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Conduct of Meetings by the Convened IRB				

1.0 Purpose:

- 1.1 The Hartford HealthCare Human Research Protection Program (HHC HRPP) has policies and procedures describing the conduct of meetings of the convened Institutional Review Board (IRB). These policies and procedures allow the IRB to carry out its functions effectively and consistently according to applicable laws, regulations, codes, and guidance and the Organization's policies and procedures.

2.0 Definitions:

- 2.1 **Ad Hoc:** Used for a particular purpose. An ad hoc member is an appointed, voting member who attends meetings as needed, and counts toward a quorum only when present.
- 2.2 **Alternate:** A voting member representing the same area of expertise (or non-scientific or unaffiliated status) as the regular member, who is designated to attend a meeting in place of the regular member.
- 2.3 **Conflicting interest:** Significant interest, financial or otherwise, of an IRB member or consultant or of their immediate family, that may compromise, or have the appearance of compromising, the member's or consultant's professional judgment in reviewing research. This may include financial interest or compensation of \$5,000 or more, a significant role in the research, or a supervisory role over the principal investigator.
- 2.4 **Majority:** The next whole number over half the members.
- 2.5 **Quorum:** A majority of the voting members, including at least one non-scientific member and one physician if drug or device studies are to be reviewed.
- 2.6 **Submission window:** The period of time in which items will be accepted for the next agenda.

3.0 References:

- 3.1 45 CFR 46.108(b)
- 3.2 21 CFR 56.108
- 3.3 ICH-GCP 3.3.2

4.0 Procedure:

4.1 Meeting Schedule and Development of the Agenda

- 4.1.1 Regular meetings of both panels of the IRB are scheduled once a month for two hours. Occasional special meetings may be called as warranted. Special meetings may be convened meetings or short meetings conducted via telephone conference. HRPP staff prepare and distribute the agenda approximately one week before a scheduled meeting.

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- 4.1.2. Items to be reviewed at a convened meeting may include new protocols, continuing reviews, modifications to previously approved research, unanticipated problems involving risk to participants, issues of non-compliance, and any other items that have been deemed by the Chair/Vice Chair to require discussion by the full board. Generally, those items received by the established submission deadline (two weeks prior to a scheduled meeting) will be included on the agenda for that meeting. However, in order to allow adequate time for review, no more than 5 initial reviews and 7 continuing reviews, at a maximum, will be placed on any one agenda, unless permission to include more is given by the Chair/Acting Chair. If a smaller number of initial reviews are received (<5), then the number of continuing reviews may be increased to >7. For example, if 2 initial reviews are scheduled, then 9 continuing reviews may be scheduled.
- 4.1.3. Items will be assigned to an agenda according to the order in which they were received, with the exception that if more than 7 continuation reports are received within the submission window, some may be deferred to the next meeting, based on their date of expiration.
- 4.1.4. The agenda follows a standard format with the following sections:
- 4.1.4.1. Minutes – minutes of the previous meeting of that panel.
 - 4.1.4.2. Old Business – includes notification of items given final approval by the chairman/vice chairman of that panel, and any items not reviewed or not approved at a previous meeting of that panel.
 - 4.1.4.3. New Business – includes protocols, modifications, and other new items requiring full review; and notification of all items given expedited approval within the submission window for that agenda (such as protocols, minor modifications, progress reports, reports of adverse events/safety reports).
 - 4.1.4.4. Continuing Education – may include bulletins, selected articles of interest, or regulatory/guidance documents. Both panels receive the same material.
 - 4.1.4.5. Progress Reports – includes notification of projects that have been terminated within the submission window, either by request of the investigator or for lack of submission of a report when due.
 - 4.1.4.6. Other Business – on occasion may list important last-minute topics for discussion, and provides the opportunity for any member to bring up an item not listed on the agenda for follow-up or inclusion on a future agenda.
- 4.1.5. The agenda indicates the reviewer to whom full review items are assigned, and which items are included in the agenda packet.

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4.1.6. The IRB meeting typically is conducted according to the agenda; however, the order may be adjusted for practical reasons, such as to accommodate a reviewer's schedule, or to conduct reviews of similar studies in succession.

4.2 Attendance and Quorum

- 4.2.1 HRPP staff are responsible for taking minutes and attendance. Members' names are checked on an attendance list when they arrive at the meeting. When an alternate is attending in place of a regular member, the initials of the alternate are added. Should an alternate attend a meeting at which the regular member is also present, only one is counted toward the quorum, and only one may vote.
- 4.2.2. If a member who has received the agenda packet is unable to physically attend the meeting, but is available by telephone, it is acceptable for the member to participate in the meeting via speaker phone.
- 4.2.3. Guests are permitted to attend meetings with the Chair's approval. On occasion, an investigator will be invited to a meeting to present information and address the committee's questions and concerns in person. The investigator then leaves the meeting before further deliberation and voting.
- 4.2.4. Once it is determined by HRPP staff that sufficient members are present to constitute a quorum, the Chair is notified, and the meeting may begin (i.e., a majority of IRB members must be present). The quorum must include at least one member whose primary interests are in non-scientific areas and at least one physician if drug or device studies are to be reviewed.
- 4.2.4.1. At least one member who represents the general perspective of participants will be present at convened meetings. The member serving in this capacity will attend at least 75% of meetings each year.
- 4.2.4.2. At least one member who is unaffiliated with the institution will be present at convened meetings. The member serving in this capacity will attend at least 75% of meetings each year.
- 4.2.4.3. If the agenda includes research that involves categories of participants vulnerable to coercion or undue influence, one or more individuals who are knowledgeable about or experienced in working with such participants will be present for the review of such research. If they are not in attendance, the review will be deferred until such expertise can be obtained.
- 4.2.5. HRPP staff monitor attendance throughout the meeting to ensure that a quorum is maintained. If quorum requirements cease to be met during the meeting, staff will notify the chairman, and the meeting will be halted, either temporarily until the quorum is restored, or the meeting will be adjourned.

