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By: Delegates Cullison, Allen, Bagnall, Bridges, Charkoudian, Fennell, Fraser-Hidalgo, Lehman, R. Lewis, Lopez, Love, Patterson, Qi, Reznik, Ruth, Shetty, Solomon, and Stein

Introduced and read first time: February 3, 2023 Assigned to: Health and Government Operations and Ways and Means

Committee Report: Favorable with amendments House action: Adopted Read second time: March 7, 2023

CHAPTER _____

1 AN ACT concerning

Animal Testing and Research – Human–Relevant Research Funding and Animal Testing and Research Licensure Contributions

- 4 FOR the purpose of establishing the Human-Relevant Research Fund under the administration of the Maryland Technology Development Corporation as a special, $\mathbf{5}$ 6 nonlapsing fund; requiring that the interest earnings of the Fund be credited to the 7 Fund; requiring the Corporation to establish a grant and loan program to provide 8 grants and loans for State-funded, human-relevant animal testing alternatives 9 research; requiring a person, on or after a certain date, to be issued a license by certain persons who engage in animal testing or research to pay a certain 10 contribution to the Secretary of Health before the person may use nonhuman 11 animals to conduct medical or product testing or research in the State; and generally 12 13 relating to the Human–Relevant Research Fund.
- 14 BY repealing and reenacting, without amendments,
- 15 Article Economic Development
- 16 Section 10–401(a) and (c) and 10–429(a) and (g)
- 17 Annotated Code of Maryland
- 18 (2018 Replacement Volume and 2022 Supplement)
- 19 BY adding to
- 20 Article Economic Development

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.

<u>Underlining</u> indicates amendments to bill.

Strike out indicates matter stricken from the bill by amendment or deleted from the law by amendment.



1	Secti	on 10–4D–01 through 10–4D–06 to be under the new subtitle "Subtitle 4D.				
2		Human–Relevant Research Fund and Program"				
3	Anno	otated Code of Maryland				
4	(2018	8 Replacement Volume and 2022 Supplement)				
5	BY adding	to				
6	Artic	ele – Health – General				
7	Secti	on 24–2201 through $\frac{24-2205}{24-2203}$ to be under the new subtitle "Subtitle 22.				
8		Animal Testing and Research License Contribution"				
9	Anno	otated Code of Maryland				
10	(2019	9 Replacement Volume and 2022 Supplement)				
11	BY repealir	ng and reenacting, without amendments,				
12	=	ele – State Finance and Procurement				
13	Section 6–226(a)(1) and (2)(i)					
14	Annotated Code of Maryland					
15		1 Replacement Volume and 2022 Supplement)				
16	BY repealir	ng and reenacting, with amendments,				
17		ele – State Finance and Procurement				
18	Secti	on 6–226(a)(2)(ii)170. and 171.				
19		otated Code of Maryland				
20		1 Replacement Volume and 2022 Supplement)				
21	BY adding	to				
22	Artic	ele – State Finance and Procurement				
23	Secti	on 6–226(a)(2)(ii)172.				
24	Annotated Code of Maryland					
25		1 Replacement Volume and 2022 Supplement)				
26	SEC'	TION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND,				
27		aws of Maryland read as follows:				
28		Article – Economic Development				
29	10-401.					
30	(a)	In this subtitle the following words have the meanings indicated.				
31	(c)	"Corporation" means the Maryland Technology Development Corporation.				
32	10-429.					
33	(a)	In this part the following words have the meanings indicated.				
34	(g)	"Institutional review board" has the meaning stated in the federal regulations				
35	on the prot	e ction of human subjects.				

 $\mathbf{2}$

SUBTITLE 4D. HUMAN-RELEVANT RESEARCH FUND AND PROGRAM.

