1. PURPOSE
   1. This procedure establishes the process to prepare for a convened IRB meeting.
   2. The process begins when the agenda is closed, approximately 10 days before a meeting date.
   3. The process ends when IRB meeting agenda materials have been sent or made available to IRB members.
2. REVISIONS FROM PREVIOUS VERSION

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| **Version** | **Date** | **Revisions** |
| R00 | 3/25/14 | Original issue |
| R01 | 9/8/17 | Reference electronic submission, remove incomplete sentence |
| R01 | 11/26/19 | Annual review, no changes |
| R01 | 12/16/2020 | Annual review, no changes |
| R01 | 10/19/2021 | Annual review, no changes |
| R02 | 12/12/2022 | Annual review, Added IRB Meeting Preparation |
| R03 | 11/13/23 | Annual review, updated header table to include SOP title, author |

1. POLICY
   1. At least one IRB member or consultant is responsible for scientific/scholarly review of research.
   2. Protocols are reviewed by IRB members and consultants with sufficient expertise.
   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.
   4. IRB members are provided sufficient information so that each member can provide an opinion on whether the regulatory criteria for approval are met.
   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.
   6. Review materials are provided to all IRB members at least 7 days before convened meetings.
2. RESPONSIBILITIES
   1. IRB staff members carry out these procedures.
   2. IRB Meeting Preparation
      1. For initial review of research by a convened IRB, when they are scheduled to attend an IRB meeting, all members (including attending alternate members) are provided and review:

• The full protocol, application, or a protocol summary containing the relevant information to determine whether the proposed research fulfills the criteria for approval.

• Proposed consent document.

• Recruitment materials.

• At least one member is provided and reviews the investigator’s brochure (when one exists).

* + 1. For continuing review of research by a convened IRB when they are scheduled to attend an IRB meeting, all IRB members (including alternate members) are provided and review:

• The full protocol, application, or a protocol summary containing the relevant information necessary to determine whether the proposed research continues to fulfill the criteria for approval.

• The current consent document.

• Any newly proposed consent document.

• A status report on the progress of the research.

* + 1. For continuing review of research by a convened IRB:

• At least one IRB member is provided and reviews the complete protocol including any protocol modifications previously approved by the IRB.

• The status report on the progress of the research includes: The number of subjects accrued. A summary since the last IRB review of: ▪ Adverse events and adverse outcomes experienced by subjects. ▪ Unanticipated problems involving risks to subjects or others. ▪ Subject withdrawals. ▪ The reasons for withdrawals. ▪ Complaints about the research. ▪ Amendments or modifications. ▪ Any relevant recent literature. ▪ Any interim findings. Any relevant multi-center trial reports. The investigator’s current risk-potential benefit assessment based on study results.

* + 1. For continuing review of research that do not require full review:
* Submission is still required to the IRB annually for Administrative review
* Administrative review will check for:
  + Conflict of Interest (COI)
  + CITI Training
  + Data Safety Report.

1. PROCEDURE
   1. Confirm which IRB members (regular, alternate, and chairs) will be present at the meeting.
   2. Consult “DATABASE: IRB Roster (HRP-601)” to be aware of the experience, expertise, and representational capacity of the IRB.
   3. Review all submissions placed on the agenda for a convened IRB meeting.
   4. Prepare an agenda for the meeting.
      1. Execute the “Assign Reviewers” activity in the meeting workspace to assign a primary reviewer to each agenda item
      2. Execute the Assign Reviewers” activity in the meeting workspace to assign a scientific/scholarly reviewer to each agenda item who has scientific/scholarly expertise in the area of research. The primary reviewer and scientific/scholarly reviewer may be the same individual
      3. If the scientific/scholarly reviewer is not an IRB member, determine whether the scientific/scholarly reviewer has a Conflicting Interest as defined in “SOP: Definitions (HRP-001).” If so, assign another scientific/scholarly reviewer.
   5. Use “WORKSHEET: Quorum and Expertise (HRP-305)” to ensure that the meeting will be appropriately convened and to ensure the IRB will have the appropriate expertise for each protocol.
      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.
      2. Follow the procedures in “SOP: Consultation (HRP-051)” to obtain consultants. Note any consultants on the agenda.
   6. Members will be provided with review materials using the electronic IRB submission system
2. MATERIALS
   1. DATABASE: IRB Roster (HRP-601)
   2. SOP: Consultation (HRP-051)
   3. SOP: Definitions (HRP-001)
   4. WORKSHEET: Review Materials (HRP-301).
   5. WORKSHEET: Quorum and Expertise (HRP-305).
3. REFERENCES
   1. 45 CFR §46.108(b)
   2. 21 CFR §56.108(b)