

116TH CONGRESS
1ST SESSION

H. R. 1209

To amend the Public Health Service Act to ensure that non-animal methods are prioritized, where applicable and feasible, in proposals for all research to be conducted or supported by the National Institutes of Health, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 13, 2019

Ms. ROYBAL-ALLARD (for herself 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 non-animal methods are prioritized, where applicable and feasible, in proposals for all research to be conducted or supported by the National Institutes of Health, 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,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Humane and Existing
5 Alternatives in Research and Testing Sciences Act of
6 2019” or the “HEARTS Act of 2019”.

1 **SEC. 2. FINDINGS.**

2 Congress finds the following:

3 (1) The National Institutes of Health has sup-
4 ported life-saving research that has greatly improved
5 the health and well-being not only of Americans but
6 also of people around the world.

7 (2) Much of this research has relied on animals.
8 It is estimated that between 17 million and 22 mil-
9 lion animals are used annually in the United States
10 in research, education, and testing.

11 (3) At the same time, however, a great deal of
12 research that utilized animal studies yielded no ben-
13 efits for humans. For example, according to NIH
14 itself, “approximately 30 percent of promising medi-
15 cations have failed in human clinical trials because
16 they are found to be toxic despite promising pre-clin-
17 ical studies in animal models. About 60 percent of
18 candidate drugs fail due to lack of efficacy”.

19 (4) The laboratory use of animals has also long
20 been an issue of public concern because animals will,
21 in most cases, experience fear, pain, disease or sur-
22 gery, and early death.

23 (5) Much more has become known about the
24 unsuitability of animal models for studying human
25 disease and many more humane, cost-effective, and

1 scientifically suitable non-animal methods are avail-
2 able.

3 (6) Under the system of oversight established
4 by the Animal Welfare Act (Public Law 89–544), re-
5 searchers are supposed to consider alternatives to
6 animal use or painful procedures and should not un-
7 necessarily duplicate previous experiments. However,
8 oversight is generally weak and little heed is paid to
9 the use of non-animal methods or the avoidance of
10 duplication, thereby unnecessarily subjecting animals
11 to pain, suffering, and death.

12 (7) A system of active incentives is needed to
13 encourage researchers to utilize humane, cost-effec-
14 tive, and scientifically suitable non-animal methods.

15 **SEC. 3. ANIMALS IN RESEARCH.**

16 Section 495 of the Public Health Service Act (42
17 U.S.C. 289d) is amended to read as follows:

18 **“SEC. 495. ANIMALS IN RESEARCH.**

19 “(a) IN GENERAL.—The Secretary, acting through
20 the Director of NIH, shall, with respect to all research
21 conducted or supported by the National Institutes of
22 Health, do the following:

23 “(1) Establish a system of meaningful incen-
24 tives to encourage the use of existing humane and

1 scientifically satisfactory non-animal methods in re-
2 search proposals.

3 “(2) Ensure that, before any research involving
4 the use of animals is approved or performed—

5 “(A) all scientifically satisfactory non-ani-
6 mal methods for obtaining the results sought
7 have been fully evaluated; and

8 “(B) a detailed explanation and an anal-
9 ysis of the harms and benefits of such use of
10 animals have been completed.

11 “(3) Ensure that—

12 “(A) research proposals are reviewed by at
13 least one person who has expertise in non-ani-
14 mal research methods; and

15 “(B) reviewers of the research proposals
16 have access to a reference librarian with exper-
17 tise in evaluating the adequacy of the searches
18 for non-animal methods described in the re-
19 search proposals.

20 “(4) Establish and maintain research proposal
21 guidelines for the following:

22 “(A) Conducting thorough searches for
23 non-animal alternatives to the use of animals
24 for biomedical and behavioral research.

1 “(B) Carrying out analyses of the harms
2 and benefits of the use of animals in proposed
3 research to assess whether the harms that
4 would be caused to animals in terms of suf-
5 fering, pain, and distress are justified by the
6 expected outcomes, taking into account ethical
7 considerations and the expected benefits to
8 human beings, animals, or the environment.

9 “(5) Establish and maintain animal care guide-
10 lines for the following:

11 “(A) The proper care of animals to be
12 used in biomedical and behavioral research.

13 “(B) The proper treatment of animals
14 while being used in such research. Guidelines
15 under this paragraph shall require—

16 “(i) the appropriate use of tranquil-
17 izers, analgesics, anesthetics, paralytics,
18 and euthanasia for animals in such re-
19 search; and

20 “(ii) appropriate pre-surgical and
21 post-surgical veterinary medical and nurs-
22 ing care for animals in such research.