1

2	10-4D-01.
3 4	(A) IN THIS SUBTITLE THE FOLLOWING TERMS HAVE THE MEANINGS INDICATED.
$5 \\ 6$	(B) "BOARD" MEANS THE HUMAN–RELEVANT RESEARCH REVIEW BOARD ESTABLISHED UNDER § 10–4D–04 OF THIS SUBTITLE.
7	(C) "CORPORATION" HAS THE MEANING STATED IN § 10–401 OF THIS TITLE.
8	(D) "FUND" MEANS THE HUMAN-RELEVANT RESEARCH FUND.
9 10	(E) "INSTITUTIONAL REVIEW BOARD" HAS THE MEANING STATED IN § 10-429 OF THIS TITLE.
11	10-4D-02.
12	(A) THERE IS A HUMAN-RELEVANT RESEARCH FUND.
13 14 15 16	(B) THE PURPOSE OF THE FUND IS TO PROMOTE STATE-FUNDED RESEARCH INTENDED TO DEVELOP HUMAN-RELEVANT ALTERNATIVES TO USING NONHUMAN ANIMALS IN MEDICAL AND PRODUCT TESTING AND RESEARCH THROUGH GRANTS AND LOANS TO PUBLIC AND PRIVATE ENTITIES IN THE STATE.
17	(C) THE CORPORATION SHALL ADMINISTER THE FUND.
18 19	(D) (1) THE FUND IS A SPECIAL, NONLAPSING FUND THAT IS NOT SUBJECT TO § 7–302 OF THE STATE FINANCE AND PROCUREMENT ARTICLE.
$\begin{array}{c} 20\\ 21 \end{array}$	(2) THE STATE TREASURER SHALL HOLD THE FUND SEPARATELY, AND THE COMPTROLLER SHALL ACCOUNT FOR THE FUND.
22	(E) THE FUND CONSISTS OF:
$\begin{array}{c} 23\\ 24 \end{array}$	(1) REVENUE DISTRIBUTED TO THE FUND UNDER § 24-2203 § <u>24-2202</u> of the Health – General Article;
25	(2) MONEY APPROPRIATED IN THE STATE BUDGET TO THE FUND;
26	(3) INTEREST EARNINGS OF THE FUND; AND

4 HOUSE BILL 626 ANY OTHER MONEY FROM ANY OTHER SOURCE ACCEPTED FOR 1 (4) $\mathbf{2}$ THE BENEFIT OF THE FUND. 3 **(F)** MONEY IN THE FUND MAY BE USED ONLY TO: 4 (1) AWARD GRANTS AND LOANS FOR STATE-FUNDED, HUMAN-RELEVANT ANIMAL TESTING ALTERNATIVES RESEARCH IN ACCORDANCE $\mathbf{5}$ 6 WITH THE RECOMMENDATIONS OF THE BOARD; AND 7 (2) PAY THE COSTS NECESSARY TO ADMINISTER THE FUND. 8 (G) (1) THE STATE TREASURER SHALL INVEST THE MONEY IN THE FUND 9 IN THE SAME MANNER AS OTHER STATE MONEY MAY BE INVESTED. 10 (2) ANY INTEREST EARNINGS OF THE FUND SHALL BE CREDITED TO 11 THE FUND. 12**(**H**)** THE GOVERNOR MAY INCLUDE IN THE STATE BUDGET BILL EACH (1) FISCAL YEAR AN APPROPRIATION TO THE FUND. 13 EXPENDITURES FROM THE FUND MAY BE MADE ONLY IN 14(2) 15ACCORDANCE WITH THE STATE BUDGET. 16 10-4D-03. 17(A) SUBJECT TO THE PROVISIONS OF THIS SUBTITLE, THE CORPORATION SHALL ESTABLISH A GRANT AND LOAN PROGRAM TO PROVIDE GRANTS AND LOANS 18 19FOR STATE-FUNDED, HUMAN-RELEVANT ANIMAL TESTING ALTERNATIVES 20**RESEARCH.** 21**(B)** A GRANT OR LOAN AWARDED UNDER THIS SUBTITLE IS CONTINGENT ON 22THE RECIPIENT: SUBMITTING TO THE BOARD APPROVAL FROM AN INSTITUTIONAL 23(1) 24REVIEW BOARD; AND 25(2) ENTERING INTO A MEMORANDUM OF UNDERSTANDING WITH THE 26**CORPORATION THAT:** 27**(1)** (1) ESTABLISHES THE SCOPE OF THE STATE'S 28OWNERSHIP OR OTHER FINANCIAL INTEREST IN THE COMMERCIALIZATION AND 29OTHER BENEFITS OF THE RESULTS, PRODUCTS, INVENTIONS, AND DISCOVERIES **RESULTING FROM STATE-FUNDED, HUMAN-RELEVANT RESEARCH; AND** 30

1 (II) (2) TO THE EXTENT CONSISTENT WITH FEDERAL AND 2 STATE LAW, REFLECTS THE INTELLECTUAL PROPERTY POLICIES OF THE 3 CORPORATION.

