

Effective Date: 3/15/20	Original Issue Date: 5/16/06	Revision No.: 05	SOP No.: 608	Page 1 of 8
IRB Membership				

1.0 Purpose:

- 1.1 This policy ensures that the structure and composition of the Hartford HealthCare Institutional Review Board (HHC IRB) are appropriate to the amount and nature of the research reviewed and in accordance with requirements of applicable laws, regulations, codes and guidance, and institutional policies and procedures.
- 1.2 This policy shall apply to each type of review, such as:
 - 1.2.1 Review by the convened IRB
 - 1.2.2 Review by the expedited procedure
 - 1.2.3 Review of unanticipated problems involving risks to subjects or others
 - 1.2.4 Review of non-compliance with regulations or laws or the requirements of the IRB

2.0 Definitions:

- 2.1 **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.
- 2.2 **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 **Immediate Family** - Spouse and dependent children.

3.0 References:

- 3.1 45 CFR 46.107
- 3.2 45 CFR 46.108(b)
- 3.3 45 CFR 46.304
- 3.4 21 CFR 56.107
- 3.5 21 CFR 56.108(c)
- 3.6 21 CFR 56.115(a)(5)
- 3.7 ICH-GCP 3.2.1, 3.2.3, 3.2.4, 3.2.5, 3.2.6

4.0 Procedures:

4.1 Composition

- 4.1.1 The composition of the IRB will be consistent with federal and state requirements; i.e. at least 5 members with varying backgrounds and professions, and including representatives from both sexes. At least one member's primary background will be in a scientific area, including a physician if device or drug studies are to be reviewed, and at least one member's primary background will be in non-scientific areas. In addition, at least one member will not be otherwise affiliated with the institution or

Effective Date: 3/15/20	Original Issue Date: 5/16/06	Revision No.: 05	SOP No.: 608	Page 2 of 8
IRB Membership				

part of the immediate family of a person affiliated with the institution. Each IRB panel will also have at least one member who represents the perspective of research participants. The IRB shall be sufficiently qualified through the experience and expertise of its members and the diversity of its members, including consideration of race, gender, cultural backgrounds, and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review the specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas.

4.1.1.1 The unaffiliated member, the member representing the general perspective of subjects, and the non-scientific member may be the same person or they may be represented by two or three different persons.

4.1.2. In addition to the above, if research subject to Subpart C (research involving prisoners) is being reviewed, membership requirements will also include the following:

4.1.2.1. A majority of the board shall have no association with the prison(s) involved.

4.1.2.2. At least one member of the board shall be a prisoner or prisoner representative with appropriate background and experience to serve in that capacity, except that this requirement need be met by only one board reviewing any particular project.

4.1.3. If at any time the expertise of a board is not sufficient for review of a specific research activity, one or more consultants may be engaged for this purpose. Such consultants may be engaged if it is determined by the HRPP Director, in consultation with the IRB Chair, 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, or inclusion of vulnerable populations needing additional representation.

4.1.4. Consultants will be requested to attend the meeting(s) at which the pertinent research activity is discussed. They will provide expert input as required in addition to the review of the assigned group, but the consultants may not vote, nor will they be counted toward a quorum.

4.2. **Appointment**

4.2.1. Scientific members are selected based on their experience and expertise to permit appropriate evaluation of proposed research according to the nature of applications being received. Non-affiliated, non-scientific, and members representing the general perspective of participants are appointed to help ensure that the needs of the community served are

Effective Date: 3/15/20	Original Issue Date: 5/16/06	Revision No.: 05	SOP No.: 608	Page 3 of 8
IRB Membership				

represented and that information will be presented in language that is understandable to members of the community who may participate in the research.

4.2.1.1. The IRB Chair will be appointed by the Vice President for Research or Director of Research., The Chair must be a physician.

4.2.1.2. All other physician members are to be appointed by the Vice President for Research or Director of Research upon recommendation by the Executive Committee of the Medical Staff Council and the IRB Chair. This membership is reviewed annually.

4.2.1.3. All non-physician members are to be appointed by the Chair. The Chair, with possible recommendation from primary members, will appoint alternate members. Alternate members will be listed on the IRB roster along with primary members. The roster will identify the primary member(s) for whom each alternate may substitute.

4.2.2. If the Chair is an active investigator while holding this position, he shall not appoint or make a recommendation for appointment of any member that would give undue advantage to consideration of his research. Nor shall he knowingly refrain from appointing an otherwise qualified person based on potential conflict with his own research. Members who are active investigators may recommend their own alternates. Otherwise, it is generally expected that active investigators will not have input into selection of committee members.

