Chapter 448

(Senate Bill 560)

AN ACT concerning

Animal Testing and Research – Human–Relevant Research Funding and Animal Testing and Research <u>Licensure</u> <u>Contributions</u>

FOR the purpose of establishing the Human-Relevant Research Fund under the administration of the Maryland Technology Development Corporation as a special, nonlapsing fund; requiring that the interest earnings of the Fund be credited to the Fund; requiring the Corporation to establish a grant and loan program to provide grants and loans for State-funded, human-relevant animal testing alternatives research; requiring a person, on or after a certain date, to be issued a license by certain research facilities who engage in animal testing or research to pay a certain contribution to the Secretary of Health before the person may use nonhuman animals to conduct medical or product testing or research in the State; and generally relating to the Human-Relevant Research Fund.

BY repealing and reenacting, without amendments,

Article – Economic Development

Section 10-401(a) and (c) and 10-429(a) and (g)

Annotated Code of Maryland

(2018 Replacement Volume and 2022 Supplement)

BY adding to

Article – Economic Development

Section 10–4D–01 through 10–4D–06 to be under the new subtitle "Subtitle 4D. Human–Relevant Research Fund and Program"

Annotated Code of Maryland

(2018 Replacement Volume and 2022 Supplement)

BY adding to

Article - Health - General

Section 24–2201 through <u>24–2205</u> <u>24–2203</u> to be under the new subtitle "Subtitle 22. Animal Testing and Research License Contribution"

Annotated Code of Maryland

(2019 Replacement Volume and 2022 Supplement)

BY repealing and reenacting, without amendments,

Article – State Finance and Procurement

Section 6–226(a)(1) and (2)(i)

Annotated Code of Maryland

(2021 Replacement Volume and 2022 Supplement)

BY repealing and reenacting, with amendments,

Article – State Finance and Procurement Section 6–226(a)(2)(ii)170. and 171. Annotated Code of Maryland (2021 Replacement Volume and 2022 Supplement)

BY adding to

Article – State Finance and Procurement Section 6–226(a)(2)(ii)172. Annotated Code of Maryland (2021 Replacement Volume and 2022 Supplement)

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:

Article - Economic Development

10-401.

- (a) In this subtitle the following words have the meanings indicated.
- (c) "Corporation" means the Maryland Technology Development Corporation.

10-429.

- (a) In this part the following words have the meanings indicated.
- (g) "Institutional review board" has the meaning stated in the federal regulations on the protection of human subjects.

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

10-4D-01.

- (A) IN THIS SUBTITLE THE FOLLOWING TERMS HAVE THE MEANINGS INDICATED.
- (B) "BOARD" MEANS THE HUMAN–RELEVANT RESEARCH REVIEW BOARD ESTABLISHED UNDER § 10-4D-04 OF THIS SUBTITLE.
 - (C) "CORPORATION" HAS THE MEANING STATED IN § 10-401 OF THIS TITLE.
 - (D) "FUND" MEANS THE HUMAN-RELEVANT RESEARCH FUND.
- (E) "INSTITUTIONAL REVIEW BOARD" HAS THE MEANING STATED IN § 10–429 OF THIS TITLE.

10-4D-02.

- (A) THERE IS A HUMAN-RELEVANT RESEARCH FUND.
- (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.
 - (C) THE CORPORATION SHALL ADMINISTER THE FUND.
- (D) (1) THE FUND IS A SPECIAL, NONLAPSING FUND THAT IS NOT SUBJECT TO § 7–302 OF THE STATE FINANCE AND PROCUREMENT ARTICLE.
- (2) THE STATE TREASURER SHALL HOLD THE FUND SEPARATELY, AND THE COMPTROLLER SHALL ACCOUNT FOR THE FUND.
 - (E) THE FUND CONSISTS OF:
- (1) REVENUE DISTRIBUTED TO THE FUND UNDER $\frac{\$}{24-2203}$ § 24-2202 OF THE HEALTH GENERAL ARTICLE;
 - (2) MONEY APPROPRIATED IN THE STATE BUDGET TO THE FUND;
 - (3) INTEREST EARNINGS OF THE FUND; AND
- (4) ANY OTHER MONEY FROM ANY OTHER SOURCE ACCEPTED FOR THE BENEFIT OF THE FUND.
 - (F) MONEY IN THE FUND MAY BE USED ONLY TO:
- (1) AWARD GRANTS AND LOANS FOR STATE-FUNDED, HUMAN-RELEVANT ANIMAL TESTING ALTERNATIVES RESEARCH IN ACCORDANCE WITH THE RECOMMENDATIONS OF THE BOARD; AND
 - (2) PAY THE COSTS NECESSARY TO ADMINISTER THE FUND.
- (G) (1) THE STATE TREASURER SHALL INVEST THE MONEY IN THE FUND IN THE SAME MANNER AS OTHER STATE MONEY MAY BE INVESTED.
- (2) ANY INTEREST EARNINGS OF THE FUND SHALL BE CREDITED TO THE FUND.