4 (C) A RECIPIENT SHALL SUBMIT THE APPROVAL REQUIRED UNDER 5 SUBSECTION (B)(1) OF THIS SECTION WITHIN 6 MONTHS AFTER THE AWARD OF THE 6 GRANT OR LOAN.

7 (D) THE CORPORATION MAY NOT DISBURSE GRANT OR LOAN MONEY TO A
8 RECIPIENT UNTIL THE RECIPIENT MEETS THE REQUIREMENTS OF SUBSECTION (B)
9 OF THIS SECTION.

10 **10–4D–04.**

11 (A) THE CORPORATION SHALL CONTRACT WITH AN INDEPENDENT 12 SCIENTIFIC REVIEW BOARD COMPOSED OF RECOGNIZED SCIENTIFIC EXPERTS IN 13 THE FIELD OF HUMAN–RELEVANT ANIMAL TESTING ALTERNATIVES TO ACT AS THE 14 HUMAN–RELEVANT RESEARCH REVIEW BOARD.

15 (B) THE BOARD SHALL:

16(1)REVIEW, EVALUATE, RANK, AND RATE RESEARCH PROPOSALS FOR17STATE-FUNDED, HUMAN-RELEVANT ANIMAL TESTING ALTERNATIVES RESEARCH:

18(I) BASED ON THE PROCEDURES AND GUIDELINES19ESTABLISHED BY THE CORPORATION; AND

20 (II) IN A MANNER THAT GIVES DUE CONSIDERATION TO THE 21 SCIENTIFIC, MEDICAL, AND ETHICAL IMPLICATIONS OF THE RESEARCH; AND

22 (2) BASED ON THE RANKINGS AND RATINGS AWARDED TO THE 23 RESEARCH PROPOSALS BY THE BOARD, MAKE RECOMMENDATIONS TO THE 24 CORPORATION FOR THE AWARD AND DISBURSEMENT OF GRANTS AND LOANS.

25 (C) A MEMBER OF THE BOARD:

26 (1) IS NOT ELIGIBLE TO RECEIVE A GRANT OR LOAN FOR 27 STATE–FUNDED, HUMAN–RELEVANT RESEARCH FROM THE FUND; AND

(2) SHALL BE SUBJECT TO CONFLICT OF INTEREST STANDARDS THAT
 ARE AT LEAST AS STRINGENT AS THE STANDARDS ON CONFLICT OF INTEREST
 30 ADOPTED BY THE FEDERAL NATIONAL INSTITUTES OF HEALTH.

31 **10–4D–05.**

1 THE CORPORATION, IN CONSULTATION WITH THE BOARD, SHALL ADOPT 2 REGULATIONS TO ESTABLISH PROCEDURES FOR AWARDING AND MAKING THE 3 DISBURSEMENT OF A GRANT OR LOAN.

4 **10–4D–06.**

5 (A) ON OR BEFORE JANUARY 1 EACH YEAR, THE CORPORATION AND THE 6 BOARD SHALL REPORT TO THE GOVERNOR AND, IN ACCORDANCE WITH § 2–1257 OF 7 THE STATE GOVERNMENT ARTICLE, THE GENERAL ASSEMBLY ON THE PROGRESS 8 OF THE HUMAN-RELEVANT ANIMAL TESTING ALTERNATIVES RESEARCH 9 CONDUCTED WITH MONEY FROM GRANTS OR LOANS AWARDED UNDER THIS 10 SUBTITLE.

- 11 (B) THE REPORT SHALL IDENTIFY:
- 12 (1) EACH RECIPIENT OF MONEY FROM THE FUND;

13 (2) THE AMOUNT OF MONEY AWARDED TO EACH RECIPIENT; AND

14(3) A DESCRIPTION OF THE TYPE OF STATE-FUNDED,15HUMAN-RELEVANT RESEARCH PERFORMED BY THE RECIPIENT AND THE ANIMAL16TESTS THE RESEARCH IS INTENDED TO REPLACE.

17

Article – Health – General

18 SUBTITLE 22. ANIMAL TESTING AND RESEARCH LICENSE CONTRIBUTION.

19 **24–2201.**

20 (A) IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS 21 INDICATED.

22 (B) "LICENSE" MEANS A LICENSE TO CONDUCT MEDICAL OR PRODUCT 23 TESTING OR RESEARCH USING ANIMALS.

