UNIVERSITY OF MIAMI

SOP: IRB Meeting Preparation

NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-040	12/10/2021	F. Conte	K. Viamonte	1 of 3

PURPOSE

1.1 This procedure establishes the process to prepare for a convened IRB meeting.
1.2 The process begins when the agenda is closed, approximately 10 days before a meeting date.
1.3 The process ends when IRB meeting agenda materials have been sent or made available to IRB members.

2 REVISIONS FROM PREVIOUS VERSION

2.1 11/13/2013
2.2 08/08/2014
2.3 06/13/2014
2.4 Reconciliation to Huron HRPP Toolkit 4.5, dated 12/10/2021

3 POLICY

3.1 At least one IRB member or consultant is responsible for primary/secondary review of research.
3.2 Protocols are reviewed by IRB members and consultants with sufficient expertise.
3.3 When IRB members review research that involves vulnerable subjects, at least one individual who is knowledgeable about or experienced in working with such subjects will be present at the meeting.
3.4 IRB members are provided sufficient information so that each member can provide an opinion on whether the regulatory criteria for approval are met.
3.5 Alternate IRB members serve the same function as other IRB members, except that if the alternate IRB member and the regular IRB member for whom the alternate member is substituting are both present only one member may vote.
3.6 Review materials are provided to all IRB members at least 7 days before convened meetings.

4 RESPONSIBILITIES

4.1 HSRO staff members carry out these procedures

5 GUIDING PRINCIPLES

5.1 IRB meetings are scheduled as per HRP-084 – SOP – IRB Meeting Scheduling and Notification and occur at least on a bi-monthly basis (every other week).
5.2 Review materials are provided to all IRB members at least three (3) days before scheduled convened meetings
5.2.1 In rare instances, submissions may be added to the IRB agenda after the three (3) day deadline as long as IRB members are provided sufficient time to review and prepare.
5.3 At least one IRB member (Primary Reviewer) or a consultant is responsible for scientific/scholarly review of research.
5.4 Protocols are reviewed by IRB members and consultants with sufficient expertise.
5.5 When IRB members review research that involves vulnerable subjects, at least one individual who is knowledgeable about or experienced in working with such subjects will be present at the meeting.
5.5.1 If the research purposefully includes prisoners and is subject to NIH or DoD funding, involve a prisoner representative in the review.
5.5.2 If the research purposefully involves disabled individuals and is funded by the Department of Education or the National Institute on Disability and Rehabilitation, involves a reviewer who has expertise with individuals with disabilities.
5.6 IRB members are provided sufficient information so that each member can provide an opinion on whether the regulatory criteria for approval are met.

5.7 Alternate IRB members serve the same function as other IRB members, except that if the alternate IRB member and the regular IRB member for whom the alternate member is substituting are both present only one member may vote.

6 PROCEDURE

6.1 Confirm which IRB members (regular, alternate, and chairs) will be present at the meeting.
6.2 Consult HRP-601 - DATABASE - IRB Roster to be aware of the experience, expertise, and representational capacity of the IRB.
6.3 Review all submissions placed on the agenda for a convened IRB meeting.
6.4 Prepare an agenda for the meeting.
- 6.4.1 Execute the “Assign Reviewers” activity in the meeting workspace to assign a primary reviewer and secondary reviewer (when applicable) to each agenda item.
- 6.4.2 Execute the Assign Reviewers” activity in the meeting workspace to assign a primary/secondary reviewer to each agenda item who has scientific/scholarly expertise in the area of research.
- 6.4.3 Determine if the primary and secondary reviewer (when applicable) has a Conflicting Interest as defined in HRP-001 - SOP - Definitions. If so, consider whether another reviewer should be assigned.

6.5 Use HRP-305 - WORKSHEET - Quorum and Expertise to ensure that the meeting will be appropriately convened and to ensure the IRB will have the appropriate expertise for each protocol.
- 6.5.1 If the meeting will not meet the quorum and expertise requirements, take steps to obtain the required attendance of members and consultants or cancel the meeting.
- 6.5.2 Follow the procedures in HRP-051 - SOP - Consultation to obtain consultants. Note any consultants on the agenda.

6.6 Ensure review materials are available in the submission using HRP-301 - WORKSHEET - Review Materials
6.7 Execute the “Send Agenda” activity in the meeting workspace to deliver review materials to reviewers.
6.8 If a conflict of interest exists notify HSRO staff or reassign the review.

7 MATERIALS

7.1 HRP-001 - SOP - Definitions
7.2 HRP-051 - SOP - Consultation
7.3 HRP-084 - SOP - IRB Meeting Scheduling and Notification
7.4 HRP-301 - WORKSHEET - Review Materials
7.5 HRP-305 - WORKSHEET - Quorum and Expertise
7.6 HRP-601 - DATABASE - IRB Roster

8 REFERENCES

8.1 45 CFR §46.108(b)
8.2 21 CFR §56.108(b)
8.3 AAHRPP elements I.1.F, I.5.D, I.6.B, I.7.A, I-9, II.1.B, II.1.D, II.1.E, II.2.D, II.2.G, II.2.E-II.2.E.2