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Use of Consultants/Ad Hoc Members in IRB Review				

1.0 Purpose:

- 1.1. The Hartford HealthCare Institutional Review Board (HHC IRB) may invite individuals with competence in special areas to assist in the review of complex issues which require expertise beyond or in addition to that available on the IRB.
- 1.2. Policies describe the process to determine that a consultant is needed.
- 1.3. Policies describe the process to obtain a consultant.
- 1.4. Policies describe the ways in which information provided by a consultant is communicated and documented.

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 the quorum only when present.
- 2.2 **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.
- 2.3 **Consultant:** A person who is not a member (regular, alternate, or ad hoc) of the IRB conducting a review, who is requested to provide professional or expert advice in a particular area. A consultant does not vote with the IRB members.
- 2.4 **Immediate Family:** Spouse and dependent children.

3.0 References:

- 3.1 45 CFR 46.107(d), 45 CFR 46.107(e)
- 3.2 21 CFR 56.107(e), 21 CFR 56.107(f)
- 3.3 ICH-GCP 3.2.6

4.0 Procedures:

4.1 Determination that a consultant is needed

- 4.1.1 At the time of compilation of the agenda, HRPP staff will determine whether a consultant or ad hoc member will be needed for review of any items requiring full review. (Generally, if an expedited reviewer does not have sufficient expertise to review an item, the item will be referred for full review.)
- 4.1.2 The primary reviewer assigned to an item, or the IRB as a whole, may also request that a consultant be utilized to supplement their review. If there is insufficient time for a consultant to accomplish the assessment

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prior to the convened meeting at which the research activity is scheduled for review, the review will be postponed to a future meeting.

- 4.1.3. Consultants may be engaged if it is determined that the field of study is not represented on the IRB, or if additional expertise may be needed for other reasons, such as involvement in the project of the committee's one expert in that field, or inclusion of vulnerable populations needing additional representation.

4.2 Process to Obtain a Consultant

- 4.2.1 A pool of consultants has been established, with representation from various areas that either are not currently represented on the IRB, or from which additional expertise may be needed because of a potential conflict of the one representative of that area on the IRB to which an item has been delegated for review.
- 4.2.2 If the HRPP staff or primary reviewer believe that additional expertise is needed for review of a particular research activity, this will be discussed with the chairman/vice chairman, and it will be decided whether to obtain a consultant or employ an ad hoc member.
- 4.2.3. If a consultant with the needed area of expertise is not available in the pool, a member of the other IRB panel may be asked to assist with the review as a consultant. Otherwise, the director of the clinical department involved in the study will be asked to identify someone from that area to serve as a consultant.
- 4.2.4. Consultants/ad hoc members will be contacted by HRPP staff, and will be provided with the same material pertinent to the review as would be given to a primary reviewer.

4.3 Ways in which Information is Communicated and Documented.

- 4.3.1 Consultants/ad hoc members will be requested either to attend the meeting at which the pertinent research activity is discussed, or to participate in the review via telephone. They will provide expert input as required in addition to any assigned reviewer (except when the consultant is an active member of another internal IRB panel), but consultants may not vote, nor will they be counted toward a quorum.
- 4.3.2 If an ad hoc member is not able to attend a meeting, either in person or via telephone, the item will not be reviewed by the IRB at that time. If a consultant is not able to actively participate in the discussion, a written evaluation must be submitted, and the consultant must confer with the primary reviewer assigned, prior to the meeting. If this cannot be done, the item will not be reviewed by the IRB at that time.
- 4.3.3 A written evaluation by a consultant or ad hoc member is acceptable for a continuing review that qualifies for expedited review.
- 4.3.4. Minutes will document how the consult/ad hoc member's assessment was provided (in person, via telephone, or written), and either the

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assessment will be included as an attachment to the minutes, or it will be summarized in the minutes.

4.4 Conflicts of Interest

- 4.4.1. HRPP staff will determine if a proposed consultant has a potential conflict of interest with the research activity to be reviewed. If a consultant has a conflict of interest, the Chairman will be so informed, and will determine whether the nature of the conflict is such that the consultant will be allowed to review the research activity. If so, the IRB will be informed of the conflict at the convened meeting.
- 4.4.2. Ad hoc members are required to have submitted a current financial disclosure, and any conflicts will be handled as for regular IRB members.
- 4.4.3. When consultants/ad hoc members have a conflict of interest, they may remain in the room to provide information requested by the IRB. However, they should leave the room before deliberation and voting.

5.0 Documentation:

- 5.1 The HHC HRPP office will maintain minutes of meetings and any evaluations submitted by a consultant/ad hoc member that is not otherwise incorporated into the minutes (such as for an expedited continuing review) for a minimum of 6 years after a meeting.
- 5.2 The HHC HRPP office will maintain documentation of IRB membership, attendance at convened meetings, and records relating to financial disclosures and training requirements completed by IRB members or consultants for a minimum of 3 years.

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	7/22/15	Lowered threshold for financial conflict of interest
03	CLB	3/15/20	General review. Updated regulatory citations.

Elements II.1.D, II.1.E