(C) "LICENSEE" MEANS A PERSON WHO HOLDS A LICENSE ISSUED UNDER
 THIS SUBTITLE, "ANIMAL AND PLANT HEALTH INSPECTION SERVICE FORM 7023"
 MEANS THE FORM REQUIRED TO BE SUBMITTED TO THE FEDERAL DEPARTMENT OF
 AGRICULTURE UNDER 7 U.S.C. § 2143 AND 9 C.F.R. § 2.36.

28 **24–2202.**

29 (A) ON OR AFTER BEFORE JANUARY 1, 15 EACH YEAR, BEGINNING IN 2024, 30 A PERSON EACH RESEARCH FACILITY THAT IS LOCATED IN THE STATE AND IS

1	REQUIRED TO SUBMIT AN ANIMAL AND PLANT HEALTH INSPECTION SERVICE FORM
2	7023 SHALL be licensed by the Secretary before the person may use
3	NONHUMAN ANIMALS TO CONDUCT-MEDICAL OR PRODUCT TESTING OR RESEARCH
4	IN THE STATE.
5	24 - 2203.
6	(A) (1) AN APPLICANT FOR A LICENSE SHALL SUBMIT AN APPLICATION
7	to the Secretary on the form that the Secretary requires.
0	
8	(2) AN INITIAL APPLICATION SHALL REQUIRE AN APPLICANT TO
9	INCLUDE:
10	(I) THE NUMBER OF ANIMALS THAT WILL BE USED TO CONDUCT
10	THE MEDICAL OR PRODUCT TESTING OR RESEARCH;
11	THE MEDICAL OR I RODUCT TESTING OR RESEARCH,
12	(II) A LIST OF THE SPECIES OF ANIMALS THAT WILL BE USED TO
13	CONDUCT THE MEDICAL OR PRODUCT TESTING OR RESEARCH; AND
10	
14	(III) ANY OTHER INFORMATION REQUIRED BY THE SECRETARY.
15	(b) (1) The annual license fee is <u>pay to the Department a</u>
16	CONTRIBUTION IN THE AMOUNT OF:
17	(1) \$5,000 FOR UP TO 500 ANIMALS;
18	(H) (2) \$10,000 FOR MORE THAN 500 100 BUT NOT MORE
19	THAN 1,000 <u>500</u> ANIMALS;
00	
20	$\frac{(\text{HH})}{(3)} = \frac{\$25,000}{\$55,000} \text{ FOR MORE THAN } \frac{1,000}{500} \text{ BUT NOT}$
21	MORE THAN 5,000 ANIMALS;
22	(IV) \$35,000 FOR MORE THAN 5,000 BUT NOT MORE THAN 10,000
$\frac{22}{23}$	ANIMALS; AND
20	
24	(V) (4)
$\overline{25}$	ANIMALS. (\cdot) $($
-	
26	(2) THE ANNUAL LICENSE FEE MAY BE PAID IN QUARTERLY
27	INSTALLMENTS.
28	(B) THE AMOUNT OF THE CONTRIBUTION TO BE PAID UNDER SUBSECTION
29	(A) OF THIS SECTION SHALL BE BASED ON THE TOTAL NUMBER OF ANIMALS

	8 HOUSE BILL 626					
1	REPORTED IN COLUMN F ON THE MOST RECENTLY SUBMITTED ANIMAL AND PLANT					
2	HEALTH INSPECTION SERVICE FORM 7023.					
0						
3	(C) THE SECRETARY SHALL#					
4	(1) Distribute the amount of licensing fees necessary to					
5	ADMINISTER THE LICENSING PROGRAM TO AN ADMINISTRATIVE COST ACCOUNT;					
6	AND					
7	(2) Distribute <u>distribute</u> the <u>remaining fees</u> <u>funds paid</u>					
8	UNDER SUBSECTION (A) OF THIS SECTION TO THE HUMAN-RELEVANT RESEARCH					
9	FUND ESTABLISHED UNDER § 10-4D-02 OF THE ECONOMIC DEVELOPMENT					
10 11	ARTICLE AFTER MAKING THE DISTRIBUTION REQUIRED UNDER-ITEM (1) OF THIS SUBSECTION.					
11	DUBSECHUN .					
12	$\frac{24-2204}{2}$					
13	(A) (1) THE SECRETARY SHALL ISSUE A LICENSE TO AN APPLICANT WHO					
13	SUBMITS THE INFORMATION REQUIRED UNDER § 24–2203(A) OF THIS SUBTITLE AND					
15	ON PAYMENT OF:					
16	(1) THE TOTAL ANNUAL LICENSE FEE; OR					
10						
17	(II) THE FIRST QUARTERLY INSTALLMENT OF THE TOTAL					
18	ANNUAL LICENSE FEE.					
19	(2) THE TERM OF A LICENSE IS 1 YEAR.					
20	(B) THE SECRETARY MAY DENY A LICENSE TO AN APPLICANT OR MAY					
21	SUSPEND OR REVOKE A LICENSE IF THE APPLICANT OR LICENSEE:					
22	(1) FRAUDULENTLY OR DECEPTIVELY MAKES A STATEMENT ON AN					
23	APPLICATION FOR A LICENSE;					
24	(2) FAILS TO MAKE A QUARTERLY INSTALLMENT PAYMENT OF THE					
$\frac{21}{25}$	ANNUAL LICENSE FEE; OR					
26 97	(3) COMMITS FREQUENT OR NUMEROUS VIOLATIONS OF THIS					
27	SUBTITLE OR THE REGULATIONS ADOPTED UNDER THIS SUBTITLE.					
28	(C) EACH LICENSEE SHALL:					

