Unofficial Copy 2002 Regular Session
J1 2lr0821

By: **Delegates Hubbard, Oaks, D. Davis, Owings, Billings, Nathan-Pulliam, Cane, Boutin, Sher, Mohorovic, Schisler, Klausmeier, Stull, Elliott, R. Baker, Bobo, and Grosfeld**

Introduced and read first time: February 8, 2002
Assigned to: Environmental Matters

A BILL ENTITLED

AN ACT concerning

Human Subject Research - Institutional Review Boards

FOR the purpose of requiring a person conducting human subject research to obtain certain consent from the human subject under certain circumstances; requiring a person conducting human subject research to obtain institutional review board approval under certain circumstances; requiring an institutional review board to invite certain individuals to assist the institutional review board under certain circumstances; providing for the exemption of certain research; defining certain terms; providing that the minutes of an institutional review board shall be open to public inspection at certain times and shall contain certain information; authorizing the Attorney General to seek injunctive or other relief under certain circumstances related to research in violation of this Act; and generally relating to human subject research and institutional review boards.

BY adding to
Article - Health - General
Section 13-1601 through 13-1606, inclusive, to be included under the new subtitle "Subtitle 16. Human Subject Research"
Annotated Code of Maryland
(2000 Replacement Volume and 2001 Supplement)

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

Article - Health - General

SUBTITLE 16. HUMAN SUBJECT RESEARCH.

13-1601.

(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" MEANS A LIVING INDIVIDUAL ABOUT WHOM AN INVESTIGATOR CONDUCTING RESEARCH OBTAINS:

(1) DATA THROUGH INTERVENTION OR INTERACTION WITH THE INDIVIDUAL; OR

(2) IDENTIFIABLE PRIVATE INFORMATION.

(D) "INSTITUTIONAL REVIEW BOARD" MEANS ANY BOARD, COMMITTEE, OR OTHER GROUP FORMALLY DESIGNATED BY AN INSTITUTION TO APPROVE THE INITIATION OF, AND TO CONDUCT PERIODIC REVIEW OF, RESEARCH INVOLVING A HUMAN SUBJECT.

(E) "RESEARCH" MEANS A SYSTEMATIC INVESTIGATION, INCLUDING RESEARCH DEVELOPMENT, TESTING, AND EVALUATION, DESIGNED TO DEVELOP OR CONTRIBUTE TO GENERAL KNOWLEDGE.

(F) "RESEARCH PROTOCOL" MEANS A WRITTEN EXPLANATION OF THE OBJECTIVES AND METHODS OF PROPOSED RESEARCH.

13-1602.

THIS SUBTITLE DOES NOT APPLY TO RESEARCH THAT IS EXEMPT UNDER TITLE 45, § 46.101(B) OF THE CODE OF FEDERAL REGULATIONS FROM FEDERAL REGULATIONS ON THE PROTECTION OF HUMAN SUBJECTS.

13-1603.

(A) THIS SECTION DOES NOT APPLY IF, UNDER THE FEDERAL REGULATIONS ON THE PROTECTION OF HUMAN SUBJECTS, RESEARCH MAY BE CONDUCTED WITHOUT INFORMED CONSENT.

(B) SUBJECT TO THE GRANT OF A WAIVER BY AN INSTITUTIONAL REVIEW BOARD UNDER SUBSECTION (C) OF THIS SECTION, A PERSON MAY NOT CONDUCT RESEARCH USING A HUMAN SUBJECT UNLESS, IN ACCORDANCE WITH FEDERAL REGULATIONS ON THE PROTECTION OF HUMAN SUBJECTS, THE PERSON HAS OBTAINED:

(1) THE VOLUNTARY WRITTEN INFORMED CONSENT OF THE HUMAN SUBJECT;

(2) IF THE HUMAN SUBJECT IS A MINOR WHO DOES NOT HAVE THE AUTHORITY UNDER STATE LAW TO CONSENT TO A TREATMENT OR PROCEDURE INVOLVED IN THE RESEARCH, THE VOLUNTARY WRITTEN INFORMED CONSENT OF A PARENT OR GUARDIAN OF THE MINOR; OR

(3) IF THE HUMAN SUBJECT IS INCAPABLE OF GIVING INFORMED CONSENT, THE VOLUNTARY WRITTEN INFORMED CONSENT OF A LEGALLY AUTHORIZED REPRESENTATIVE ON BEHALF OF THE HUMAN SUBJECT.

(C) IN ACCORDANCE WITH FEDERAL REGULATIONS ON THE PROTECTION OF HUMAN SUBJECTS, AN INSTITUTIONAL REVIEW BOARD MAY WAIVE:

(1) INFORMED CONSENT;

(2) CERTAIN ELEMENTS OF INFORMED CONSENT; OR

(3) WRITTEN DOCUMENTATION OF INFORMED CONSENT.