- (H) (1) THE GOVERNOR MAY INCLUDE IN THE STATE BUDGET BILL EACH FISCAL YEAR AN APPROPRIATION TO THE FUND.
- (2) EXPENDITURES FROM THE FUND MAY BE MADE ONLY IN ACCORDANCE WITH THE STATE BUDGET.

10-4D-03.

- (A) SUBJECT TO THE PROVISIONS OF THIS SUBTITLE, THE CORPORATION SHALL ESTABLISH A GRANT AND LOAN PROGRAM TO PROVIDE GRANTS AND LOANS FOR STATE-FUNDED, HUMAN-RELEVANT ANIMAL TESTING ALTERNATIVES RESEARCH.
- (B) A GRANT OR LOAN AWARDED UNDER THIS SUBTITLE IS CONTINGENT ON THE RECIPIENT:
- (1) SUBMITTING TO THE BOARD APPROVAL FROM AN INSTITUTIONAL REVIEW BOARD: AND
- (2) ENTERING INTO A MEMORANDUM OF UNDERSTANDING WITH THE CORPORATION THAT:
- (1) ESTABLISHES THE SCOPE OF THE STATE'S OWNERSHIP OR OTHER FINANCIAL INTEREST IN THE COMMERCIALIZATION AND OTHER BENEFITS OF THE RESULTS, PRODUCTS, INVENTIONS, AND DISCOVERIES RESULTING FROM STATE-FUNDED, HUMAN-RELEVANT RESEARCH; AND
- (H) (2) TO THE EXTENT CONSISTENT WITH FEDERAL AND STATE LAW, REFLECTS THE INTELLECTUAL PROPERTY POLICIES OF THE CORPORATION.
- (C) A RECIPIENT SHALL SUBMIT THE APPROVAL REQUIRED UNDER SUBSECTION (B)(1) OF THIS SECTION WITHIN 6 MONTHS AFTER THE AWARD OF THE GRANT OR LOAN.
- (D) THE CORPORATION MAY NOT DISBURSE GRANT OR LOAN MONEY TO A RECIPIENT UNTIL THE RECIPIENT MEETS THE REQUIREMENTS OF SUBSECTION (B) OF THIS SECTION.

10-4D-04.

(A) THE CORPORATION SHALL CONTRACT WITH AN INDEPENDENT SCIENTIFIC REVIEW BOARD COMPOSED OF RECOGNIZED SCIENTIFIC EXPERTS IN

THE FIELD OF HUMAN-RELEVANT ANIMAL TESTING ALTERNATIVES TO ACT AS THE HUMAN-RELEVANT RESEARCH REVIEW BOARD.

(B) THE BOARD SHALL:

- (1) REVIEW, EVALUATE, RANK, AND RATE RESEARCH PROPOSALS FOR STATE-FUNDED, HUMAN-RELEVANT ANIMAL TESTING ALTERNATIVES RESEARCH:
- (I) BASED ON THE PROCEDURES AND GUIDELINES ESTABLISHED BY THE CORPORATION; AND
- (II) IN A MANNER THAT GIVES DUE CONSIDERATION TO THE SCIENTIFIC, MEDICAL, AND ETHICAL IMPLICATIONS OF THE RESEARCH; AND
- (2) BASED ON THE RANKINGS AND RATINGS AWARDED TO THE RESEARCH PROPOSALS BY THE BOARD, MAKE RECOMMENDATIONS TO THE CORPORATION FOR THE AWARD AND DISBURSEMENT OF GRANTS AND LOANS.