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4.3. **Chair/ViceChair Duties**

4.3.1. The Chair presides over convened meetings. In the event he is not able to attend a meeting, or if he must leave a meeting for any reason, the Vice Chair or other member designated by the Chair as Acting Chair will assume the role of Chair in his absence. The Acting Chair generally is responsible for granting final approval on items approved by the committee pending minor revisions. Another member of the committee (e.g., one of the primary reviewers) also may be designated to do this for any given study.

4.4. **Voting**

4.4.1. All members, including the chairman, are voting members, except that any member having a conflicting interest in the research under review may not participate in the review except to provide requested information. The member is expected to leave the meeting or recuse himself during the discussion and voting.

4.4.2. With few exceptions, motions are to approve, approve pending minor revisions, to table (i.e., for re-review at another meeting), or to disapprove. Once a motion is made and seconded, a vote is taken by show of hands, and is counted and recorded by HRPP staff by number in favor of the motion, number opposed, and number abstaining.

4.4.3. If a member abstains for reasons of a potential bias (for example, when reviewing a colleague's study), the member's name will be included after the number abstained.

4.4.4. A majority of those present must vote in favor of a motion to carry it.

4.5. **Materials Provided for Review**

4.5.1. Items to be reviewed by the full committee (initial reviews, continuing reviews, substantive revisions, and any other items deemed by the Chair or Vice Chair to merit full committee discussion) are assigned by HRPP staff to a reviewer. The reviewer assigned receives a full copy of all materials to be reviewed. All other members a full copy of the materials for review. The assigned reviewer presents the item to the committee and proposes items for revision or clarification. Any member may comment on the item after the formal presentation and may suggest revisions.

4.6. **Education**

4.6.1. Meetings may include an educational component. At a minimum, material is provided for members to read, which may be discussed during the meeting if time permits.

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4.7. Use of Consultants and Ad Hoc Members

- 4.7.1. If there is no member currently on the committee with appropriate experience to give an in-depth review to any particular item, an ad hoc member (such as a prisoner representative) or a consultant with the appropriate experience will be requested to attend the meeting and provide an expert assessment of the study.
- 4.7.2. Any ad hoc members appointed to the committee are voting members and will count toward the quorum only when present. Should other consultants be utilized to provide expert assessments, they will not be voting members, and will not count toward the quorum.

4.8. Teleconference

- 4.8.1. A meeting may be convened by teleconference under certain circumstances, at the Chair/Vice Chair's discretion. This may be done to review an item or items requiring review in a timely manner, when it is not practical to arrange a special full convened meeting. Such meetings are usually short in duration, typically 15 minutes or less. The item(s) to be reviewed will be available to all members according to the standard full review policy.
- 4.8.2. Attendance will be taken by HRPP staff by voice acknowledgement or using the participant roll call feature of the teleconferencing system. A quorum must be established to conduct the meeting, as for a regular convened meeting. Failure to reach a quorum with appropriate representation will result in the cancellation or postponement of the meeting.
- 4.8.3. Votes are taken by the Chair asking for acknowledgement of any opposed to the motion and those abstaining, and stating that unless anything is heard otherwise, it will be recorded that all others are in favor of the motion. All members known to be present will be counted in the vote. However, should the number of votes opposed and abstained be close to half the quorum, members will be asked for their votes individually.
- 4.8.4. Minutes will be recorded as for regular meetings, and will show that the meeting was conducted via teleconference.

5.0 Documentation:

- 5.1 The HHC HRPP office will maintain copies of agendas, minutes, and correspondence related to the reviews for a minimum of 6 years after the meeting.

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6.0 Revision History:

Rev #	Initials	Effective Date	Description of Change(s)
01	SMH	7/1/11	Conversion to new policy template; general expansion of policy
02	CLB	10/13/11	Added sections 4.2.4.1. and 4.2.4.2. – clarifying attendance by members representing the general perspective of participants and populations vulnerable to coercion.
03	CLB	7/22/15	Lowered the threshold for financial conflict of interest; added clarification that a majority of members must be present to begin a convened meeting; clarified attendance by the unaffiliated member.
04	CLB	3/15/20	General review and minor clarifications. Updated section 4.1.2. Updated AAHRPP element.

Element II.2.D.