

SENATE BILL No. 388

April 14, 2005, Introduced by Senators OLSHOVE, BASHAM, SCHAUER, JACOBS, CHERRY, CLARK-COLEMAN and BRATER and referred to the Committee on Health Policy.

A bill to amend 1978 PA 368, entitled
"Public health code,"
(MCL 333.1101 to 333.25211) by adding part 96A.

THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

1 PART 96A. CLINICAL TRIALS - HUMAN SUBJECT RESEARCH

2 SEC. 9651. AS USED IN THIS PART:

3 (A) "CLINICAL TRIAL" MEANS RESEARCH INVOLVING HUMAN SUBJECTS
4 THAT IS CONDUCTED FOR THE PRIMARY PURPOSE OF DETERMINING WHETHER OR
5 NOT A PARTICULAR DRUG OR MEDICAL TREATMENT IS SAFE AND EFFECTIVE.

6 (B) "HUMAN SUBJECT" MEANS A LIVING INDIVIDUAL ABOUT WHOM AN
7 INVESTIGATOR CONDUCTING RESEARCH OBTAINS DATA THROUGH INTERVENTION
8 OR INTERACTION WITH THE INDIVIDUAL OR OBTAINS IDENTIFIABLE PRIVATE

1 INFORMATION.

2 (C) "INSTITUTIONAL REVIEW BOARD" MEANS ANY BOARD, COMMITTEE,
3 OR OTHER GROUP FORMALLY DESIGNATED BY A PERSON TO REVIEW, TO
4 APPROVE THE INITIATION OF, AND TO CONDUCT PERIODIC REVIEW OF,
5 BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS.

6 (D) "PERSON" MEANS AN INDIVIDUAL, PARTNERSHIP, CORPORATION,
7 ASSOCIATION, GOVERNMENTAL ENTITY, OR OTHER LEGAL ENTITY, PUBLIC OR
8 PRIVATE.

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

12 SEC. 9653. A PERSON SHALL NOT CONDUCT A CLINICAL TRIAL UNLESS
13 THAT RESEARCH IS CONDUCTED IN COMPLIANCE WITH THIS PART AND IN
14 ACCORDANCE WITH FEDERAL RULES AND REGULATIONS ON THE PROTECTION OF
15 HUMAN SUBJECTS.

16 SEC. 9655. AN INSTITUTIONAL REVIEW BOARD SHALL NOT APPROVE A
17 CLINICAL TRIAL FUNDED IN WHOLE OR IN PART WITH STATE FUNDS UNLESS
18 THE PERSON AGREES TO MAKE THE RESULTS OF THE RESEARCH AVAILABLE TO
19 THE PUBLIC AND TO REGISTER THE CLINICAL TRIAL WITH THE CLINICAL
20 TRIALS DATA BANK MAINTAINED BY THE UNITED STATES DEPARTMENT OF
21 HEALTH AND HUMAN SERVICES PURSUANT TO SECTION 113 OF THE FOOD AND
22 DRUG ADMINISTRATION MODERNIZATION ACT OF 1997, PUBLIC LAW 105-115,
23 111 STAT. 2296, 42 USC 282.