(C) A MEMBER OF THE BOARD:

- (1) IS NOT ELIGIBLE TO RECEIVE A GRANT OR LOAN FOR 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 ADOPTED BY THE FEDERAL NATIONAL INSTITUTES OF HEALTH.

10-4D-05.

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

10-4D-06.

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

- (1) EACH RECIPIENT OF MONEY FROM THE FUND;
- (2) THE AMOUNT OF MONEY AWARDED TO EACH RECIPIENT; AND
- (3) A DESCRIPTION OF THE TYPE OF STATE-FUNDED, HUMAN-RELEVANT RESEARCH PERFORMED BY THE RECIPIENT AND THE ANIMAL TESTS THE RESEARCH IS INTENDED TO REPLACE.

Article - Health - General

SUBTITLE 22. ANIMAL TESTING AND RESEARCH LICENSE CONTRIBUTION.
24–2201.

- (A) IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS INDICATED.
- (B) "LICENSE" MEANS A LICENSE TO CONDUCT MEDICAL OR PRODUCT 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.

24-2202.

(A) ON OR AFTER BEFORE JANUARY 1, 15 EACH YEAR, BEGINNING IN 2024, A PERSON EACH RESEARCH FACILITY THAT IS LOCATED IN THE STATE AND IS REQUIRED TO SUBMIT AN ANIMAL AND PLANT HEALTH INSPECTION SERVICE FORM 7023 SHALL BE LICENSED BY THE SECRETARY BEFORE THE PERSON MAY USE NONHUMAN ANIMALS TO CONDUCT MEDICAL OR PRODUCT TESTING OR RESEARCH IN THE STATE.

24_2203

- (A) (1) AN APPLICANT FOR A LICENSE SHALL SUBMIT AN APPLICATION TO THE SECRETARY ON THE FORM THAT THE SECRETARY REQUIRES.
- (2) AN INITIAL APPLICATION SHALL REQUIRE AN APPLICANT TO INCLUDE:
- (1) THE NUMBER OF ANIMALS THAT WILL BE USED TO CONDUCT THE MEDICAL OR PRODUCT TESTING OR RESEARCH:

- (II) A LIST OF THE SPECIES OF ANIMALS THAT WILL BE USED TO CONDUCT THE MEDICAL OR PRODUCT TESTING OR RESEARCH: AND
 - (HI) ANY OTHER INFORMATION REQUIRED BY THE SECRETARY.
- (B) (1) THE ANNUAL LICENSE FEE IS PAY TO THE DEPARTMENT A CONTRIBUTION IN THE AMOUNT OF:
 - (1) (1) \$5,000 FOR UP TO 500×100 ANIMALS;
- $\frac{\text{(H)}}{\text{(2)}}$ \$10,000 for more than $\frac{500}{100}$ but not more than $\frac{1,000}{500}$ animals;
- $\frac{\text{(HI)}}{\text{(3)}}$ \$25,000 \$55,000 FOR MORE THAN $\frac{1,000}{500}$ BUT NOT MORE THAN 5,000 ANIMALS;
- (IV) \$35,000 For more than 5,000 But not more than 10,000 Animals; and
- $\frac{\text{(V)}}{\text{(4)}}$ \$50,000 FOR MORE THAN $\frac{10,000}{5,000}$ ANIMALS.
- (2) THE ANNUAL LICENSE FEE MAY BE PAID IN QUARTERLY INSTALLMENTS.
- (B) THE AMOUNT OF THE FEE CONTRIBUTION TO BE PAID UNDER SUBSECTION (A) OF THIS SECTION SHALL BE BASED ON THE TOTAL NUMBER OF ANIMALS REPORTED IN COLUMN F ON THE MOST RECENTLY SUBMITTED ANIMAL AND PLANT HEALTH INSPECTION SERVICE FORM 7023.
 - (C) THE SECRETARY SHALL#
- (1) DISTRIBUTE THE AMOUNT OF LICENSING FEES NECESSARY TO ADMINISTER THE LICENSING PROGRAM TO AN ADMINISTRATIVE COST ACCOUNT;
- (2) DISTRIBUTE DISTRIBUTE THE REMAINING FEES FUNDS PAID UNDER SUBSECTION (A) OF THIS SECTION TO THE HUMAN-RELEVANT RESEARCH FUND ESTABLISHED UNDER § 10–4D–02 OF THE ECONOMIC DEVELOPMENT ARTICLE AFTER MAKING THE DISTRIBUTION REQUIRED UNDER ITEM (1) OF THIS SUBSECTION.

