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Baker, Bobo, and Grosfeld**

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Assigned to: Environmental Matters

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Committee Report: Favorable with amendments  
House action: Adopted  
Read second time: March 23, 2002

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CHAPTER \_\_\_\_\_

1 AN ACT concerning

2 **Human Subject Research - Institutional Review Boards**

3 FOR the purpose of requiring a person conducting human subject research to ~~obtain~~  
4 ~~certain consent from the human subject under certain circumstances; requiring~~  
5 ~~a person conducting human subject research to obtain institutional review board~~  
6 ~~approval under certain circumstances; requiring an institutional review board~~  
7 ~~to invite certain individuals to assist the institutional review board under~~  
8 ~~certain circumstances; providing for the exemption of certain research; comply~~  
9 ~~with federal regulations on the protection of human subjects; defining certain~~  
10 ~~terms; providing that the minutes of an institutional review board shall be open~~  
11 ~~to public inspection at certain times and shall contain certain information; made~~  
12 ~~available upon request within a certain period of time; authorizing the Attorney~~  
13 ~~General to seek injunctive or other relief under certain circumstances related to~~  
14 ~~research in violation of this Act; and generally relating to human subject~~  
15 ~~research and institutional review boards.~~

16 BY adding to  
17 Article - Health - General  
18 Section 13-1601 through ~~13-1606~~ 13-1604, inclusive, to be ~~included~~ under the  
19 new subtitle "Subtitle 16. Human Subject Research"  
20 Annotated Code of Maryland  
21 (2000 Replacement Volume and 2001 Supplement)

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

1 **Article - Health - General**2 **SUBTITLE 16. HUMAN SUBJECT RESEARCH.**

3 13-1601.

4 (A) IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS  
5 INDICATED.6 (B) "FEDERAL REGULATIONS ON THE PROTECTION OF HUMAN SUBJECTS"  
7 MEANS:8 (1) TITLE 45, PART 46 OF THE CODE OF FEDERAL REGULATIONS, AND  
9 ANY SUBSEQUENT REVISION OF THOSE REGULATIONS; AND10 (2) WITH RESPECT TO RESEARCH THAT IS SUBJECT TO THE  
11 JURISDICTION OF THE FEDERAL FOOD AND DRUG ADMINISTRATION, TITLE 21, PARTS  
12 50 AND 56 OF THE CODE OF FEDERAL REGULATIONS, AND ANY SUBSEQUENT  
13 REVISION OF THOSE REGULATIONS.14 (C) "HUMAN SUBJECT" ~~MEANS A LIVING INDIVIDUAL ABOUT WHOM AN~~  
15 ~~INVESTIGATOR CONDUCTING RESEARCH OBTAINS:~~16 ~~(1) DATA THROUGH INTERVENTION OR INTERACTION WITH THE~~  
17 ~~INDIVIDUAL; OR~~18 ~~(2) IDENTIFIABLE PRIVATE INFORMATION HAS THE MEANING STATED~~  
19 ~~IN THE FEDERAL REGULATIONS ON THE PROTECTION OF HUMAN SUBJECTS.~~20 (D) "INSTITUTIONAL REVIEW BOARD" ~~MEANS ANY BOARD, COMMITTEE, OR~~  
21 ~~OTHER GROUP FORMALLY DESIGNATED BY AN INSTITUTION TO APPROVE THE~~  
22 ~~INITIATION OF, AND TO CONDUCT PERIODIC REVIEW OF, RESEARCH INVOLVING A~~  
23 ~~HUMAN SUBJECT HAS THE MEANING STATED IN THE FEDERAL REGULATIONS ON~~  
24 ~~THE PROTECTION OF HUMAN SUBJECTS.~~25 (E) "RESEARCH" ~~MEANS A SYSTEMATIC INVESTIGATION, INCLUDING~~  
26 ~~RESEARCH DEVELOPMENT, TESTING, AND EVALUATION, DESIGNED TO DEVELOP OR~~  
27 ~~CONTRIBUTE TO GENERAL KNOWLEDGE HAS THE MEANING STATED IN THE~~  
28 ~~FEDERAL REGULATIONS ON THE PROTECTION OF HUMAN SUBJECTS.~~29 (F) "RESEARCH PROTOCOL" ~~MEANS A WRITTEN EXPLANATION OF THE~~  
30 ~~OBJECTIVES AND METHODS OF PROPOSED RESEARCH.~~

31 13-1602.

