conflict of Interest**.

3.1.4 **Voting members** must be listed on the IRB roster at the time of the meeting (**SOP IRB**

**Members**). Members and their alternates may attend the same meeting, but only one may vote

on any one item being reviewed. Alternates may only vote in place of a member for which they

are an alternate, and only when that member, or another alternate for that member, is not

voting.

3.1.5 **Non-voting members** still participate in all aspects of the meeting conduct as described in this SOP, including presentation of agenda items and review discussions.

3.1.6 Members attending virtually are active participants in the meeting and have access to the same materials and information as members attending in-person.

3.2 **Opening business,** which is conducted by the Chair**.**

3.2.1 Call the meeting to order and introduce any observers or guests in attendance.

3.2.2 Ask whether any members have a conflict of interest, remind all attendees that the discussion

and votes are confidential and confirm that the report of expedited submissions and any minutes from previous meetings have been received by the IRB members.

3.2.3 Facilitate the conduct of any other business, including announcements and any education and training activities.

3.3 **Reviewing items.**

3.3.1 **Tabling an item.** The Chair tables an item when the requirements for the meeting are not met.

3.3.2 **Presentation of agenda items.** The Chair facilitates the following actions in a sequence

appropriate to the item and circumstances:

* Ask the primary reviewer to provide a descriptive summary of the item
* If applicable, ask the secondary reviewer and/or prisoner advocate to provide their feedback on the item
* If applicable, ask consultant(s) to present their review
* If applicable, ask the member(s) of the research team to present information or answer questions from the IRB
* For members with a conflict of interest, invite the IRB to ask questions of the member

3.3.3 **Discussion of criteria for approval and regulatory determinations.** The Chair is responsible for

overseeing the discussion of each item and ensuring that the IRB remains focused on the criteria

for approval and on other regulatory determinations required for the item. The Chair is also responsible for ensuring that all voices are heard during the discussion, particularly those of nonscientist members and unaffiliated members who may feel reluctance to express questions or contrary opinions.

The Chair facilitates the following actions during the discussion:

* Any member(s) with a conflict of interest are asked to disclose it. If requested by the Chair, the conflicted member may contribute to discussion of the item.
* The primary reviewer leads the discussion of the criteria for approval and other required regulatory determinations. The IRB should reference the **Pre-Review Note**, **WORKSHEETs Primary Reviewer**,the **WORKSHEET Criteria for IRB Approval**, and any other regulatory guidance provided by HSD staff.
* IRB members rely on HSD staff to provide regulatory guidance during the discussion.
* IRB members rely on HSD staff to capture discussion points, which may become IRB letter points or controverted issues (**SOP Convened IRB Meeting Administration**).
* Guests and observers are expected to follow the guidelines outlined in **SOP Guests at IRB Meetings**,may not participate in the discussion unless specifically requested to do so, and may be asked to leave the meeting during review and discussion of highly sensitive issues.

3.3.4 **Motion proposing IRB review outcome and vote.** The Chair monitors the discussion and

identifies an appropriate time to end the discussion and move to the next steps of proposing an

IRB action and voting. The Chair is responsible for facilitating the following actions:

* Members with a conflict of interest with respect to the item under consideration must recuse themselves from voting and may not be present at the meeting during the vote. If a conflicted member is participating in-person, the Chair asks the conflicted member to step outside the meeting room. When the member is participating virtually, the Team Lead and Chair will determine the best method for the conflicted member to recuse themselves. Options include being placed in a waiting room or logging out of the meeting until notified (e.g., via email) to log back in.
* An IRB member, usually the primary reviewer, makes a motion recommending specific IRB determinations and actions according to the **WORKSHEET IRB Review Outcomes** or **WORKSHEET Options for IRB Actions** and the **Pre-Review Note**.
* For studies that are approved or conditionally approved, the IRB must determine whether the study requires continuing review and, if so, its frequency and duration (**Pre-Review Note**, **WORKSHEETs Primary Reviewer**).
* The Chair asks for and facilitates additional discussion and, at an appropriate point, the Chair or a designee summarizes the motion and determinations and works with HSD to staff to verify the IRB determinations and letter points and to ensure the nature of the vote is understood by all.
* The Chair calls for a vote and ensures that HSD staff have recorded it.
  + For a motion to be approved, more than half of the members participating must vote “yes”.
  + Voting is conducted by voice and/or raising hands for members attending in person. Members attending virtually may vote by voice, by using tools in the virtual meeting platform (e.g., raising a virtual hand), or some other method determined by the Chair and HSD staff. Whatever method is used, each voting member must be individually polled. Voting may be conducted anonymously using a method that works for the format, if requested by a member or deemed appropriate by the Chair.
* After the vote is complete, recused members may be invited back into the room or the virtual meeting.
* For studies that are conditionally approved, the IRB must determine who should verify that the researcher’s response satisfactorily addresses the IRB’s conditions. Unless particular expertise is required, verification is generally completed by a member of HSD staff (**WORKSHEET IRB Review Outcomes**).

3.3.5 **Documentation of the review.** The IRB Chair relies on HSD staff to record the required

information in the IRB meeting minutes, complete documentation in the IRB electronic system, and draft any IRB letters for Chair, primary reviewer, and/or other IRB member or consultant review (**SOP Convened IRB Meeting Administration**).

3.4 **Adjourning the meeting.** The Chair adjourns the meeting when there is no further business, when quorum has been permanently lost, or when the length of the meeting is negatively affecting the quality of the review and discussion.

**4 RELATED MATERIALS**

4.1 SOP Convened IRB Meeting Administration

4.2 [SOP Guests at IRB Meetings](https://www.washington.edu/research/policies/sop-guests-at-irb-meetings-2/)

4.2 [SOP IRB Members](https://www.washington.edu/research/policies/sop-irb-members/)

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

4.4 [SOP IRB Review](https://www.washington.edu/research/policies/sop-irb-review-2/)

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

4.5 [WORKSHEET IRB Review Outcomes](https://www.washington.edu/research/forms-and-templates/worksheet-irb-review-outcomes/)

4.6 [WORKSHEET Options for IRB Actions](https://www.washington.edu/research/forms-and-templates/worksheet-options-for-irb-actions/)

4.7 WORKSHEET Primary Reviewer, Initial Application

4.8 WORKSHEET Primary Reviewer, CR and Mod

**5 REGULATORY REFERENCES**

45 CFR 46.107 [pre-2018 and 2018 requirements]

45 CFR 46.108(b) [pre-2018 & 2018 requirements]

21 CFR 56.107

21 CFR 56.108(c)

OHRP Memorandum, “IRB Meetings Convened Via Telephone Conference Call”, March 28, 2000

|  |  |  |  |
| --- | --- | --- | --- |
| **Version Number** | **Posted Date** | **Implementation Date** | **Summary of Changes** |
| 2.1 | 02.01.2024 | 02.01.2024 | Add role of Vice-Chair |
| 2.0 | 12.09.2020 | 12.09.2020 | Significant revision and renaming of SOP IRB Meeting Conduct to SOP Convened IRB Meetings |
| 1.2 | 08.30.2017 | 08.30.2017 | Updated links |
| 1.1 | 11.26.2014 | 11.26.2014 | Updated to allow for flexibility policy longer approval periods |
| 1.0 | 8.9.2013 | 8.9.2013 | Newly implemented document SOP IRB Meeting Conduct |

**Keywords:** IRB meeting; IRB review