1.0 Purpose:

1.1 Minutes of Hartford HealthCare Institutional Review Board (HHC IRB) meetings should be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

2.0 Definitions:

2.1 **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.

2.2 **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.

3.0 References:

3.1 45 CFR 46.115(a)(2)

3.2 21 CFR 56.115(a)(2)

4.0 Procedure:

4.1 Minute-taking is the responsibility of the HRPP staff.

4.2 Minutes will include the committee name, date and scheduled time of meeting and time of adjournment, type of meeting (regular or special), location, primary chairman for the meeting, as well as the members in attendance (including alternates and the member for whom they are substituting), members absent, and any guests. If any member participates in a meeting via speaker phone, this will be documented.

4.3 Minutes will indicate the approval of minutes from the previous meeting. If a correction or amendment is made to the minutes, this should be documented in the current minutes, and the correction made to the original minutes. Minutes cannot be altered by anyone, including a higher authority, once approved by the members at a subsequent IRB meeting.

4.4 If a meeting must be cancelled because a quorum is not attained, this should be reflected in the minutes of either the current or the next meeting. Minutes will note when a member leaves the room and returns if this affects the vote, in order to document that the quorum is maintained throughout the meeting. If quorum requirements cease to be met during the meeting, the minutes should show that the meeting was adjourned for this reason.

4.5 If a member leaves the meeting for reasons of conflict of interest, this should be indicated in the minutes. If the chairman leaves the meeting for any reason, the minutes will reflect this, and note who assumed the chair in his absence.

4.6 Minutes will indicate the separate deliberation for each action and vote for each full review item. Actions generally are to approve, approve pending minor revisions, table, or to disapprove. The number of members voting for, against, and abstaining from the motion should be noted, the names of members abstaining when pertinent, and the total number of members present for the vote.

4.7 Minutes will note which reviewer was assigned to present an item for full review, and if input from a consultant was provided, and shall include any discussion of controverted issues in sufficient detail to define the issues and their resolution. Specific revisions requested should be clearly delineated, as well as the reason(s) for requesting these modifications. If an item is approved pending revisions, the minutes will indicate who will be responsible for reviewing the revisions and granting final approval. Minutes will document the reason(s) for disapprovals.

4.8 The approval period and “valid through” date will be indicated for all new protocols and continuing reviews. A statement also will be included regarding the level of risk and frequency of review.

4.9 Minutes will show when determinations were made regarding findings required by regulations and justification for the determinations for studies involving waivers, pregnant women/fetuses/neonates, prisoners, and children, and, for FDA-governed device studies, determinations of significant/non-significant risk. Minutes will also show justification for any deletion or substantive modification of information concerning risks or alternative procedures contained in a DHHS-approved sample consent form.

4.10 Minutes will indicate what items have been given expedited approval since the previous meeting.

4.11 Minutes will show significant discussions of other items, such as educational materials, procedural decisions, etc.

4.12 A copy of the minutes is provided to the Institutional Official (IO).

4.13 The IRB shall prepare and maintain adequate documentation of IRB activities, in addition to minutes of IRB meetings, including the following:

4.13.1 Records of continuing review activities, including, for federally funded or supported, the rationale for conducting continuing review of research that otherwise would not require continuing review as described in §46.109(f)(1).

4.13.2 Copies of all correspondence between the IRB and the investigators.

4.13.3 A list of IRB members in the same detail as described in §46.108(a)(2).

4.13.4 Written procedures for the IRB in the same detail as described in §46.108(a)(3) and (4).

4.13.5 Statements of significant new findings provided to subjects, as required by §46.116(c)(5).

4.13.6 The rationale for an expedited reviewer's determination under §46.110(b)(1)(i) that research appearing on the expedited review list described in §46.110(a) is more than minimal risk.

4.13.7 Documentation specifying the responsibilities HHC and any organization operating an IRB each will undertake to ensure compliance with the requirements of this policy, as described in §46.103(e).

5.0 Documentation:

5.1 The HHC HRPP office will maintain complete copies of minutes for a minimum of 6 years after a meeting. In addition, minutes documenting initial and continuing reviews and discussion of major revisions pertinent to individual research activities will be retained with the project until discarded.

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; minor clarification in section 4.6
03	CLB	3/15/20	Updates based on the Revised Common Rule

ElementII.5.B.