4.2.3. The Chair or members may be removed from the board for a justified reason; e.g., a conflict that may affect the proper functioning of the committee, or failure to attend a minimum of 50% of the scheduled meetings within a twelve month period. There is no limit on the length of service of the chairman or the members. The chairman and members are not compensated for their time.

4.3. **Responsibilities**

4.3.1. The Chair will:

4.3.1.1. Preside over all convened meetings or designate an acting Chair in his absence.

4.3.1.2. Attend a minimum of 75% of scheduled meetings in a 12-month period.

4.3.1.3. Make recommendations for appointment of physician members, and appoint non-physician members and alternates.

4.3.1.4. Review or designate another experienced member to review items meeting the criteria for expedited review.

Effective Date: 3/15/20	Original Issue Date: 5/16/06	Revision No.: 05	SOP No.: 608	Page 4 of 8
IRB Membership				

- 4.3.1.5 Review or designate another experienced physician member to review compassionate/emergency use requests.
- 4.3.1.6. Sign correspondence as necessary.
- 4.3.1.7. Complete the IRB Member CITI training course and the designated modules of the training course of the Office for Human Research Protections (OHRP).
- 4.3.1.8. Provide a current Financial Disclosure form.
- 4.3.1.9. Provide a curriculum vitae.
- 4.3.2. The Vice Chair will:
 - 4.3.2.1. Preside over convened meetings in the Chair's absence or designate an acting Chair in his absence.
 - 4.3.2.2. Attend a minimum of 75% of scheduled meetings in a 12-month period.
 - 4.3.2.3. In the Chair's absence, or when the Chair has a potential conflict of interest, review or designate another experienced member to review items meeting the criteria for expedited review.
 - 4.3.2.4. Sign correspondence as necessary.
 - 4.3.2.5. Complete the IRB Member CITI training course.
 - 4.3.2.6. Provide a current Financial Disclosure form.
 - 4.3.2.7. Provide a curriculum vitae.
- 4.3.3. The IRB members will:
 - 4.3.3.1. Attend a minimum of 50% of scheduled meetings in a 12-month period.
 - 4.3.3.1.1. Members representing the general perspective of participants will attend a minimum of 75% of scheduled meetings in a 12-month period.
 - 4.3.3.2. Review in depth all items assigned to them and be prepared to present them to the committee at convened meetings, and be sufficiently familiar with other items in order to vote on them.
 - 4.3.3.3. Assist with review of items meeting the criteria for expedited review and other items as requested by the Chair/Vice Chair.

Effective Date: 3/15/20	Original Issue Date: 5/16/06	Revision No.: 05	SOP No.: 608	Page 5 of 8
IRB Membership				

- 4.3.3.4. (Physicians only) Review compassionate/emergency use requests as requested by the Chair or in his absence.
- 4.3.3.5. Participate in audits as needed.
- 4.3.3.6. Complete the IRB Member CITI Training course.
- 4.3.3.7. Provide a current Financial Disclosure form.
- 4.3.3.8. Provide a curriculum vitae.

4.3.4. The alternates will:

- 4.3.4.1. Review in depth all items assigned to them (or a regular member for whom they may substitute) and be prepared to present them to the committee, and be sufficiently familiar with other items in order to vote on them.
- 4.3.4.2. Complete the IRB Member CITI Training course.
- 4.3.4.3. Provide a current Financial Disclosure form.
- 4.3.4.4. Provide a curriculum vitae.

4.4. Conflicts

- 4.4.1. IRB members, alternates, consultants (etc.) (anyone reviewing or approving research) should not participate in a review in which they or a member of their immediate family have a potential conflicting interest other than to provide information requested by the IRB. All members and alternates are required to complete a Financial Disclosure form on an annual basis, and are expected to leave a meeting for the discussion and voting on any component of a study in which a conflicting interest may exist.

4.5. Evaluation

4.5.1. Chair/Vice Chair

- 4.5.1.1. The HRPP Director will conduct an annual assessment of the Chair. This assessment will be shared with the IO. The IO will provide formal written feedback to the Chair.

- 4.5.1.1.1. The HRPP Director will conduct an annual assessment of the Vice Chairs with input from the Chair. Written feedback will be provided to the Vice Chairs and the IO will be copied on that communication.

- 4.5.1.1.1.1. Objective and subjective criteria to be evaluated may include: attendance, number of reviews completed as the primary reviewer, completion of educational

Effective Date: 3/15/20	Original Issue Date: 5/16/06	Revision No.: 05	SOP No.: 608	Page 6 of 8
IRB Membership				

requirements, attendance at educational sessions, preparedness for meetings, ability to lead meetings, communication with investigators, ability to work with IRB staff, etc.

