Department of Legislative Services

Maryland General Assembly
2005 Session

FISCAL AND POLICY NOTE

Senate Bill 289 (Senator Grosfeld, *et al.*)
Education, Health, and Environmental Affairs

Human Subject Research - Clinical Trials

This bill provides that an institutional review board may only approve a clinical trial involving human subjects of a particular medical treatment if the clinical trial results will be made available to the public, and the clinical trial will be registered with the federal Clinical Trials Data Bank.

Fiscal Summary

State Effect: None. The change would not directly affect governmental finances.

Local Effect: None.

Small Business Effect: None.

Analysis

Current Law:

Clinical Trials Data Bank

The federal Food and Drug Administration Modernization Act of 1997 established the Clinical Trials Data Bank. It contains: (1) information on federal and private clinical trials for experimental treatments (drug and biological products) for patients with serious or life-threatening diseases and conditions; (2) a description of the drug's purpose; (3) patient eligibility criteria; (4) a description of the location of clinical trial sites; and (5) a

point of contact for patients who want to enroll in the trial. Information in the data bank is available to the public and health care providers and researchers.

The Act requires research sponsors to submit information to the data bank about a clinical trial conducted under an investigational new drug application if it is for a drug to treat a serious or life-threatening disease or condition and it is a trial to test effectiveness. Research sponsors also may provide information on noneffectiveness trials for drugs to treat conditions that are not considered serious or life-threatening.

Federal Guidelines on Research Using Human Subjects

A person may not conduct research using human subjects unless the research is conducted according to federal regulations on the protection of human subjects. OAG may seek injunctive or other relief to prevent human subject research that violates federal regulations on the protection of human subjects. However, OAG may not duplicate federal government actions or bring an action if a federal agency has determined an investigation is not warranted.

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 are reasonable. Prospective subjects or their legal representatives must give documented, informed consent. 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 agency must submit a written assurance to the 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.

Insurance Coverage for Clinical Trial Participants

State law requires health insurers to provide coverage for patient costs to a member in a clinical trial as a result of: (1) treatment provided for a life-threatening condition; or (2) prevention, early detection, and treatment studies on cancer.

Human Subject Research Regulated by Health Occupations Boards

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: Information regarding an estimated 12,400 clinical studies sponsored by the National Institutes of Health (NIH), other federal agencies, and private industry is available through the Clinical Trials Data Bank at www.clinicaltrials.gov. Studies included in the online database are conducted in all 50 states and in more than 100 countries. The data bank was developed by NIH, through its National Library of Medicine, in collaboration with FDA. A search of the data bank on January 20, 2005 showed 1,600 studies are being conducted in Maryland.

The Pharmaceutical Research and Manufacturers of America's member companies will voluntarily post information to the federal data bank about all new mid-to-late stage clinical trials beginning July 1, 2005. All ongoing mid-to-late stage clinical trials will be posted by September 13, 2005. Member companies are encouraged to establish procedures for verifying compliance with this policy and making those procedures available to the public.

Legislation dealing with clinical trials has been introduced in three states during their current legislative sessions, according to the National Conference of State Legislatures. A Nevada bill urges that state's congressional delegation to support mandatory reporting of clinical trials results. Two New Jersey bills create a clinical trials registry in that

state's Department of Health and Social Services. A North Dakota bill provides for hospitals and institutions of higher education to report the results of clinical trials of experimental treatments for serious or life-threatening diseases or conditions.

Additional Information

Prior Introductions: None.

Cross File: None.

Information Source(s): Department of Health and Mental Hygiene; Office of the Attorney General; *Guidance for Industry: Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions*, Food and Drug Administration, U.S. Department of Health and Human Services; National Institutes of Health; Pharmaceutical Research and Manufacturers of America; National Conference of State Legislatures; Department of Legislative Services

Fiscal Note History: First Reader - February 28, 2005
ncs/jr

Analysis by: Lisa A. Daigle

Direct Inquiries to:
(410) 946-5510
(301) 970-5510