

## I. PURPOSE

The purpose of this standard operating procedure is to describe the management of convened meetings of the IRB, including the material provided to IRB members for review, and the information documented in the IRB meeting agenda and minutes.

## II. POLICY STATEMENT

Meetings of the CHOP IRB will generally be convened weekly, with additional meetings convened as required, based on urgency and submission volume. The meetings will be conducted and documented as described within this SOP as required by the regulations.

## III. SCOPE

These policies and procedures apply to all IRB Chairs, IRB members and alternates, and IRB Office staff.

## IV. DEFINITIONS

Alternate: An individual appointed to the IRB who serves in the same capacity as an IRB member for whom the alternate is named, who substitutes for the member at a convened meeting when the member is not voting.

Chair, CPHS: The Chair functions as the executive chair of all of the IRB committees and subcommittees and provides input for IRB policies and educational training requirements. The Chair works with the Director, Human Subjects Research and the VP, Research Compliance and Regulatory Affairs on procedural matters pertaining to the IRB. The Chair serves as Chair or Vice-Chair for one or more of the CHOP IRBs.

Consultants: When the IRB determines that additional expertise is required for an IRB review, an individual with the appropriate expertise is asked to assist with a review of a proposal. Consultants are selected based on education, training, and experience with the research topic, the subject population to be recruited, the research test article, and/or the research intervention. Consultants may not provide expertise or advise when they have a conflict of interest.

Director, HSR: Director, Human Subjects Research.

eIRB: The electronic IRB management system.

Full Board Review: Review of proposed research at a convened Full IRB meeting at which a majority of the membership of the IRB is in attendance, including at least one member whose primary concerns are in non-scientific areas. For the research to be approved, it must receive the approval of a majority of those members attending the meeting.

Quorum: Quorum is a majority of the IRB members (more than half), including at least one member whose primary concerns are in scientific areas, and one member whose

primary concerns are in non-scientific areas. When FDA-regulated research is reviewed, there shall be at least one member who is a physician. An IRB alternate may substitute for a member in order to meet quorum requirements at an IRB meeting.

## V. PROCEDURES

### A. Development of the Meeting Agenda

The IRB agenda lists all items that will be discussed at the convened meeting.

1. Complete submissions determined to require review at a convened IRB meeting are generally placed on the next available IRB meeting agenda for review.
2. The Director, HSR, or designee, and the assigned meeting chair monitor the items – both the number and complexity – on the agenda to ensure there will be adequate time for discussion.

### B. Distribution of Meeting Materials

1. Each committee will include scientific members, non-scientific members and non-affiliated members or alternates who represent the general perspective of subjects. To ensure consistent representation of scientific, non-scientific and non-affiliated members, attendance at meetings will be evaluated at least annually by the Director, HSR and the IRB Chairs, in accordance with **SOP 201**.
2. Members and alternates participating in a given IRB meeting will have access to the protocol, consent documents and other pertinent study materials as described in **SOP 301**.
3. Consultants receive the materials specific to the research for which their input is requested.
4. The IRB Analyst finalizes the IRB meeting agenda, which includes:
  - (a) Reminder for members to disclose, at the beginning of each meeting, any actual or potential conflicts of interest they may have with an agenda item.
  - (b) IRB educational materials;
  - (c) The report of actions taken using expedited review procedures;
  - (d) Minutes from the previous convened IRB meeting, as applicable; and
  - (e) Submissions scheduled for review.
5. The agenda is distributed via the electronic IRB management system.

### C. IRB Meeting

1. The meeting may begin when a quorum is established; if the quorum is lost during a meeting, the IRB may not deliberate or vote until a quorum is restored.

**SOP 303: IRB Meeting Administration**

2. The IRB Analyst is responsible for ensuring and tracking quorum.
3. At the discretion of the presiding Chair, the Principal Investigator may be invited to appear at a convened meeting (in person, by video, or by telephone) to provide additional information. Principal Investigators will not be present during the deliberation or vote on agenda items for which they have conflicts.

#### **D. Voting**

1. The minutes for each IRB meeting will reflect the votes (number for, against, and abstain) of the members and alternates participating in the IRB meeting. Any member or alternate who abstains and is present for the deliberation and vote is counted toward the quorum.
2. In the case of a conflict of interest, the conflicted member or alternate must recuse themselves. Recusals are identified in the minutes. A recused member or alternate is not counted toward the quorum. When an alternate member substitutes for a member due to a conflicting interest, the minutes will identify the name of the member for whom the alternate member is substituting, and state the reason for the substitution.
3. Consultants may not vote with the IRB on the submission for which their expertise is required.

