

HOUSE BILL No. 5390

October 31, 2007, Introduced by Reps. Donigan, Brown, Byrum, Simpson, McDowell, Bieda, Vagnozzi, Valentine, Corriveau, Polidori, Leland, Hopgood, Dean, Miller, Alma Smith, Lemmons, Wojno, Kathleen Law, Constan, Accavitti and Hammel 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 A CLINICAL INVESTIGATION APPROVED**
4 **BY THE FEDERAL FOOD AND DRUG ADMINISTRATION THAT INVOLVES ANY**
5 **EXPERIMENT TO TEST THE SAFETY OR EFFICACY OF A DRUG OR BIOLOGICAL**
6 **PRODUCT AND 1 OR MORE HUMAN SUBJECTS AND IS INTENDED TO BE**
7 **SUBMITTED TO, OR HELD FOR INSPECTION BY, THE FEDERAL FOOD AND DRUG**
8 **ADMINISTRATION AS PART OF AN APPLICATION FOR A RESEARCH OR**
9 **MARKETING PERMIT.**

1 (B) "DEPARTMENT" MEANS THE DEPARTMENT OF COMMUNITY HEALTH.

2 (C) "HUMAN SUBJECT" MEANS A LIVING INDIVIDUAL ABOUT WHOM AN
3 INVESTIGATOR CONDUCTING RESEARCH OBTAINS DATA THROUGH INTERVENTION
4 OR INTERACTION WITH THE INDIVIDUAL OR OBTAINS IDENTIFIABLE PRIVATE
5 INFORMATION.

6 (D) "INSTITUTIONAL REVIEW BOARD" MEANS ANY BOARD, COMMITTEE,
7 OR OTHER GROUP FORMALLY DESIGNATED BY A PERSON TO REVIEW, TO
8 APPROVE THE INITIATION OF, AND TO CONDUCT PERIODIC REVIEW OF,
9 BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS.

10 (E) "MANUFACTURER" MEANS A PERSON WHO PREPARES, PRODUCES,
11 DERIVES, PROPAGATES, COMPOUNDS, PROCESSES, PACKAGES, OR REPACKAGES
12 A DRUG OR DEVICE SALABLE ON PRESCRIPTION ONLY, OR OTHERWISE CHANGES
13 THE CONTAINER OR THE LABELING OF A DRUG OR DEVICE SALABLE ON
14 PRESCRIPTION ONLY, AND WHO SUPPLIES, DISTRIBUTES, SELLS, OFFERS FOR
15 SALE, BARTERS, OR OTHERWISE DISPOSES OF THAT DRUG OR DEVICE AND ANY
16 OTHER DRUG OR DEVICE SALABLE ON PRESCRIPTION ONLY, TO ANOTHER
17 PERSON FOR RESALE, COMPOUNDING, OR DISPENSING.

18 (F) "PERSON" MEANS AN INDIVIDUAL, PARTNERSHIP, CORPORATION,
19 ASSOCIATION, GOVERNMENTAL ENTITY, OR OTHER LEGAL ENTITY, PUBLIC OR
20 PRIVATE.

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

24 SEC. 9653. (1) THE DEPARTMENT SHALL ADOPT RULES TO INCORPORATE
25 BY REFERENCE FEDERAL STATUTES AND REGULATIONS ON CLINICAL TRIALS
26 AND THE PROTECTION OF HUMAN SUBJECTS. THE DEPARTMENT MAY ADOPT
27 AMENDMENTS TO THOSE STATUTES AND REGULATIONS THAT ARE NOT

1 INCONSISTENT WITH THOSE STATUTES AND REGULATIONS. A MANUFACTURER OR
2 OTHER PERSON THAT DOES BUSINESS IN THIS STATE SHALL NOT CONDUCT A
3 CLINICAL TRIAL UNLESS THAT RESEARCH IS CONDUCTED IN COMPLIANCE WITH
4 THIS PART AND RULES PROMULGATED PURSUANT TO THIS PART.

5 (2) A MANUFACTURER OR OTHER PERSON WHO DOES BUSINESS IN THIS
6 STATE SHALL REPORT TO THE DEPARTMENT AS PRESCRIBED UNDER SECTION
7 9655 ANY CLINICAL TRIAL THAT IT CONDUCTS OR SPONSORS AND SHALL MAKE
8 THE RESULTS OF THE CLINICAL TRIAL AVAILABLE TO THE DEPARTMENT AND
9 THE PUBLIC.

10 Enacting section 1. This amendatory act does not take effect
11 unless all of the following bills of the 94th Legislature are
12 enacted into law:

13 (a) Senate Bill No. ____ or House Bill No. 5395 (request no.
14 02308'07).

15 (b) Senate Bill No. ____ or House Bill No. 5392 (request no.
16 02311'07).

17 (c) Senate Bill No. ____ or House Bill No. 5393 (request no.
18 02312'07).

19 (d) Senate Bill No. ____ or House Bill No. 5391 (request no.
20 02313'07).

21 (e) Senate Bill No. ____ or House Bill No. 5394 (request no.
22 02314'07).