

HOUSE BILL No. 5392

October 31, 2007, Introduced by Reps. Espinoza, Brown, Byrum, Simpson, McDowell, Bieda, Donigan, Vagnozzi, Valentine, Corriveau, Cheeks, Polidori, Leland, Hopgood, Dean, Miller, Alma Smith, Ebli, Lemmons, Wojno, Kathleen Law, Constan, Jackson, 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. 9655. THE DEPARTMENT SHALL ESTABLISH A FORM FOR THE
3 REPORTING OF CLINICAL TRIALS AND MAKE THE FORM AVAILABLE ON ITS
4 WEBSITE. THE FORM SHALL INCLUDE THE FOLLOWING INFORMATION
5 CONCERNING ANY CLINICAL TRIAL THAT A MANUFACTURER OR OTHER PERSON
6 HAS CONDUCTED OR SPONSORED OR IS IN THE PROCESS OF CONDUCTING OR
7 SPONSORING:

8 (A) THE NAME OF THE PERSON THAT CONDUCTED OR IS CONDUCTING THE

1 CLINICAL TRIAL.

2 (B) A SUMMARY OF THE PURPOSE OF THE CLINICAL TRIAL.

3 (C) THE DATES DURING WHICH THE TRIAL HAS TAKEN OR WILL TAKE
4 PLACE.

5 (D) INFORMATION CONCERNING THE RESULTS OF THE CLINICAL TRIAL
6 INCLUDING POTENTIAL OR ACTUAL ADVERSE EFFECTS OF THE DRUG OR
7 BIOLOGICAL PRODUCT.

8 (E) ANY OTHER INFORMATION DETERMINED BY THE DEPARTMENT TO BE
9 RELEVANT.

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. 5390 (request no.
16 02309'07).

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).