P&P: FO 303 Version No: 1.2 Effective Date: 7/1/2017	**IRB MEETING ADMINISTRATION**	Supercedes: CPHS Policies and Procedures 5/1/2015

1. POLICY

Except when an expedited review procedure is used, the IRB will review proposed research at convened meetings at which a quorum of members is present. The IRB may be one or more committees. Quorum permitting, each Committee will meet once a month, or at some other frequency determined by the OPHS Director and/or IRB Chair. The Chair may call an unscheduled meeting as necessary.

Specific Policies

1.1 Quorum

1.1.1 A quorum is defined as greater than 50% of the membership of IRB and must include at least one member whose primary concerns are in nonscientific areas.

1.1.2 In order to meet the quorum requirements outlined above, a member's alternate may attend in the member's place.

1.1.3 A member participating via telephone, Skype, or other real-time electronic communication connection can be used to establish a quorum.

1.1.4 The non-affiliated member is strongly encouraged to attend every meeting and expected to attend no less than one-half of all scheduled meetings per appointment term.

1.1.5 A special consultant(s) cannot be used to establish a quorum.

1.1.6 Should the quorum fail during a meeting (e.g. due to recusal of those with conflicts, loss of a non-scientist, early departures), discussions may proceed; however, votes may not be taken.

1.2 Primary and Secondary Reviewers

Prior to the meeting, the OPHS Director, Assistant Director and/or the IRB Administrator will designate a primary reviewer for each research protocol included on the agenda. A secondary reviewer may also be assigned. The primary and secondary reviewers' duties as well as those of members at large are described in P&P OR 203 – Duties of IRB Members. All members are strongly encouraged to be physically present for convened meeting discussion and voting.

1.3 Use of Special Consultants

When the IRB reviews research that involves a vulnerable category of subjects (e.g., children, prisoners, or handicapped or mentally disabled persons), one or more individuals who are knowledgeable about and/or experienced in working with these subjects will participate in the review. If IRB members lack this expertise, special consultants will be used in the review of these protocols. These individuals may not vote with the IRB.

The IRB may also invite individuals with competence in special areas (other than vulnerable populations) to assist in the review of issues that require expertise beyond or in addition to that available on the IRB.

1.4 Meeting Materials Sent Prior to IRB Meetings

A meeting agenda, application materials and other documentation required for review will be prepared by the OPHS Staff. These will generally be distributed to IRB members at least four (4) calendar days in advance of the meeting to allow time for adequate review; however, exceptions may be made under extenuating circumstances. The meeting agenda, reports and the meeting minutes as approved by the IRB will be maintained electronically on the shared drive of the Office for the Protection of Human Subjects by the IRB Administrator of each committee.

Members must declare to the IRB Chair and/or OPHS Director any potential financial conflict of interest (COI) they may have with research that is about to be reviewed prior to that protocol being reviewed.

1.5 Telephone, Skype, or other Electronic Communication Use

1.5.1 Convened Meeting Using Electronic Real-Time Media:

Should a member be unable to physically attend a convened meeting, but available by telephone or other real-time electronic media, the meeting may be convened using a speakerphone or other appropriate device. In this manner, the member who is not physically present will be able to discuss the protocol with the rest of the members in real time. Members participating remotely by one of the aforementioned methods may vote, provided that they have had an opportunity to receive and review the meeting materials in advance of the meeting.

1.5.2 Meetings Conducted Via Conference Calls:

On rare occasion, meetings may be convened via a telephone or computer-based software program for a simultaneous conference call of a group meeting. A quorum (as defined above) must be present and participate for the conference call meeting to be convened. To allow for appropriate discussion, all members must be connected simultaneously for a conference call to take place. "Telephone polling" (where members are contacted individually) will not be accepted as a conference call.

Members who are neither present at the convened meeting nor participating in the conference call may not vote on an issue discussed during a convened meeting (no voting by proxy).

1.6 Recusal of IRB Members

1.6.1 IRB Members with a financial conflict of interest must recuse themselves from discussion and vote (see GA 104).

1.6.2 IRB Members who are the primary mentor for a student or post-doctoral researcher have a conflict of interest and must recuse themselves from the discussion and vote on the mentee's protocol.

1.6.3 IRB Members who for any other reason do not feel it is appropriate for them to participate in the discussion and vote may recuse themselves while said protocol is being reviewed.

1.6.4 Members who declare a COI on any matter will recuse themselves and not participate in the discussion (except to answer questions or provide information as requested by the IRB) or vote. The IRB minutes will reflect such recusals as they occur during meetings.

1.7 Discussion and Vote

1.7.1 At the meeting, the primary reviewer introduces the research and provides the first comments resulting from his or her in-depth review. After the primary reviewer has provided his or her comments, the IRB Chair will ask the secondary reviewer (if one is assigned) for his or her comments, and then any special consultants will be asked to provide their comments.

The discussion of each new research proposal, continuing review progress report, amendment, adverse/unanticipated event, protocol deviation or non-compliance on the agenda is led by the Chair and any designated reviewer(s). Discussion by all members present at the convened meeting is conducted on the necessary ethical and regulatory questions, controverted issues, determinations of scientific/scholarly validity, risk, benefit, and additional safeguards for vulnerable populations.

