

**DECATUR MEMORIAL HOSPITAL  
INSTITUTIONAL REVIEW BOARD**

**SUBJECT:** IRB MEETING ADMINISTRATION

**STANDARD:** PATIENT RIGHTS AND ORGANIZATION ETHICS

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

**POLICY:**

Except when an expedited review procedure is used, the IRB will review proposed research at convened meetings at which a quorum is present. The IRB will meet monthly, or at some other frequency determined by the IRB Co-Chairperson and the IRB Administrator.

**Specific Policies**

***Quorum***

A quorum is defined as one half of the number of regular members, plus one.

A quorum consists of regular and/or their alternate members and includes: at least one member whose primary concerns are in scientific areas, and one member whose primary concerns are in nonscientific areas.

When FDA-regulated research is reviewed, there shall be one member who is a physician.

An alternate member may attend in the place of an absent regular member in order to meet the quorum requirements outlined above.

A special consultant will not be used to establish a quorum.

***Primary Reviews***

Prior to the meeting, the IRB Administrator will designate primary reviewers for each research proposal.

***Meeting Materials Sent Prior to IRB Meetings***

All IRB members will be sent study documentation required for review sufficiently in advance of the meeting to allow time for adequate review. These include:

Agenda: A meeting agenda will be prepared by the IRB Administrator or designee and distributed to IRB members prior to each meeting. A copy of the agenda and attached materials will be maintained on file with the meeting minutes.

Reviewer Material: All IRB members will have access to the entire submission.

***Minutes***

The Federal regulations for the protection of human participants [45 CFR 46.115(a)(2)] require that "Minutes of IRB meetings...shall be in sufficient detail to show attendance at the meeting; 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." These requirements are minimal.

However, Decatur Memorial Hospital does not believe it can be assumed that all regulatory requirements for review of research have taken place at an IRB meeting unless the IRB minutes record that they were considered and discussed. Good minutes should enable a reader who was not present at the meeting to determine exactly how and with what justification the IRB arrived at its decision.

**Recording:** The IRB Administrator or designee will take minutes of each meeting using the IRB Agenda/Minutes Template. Minutes will be written in sufficient detail to show the following:

- Meeting attendance, including status of each attendee (regular member, consultant, etc.), and any conflicts of interest;
- Actions taken by the IRB on each agenda item requiring full IRB action, including the basis for requiring changes in or disapproving the research;
- Summary of the discussion of controverted issues and resolution;
- Voting results, including the number for, against and members who recused themselves and reason for recusal.

**Minutes:** Draft minutes will be made available electronically to members prior to the IRB meeting.

- Corrections requested by the IRB will be made by the IRB Administrator or designee and the minutes will be printed in final form. The Co-Chairperson of the IRB shall sign and date the final, approved minutes.
- The IRB Administrator will maintain copies of the minutes, as well as the agenda and pertinent materials on file.

A majority of members must vote in favor of an action for that category of action to be accepted by the IRB. Only regular and alternate members acting in place of absent regular members may vote. The vote will be recorded in the minutes. Members with a conflict of interest will recuse themselves from the discussion and voting, and such will be noted in the minutes.

### ***Voting***

Members of the IRB vote upon the recommendations made by the primary reviewers according to the criteria for approval. Members also will determine the levels of risk and the frequency of review for each protocol.

### **APPLICABLE TO:**

These policies and procedures apply to all research submitted to the IRB.

### **RESPONSIBILITY:**

IRB Administrator is responsible for IRB meeting procedural conduct and documentation.

IRB Co-Chairperson is responsible for IRB meeting review conduct and leadership.

### **APPROVED BY:**

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President and CEO