

118TH CONGRESS
1ST SESSION

H. R. 1024

To amend the Public Health Service Act to ensure that nonanimal methods are prioritized, where applicable and feasible, in proposals for all research to be conducted or supported by the National Institutes of Health, to provide for the establishment of the National Center for Alternatives to Animals in Research and Testing, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 14, 2023

Mr. PAPPAS (for himself and Mr. CALVERT) introduced the following bill;
which was referred to the Committee on Energy and Commerce

A BILL

To amend the Public Health Service Act to ensure that nonanimal methods are prioritized, where applicable and feasible, in proposals for all research to be conducted or supported by the National Institutes of Health, to provide for the establishment of the National Center for Alternatives to Animals in Research and Testing, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Humane and Existing
3 Alternatives in Research and Testing Sciences Act of
4 2022” or the “HEARTS Act of 2022”.

5 **SEC. 2. FINDINGS.**

6 Congress finds the following:

7 (1) The National Institutes of Health (NIH)
8 has supported life-saving research that has greatly
9 improved the health and well-being not only of
10 Americans but also of people around the world.

11 (2) Much of this research has relied on animals.
12 It is estimated that between 17,000,000 and
13 100,000,000 animals are used annually in the
14 United States in research, education, and testing.
15 However, the precise number of animals used in re-
16 search in the United States is unknown. Such im-
17 precise numbers make it impossible to effectively
18 track and reduce the numbers of animals used.

19 (3) According to the NIH, “approximately 30
20 percent of promising medications have failed in
21 human clinical trials because they are found to be
22 toxic despite promising pre-clinical studies in animal
23 models. About 60 percent of candidate drugs fail
24 due to lack of efficacy.”. These statistics indicate
25 that new, human-focused biology is needed.

1 (4) The laboratory use of animals has also long
2 been a matter of public concern because, among
3 other things, there is very little publicly available
4 data provided by the NIH about the number and
5 species of animals used in research.

6 (5) Effective alternatives to animals are becom-
7 ing available, and their number is growing. Cutting-
8 edge technologies have forged new frontiers in toxi-
9 cology, biology, and medicine that have produced
10 human-relevant models, including organoid cell cul-
11 tures, multiphysiological systems, genomics, induced
12 pluripotent adult stem cells, 3D modeling with
13 human cells, molecular imaging, computer models, in
14 silico trials, digital imaging, artificial intelligence,
15 and other innovative methods, all of which have
16 launched a technological revolution in biomedical re-
17 search.

18 (6) The Animal Welfare Act (Public Law 89-
19 544) requires researchers to consider alternatives to
20 animal use for painful procedures and stresses that
21 researchers should not unnecessarily duplicate pre-
22 vious experiments. However, oversight is lacking,
23 and these provisions are not implemented the way
24 that Congress intended. As a result, researchers are

1 not capitalizing on nonanimal models that might
2 more effectively recapitulate human biology.

3 (7) A system of active incentives is needed to
4 encourage researchers to develop and utilize hu-
5 mane, cost-effective, and scientifically suitable non-
6 animal methods based on human biology.

7 (8) Further, under the National Institutes of
8 Health Revitalization Act of 1993 (Public Law 103–
9 43), the NIH is supposed to outline a plan for re-
10 ducing the use of animals in research. Section
11 404C(a)(1) of the Public Health Service Act (42
12 U.S.C. 283e(a)(1)), as added by section 205 of the
13 National Institutes of Health Revitalization Act of
14 1993, calls for the NIH to “conduct or support re-
15 search into. . . methods of biomedical research and
16 experimentation that do not require the use of ani-
17 mals [and] methods of such research and experimen-
18 tation that reduce the number of animals used in
19 such research”.

20 (9) A dedicated center that provides resources,
21 funding, and training to encourage researchers to
22 utilize humane, cost-effective, and scientifically suit-
23 able nonanimal methods based on human biology will
24 result in more progress toward understanding
25 human diseases and their treatments and cures. It

1 will complete the vision that Congress set out in the
2 National Institutes of Health Revitalization Act of
3 1993 (Public Law 103–43), which has been thwart-
4 ed because of lack of oversight.

5 **SEC. 3. ANIMALS IN RESEARCH.**

6 Section 495 of the Public Health Service Act (42
7 U.S.C. 289d) is amended—

8 (1) in subsection (a)—

9 (A) in paragraph (2)—

10 (i) in the matter preceding subpara-
11 graph (A), by striking “paragraph” and in-
12 serting “subparagraph”; and

13 (ii) by redesignating subparagraphs
14 (A) and (B) as clauses (i) and (ii), respec-
15 tively, and moving the margins of such
16 clauses (as so redesignated) two ems to the
17 right;

18 (B) by redesignating paragraphs (1), (2)
19 (as so amended), and (3) as subparagraphs (A),
20 (B), and (C), respectively, and moving the mar-
21 gins of such subparagraphs (as so redesignated)
22 two ems to the right;

23 (C) in the matter preceding subparagraph
24 (A) (as so redesignated), by striking “shall es-
25 tablish guidelines for the following:” and insert-

1 ing the following: “, with respect to all research
2 conducted or supported by the National Insti-
3 tutes of Health, do the following:

4 “(1) Establish and maintain animal care guide-
5 lines for the following:”;

6 (D) by adding at the end the following:

7 “(2) Establish a system of meaningful incen-
8 tives to encourage the use of existing humane and
9 scientifically satisfactory nonanimal methods in re-
10 search proposals.

11 “(3) Ensure that, before any research involving
12 the use of animals is approved or performed all sci-
13 entifically satisfactory nonanimal methods for ob-
14 taining the results sought have been fully evaluated.