1.7.2 At the end of the discussion of an application, the Chair looks for a motion on an action, as well as a second. Hearing these, the Chair calls for a vote on the motion and the members may vote by voice as well as by raising their hands. The Chair asks for votes for the motion, then against, and finally for abstentions. A simple majority carries the vote. The Chair will strive to build consensus as much as possible and may take a straw vote before a binding vote in order to assess whether additional discussion is needed. A deeply divided vote may indicate that further discussion or deferral is appropriate. OPHS Staff will count the final vote and the vote is recorded in the minutes.

1.7.3 Members with a COI will recuse themselves from participating in the deliberation and vote for protocols or matters with which they have a conflict. In addition, recused members will leave the meeting room during the review and vote, unless requested by the IRB to remain to answer specific questions.

1.8 Minutes

1.8.1 Recording: OPHS Staff will take minutes of each meeting. Minutes will be written in sufficient detail to show the following:

- Meeting attendance; including status of each attendee (member, consultant, etc.), and conflicts of interest, if any;
- Actions taken by the IRB on each agenda item requiring full IRB action, including the basis for requiring changes in or disapproving the research;
- Summary of the discussion of controverted issues and resolution;
- Determination of the level of risk and the duration of approval;

- Voting results, including number for, against, members abstaining (listed by name), and members who recused themselves and reason for recusal.
- Consideration of the requisite criteria for approval as well as any additional criteria for the protection of vulnerable populations.

1.8.2 Approval: Draft minutes will usually be distributed to members prior to the next IRB meeting for review and approval, or as soon as available for the next possible meeting. (Note: CPHS-1 draft minutes go back to CPHS-1 for review and approval, and likewise for CPHS-2).

- Corrections requested by the IRB will be made by the staff and the minutes will be printed in final form for documentation and made available by electronic means to members at the following meeting.
- The OPHS Director and/or IRB Administrator will maintain copies of the minutes, as well as the agenda and pertinent materials on file (see SOP FO 304 –Record Retention and Disposition).
- Audio recordings and audio files of the meetings will be destroyed (deleted) between 60-90 days after final approval of the minutes by the IRB.

1.9 Guests

At any given IRB meeting, there can be various observers present. IRB staff members are to attend IRB meetings on an as-needed basis to support the work of the committee. The Institutional Official, Associate Vice Chancellor for Research or the Assistant Vice Chancellor for Research Administration and Compliance may attend as a guest. Other individuals who wish to attend one or more meetings must receive permission from the IRB Chair and/or Director of OPHS to do so.

1.9.1 Investigators and co-investigators may be called into the IRB meeting if needed to provide information about a study being reviewed. He or she will come only for that purpose and will leave before the final discussion and vote on the study.

1.9.2 Research Managers or other staff may be called into the IRB meeting if needed to provide information about a study being reviewed. They will leave before the final discussion and vote on the study. These staff members will attend and speak on behalf of the investigator only after the investigator has made it clear to IRB staff that this is appropriate.

1.9.3 Any guest at an IRB meeting may be asked to leave, at any time, at the discretion of the IRB Chair or OPHS Director.

2. SCOPE

These policies and procedures apply to all research submitted to the IRB.

3. RESPONSIBILITY

The IRB Chair (or designee) is responsible for IRB meeting review, conduct, and leadership.

The OPHS Director and/or IRB Administrator is responsible for IRB meeting procedural conduct and acts as a technical consultant when necessary.

OPHS Staff are responsible for IRB meeting documentation.

4. PROCESS OVERVIEW

The OPHS Staff provide documentation required for review to all IRB members approximately four calendar days in advance of the meeting to allow time for adequate review. Staff members draft the agenda for the IRB meetings in consultation with the OPHS Director and/or IRB Administrator regarding applications, issues, and announcements to be included as agenda items.

Once the OPHS Director and/or IRB Administrator have, in consultation with the Chair, finalized the agenda, staff provide a copy of the agenda, monthly reports (e.g., Continuing Reviews, Amendments Approved via Expedited Review, Expedited Review Report), the previous meeting's minutes, and materials for review to all members approximately four calendar days prior to the meeting. In rare instances, questions and comments made by the primary reviewer and secondary reviewer, if applicable, will be compiled and sent via email to investigators to enable them to address issues in advance of the meeting. In such cases, a copy of investigators' responses to the committee's comments will be sent to the primary reviewer and secondary reviewer prior to the meeting, time permitting.

All relevant files (e.g. new applications, modification requests, continuing reviews, non-compliance notices) and all reports referenced in the agenda will be available upon request in hard copy for the members at the meeting.

The IRB Chair presides over the meeting, using the agenda as a guide. IRB Members with conflicts of interest do not participate in the discussion nor vote on protocols with which they have a conflict. However, they may be present for the discussion and available for questions if the IRB determines that they may have information that is beneficial to the deliberation.

The OPHS staff record detailed minutes of the meeting, including summary of discussion, controverted issues, motions, and voting results. Staff will also record the names of members who abstain from voting or leave the meeting due to a conflicting interest or any other reason. All documentation from the meeting is handled according to UC Berkeley record retention policies.

The OPHS Director in consultation with the IRB Chair extends invitations to guests or approves requests to attend as a guest at an IRB meeting. Attendance of guests will be documented in the minutes.

5. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.103

45 CFR 46.108

21 CFR 56.108

45 CFR 46.109

21 CFR 56.109

FDA Information Sheets, 1998