

BY: Education, Health, and Environmental Affairs Committee

AMENDMENTS TO HOUSE BILL NO. 54

(Third Reading File Bill)

AMENDMENT NO. 1

On page 1, in line 2, strike “Trials” and substitute “Trials -”; in the same line, after “Bank” insert “Information and Publication of Results”; in line 7, after “exception:” insert “authorizing an institutional review board to approve a certain clinical trial only if a certain investigator has made certain written statements;”; in line 10, after “requirements;” insert “providing that this Act may not be construed to prevent certain disclosures, submissions, or decisions to publish certain research;”; in line 16, strike “Assembly,” and substitute “Assembly”; in the same line, strike “and annually thereafter;”; strike in their entirety lines 18 and 19 and substitute “generally relating to clinical trials.”; and in line 23, after “Bank” insert “Information and Publication of Results”.

AMENDMENT NO. 2

On page 2, in line 4, after “BANK” insert “INFORMATION AND PUBLICATION OF RESULTS”; after line 19, insert:

“(D) “INSTITUTIONAL REVIEW BOARD” HAS THE MEANING STATED IN § 13-2001(D) OF THIS TITLE.

(E) “PRINCIPAL INVESTIGATOR” MEANS AN INDIVIDUAL WHO:

(1) IS ACCOUNTABLE FOR THE CONDUCT OF A CLINICAL TRIAL; AND

(2) REQUESTS APPROVAL FROM AN INSTITUTIONAL REVIEW BOARD TO CONDUCT A CLINICAL TRIAL IN THE STATE.

(F) “RESULTS OF A CLINICAL TRIAL” MEANS OUTCOMES, AS DETERMINED BY THE PRINCIPAL INVESTIGATOR AND OTHERS INVOLVED IN THE CLINICAL TRIAL IN ACCORDANCE WITH CUSTOMARY SCIENTIFIC PRACTICE, WITH RESPECT TO THE

(Over)

HYPOTHESES AND GOALS IDENTIFIED AT THE INITIATION OF THE CLINICAL TRIAL.”;

and in lines 20 and 24, strike “(D)” and “(E)”, respectively, and substitute “(G)” and “(H)”, respectively.

AMENDMENT NO. 3

On page 2, in line 30, after “TO” insert “:

(1)”;

and in line 31, after “TITLE” insert “; OR

(2)     PREVENT:

(I)     DISCLOSURE BY A SPONSOR OF INFORMATION ABOUT A CLINICAL TRIAL TO THE PUBLIC BY A METHOD IN ADDITION TO THE DATA BANK;

(II)    SUBMISSION BY A SPONSOR OF INFORMATION ABOUT RESEARCH THAT IS NOT A CLINICAL TRIAL TO THE DATA BANK; OR

(III)   ANY VOLUNTARY DECISION OR CONTRACTUAL OBLIGATION TO PUBLISH OR OTHERWISE PUBLICLY DISSEMINATE THE RESULTS OF RESEARCH THAT IS NOT A CLINICAL TRIAL”.

AMENDMENT NO. 4

On page 3, after line 19, insert:

“AN INSTITUTIONAL REVIEW BOARD MAY APPROVE A CLINICAL TRIAL ONLY IF THE PRINCIPAL INVESTIGATOR HAS STATED IN WRITING TO THE INSTITUTIONAL REVIEW BOARD THAT:

(1)     THE PRINCIPAL INVESTIGATOR HAS BEEN INFORMED BY THE SPONSOR THAT THE SPONSOR INTENDS TO COMPLY WITH § 13-2103 OF THIS SUBTITLE; AND

(2)     (I)     EXCEPT AS PROVIDED IN ITEM (II) OF THIS PARAGRAPH, THE RESULTS OF THE CLINICAL TRIAL WILL BE SUBMITTED FOR PUBLICATION IN A

PEER-REVIEWED JOURNAL; OR

(II) IF THE RESULTS OF THE CLINICAL TRIAL WILL NOT BE SUBMITTED OR ARE NOT ACCEPTED FOR PUBLICATION IN A PEER-REVIEWED JOURNAL, THE PRINCIPAL INVESTIGATOR WILL MAKE AVAILABLE TO THE PUBLIC AN EXPLANATION RELATED TO THE RESULTS OF THE CLINICAL TRIAL.

13-2105.”.

AMENDMENT NO. 5

On pages 3 and 4, strike in their entirety the lines beginning with line 28 on page 3 through line 3 on page 4 and substitute:

“SECTION 2. AND BE IT FURTHER ENACTED, That on or before December 31, 2007, the Office of the Attorney General shall report, in accordance with § 2-1246 of the State Government Article, to the General Assembly on the number and types of violations of this Act that occurred during the previous calendar year and the actions taken by the Office in response to the violations.”.

On page 4, in line 4, strike “2.” and substitute “3.”.