

SOP: OR 201 Version No.: 06 Effective Date: 12/17/10	IRB COMPOSITION AND OVERSIGHT OF IRB MEMBERSHIP	Supersedes Document: Dated: 7/1/08
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Steering Committee approved 12/17/10

1. POLICY

Each IRB shall be able to evaluate the acceptability of proposed research in accordance with the applicable institutional commitments and guidelines of the Facility, applicable law, and standards of professional conduct and practice. Each IRB should also be able to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.

Therefore, each IRB shall consist of at least five regular, voting members. Qualified persons from multiple professions and of both sexes shall be considered for membership. IRB membership shall not consist entirely of men or of women.

The RSPP will make every effort to have a diverse membership appointed to each IRB, as practicable given the scope of expertise needed to conduct its functions.

Specific Policies

Terms used in this policy, but not defined herein shall have the meanings set forth in the Glossary.

1.1. Membership Selection Criteria

1.1.1. The members of each IRB shall be sufficiently qualified through experience and expertise to review research proposals in terms of regulations, applicable law, standards of professional conduct and practice, and the applicable institutional commitments. Therefore, each IRB shall include persons knowledgeable in these areas.

1.1.2. The membership shall be diverse, so selection shall include consideration of race, gender, cultural backgrounds, clinical experience, healthcare experience and sensitivity to such issues as community attitudes to assess the research submitted for review.

1.1.3. There shall be at least one member for each IRB whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas. There shall be at least one member for each IRB who has no affiliation with Aurora and who does not have any family members with affiliations to Aurora.

1.1.4. For each IRB considering research studies that enroll patients suffering from mental illness, developmental disabilities, alcoholism or drug abuse there shall be at least one member who has been a consumer of services related to mental health, developmental disabilities, alcoholism or drug abuse, and at least one member who represents either an agency or organization which advocates the rights of patients suffering from mental illness, developmental disabilities, alcoholism or drug abuse.

1.1.5. Any member of the IRB who has medical staff privileges at any Aurora-affiliated hospital at the time he/she is appointed may be removed from the IRB, at

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the discretion of the Institutional Official, if such member’s medical staff privileges are suspended, removed or revoked. Such individuals may be eligible for reappointment by the Steering Committee when they have regained full medical staff privileges.

1.1.6. Voting membership shall not include individuals who are responsible for Aurora business development.

1.2. Composition of the Board

1.2.1. Regular members: The backgrounds of the regular members shall be varied in order to promote complete and adequate reviews of the types of research activities commonly reviewed by each IRB. Regular members must include:

(i) Unaffiliated member(s): The unaffiliated member(s), who can be either scientific or nonscientific reviewers, should be knowledgeable about the local community and be willing to discuss issues and research from that perspective. Consideration should be given to recruiting individuals who speak for the communities from which the subjects are drawn. The unaffiliated member(s) should not be vulnerable to intimidation by the professionals on the respective IRB.

(ii) Scientific members: Each IRB shall include at least one physician and one non-physician level scientist. Such members satisfy the requirement for at least one scientist. When any of the IRBs encounter studies involving science beyond the expertise of the members, the IRB may use a consultant to assist in the review, as provided by 21 C.F.R. 56.107(f) and 45 C.F.R 46.107(f).

(iii) Nonscientific member: The intent of the requirement for diversity of disciplines is to include members whose main concerns are not in scientific areas. Therefore, nonscientific members are individuals whose education, work, or interests are not solely in medical or scientific areas. At least one nonscientific IRB member must be at each IRB meeting for the quorum requirements to be satisfied.

(iv) Consumer and Patient Advocate: When research involves the enrollment of subjects who are inpatients in a hospital and are being treated primarily for conditions related to mental health, developmental disabilities, alcoholism, or drug abuse, to meet quorum requirements at least one member must be or must have been a consumer of such services and one member must represent an organization or agency that advocates the rights of such inpatients.

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(v) Representatives of special groups of subjects (a.k.a. Consultants): When certain types of research are reviewed, members or consultants who are knowledgeable about the concerns of certain groups may be required. For example, if an IRB reviews research targeting prisoners as subjects, a member who can represent this group, either an ex-prisoner or an individual with specialized knowledge about this group, must be included on the IRB.

Other vulnerable populations that may require participation by non-voting IRB members or consultants include children, pregnant women, handicapped, or mentally disabled individuals (see Policy SC 501).

