1 PURPOSE

1.1 This procedure establishes the process to prepare for a convened IRB meeting.

1.2 The process begins when the agenda[1] is closed, approximately 5-10 business days before a scheduled meeting date.

1.3 The process ends when IRB members are notified of the agenda.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None.

3 REQUIREMENTS

3.1 IRB members are provided sufficient information so that each member can provide an opinion on whether the regulatory criteria for approval are met.

3.2 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.

3.3 Review materials are generally made available to all IRB members at least 5 business days before convened meetings.

3.4 Members who attend ad hoc meetings generally will receive review materials in advance of the meeting, and will be allowed sufficient time to complete a thorough review prior to start of the meeting.

3.5 If a submission is added on to an IRB meeting, the members will receive the review materials in advance of the meeting and will be allowed sufficient time to complete a thorough review prior to the start of the meeting.

3.6 If documents are added to or removed from a submission prior to a meeting, the members will be notified prior to deliberation and vote.

4 RESPONSIBILITIES

4.1 Office of IRB Administration (OIA) staff members carry out these procedures.

5 PROCEDURE

5.1 Confirm which IRB members (regular, alternate, and chairs) will be present at the meeting.

5.2 Consult *OIA-601 DATABASE: IRB Roster*, or equivalent, to be aware of the experience, expertise, and representational capacity of the IRB members.

5.3 Use *OIA-308 WORKSHEET: Admin Pre-Review*, or equivalent, and *OIA-401 CHECKLIST: Pre-Review*, or equivalent, or revise, as needed, the previously completed *OIA-401 CHECKLIST: Pre-Review*, or equivalent, for each item on the agenda.

5.4 Review all submissions placed on the agenda for a convened IRB meeting to determine the member expertise required.

5.5 Prepare an agenda for the meeting.

5.5.1 Confirm all members who will be in attendance are current on required training.

5.5.2 Assign a primary reviewer to each agenda item.

5.5.3 Assign a scientific/scholarly reviewer, who has scientific/scholarly expertise in the research area, to each agenda item. The primary reviewer and scientific/scholarly reviewer may be the same individual.

5.5.4 If the scientific/scholarly reviewer is not an IRB member, determine whether the scientific/scholarly reviewer has a conflicting interest as defined in *OIA-001 SOP: Definitions*. If so, assign another scientific/scholarly reviewer.

5.5.5 For new projects, assign a secondary reviewer to review the study, focusing on informed consent. The secondary reviewer's role is not limited to informed consent; however, the consent is the primary focus.

5.6 Use *OIA-305 WORKSHEET: Evaluation of Quorum and Expertise*, or equivalent, to ensure that the meeting will be appropriately convened and to ensure the IRB will have the necessary expertise for each protocol.

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[1] Items can be added to the agenda after closure based on OIA staff's assessment of necessity, e.g., for impending expiration of continuing review, funding deadlines requiring IRB determination, etc.

5.6.1 If the members in attendance at the meeting will not meet the quorum and expertise requirements, take steps to obtain the required attendance of members and consultants; move agenda items, as appropriate, to an IRB meeting with appropriate scope and expertise; or cancel the meeting.

5.6.2 Follow the procedures in *OIA-051 SOP: Consultation to the IRB,* to obtain consultants. Note any consultants on the agenda.

5.6.2.1 If the agenda includes research with vulnerable populations, ensure the members will have access to appropriate expertise and knowledge to determine the acceptability of involving the vulnerable population(s).

5.6.2.2 If the agenda includes research being conducted outside of the United States, ensure the members will have access to appropriate expertise and knowledge of the country where the research will be conducted to ascertain the acceptability of the proposed research.

5.6.2.3 If the agenda includes research involving prisoners, ensure a member designated as a prisoner representative will attend the meeting.

5.7 Deliver the review materials using *OIA-301 WORKSHEET: Review Materials*, or equivalent, according to the individual's role.

5.8 Notify IRB members of the agenda.

6 MATERIALS

6.1 *OIA-001 SOP: Definitions*

6.2 *OIA-051 SOP: Consultation to the IRB*

6.3 *OIA-301 WORKSHEET: Review Materials*

6.4 *OIA-305 WORKSHEET: Evaluation of Quorum and Expertise*

6.5 *OIA-308 WORKSHEET: Admin Pre-Review*

6.6 *OIA-401 CHECKLIST: Pre-Review*

6.7 *OIA-601 DATABASE: IRB Roster*

7 REFERENCES

7.1 21 CFR 56.107

7.2 21 CFR 56.108(c)

7.3 45 CFR 46.107

7.4 45 CFR 46.108(b)