15 “(4) Ensure that—

16 “(A) research proposals are reviewed by at
17 least one person who has expertise in nonanimal
18 research methods; and

19 “(B) reviewers of the research proposals
20 have access to a reference librarian with exper-
21 tise in evaluating the adequacy of the searches
22 for nonanimal methods described in the re-
23 search proposals.

24 “(5) Establish and maintain research proposal
25 guidelines for conducting thorough searches for non-

1 animal alternatives to the use of animals for bio-
2 medical and behavioral research.”; and

3 (2) in subsection (c)(1)—

4 (A) in subparagraph (A), by striking
5 “and” at the end; and

6 (B) by adding at the end the following:

7 “(C) a statement of assurance that a sci-
8 entifically satisfactory nonanimal method of ob-
9 taining the result sought is not available; and”.

10 **SEC. 4. NATIONAL CENTER FOR ALTERNATIVES TO ANI-**
11 **MALS IN RESEARCH AND TESTING.**

12 (a) ADDITION TO LIST OF INSTITUTES AND CEN-
13 TERS.—Section 401 of the Public Health Service Act (42
14 U.S.C. 281) is amended—

15 (1) by redesignating paragraph (25) as para-
16 graph (26); and

17 (2) by inserting after paragraph (24) the fol-
18 lowing new paragraph:

19 “(25) The National Center for Alternatives to
20 Animals in Research and Testing.”.

21 (b) CONFORMING CHANGE TO NUMBER OF INSTI-
22 TUTES AND CENTERS.—Section 401(d)(1) of the Public
23 Health Service Act (42 U.S.C. 281(d)(1)) is amended by
24 striking “27” and inserting “28”.

1 (c) ESTABLISHMENT; DUTIES.—Part E of title IV of
2 the Public Health Service Act (42 U.S.C. 287 et seq.) is
3 amended by inserting after subpart 5 of such part E (42
4 U.S.C. 287c–21) the following new subpart:

5 **“Subpart 6—National Center for Alternatives to**
6 **Animals in Research and Testing**

7 **“SEC. 485E. ESTABLISHMENT; DUTIES.**

8 “(a) ESTABLISHMENT.—Not later than one year
9 after the date of enactment of the Humane and Existing
10 Alternatives in Research and Testing Sciences Act of
11 2022, the Secretary shall establish a National Center for
12 Alternatives to Animals in Research and Testing (in this
13 subpart referred to as the ‘National Center’) within the
14 National Institutes of Health. The Center shall be headed
15 by a director, who shall be appointed by the Secretary.

16 “(b) PURPOSE.—The general purpose of the National
17 Center shall be—

18 “(1) developing, promoting, and funding alter-
19 natives to animal research and testing; and

20 “(2) developing a plan for reducing the number
21 of animals used in federally funded research and
22 testing.

23 “(c) DUTIES.—The Director of the National Center
24 shall—

1 “(1) provide assistance (including funding) to
2 federally funded researchers to incentivize the devel-
3 opment and qualification of nonanimal methods,
4 such as advanced cell cultures or technology such as
5 3D organoids, microphysiological systems, induced
6 pluripotent adult stem cell models, in silico mod-
7 eling, advanced imaging systems, artificial intel-
8 ligence, and other innovative methods;

9 “(2) train and inform scientists about the
10 methods developed pursuant to paragraph (1);

11 “(3) establish collaborations among research in-
12 stitutions so that scientists who lack resources (such
13 as bioengineering and advanced bio-imaging equip-
14 ment) can develop and use methods developed pursu-
15 ant to paragraph (1); and

16 “(4) collect information regarding the numbers
17 of animals used in federally funded research and
18 testing, and make such information available to the
19 public in a timely manner.”.

20 **SEC. 5. REPORTING BY FEDERALLY FUNDED RESEARCH**
21 **ENTITIES ON NUMBERS OF ANIMALS USED IN**
22 **RESEARCH AND TESTING.**

23 (a) IN GENERAL.—Each covered reporting entity
24 shall do the following:

1 (1) Not later than 2 years after the date of en-
2 actment of this Act, report to the National Center
3 for Alternatives to Animals in Research and Testing
4 and make publicly available—

5 (A) the number of animals used by the
6 covered reporting entity in federally funded re-
7 search and testing at facilities of the covered
8 reporting entity, disaggregated by species; and

9 (B) the total number of such animals that
10 were bred or acquired by the covered reporting
11 entity for research or testing purposes,
12 disaggregated by species.

13 (2) Every 2 years thereafter—

14 (A) update the latest report of the covered
15 reporting entity under this section and make
16 publicly available such updated report to meas-
17 ure the progress of the covered reporting entity
18 in reducing the number of animals used in fed-
19 erally funded research and testing; and

20 (B) develop and submit to the National
21 Center for Alternatives to Animals in Research
22 and Testing and make publicly available a plan
23 for reducing the numbers described in subpara-
24 graphs (A) and (B) of paragraph (1).

1 (b) STANDARDIZED PROCESS.—The Director of the
2 National Center for Alternatives to Animals in Research
3 and Testing shall establish a standardized process for sub-
4 mitting and updating reports and plans under subsection
5 (a), including for making such reports and plans publicly
6 available.

7 (c) DEFINITION.—In this section:

8 (1) ANIMAL.—The term “animal” means any
9 live, nonhuman vertebrate animal or cephalopod
10 used or intended for use in research, research train-
11 ing, experimentation, or biological testing, or for re-
12 lated purposes.

13 (2) COVERED REPORTING ENTITY.—The term
14 “covered reporting entity” means—

15 (A) any entity that—

16 (i) receives Federal funds for research
17 or testing; and

18 (ii) uses animals in research and test-
19 ing; and

20 (B) any Federal department or agency
21 that uses animals in research or testing.

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