

117TH CONGRESS  
1ST SESSION

# H. R. 4101

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.

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## IN THE HOUSE OF REPRESENTATIVES

JUNE 23, 2021

Ms. ROYBAL-ALLARD (for herself and Mr. CALVERT) introduced the following bill; which was referred to the Committee on Energy and Commerce

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## 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 2021” or the “HEARTS Act of 2021”.

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—

18 (1) in subsection (a)—

19 (A) in paragraph (2)—

20 (i) in the matter preceding subpara-  
21 graph (A), by striking “paragraph” and in-  
22 serting “subparagraph”; and

23 (ii) by redesignating subparagraphs  
24 (A) and (B) as clauses (i) and (ii), respec-  
25 tively, and moving the margins of such

1 clauses (as so redesignated) two ems to the  
2 right;

3 (B) by redesignating paragraphs (1), (2)  
4 (as so amended), and (3) as subparagraphs (A),  
5 (B), and (C), respectively, and moving the mar-  
6 gins of such subparagraphs (as so redesignated)  
7 two ems to the right;

8 (C) in the matter preceding subparagraph  
9 (A) (as so redesignated), by striking “shall es-  
10 tablish guidelines for the following:” and insert-  
11 ing the following: “, with respect to all research  
12 conducted or supported by the National Insti-  
13 tutes of Health, do the following:

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

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

17 “(2) Establish a system of meaningful incen-  
18 tives to encourage the use of existing humane and  
19 scientifically satisfactory non-animal methods in re-  
20 search proposals.

21 “(3) Ensure that, before any research involving  
22 the use of animals is approved or performed all sci-  
23 entifically satisfactory non-animal methods for ob-  
24 taining the results sought have been fully evaluated.

25 “(4) