Policy on IRB Meeting and Minutes

Effective date: 9/20/2019

I. Background
UC Santa Cruz records meeting minutes for their convened IRB meetings. The procedure for conducting convened IRB meetings and recording their minutes is outlined in this policy and reflects Office for Human Research Protections (OHRP) guidance.

II. Attendance
a. Members must attend convened meetings in real time, either in person, via videoconference, or via telephone. Those attending by video or phone will be recorded as attending remotely in the minutes.
b. The minutes will document who is present at the meeting by name and role (e.g., scientist, non-scientist, alternate, etc.) and show that a quorum was maintained (half the membership plus one).
c. An alternate may only vote and count towards quorum if the primary member is absent. If the alternate is voting for a primary member due to a conflict of interest, this must be stated in the minutes.
d. A non-scientist member must be present for the duration of the meeting.
e. If a consultant is present for a protocol review, they must be documented by name and area of expertise. The consultant does not vote.
f. Any guests will be listed by name.
g. Late arrivals, temporary departures, and early departures will be recorded and a quorum must be maintained in order to conduct IRB business.
h. The meeting must maintain a quorum of members. This is half plus one of the primary IRB membership. Quorum also must have at least one nonscientist member present. If quorum is lost, IRB business will stop until quorum is restored or the meeting must adjourn and any outstanding items must be tabled for a future meeting.

III. Meeting Preparation
a. The IRB is an ad hoc committee. When a protocol is referred to full board by the Chair or designated reviewer, or when IRB policies and procedures need to be discussed at a convened meeting, ORCA staff poll the membership to find the earliest possible date that a quorum can be convened.
b. ORCA staff prepare the IRB agenda and send the agenda and attachments related to agenda items to all committee members planning to attend approximately 1 calendar week of the meeting. On occasion, an urgent agenda item may be added less than 1 week prior to the meeting and a
revised agenda will be sent. Agenda items include but are not limited to initial and continuing reviews, amendments, potential serious or continuing noncompliance, potential unanticipated problems involving risks to subjects or others, draft policies, major changes to IRB/ORCA procedures, review of last IRB minutes, and review of list of exempt and expedited studies approved since the last convened meeting.

IV. Meeting Procedures
   a. The meeting may begin at the scheduled time once quorum is present in the room. The meeting ends when the agenda items are completed or at the scheduled end time, unless a quorum of members agrees to stay beyond the end time to complete the agenda. The meeting must adjourn if quorum is lost.
   b. Any protocols listed on the agenda are assigned to each member and each are expected to review the entire protocol contents (application, recruitment, consent, study instruments, etc.) before the meeting and be prepared to discuss at the meeting. The Chair or designee provides a short summary of the protocol at the beginning of the discussion, then opens the meeting to reviewers to provide any concerns and/or required modifications.
   c. Any other agenda item attachments should be reviewed by each member prior to the meeting for them to be prepared to discuss at the meeting. Not every agenda item requires a vote.
   d. Members are reminded on the agenda to recuse themselves if they have a conflict of interest with any study. Any member with a conflict of interest related to a given protocol must step out of the room during discussion and vote on the protocol in question. A conflicted member cannot count towards quorum and this will be documented in the minutes as stated in Section XII.
   e. When the committee determines that no one present has appropriate scientific or scholarly expertise to conduct satisfactory review of the protocol, and no such prior consultation was received, the IRB must table the protocol for a future meeting and the IRB and/or ORCA must locate a consultant to review the protocol before it can be placed on an agenda.

V. Actions
   a. The IRB may review initial studies, amendments, continuing reviews, event reports, noncompliance, policies, and other human research issues.
   b. For initial studies, amendments and continuing reviews, the IRB may approve as written, require modifications, defer to another meeting with requests for information and/or required modifications, disapprove, or table submissions. In order to approve a non-exempt study, the IRB must determine that all of the criteria for IRB approval of research are satisfied as outlined in 45 CFR 46.111. IRB members refer to the non-exempt reviewer checklist to make this determination.
c. For initial studies approved on or after January 21, 2019, the approval period is 10 years unless greater than minimal risk (1 year), or otherwise noted. For initial and continuing studies initially approved before January 21, 2019, the approval period generally was either 1 year for federally funded studies or greater than minimal risk, or 3 years. Approval period must be documented in the minutes.

d. For studies requiring modifications, deferrals, and disapprovals, the action must be stated along with the basis for the action.

e. The principal investigator may respond to the IRB either in person at a convened meeting or in writing to be discussed at a convened meeting.

f. If approved at a convened meeting, the study approval date is the date of the meeting. If modifications are required, the study approval date is the date that the modifications are deemed satisfied by the expedited reviewer.

g. Members must vote on actions regarding suspension or termination of a study, on whether a noncompliance is serious or continuing, and on whether an event is an unanticipated problem involving risks to subjects or others.

h. Suspensions and terminations must follow UCSC policy and any decision of such that was made outside of a meeting (e.g., by the Institutional Official) should be reported to the convened IRB, discussed, and summarized in the minutes along with any subsequent action of the IRB.

i. Actions are approved with a majority vote.

VI. Informed Consent

a. The IRB must determine that informed consent will be sought from each prospective subject or the subject’s legally authorized representative (LAR) in accordance with the regulations (45 CFR 46.111(a)(4) and determine that informed consent will be appropriately documented in accordance with the regulations (45 CFR 46.111(a)(5) unless the study meets criteria for waivers.

b. Members refer to the informed consent checklist to review informed consent materials.

c. Approval of a waiver of documentation of consent under 45 CFR 46.117(c) should be noted in minutes.

d. Approval of a waiver or alteration of consent under 45 CFR 46.116(c) and (d) should be noted in minutes.

VII. Children

a. Studies involving children should follow the relevant UCSC policy.

b. Approval for research involving children under 45 CFR part 46 subpart D should be noted in minutes and state under which condition (e.g., 45 CFR 46.404, 45 CFR 46.405, etc.).
c. IRB must also determine that requirements for permission by parents or guardians and for assent by children under 45 CFR 46.408 are met and document any waiver of parent permission.

VIII. Pregnant Women, Human Fetuses, and Neonates  
   a. Studies involving Pregnant Women, Human Fetuses, and Neonates should follow the relevant UCSC policy.  
   b. The minutes should reflect that requirements under 45 CFR part 46, subpart B were met.

IX. Prisoners  
   a. Studies involving Prisoners should follow the relevant UCSC policy.  
   b. The minutes should reflect that requirements under 45 CFR part 46, subpart C were met should be documented.

X. Unanticipated Problems, Serious or Continuing Noncompliance, Suspension or Termination of IRB Approval  
If at a convened meeting, the IRB reviews an issue that requires prompt reporting to the IRB under 45 CFR 46.108(4), such as an unanticipated problem involving risk to human subjects or others, the minutes should summarize the report and document the IRB’s action, if any, resulting from that review as per 45 CFR 46.115(a)(2). Any review of such information and any decisions made outside of a convened meeting (e.g., by the Institutional Official for subject safety reasons) should be reported to the convened IRB and the discussion and subsequent action (e.g., to lift suspension or to terminate the study), if any, summarized in the minutes as per 45 CFR 46.115(a)(2).

XI. Expedited and Exempt Reviews  
With the agenda for the convened meeting, members are provided with a list of proposals approved under expedited review and proposals determined exempt since the last convened meeting. Members have the opportunity to ask questions or raise concerns at the meeting.

XII. Voting  
For any items requiring a vote, the minutes show the action and the number of members voting for, against, and abstaining. Those recusing due to a conflict of interest must be documented as such and do not count towards quorum.

XIII. Controverted Issues  
   a. The minutes should reflect any discussion of controverted issues and their resolution.
b. Controverted issues are those that cause controversy and dispute among the IRB membership during a convened meeting. Controverted issues that arise during the convened meeting usually are the result of opposition to some aspect of the proposed research. During the review of proposed research, IRB members may express a difference of opinion, or raise issues, questions or concerns that cause debate among the IRB members, or even result in disagreement. Some research, by its very nature, is considered to be controversial (e.g., emergency research where informed consent may not be obtained for all subjects or some research involving vulnerable populations).

c. IRB members may resolve controverted issues and concerns with continued discussion and deliberation, decide to seek further clarification from the investigator or sponsor of the proposed research, or decide to settle the issue by vote. The minutes must summarize the IRB’s discussion and resolution of any controverted issues.

XIV. Approval of Minutes
ORCA Director or their designee approves the list of required modifications to be sent back to investigators and documented in the minutes. The minutes will be reviewed and voted on at a future convened meeting.

XV. Other Items
a. Any continuing education at the meeting will be documented in the minutes.
b. Minutes may contain announcements pertinent to the committee or to human research at UCSC.

XVI. References
a. Minutes of Institutional Review Board (IRB) Meetings Guidance for Institutions and IRBs
b. 45 CFR 46.115(a)(2)