32 ~~THIS SUBTITLE DOES NOT APPLY TO RESEARCH THAT IS EXEMPT UNDER TITLE~~  
33 ~~45, § 46.101(B) OF THE CODE OF FEDERAL REGULATIONS FROM FEDERAL~~  
34 ~~REGULATIONS ON THE PROTECTION OF HUMAN SUBJECTS.~~

1 (A) A PERSON MAY NOT CONDUCT RESEARCH USING A HUMAN SUBJECT  
2 UNLESS THE PERSON CONDUCTS THE RESEARCH IN ACCORDANCE WITH THE  
3 FEDERAL REGULATIONS ON THE PROTECTION OF HUMAN SUBJECTS.

4 (B) NOTWITHSTANDING ANY PROVISION IN THE FEDERAL REGULATIONS ON  
5 THE PROTECTION OF HUMAN SUBJECTS THAT LIMITS THE APPLICABILITY OF THE  
6 FEDERAL REGULATIONS TO CERTAIN RESEARCH, SUBSECTION (A) OF THIS SECTION  
7 APPLIES TO ALL RESEARCH USING A HUMAN SUBJECT.

8 ~~13-1603.~~

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

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

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

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

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

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

28 (1) ~~INFORMED CONSENT;~~

29 (2) ~~CERTAIN ELEMENTS OF INFORMED CONSENT; OR~~

30 (3) ~~WRITTEN DOCUMENTATION OF INFORMED CONSENT.~~

31 ~~13-1604.~~

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

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

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

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

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

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

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

17 ~~13-1605.~~

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

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

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

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

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

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

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

1 13-1603.

2 (A) AN INSTITUTIONAL REVIEW BOARD SHALL MAKE THE FINAL MINUTES OF  
3 A MEETING AVAILABLE FOR INSPECTION WITHIN 30 DAYS OF RECEIPT OF A REQUEST  
4 FOR THE MINUTES FROM ANY PERSON.

5 (B) PRIOR TO MAKING THE MINUTES OF A MEETING AVAILABLE FOR  
6 INSPECTION UNDER SUBSECTION (A) OF THIS SECTION, AN INSTITUTIONAL REVIEW  
7 BOARD MAY REDACT CONFIDENTIAL OR PRIVILEGED INFORMATION.

8 (C) THE MINUTES OF A MEETING OF AN INSTITUTIONAL REVIEW BOARD ARE  
9 NOT PUBLIC RECORDS UNDER TITLE 10, SUBTITLE 6 OF THE STATE GOVERNMENT  
10 ARTICLE.

11 ~~13-1606.~~ 13-1604.

12 (A) THE OFFICE OF THE ATTORNEY GENERAL MAY SEEK APPROPRIATE  
13 INJUNCTIVE OR OTHER RELIEF TO PREVENT THE CONDUCT OF ~~RESEARCH IN~~  
14 ~~VIOLATION OF~~ HUMAN SUBJECT RESEARCH IN VIOLATION OF THE FEDERAL  
15 REGULATIONS ON THE PROTECTION OF HUMAN SUBJECTS OR THIS SUBTITLE.

16 (B) IN EXERCISING THE AUTHORITY GRANTED UNDER SUBSECTION (A) OF  
17 THIS SECTION, THE OFFICE OF THE ATTORNEY GENERAL MAY NOT:

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

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

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