23 Such guidelines shall not be construed to pre-
24 scribe methods of research.

1 “(C) The organization and operation of
2 animal care committees in accordance with sub-
3 section (b).

4 “(b) ANIMAL CARE COMMITTEES.—

5 “(1) IN GENERAL.—The guidelines under sub-
6 section (a)(5)(C) shall require animal care commit-
7 tees at each entity which conducts biomedical and
8 behavioral research with funds provided under this
9 Act (including the National Institutes of Health and
10 the national research institutes) to assure compli-
11 ance with the guidelines established under sub-
12 section (a)(5).

13 “(2) APPOINTMENT OF MEMBERS.—Each ani-
14 mal care committee shall—

15 “(A) be appointed by the chief executive
16 officer of the entity for which the committee is
17 established;

18 “(B) be composed of not fewer than three
19 members; and

20 “(C) include at least one individual who
21 has no association with such entity and at least
22 one doctor of veterinary medicine.

23 “(3) REQUIREMENTS.—Each animal care com-
24 mittee of a research entity shall—

1 “(A) review the care and treatment of ani-
2 mals in all animal study areas and facilities of
3 the research entity at least semiannually to
4 evaluate compliance with applicable guidelines
5 established under subsection (a)(5) for appro-
6 priate animal care and treatment;

7 “(B) keep appropriate records of reviews
8 conducted under subparagraph (A); and

9 “(C) for each review conducted under sub-
10 paragraph (A), file with the Director of NIH at
11 least annually—

12 “(i) a certification that the review has
13 been conducted; and

14 “(ii) reports of any violations of the
15 guidelines under subsection (a)(5) or as-
16 surances required under paragraph (1)
17 which were observed in such review and
18 which have continued after notice by the
19 committee to the research entity involved
20 of the violations.

21 “(4) MINORITY VIEWS.—Reports filed under
22 paragraph (3)(C) shall include any minority views
23 filed by members of the committee.

24 “(c) APPLICATIONS AND CONTRACTS.—

1 “(1) CONTENTS.—The Director of NIH shall
2 require each applicant for a grant, contract, or coop-
3 erative agreement involving research on animals
4 which is administered by the National Institutes of
5 Health or any national research institute to include
6 in its application or contract proposal—

7 “(A) assurances satisfactory to the Direc-
8 tor of NIH that—

9 “(i) the applicant meets the require-
10 ments under paragraphs (2), (3), (4), and
11 (5) of subsection (a) and has an animal
12 care committee which meets the require-
13 ments of subsection (b); and

14 “(ii) scientists, animal technicians,
15 and other personnel involved with animal
16 care, treatment, and use by the applicant
17 have available to them instruction or train-
18 ing in—

19 “(I) the humane practice of ani-
20 mal maintenance and experimen-
21 tation; and

22 “(II) the concept, availability,
23 and use of research or testing meth-
24 ods that replace the use of animals,

1 limit the use of animals, or limit ani-
2 mal distress;

3 “(B) a statement of the reasons for the
4 use of animals in the research to be conducted
5 with funds provided under such grant or con-
6 tract;

7 “(C) a statement of assurance that a sci-
8 entifically satisfactory non-animal method of
9 obtaining the result sought is not available; and

10 “(D) an analysis of the harms and benefits
11 of the use of animals in the proposed research
12 assessing whether the harms that would be
13 caused to animals in terms of suffering, pain,
14 and distress is justified by the expected out-
15 comes, taking into account ethical consider-
16 ations and the expected benefits to human
17 beings, animals, or the environment.

18 “(2) REGULATORY PROCESS.—Notwithstanding
19 subsection (a)(2) of section 553 of title 5, United
20 States Code, regulations under this subsection shall
21 be promulgated in accordance with the notice and
22 comment requirements of such section.

23 “(d) SUSPENSION OR REVOCATION.—If the Director
24 of NIH determines that—

1 “(1) the conditions of animal care, treatment,
2 or use in an entity which is receiving a grant, con-
3 tract, or cooperative agreement involving research on
4 animals under this title do not meet applicable
5 guidelines established under subsection (a)(5);

6 “(2) the entity has been notified by the Direc-
7 tor of NIH of such determination and has been
8 given a reasonable opportunity to take corrective ac-
9 tion; and

10 “(3) no action has been taken by the entity to
11 correct such conditions,
12 the Director of NIH shall suspend or revoke such grant,
13 contract, or cooperative agreement under such conditions
14 as the Director determines appropriate.

15 “(e) PROTECTION OF CERTAIN INFORMATION.—No
16 guideline or regulation promulgated under subsection
17 (a)(5) or (c) may require a research entity to disclose pub-
18 licly trade secrets or commercial or financial information
19 which is privileged or confidential.”.

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