When additional expertise is required and is not available among the IRB membership, a consultant may be requested. Consultants to the IRB shall not vote, count toward quorum nor serve as primary reviewer, however they may be requested to attend the IRB meeting and to provide a written report to the IRB. Consultants will be required to sign the Meeting Visitors/Consultants Confidentiality Agreement (Form 304-A), the Consultant Conflict of Interest form (GA 104-D), and to provide the RSPP office with a current curriculum vitae.

1.2.2. Nonvoting members: One or more nonvoting members may sit on the IRB on an as -needed basis when the research reviewed requires specific expertise of an IRB member from a different Aurora IRB, an Administrator of a Facility or representative of an Aurora region. Nonvoting members shall not vote on any research proposals or be counted toward quorum.

1.2.3. Alternate Members: An alternate member may sit on the IRB for his/her designated regular voting member. The appointment of alternate member(s) should be based on expertise similar to that of the regular voting member(s) to ensure that the IRB maintains the expertise required to review research proposals. An alternate member shall be assigned to the regular voting member for whom he/she may vote, and an alternate member may be designated to serve for more than one regular member, as long as the alternate possesses expertise similar to that of each regular voting member for whom he/she is designated. An alternate member may be considered for quorum and vote even if the regular voting member is present, provided the minutes reflect that the regular member is not voting. IRB meeting minutes will document when an alternate member replaces a regular voting member. When alternate members substitute for a regular voting member, the alternate member will have received and reviewed the same material that the regular voting member received or would have received. At times, an alternate member may be asked to serve as Primary Reviewer and provide expertise for a specific protocol. If quorum requirements are met, the alternate member will not count toward quorum and will not vote. This will be reflected in the meeting minutes.

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1.2.4. IRB Chairs: The individual IRB Chairs should be highly respected individuals, from within Aurora Health Care, who are fully capable of managing the IRB and the matters brought before it with fairness and impartiality.

1.3. **Appointments**

The IRB Steering Committee has the authority to appoint members (voting, nonvoting and alternate) to the IRB. Members will be solicited from Aurora Health Care and greater Milwaukee communities and any other communities where the respective IRB meets or Facilities from which research studies are submitted frequently.

The Steering Committee, in consultation with Aurora administrators as necessary, has the authority to appoint the IRB Chairs and Senior IRB Chair. The IRB Chairs will be employees or staff members of Aurora Health Care, Inc.

1.4. **Term.**

Members, including the IRB Chair, will serve on the IRB for a term of three years. Reappointment for additional terms may occur by IRB Steering Committee process. There is no limit to the number of terms an individual can serve.

1.5. **Resignations and Removals**

An IRB member may resign before the conclusion of his/her term. It is at the IRB Steering Committee's discretion to recommend replacement of the resigning member. An IRB member may be removed at any time, with or without cause, by the IRB Chair(s) in consultation with the Institutional Official and the IRB Steering Committee. The Institutional Official may remove IRB Chairs or other IRB members at any time with or without cause. Failure to attend the meetings in accordance with Policy OR 202, Section 1.3 may be the basis for removal.

1.6. **Compensation**

IRB members are not compensated for their participation on an Aurora IRB.

1.7. **Reimbursement of Expenses**

1.7.1. The RSPP Manager shall have the discretion to reimburse IRB members for expenses associated with their membership including expenses incurred for continuing education. Any such expense must receive prior approval of the Institutional Official.

1.7.2. Unaffiliated IRB members will be paid a modest stipend for each meeting attended. Payment is not related to or dependent upon a favorable decision or vote on a protocol.

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2. SCOPE

These policies and procedures apply to the membership of the IRB.

3. APPLICABLE REGULATIONS, GUIDELINES AND STANDARDS

45 C.F.R. 46.107 (a) through (d)

21 C.F.R. 56.107 (a) through (d)

Wis. Stats. § 51.61 (l)(j)

Wis. Admin. Code DHS § 94.13

FDA Information Sheets, IRB FAQ, Question #8 and #17

ICH Guidelines 3.2.1 and 3.2.3

OHRP IRB Guidebook, Section I (B)

OHRP Common Findings and Guidance #54

OHRP Guidance on Continuing Review (January 15, 2007)

OHRP Guidance on Written IRB Procedures (January 15, 2007)

OHRP Sample IRB Registration

AAHRPP Elements II.1.A., II.1.B., II.1.C., and II.1.E.

4. REFERENCES TO OTHER APPLICABLE SOPS

This SOP affects all other SOPs.