

NOTICE OF INTENT

Department of Health and Hospitals Office of Public Health

Institutional Review Board for Human Subjects

There is established within the Office of Public Health (OPH) the Institutional Review Board for Human Subjects (IRB). Each member of this IRB shall be appointed by the state health officer, and shall serve until removed by the state health officer, or upon the resignation of the member from the appointed position on the IRB. Herewith are appointed the following persons:

From the Office of Public Health—at least five persons, one of whom will serve as chair of the board;

From the New Orleans Aids Task Force—at least one person, who will serve as the community representative.

In accord and compliance with Title 45, Code of Federal Regulations, Part 46, revised June 18, 1991 and Public Law 99-158 of 1985, the Public Health Service Act, as amended by the Health Research Extension Act of 1985, the following summarizes the guidelines used and complied with by the OPH - IRB:

Research activities considered for approval by the OPH - IRB will be accomplished whether or not funding is to be provided by any federal department or agency, but is to be provided or participated in, as part of official public health work, by any employee of OPH or, for the specific purposes of accomplishing the research activities, any contractee of OPH.

Ethical considerations will be made by the IRB in considering its approval in accord with the above-cited law and code in regard, but not limited, to:

Protection of human subjects from harmful research risks. Protection of the privacy and confidentiality of human subjects.

Protection of the known rights and welfare of human subjects.

Fetal research.

Further,

1. the procedures of the OPH - IRB will not conflict with and will be in accord and compliance with the provisions of the "Rules and Procedures on Disclosures of Medical Information" of the Department of Health and Hospitals, Policy No. 0008-79, as revised September 25, 1990 and December 19, 1991; and

2. the procedures of the OPH - IRB will not conflict with and will be in accord and compliance with the provisions of Louisiana Revised Statutes 40:41(D), as amended by the 1983 session of the state legislature, providing for the disclosure of vital records for public health research purposes, and the rules therefore, as promulgated in the *Louisiana Register*, Volume 15, Number 6, June 20, 1989.

Questions or comments concerning this notice of intent may be addressed to Dr. Louis Trachtman, Office of Public Health, 325 Loyola Avenue, Room 513, New Orleans, LA 70112 or at mailing address, Box 60630, New Orleans, LA 70160-0630. The telephone number is (504) 568-5048 or LINC 621-5048. The FAX number is (504)568-2609.

Bobby P. Jindal
Secretary

FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES RULE TITLE: Institutional Review Board

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

There are zero implementation costs and zero savings to state or local units with the implementation of this rule.

II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

There is a zero effect on revenue collections of state or local governmental units with the implementation of this rule.

III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NONGOVERNMENTAL GROUPS (Summary)

There are zero estimated costs and/or economic benefits to directly affected persons or nongovernmental groups with the implementation of this rule.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

There is a zero estimated effect on competition and employment with the implementation of this rule.

Secretary
9602#059

Assistant to the
Legislative Fiscal Officer