24-2204

- (A) (1) THE SECRETARY SHALL ISSUE A LICENSE TO AN APPLICANT WHO SUBMITS THE INFORMATION REQUIRED UNDER § 24–2203(A) OF THIS SUBTITLE AND ON PAYMENT OF:
 - (I) THE TOTAL ANNUAL LICENSE FEE; OR
- (H) THE FIRST QUARTERLY INSTALLMENT OF THE TOTAL ANNUAL LICENSE FEE.
 - (2) THE TERM OF A LICENSE IS 1 YEAR.
- (B) THE SECRETARY MAY DENY A LICENSE TO AN APPLICANT OR MAY SUSPEND OR REVOKE A LICENSE IF THE APPLICANT OR LICENSEE:
- (1) FRAUDULENTLY OR DECEPTIVELY MAKES A STATEMENT ON AN APPLICATION FOR A LICENSE;
- (2) FAILS TO MAKE A QUARTERLY INSTALLMENT PAYMENT OF THE ANNUAL LICENSE FEE; OR
- (3) COMMITS FREQUENT OR NUMEROUS VIOLATIONS OF THIS SUBTITLE OR THE REGULATIONS ADOPTED UNDER THIS SUBTITLE.
 - (C) EACH LICENSEE SHALL:
- (1) MAINTAIN A RECORD OF ALL ANIMALS USED AND DISPOSED OF TO CONDUCT MEDICAL OR PRODUCT TESTING OR RESEARCH, INCLUDING THE NUMBER AND TYPES OF ANIMALS USED; AND
- (2) SUBMIT TO THE SECRETARY A QUARTERLY REPORT INCLUDING THE INFORMATION REQUIRED UNDER ITEM (1) OF THIS SUBSECTION.
- (D) ON OR BEFORE JANUARY 1 EACH YEAR, BEGINNING IN 2024, THE SECRETARY SHALL REPORT TO THE GENERAL ASSEMBLY, IN ACCORDANCE WITH § 2–1257 OF THE STATE GOVERNMENT ARTICLE, THE AGGREGATE NUMBER OF EACH SPECIES OF ANIMAL USED IN MEDICAL OR PRODUCT TESTING OR RESEARCH BY LICENSEES IN THE STATE.

24 2205

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

- (2) A PERSON MAY NOT AID OR ABET THE UNAUTHORIZED USE OF NONHUMAN ANIMALS TO CONDUCT MEDICAL OR PRODUCT TESTING OR RESEARCH IN THE STATE.
- (B) A PERSON IN VIOLATION OF SUBSECTION (A) OF THIS SECTION IS CUILTY OF A FELONY AND ON CONVICTION IS SUBJECT TO:
 - (1) FOR A FIRST OFFENSE, A FINE NOT EXCEEDING \$5,000; OR
- (2) FOR EACH SUBSEQUENT OFFENSE, A FINE NOT EXCEEDING \$20,000.

24-2203.

A RESEARCH FACILITY THAT FAILS TO PAY THE CONTRIBUTION REQUIRED UNDER § 24–2202(A) OF THIS SUBTITLE MAY BE SUBJECT TO A CIVIL PENALTY OF NOT MORE THAN \$1,000 PER DAY.

Article - State Finance and Procurement

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.
- (2) (i) Notwithstanding any other provision of law, and unless inconsistent with a federal law, grant agreement, or other federal requirement or with the terms of a gift or settlement agreement, net interest on all State money allocated by the State Treasurer under this section to special funds or accounts, and otherwise entitled to receive interest earnings, as accounted for by the Comptroller, shall accrue to the General Fund of the State.
- (ii) The provisions of subparagraph (i) of this paragraph do not apply to the following funds:
 - 170. the Cannabis Public Health Fund; [and]
 - 171. the Community Reinvestment and Repair Fund; AND
 - 172. THE HUMAN-RELEVANT RESEARCH FUND.

SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect July 1, 2023.

Approved by the Governor, May 8, 2023.