4.5.1.2. In addition, IRB members (and alternates who attended meetings during the evaluation period) will complete an evaluation checklist once a year, which includes a section on the performance of the Chair/Vice Chair. These will be reviewed by the HRPP Director, and the results will be shared with the Chair as part of the above described written feedback.

4.5.1.2. If necessary, educational materials will be provided to the Chair to address any issues identified in the survey.

4.5.2. Members/alternates

4.5.2.1. The HRPP Director will conduct an annual assessment of individual members with input from the Chair. Written feedback will be provided. The IO and the member's Department Head will be copied on that communication.

4.5.2.1.1. Objective and subjective criteria to be evaluated may include: attendance, number of reviews completed as the primary reviewer, completion of educational requirements, attendance at educational sessions, preparedness for meetings, ability to lead meetings, communication with investigators, ability to work with IRB staff, etc.

4.5.2.2. In addition, IRB members (and alternates who attended meetings during the evaluation period) will complete an evaluation checklist once a year, which includes a self-evaluation section on their performance. These will be reviewed by the HRPP Director and included as part of the above described written feedback.

4.5.2.3. Any problematic issues identified will be brought to the attention of the Chair, who will discuss them with the member. Educational materials may be provided to the members if deemed necessary.

4.5.3. HRPP Staff

4.5.3.1. The HRPP Director will conduct an annual assessment of IRB Administrators with input from the Chair and Vice Chairs. The HRPP Director will be evaluated by the IRB Chair. Written feedback will be provided. These evaluations will be performed at the time of, and in addition to, annual Performance Evaluations mandated by Human

Effective Date: 3/15/20	Original Issue Date: 5/16/06	Revision No.: 05	SOP No.: 608	Page 7 of 8
IRB Membership				

Resources. The IO will be copied on the written communication.

4.5.3.1.1. Objective and subjective criteria to be evaluated may include: workload, timeliness of processing materials and IRB minutes, maintenance of paper files, agenda preparation, , completion of educational requirements, attendance at educational sessions, preparedness for meetings, quality of pre-reviews, knowledge of regulations and organizational policies and procedures, communication with IRB Chair/Vice Chairs, supervisor, and investigators, ability to help investigators, etc.

4.5.3.2 IRB members (and alternates who attended meetings during the evaluation period) will complete an evaluation checklist once a year, which includes a section on the performance of the HRPP staff. These will be reviewed by the HRPP Director, and the results will be shared with the staff.

4.5.3.3. Any issues regarding the HRPP Director will be reviewed by the Chair and the Institutional Official, if necessary.

4.5.3.4. Corrective measures will be taken as necessary. These may involve education or development and implementation of new processes.

4.5.4. Investigators may be asked to complete a satisfaction survey once a year, and the results would be included with the above evaluations.

5.0 Documentation:

5.1. The HHC Human Research Protection Program (HRPP) office will maintain documentation related to IRB membership, including attendance, rosters, and curricula vitae, and records relating to financial disclosures and training requirements, and written evaluations completed for a minimum of 3 years.

5.1.1. IRB rosters will include each member/alternate's name, earned degree(s), representative capacity (i.e., experience with vulnerable populations), area of scientific expertise (if any), and relationship to institution. Information for alternates will also indicate for what member(s) the alternate may substitute.

5.2. Changes in membership will be reported to OHRP as an update to the IRB Registration.

Effective Date: 3/15/20	Original Issue Date: 5/16/06	Revision No.: 05	SOP No.: 608	Page 8 of 8
IRB Membership				

6.0 Revision History:

Rev #	Initials	Effective Date	Description of Change(s)
01	SMH	7/1/11	Conversion to new policy template; expansion of policy to include evaluation of members
02	CLB	10/13/11	Clarified that IRB membership will include an individual representing the general perspective of subjects and added section 4.1.1.1. Added section 4.3.3.1.1. to define the attendance requirement for this member.
03	CLB	1/28/13	Details regarding evaluation of IRB Chair, Vice Chairs, IRB members, and IRB staff were added to include the criteria for evaluation and the format of feedback.
04	CLB	7/22/15	Added clarification that IRB shall not have members representing a single profession; lowered the Financial Conflict of Interest threshold; clarified that this policy covers each type of review
05	CLB	3/15/20	General review; replace chairman with Chair throughout

Elements II.1.B., II.1.D.