#### **E. Minutes**

1. Minutes will contain sufficient detail about the following issues/areas:
  - (a) Meeting attendance; including status of each attendee (member or alternate, affiliated or non-affiliated, consultants and their expertise, etc.), guest and staff present; and when FDA-regulated research is reviewed, that a physician was present for the review, and if meeting attendance is via an alternative mechanism (e.g. videoconference). When an alternate substitutes for a member, the minutes will identify the name of the member for whom the alternate is substituting.
  - (b) A summary of the separate deliberations for each action, including:
    - (1) The approval period for initial and continuing reviews;
    - (2) The action taken by the IRB, including the number of votes for, against, and abstaining;
    - (3) That the regulatory criteria for approval were met for submissions the IRB approves or approves with modification (eIRB will include documentation of the details for each required element for approval);
    - (4) The basis for requiring changes in or disapproving research; and

- (5) The discussion of controverted issues (if any) and their resolution. If there are no controverted issues associated with a submission, the minutes will not reference controverted issues.
- (c) Any protocol-specific information required for specific categories of research, including:
- (1) Required Consent Documentation (**SOP 701**)
  - (2) Research involving Children (**SOP 504**)
  - (3) Pregnant women, human fetuses or neonates (**SOP 502**)
  - (4) Prisoners (**SOP 503**)
  - (5) For research involving other potentially vulnerable subjects due to their (a) impaired decision-making capacity or mental health, (b) status as wards of the state, (c) social or economic conditions or (d) other factors, the additional safeguards and protections deemed appropriate by the convened committee (if any) as described in **SOP 501**.
  - (6) For research involving investigational medical devices, the IRB's Significant or Non-Significant risk determination, unless the FDA has already made a risk determination for the device study.
  - (7) For research involving the investigation of an approved drug(s) or biologic(s), the IRB's determination as to whether or not the research meets the criteria for exemption from the requirement for an IND in accordance with 21 CFR 312.2.
- (d) For expedited review actions, including the review of issues requiring prompt reporting (e.g. unanticipated problems involving risks to subjects or others, serious or continuing noncompliance, suspension or termination of IRB approval), reported to the convened committee, an indication that the IRB members had an opportunity to ask questions or raise concerns, and a summary of questions or concerns, if any, raised by the IRB members.
- (e) Any discussion related to issues that require prompt reporting to the IRB (e.g., an unanticipated problem involving risk to human subjects or others), which were reviewed or decisions made outside the convened meeting.
- (f) Any discussion related to the educational information shared with the IRB.
2. During the convened IRB meeting, the IRB will review the IRB Meeting Minutes approved by the Chair from the previous meeting, if available, that were distributed to members prior to the IRB meeting.
- (a) Comments and corrections provided by the members, will be incorporated

into the minutes (when applicable).

## **F. Participation from Remote Locations**

1. Members unable to attend an IRB meeting in person may participate via telephone conference or videoconference. They may vote and be counted towards the quorum.
2. Members participating by a remote mechanism will receive and have access to IRB submission materials and will be able to participate in the discussion as if they were physically present.
3. The meeting minutes will indicate which members attended via an alternate mechanism (e.g. telephone or video conferencing). If the entire meeting is held via telephone or video conference, the minutes will state that.

## **VI. APPLICABLE REGULATIONS AND GUIDELINES**

45 CFR 46.103, 45 CFR 46.108	21 CFR 56.108, 21 CFR 56.109
FDA Guidance for Institutions and IRBs: Minutes of Institutional Review Board (IRB) Meetings, September 2017	

## **VII. REFERENCES TO OTHER APPLICABLE SOPS**

SOP 201: Composition and Management of the IRB	SOP 301: Research Submission Requirements
SOP 401: Expedited Review Procedures	SOP 501: Vulnerable Subjects
SOP 502: Research Involving Pregnant Women, Fetuses and Neonates	SOP 503: Research Involving Prisoners
SOP 504: Research Involving Children	SOP 701: Required Elements of Consent and Documentation of Consent

## **VIII. RESPONSIBILITIES**

<b>Title</b>	<b>Responsibility</b>
Director, HSR	Responsible for ensuring that there are adequate staff assigned and prepared for each IRB meeting.
Chair, CPHS	Responsible for IRB meeting review conduct and

	leadership.
IRB Analyst	Responsible for meeting quorum, recording of votes and preparation of minutes.

## IX. ATTACHMENTS

### X. REVISIONS:

- 06-19-2006 Initial approval date
- 02-14-2007 Revised to incorporate changes in IRB office staff responsibilities.
- 11-10-2008 Revised to incorporate the use of the electronic management system.
- 06-09-2010 Revised to correct minor typographic errors, clarify the procedures for developing the agenda and minutes.
- 07-08-2010 Revised to clarify non-affiliated members attendance requirement and to update the list of referenced related SOPs.
- 10-18-2011 Revised to clarify the approval process for minutes.
- 02-25-2013 Minor administrative edits.
- 07-22-2015 Clarification regarding the absence of controverted issues and minor administrative edits.
- 09-25-2018 Revised to include updated CHOP Logo and reflect September 2017 FDA guidance on minutes of IRB meetings.
- 06-09-2022 Revised to reflect current processes.

### XI. APPROVAL:

Approval Indicator: Approved by Amy Schwarzhoff and Barbara Engel on 06/09/22  
Amy Schwarzhoff, Director, Human Subjects Research and Barbara Engel, Chair, CPHS