

**INSTITUTIONAL REVIEW BOARD  
SOP 201: COMPOSITION OF THE DMH IRB**

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**POLICY**

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 also be able to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.

Therefore, the 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.

**PROCEDURES**

**1. Membership Selection Criteria**

- 1.1 Members of the DMH 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 DMH IRB shall include persons knowledgeable in these areas.
- 1.2 The membership shall be diverse, so selection will 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.
- 1.3 There shall be at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in non-scientific areas. There shall be one member who has no affiliation with Decatur Memorial Hospital, either self or family member. One member can be unaffiliated with Decatur Memorial Hospital and have a primary concern in a non-scientific area. This individual would satisfy two of the membership requirements of the regulations.
- 1.4 The IRB shall include members who are knowledgeable about the concerns of participants who may be vulnerable (e.g. prisoners, extreme elderly [age  $\geq$  85], and handicapped or mentally disabled persons, etc.). Examples of such members might be individuals who are employed by the Sheriff's Office, or who work directly and advocate for these special groups.

**2. Composition of the Board**

- 2.1 Regular Board Members: The backgrounds of the regular board 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:
  - 2.1.1 Non-Affiliated Member(s): The non-affiliated members, who can be either scientific or non-scientific, should be knowledgeable about the communities in which they serve and be willing to discuss issues and research from that perspective.
  - 2.1.2 Scientific Member(s): Most IRBs include physicians and doctorate level physical or biological scientists, nurses, pharmacists, and other biomedical healthcare professionals. Such members satisfy the regulatory requirement for at least one scientist. When the DMH IRB encounters device studies or studies involving science beyond the expertise of the members, the IRB may use an ad hoc 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 or retired physician.

2.1.3 Non-Scientific Member(s): 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.

2.2 Alternate Board Member(s): Alternates are members who may substitute for another member while serving in the same capacity, i.e. scientific member for another scientific member. It is not a requirement to have alternate board members.

### **3. IRB Leadership**

3.1 The IRB Co-Chairs should be highly respected individuals from within Decatur Memorial Hospital (past or present), fully capable of managing the IRB and the matters brought before it with fairness and impartiality.

#### **SCOPE**

This SOP applies to all IRB members and ad hoc consultants.