1(1)MAINTAIN A RECORD OF ALL ANIMALS USED AND DISPOSED OF TO2CONDUCT MEDICAL OR PRODUCT TESTING OR RESEARCH, INCLUDING THE NUMBER3AND TYPES OF ANIMALS USED; AND

4 (2) SUBMIT TO THE SECRETARY A QUARTERLY REPORT INCLUDING 5 THE INFORMATION REQUIRED UNDER ITEM (1) OF THIS SUBSECTION.

6 (D) ON OR BEFORE JANUARY 1 EACH YEAR, BEGINNING IN 2024, THE 7 SECRETARY SHALL REPORT TO THE GENERAL ASSEMBLY, IN ACCORDANCE WITH § 8 2–1257 OF THE STATE GOVERNMENT ARTICLE, THE AGGREGATE NUMBER OF EACH 9 SPECIES OF ANIMAL USED IN MEDICAL OR PRODUCT TESTING OR RESEARCH BY 10 LICENSEES IN THE STATE.

11 **<u>24 2205.</u>**

12 (A) (1) A PERSON MAY NOT USE NONHUMAN ANIMALS TO CONDUCT 13 MEDICAL OR PRODUCT TESTING OR RESEARCH IN THE STATE UNLESS LICENSED BY 14 THE SECRETARY.

15 (2) A PERSON MAY NOT AID OR ABET THE UNAUTHORIZED USE OF
 16 NONHUMAN ANIMALS TO CONDUCT MEDICAL OR PRODUCT TESTING OR RESEARCH
 17 IN THE STATE.

18 **(B)** A PERSON IN VIOLATION OF SUBSECTION (A) OF THIS SECTION IS 19 GUILTY OF A FELONY AND ON CONVICTION IS SUBJECT TO:

20 (1) FOR A FIRST OFFENSE, A FINE NOT EXCEEDING \$5,000; OR

21 (2) FOR EACH SUBSEQUENT OFFENSE, A FINE NOT EXCEEDING 22 \$20,000.

23 **<u>24–2203.</u>**

24A RESEARCH FACILITY THAT FAILS TO PAY THE CONTRIBUTION REQUIRED25UNDER § 24–2202(A) OF THIS SUBTITLE MAY BE SUBJECT TO A CIVIL PENALTY OF26NOT MORE THAN \$1,000 PER DAY.

- 27 Article State Finance and Procurement
- 28 6-226.

(a) (1) Except as otherwise specifically provided by law or by regulation of the
 Treasurer, the Treasurer shall credit to the General Fund any interest on or other income
 from State money that the Treasurer invests.

1 (2) (i) Notwithstanding any other provision of law, and unless 2 inconsistent with a federal law, grant agreement, or other federal requirement or with the 3 terms of a gift or settlement agreement, net interest on all State money allocated by the 4 State Treasurer under this section to special funds or accounts, and otherwise entitled to 5 receive interest earnings, as accounted for by the Comptroller, shall accrue to the General 6 Fund of the State.

- 7 The provisions of subparagraph (i) of this paragraph do not apply (ii) 8 to the following funds: 9 the Cannabis Public Health Fund; [and] 170. 10 171. the Community Reinvestment and Repair Fund; AND 172. THE HUMAN-RELEVANT RESEARCH FUND. 11 12SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect July
- 13 1, 2023.

Approved:

Governor.

Speaker of the House of Delegates.

President of the Senate.