

DEPARTMENT OF HEALTH AND HOSPITALS  
INSTITUTIONAL REVIEW BOARD

-BYLAWS-

I. **PURPOSE AND SCOPE**

- A. The purpose of the DHH Institutional Review Board (hereinafter referred to as the DHH IRB) is to assess conformity to the Department's research policies and approval guidelines to ensure that:
1. all appropriate individual rights of research subjects are protected;
  2. research procedures are ethical, humane and involve minimal risk; if more than minimal risk is involved, research is justifiable in terms of potential benefit to the subjects and/or humanity;
  3. adequate procedures for obtaining subject's and/or guardian's informed consent exist;
  4. the proposed research design conforms to appropriate scientific or methodological standards (as established in NIH/OPRR's Institutional Review Board Guidebook).
- B. The scope of the DHH IRB is to review research conducted in programs/facilities operated and/or funded by DHH and to recommend to the Secretary approval or disapproval of such research.

II. **AUTHORITY**

- A. The Secretary delegates to the DHH IRB authority to review and make recommendations for all research proposals under its scope.
- B. Research approved by the DHH IRB must have final approval by the Secretary or designee in the form of a dated signature on the research application or a cover memorandum. Without such approval, research cannot begin. However, the Secretary or designee cannot approve research unless it has been approved by the IRB.
- C. A decision by the DHH IRB taken in a regular meeting by a simple majority vote of the members present and constituting a quorum which does not approve research or which temporarily or permanently stops a research project **may not be overridden**.

- D. Issues cannot be resolved by the DHH IRB should be brought to the attention of the Secretary
- E. The DHH IRB has the authority and responsibility to oversee research in progress and to recommend suspension or termination to the Secretary if warranted.

### III. **ORGANIZATION AND COMPOSITION**

#### A. Membership

1. The membership shall consist of at least seven members, chosen by the Secretary from recommendations made by the Program Offices, the Bureau of Health Services Financing, and Director of the Division of Research and Development.
2. The Board shall consist of both men and women, and - as far as possible - reflect racial and cultural diversity of the State.
3. At least one (1) member shall not be employed by the Department.
4. At least one (1) member shall have nonscientific interests and concerns.
5. At least one (1) member shall represent consumers and families.
6. At least one (1) member shall be an ethicist, and at least one (1) member shall be an attorney.
7. All members are appointed by the Secretary.
8. *Ad hoc* members or consultants may be recruited by the IRB Chair, especially if appointed members do not have the requisite scientific and professional expertise to review comprehensively a particular research proposal.

#### B. Chairperson and Secretary

1. The Chairperson shall be the Director of Research as appointed by the Executive Director of the Division of Research and Development. A replacement (due to extended absence of the Director) shall be appointed by the Secretary.
2. The Chairperson of the IRB should have some experience in research and have some experience in clinical human subject research.

3. The Chairperson shall review initially all protocols, call meetings, set agendas, and encourage member participation.
4. The Chairperson shall provide a communications link between the Secretary, researchers, and other IRB members.
5. The IRB Secretary shall be appointed by the Chairperson to record all minutes and correspondence and, together with the Chairperson, to retain all records.

C. Term of Membership

1. IRB members shall serve one (1) year terms, with the option to renew membership annually thereafter.
2. Members who miss three (3) consecutive meetings (unless excused by the Chairperson or the Secretary) will be subject to removal by the Secretary.

D. Quorum

1. A quorum shall consist of a simple majority of appointed members and must include at least one (1) licensed medical practitioner, one (1) external nonmedical person (e.g., clergy, attorney, consumer), one (1) scientist (e.g., a licensed professional familiar with scientific methods and statistics), and one (1) member actively concerned with protection of client rights.

IV. **MEETINGS**

- A. The IRB shall meet quarterly or more often if necessary.
- B. An agenda including items such as time and place of the meeting, the order of business, and/or materials to be reviewed shall be distributed to each member prior to the meetings.

V. **RECORDS**

- A. Minutes of all meetings, notifications to investigators concerning recommendations and reviews, and all protocols and consent forms in original and final forms, conclusions, and all publications shall be kept in the office of the IRB Chairperson.
- B. Records shall be retained three (3) years after completion of the project.
- C. Copies of minutes, directives, and recommendations shall go to the Secretary, the Deputy Secretary and the Undersecretary.



## VI. VOTING

- A. A majority vote of those attending the meeting is required for approval or disapproval.
- B. In the instance of a tie vote, another regular meeting shall be called, at which time the proposal will again be voted upon after further consideration.
- C. A poll vote by phone or mail may be taken by the Chairperson if the proposal has been granted prior (partial) approval by a majority vote.
- D. Proposals granted provisional approval by the IRB at a regular meeting do not require another full Board vote. Instead the researcher will submit within thirty (30) days necessary revisions to the Chairperson for approval and forwarding to the Secretary. The Chairperson will inform the board of such approvals at the next meeting.
- E. If a Board member's research proposal is under consideration, she/he must absent herself/himself from that meeting and voting. If this results in lack of a quorum, the Chairperson may call in alternate members.

## VII. GUIDELINES FOR PROPOSALS

- A. The attached "Guidelines and Application Materials for Research" involving clients in the Department of Health and Hospitals embodies, in brief, the IRB's requirements and procedures for research applications and review/approval of research projects.
- B. Research projects conducted by Quality Assurance Committee and involving only record reviews are normally exempt from Board review.
- C. Research proposals which may be granted expedited review and approval are specified in IRB Policies and Procedures.