Department of Legislative Services

Maryland General Assembly
2002 Session

FISCAL NOTE
Revised

House Bill 917 (Delegate Hubbard, *et al*.)
Environmental Matters Education, Health, and Environmental Affairs

Human Subject Research - Institutional Review Boards

This bill prohibits a person from conducting research using a human subject unless the research complies with federal regulations on the protection of human subjects. Despite any provision in federal regulations limiting protection to human subjects in certain research, the protections apply to all research using a human subject in the State.

Fiscal Summary

State Effect: None. The change is procedural in nature and would not directly affect governmental finances.

Local Effect: None.

Small Business Effect: None.

Analysis

Bill Summary: An institutional review board must make the final minutes of a meeting available for inspection within 30 days of receiving a request. Before making the minutes available, confidential or privileged information may be removed. The minutes are not public records.

The Office of the Attorney General may seek appropriate injunctive or other relief to prevent research that violates the bill's requirements. The Attorney General may not duplicate the investigatory, compliance, or enforcement action taken by a federal agency or bring an action if the federal government has determined that an investigation is not warranted.

Current Law: The federal Department of Health and Human Services requires individuals conducting research with human subjects to minimize the risks to subjects and ensure that the risks they take are reasonable. The prospective subjects or their legal representatives must give their informed consent, which must be documented. When appropriate, researchers must adequately provide for monitoring the data collected and protect subjects' privacy.

Each institution that proposes research to be conducted or supported by a federal department or agency must submit a written assurance to the department or agency head that the institution will comply with the requirements in the basic protection of human research subjects policy. At a minimum, the assurances must include a statement of principles on how it protects the rights and welfare of human research subjects and the designation of an institutional review board and the board's criteria.

When research is federally regulated, the Office of Human Research Protections (OHRP) oversees and ensures compliance with federal regulations. OHRP also negotiates assurances of compliance with research institutions that propose using human research subjects.

Several Department of Health and Mental Hygiene (DHMH) boards have regulations specifying how research using human subjects must be conducted.

The Board of Dental Examiners requires that all proposed experimental programs be conducted in a dental school or college. Dental procedures not approved by law or regulation must first be submitted to the board and the Maryland State Dental Association for review and comment at least 180 days before the program begins.

The Board of Professional Counselors and Therapists requires that a counselor involved in research must: respect the dignity, privacy, and welfare of research subjects; comply with existing federal and State laws and regulations concerning how research subjects are treated; take responsibility for the ethical treatment of research subjects; and clearly indicate to potential subjects the treatment that will be given as part of the study and obtain written permission in advance.

The Board of Examiners for Audiologists, Hearing Aid Dispensers, and Speech-Language Pathologists requires licensees to obtain informed consent before using an individual for research or as a subject of a teaching demonstration.

Background: In August 2001, the Court of Appeals issued an opinion in the case of *Grimes v. Kennedy Krieger* setting guidelines regarding the consent of a parent or surrogate to the participation of a child or disabled person in non-therapeutic human research. The issue came before the Court of Appeals when the Circuit Court for Baltimore City granted summary judgment to Kennedy Krieger Institute (KKI) in two cases brought by parents of children who had participated in a lead paint research study

from 1993 to 1995. The families alleged that KKI discovered lead hazards in their homes and, having a duty to notify them, failed to warn them in a timely manner or otherwise act to prevent the children's exposure to the known presence of lead

The Court of Appeals reversed the grant of summary judgment, holding that researchers owe a duty to research subject and that a parent cannot consent to the participation of a child in non-therapeutic research or studies in which there is any risk to the subject. Any risk was defined as any articulable risk beyond the minimal kind of risk inherent in any endeavor, which brought the State standard in line with federal regulations.

In June 2001, a 24-year-old healthy research subject died after volunteering to participate in a study conducted by Johns Hopkins Medicine. As a result of her death, OHRP suspended virtually all experiments conducted by Johns Hopkins that involved human subjects and allowed Johns Hopkins to resume experiments only after the institutional review boards re-evaluated the safety of the experiment.

Johns Hopkins convened an internal and external review committee to identify certain weaknesses in the institution's implementation of federal regulations and submitted a corrective action plan to OHRP. According to the plan, Johns Hopkins will make several changes to institutional review board procedures including: increasing the number of boards from three to six; providing enhanced training to board members; implementing a more stringent data requirement to support an application for research; and implementing a system of random quality control checks for ongoing protocols.

Additional Information

Prior Introductions: None.

Cross File: None.

Information Source(s): Department of Health and Mental Hygiene, Office of the Attorney General, Department of Legislative Services

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