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By: **Senators Grosfeld, Gladden, Green, and Stone**
Introduced and read first time: January 28, 2005
Assigned to: Education, Health, and Environmental Affairs

A BILL ENTITLED

AN ACT concerning

Human Subject Research - Clinical Trials

FOR the purpose of requiring institutional review boards to approve clinical trials only if the results of the clinical trials will be made available to the public and the clinical trials are registered with a certain data bank; defining a certain term; and generally relating to clinical trials.

BY repealing and reenacting, without amendments,
Article - Health - General
Section 13-2001 and 13-2004
Annotated Code of Maryland
(2000 Replacement Volume and 2004 Supplement)

BY adding to
Article - Health - General
Section 13-2005
Annotated Code of Maryland
(2000 Replacement Volume and 2004 Supplement)

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:

Article - Health - General

13-2001.

(a) In this subtitle the following words have the meanings indicated.

(b) "Federal regulations on the protection of human subjects" means:

(1) Title 45, Part 46 of the Code of Federal Regulations, and any subsequent revision of those regulations; and

(2) With respect to research that is subject to the jurisdiction of the federal Food and Drug Administration, Title 21, Parts 50 and 56 of the Code of Federal Regulations, and any subsequent revision of those regulations.

(c) "Human subject" has the meaning stated in the federal regulations on the protection of human subjects.

(d) "Institutional review board" has the meaning stated in the federal regulations on the protection of human subjects.

(e) "Research" has the meaning stated in the federal regulations on the protection of human subjects.

13-2004.

(a) The Office of the Attorney General may seek appropriate injunctive or other relief to prevent the conduct of human subject research in violation of the federal regulations on the protection of human subjects or this subtitle.

(b) In exercising the authority granted under subsection (a) of this section, the Office of the Attorney General may not:

(1) Duplicate the investigatory, compliance, or enforcement action undertaken by an agency of the federal government; or

(2) Bring an action under subsection (a) of this section if an agency of the federal government has determined that an investigation is not warranted.

13-2005.

(A) IN THIS SECTION, "CLINICAL TRIAL" MEANS RESEARCH INVOLVING HUMAN SUBJECTS THAT IS CONDUCTED FOR THE PRIMARY PURPOSE OF DETERMINING WHETHER OR NOT A PARTICULAR MEDICAL TREATMENT IS SAFE AND EFFICACIOUS.

(B) AN INSTITUTIONAL REVIEW BOARD MAY APPROVE A CLINICAL TRIAL ONLY IF:

(1) THE RESULTS OF THE CLINICAL TRIAL WILL BE MADE AVAILABLE TO THE PUBLIC; AND

(2) THE CLINICAL TRIAL WILL BE REGISTERED WITH THE CLINICAL TRIALS DATA BANK IN THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES ESTABLISHED UNDER SECTION 113 OF THE FOOD AND DRUG ADMINISTRATION MODERNIZATION ACT OF 1997.

SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 2005.