13-1604.

(A) THIS SECTION DOES NOT APPLY IF, UNDER FEDERAL REGULATIONS ON THE PROTECTION OF HUMAN SUBJECTS, RESEARCH MAY BE CONDUCTED WITHOUT INSTITUTIONAL REVIEW BOARD REVIEW.

(B) A PERSON MAY NOT CONDUCT RESEARCH USING A HUMAN SUBJECT UNLESS THE INSTITUTIONAL REVIEW BOARD HAS DETERMINED THAT:

(1) IN ACCORDANCE WITH THE PRINCIPLES AND REQUIREMENTS FOR THE PROTECTION OF HUMAN SUBJECTS ADOPTED BY THE INSTITUTION, THE RIGHTS AND WELFARE OF HUMAN SUBJECTS IN THE RESEARCH ARE PROTECTED; AND

(2) ALL COMPONENTS OF THE RESEARCH COMPLY WITH FEDERAL AND STATE LAW.

(C) (1) AN INSTITUTIONAL REVIEW BOARD SHALL INVITE AN INDIVIDUAL WITH SPECIAL KNOWLEDGE ABOUT AN AREA OF RESEARCH TO ASSIST THE INSTITUTIONAL REVIEW BOARD IN THE REVIEW OF ISSUES THAT, AS DETERMINED BY THE INSTITUTIONAL REVIEW BOARD, REQUIRE EXPERTISE IN ADDITION TO THAT AVAILABLE ON THE INSTITUTIONAL REVIEW BOARD.

(2) THE INDIVIDUAL WHO ASSISTS THE INSTITUTIONAL REVIEW BOARD UNDER PARAGRAPH (1) OF THIS SUBSECTION MAY NOT VOTE WITH THE INSTITUTIONAL REVIEW BOARD.

(D) AN INSTITUTIONAL REVIEW BOARD SHALL REVIEW RESEARCH IN ACCORDANCE WITH THE FEDERAL REGULATIONS ON THE PROTECTION OF HUMAN SUBJECTS.

13-1605.

(A) THE MINUTES MAINTAINED BY AN INSTITUTIONAL REVIEW BOARD SHALL BE OPEN TO PUBLIC INSPECTION IN THE INSTITUTION DURING BUSINESS HOURS.

(B) THE INSTITUTIONAL REVIEW BOARD SHALL REDACT ANY CONFIDENTIAL OR PRIVILEGED INFORMATION FROM THE MINUTES MAINTAINED BY THE INSTITUTIONAL REVIEW BOARD.

(C) FOR EACH RESEARCH PROTOCOL SUBMITTED TO AN INSTITUTIONAL REVIEW BOARD, THE MINUTES SHALL:

(1) IDENTIFY THE ATTENDEES OF THE MEETING OF THE INSTITUTIONAL REVIEW BOARD;

(2) SUMMARIZE THE DISCUSSION OF THE INSTITUTIONAL REVIEW BOARD CONCERNING RISKS TO SUBJECTS, INFORMED CONSENT, AND OTHER MATTERS DETERMINED BY THE INSTITUTIONAL REVIEW BOARD TO BE MATERIAL TO THE INSTITUTIONAL REVIEW BOARD'S DECISION CONCERNING THE RESEARCH PROTOCOL;

(3) DOCUMENT ANY FINDINGS OF THE INSTITUTIONAL REVIEW BOARD REQUIRED UNDER ANY PROVISION OF FEDERAL OR STATE LAW; AND

(4) DOCUMENT THE ACTION TAKEN BY THE INSTITUTIONAL REVIEW BOARD WITH RESPECT TO THE RESEARCH PROTOCOL, INCLUDING THE NUMBER OF MEMBERS VOTING FOR OR AGAINST THE RESEARCH PROTOCOL, OR THAT HAVE ABSTAINED FROM VOTING.

13-1606.

(A) THE OFFICE OF THE ATTORNEY GENERAL MAY SEEK APPROPRIATE INJUNCTIVE OR OTHER RELIEF TO PREVENT THE CONDUCT OF RESEARCH IN VIOLATION OF THIS SUBTITLE.

(B) IN EXERCISING THE AUTHORITY GRANTED UNDER SUBSECTION (A) OF THIS SECTION, THE OFFICE OF THE ATTORNEY GENERAL:

(1) SHALL AVOID DUPLICATION OF INVESTIGATORY, COMPLIANCE, OR ENFORCEMENT ACTION UNDERTAKEN BY AN AGENCY OF THE FEDERAL GOVERNMENT; AND

(2) MAY NOT BRING AN ACTION UNDER SUBSECTION (A) OF THIS SECTION IF AN AGENCY OF THE FEDERAL GOVERNMENT HAS DETERMINED THAT AN INVESTIGATION IS NOT WARRANTED.

SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 2002.