

**DECATUR MEMORIAL HOSPITAL  
INSTITUTIONAL REVIEW BOARD**

**SUBJECT:** COMPOSITION OF THE IRB

**STANDARD:** PATIENT RIGHTS AND ORGANIZATION ETHICS

**EFFECTIVE:** 1/98; 4/08

**POLICY:**

Each 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. 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.

Decatur Memorial Hospital will make every effort to have a diverse membership appointed to the IRB, within the scope of available expertise needed to conduct its function. All IRB members shall be approved by the hospital Board of Directors.

**Specific Policies**

***Membership Selection Criteria***

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

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.

There shall be at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas. There shall be one member who has no affiliation with Decatur Memorial Hospital, either self or family member.

***Composition of the Board***

**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 the IRB. Regular members must include:

Non-Affiliated members: The non-affiliated member(s), who can be either scientific or non-scientific 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 Decatur Memorial Hospital will draw its research participants. The non-affiliated member(s) should not be vulnerable to intimidation by the professionals on the IRB, and their services should be fully utilized by the IRB.

Scientific members: Most IRBs include physicians and Ph.D. level physical or biological scientists. Such members satisfy the requirement for at least one scientist. When an IRB encounters studies involving science beyond the expertise of the members, the IRB may use a consultant to assist in the review, as provided by 21 CFR 56.107(f). However, when FDA regulated products are reviewed, the convened meeting must include a licensed physician member.

Non-Scientific members: The intent of the requirement for diversity of disciplines is to include members whose main concerns are not in scientific areas. Therefore, non-scientific members are individuals whose education, work, or interests are not solely in medical or scientific areas.

Representatives of special groups of participants: 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 involving prisoners, 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.

Co-Chairpersons: The individual IRB Chairpersons should be highly respected individuals, from within Decatur Memorial Hospital, fully capable of managing the IRB and the matters brought before it with fairness and impartiality.

**APPLICABLE TO:**

These policies and procedures apply to the IRB members.

**RESPONSIBILITY:**

The Institutional Official is responsible for ensuring the IRB has adequate resources to identify and recruit qualified potential members.

The IRB Co-Chairperson(s) is responsible for recruiting and evaluating new IRB members.

The IRB Administrator is responsible for recruiting and installing new IRB members.

**APPROVED BY:**

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President and CEO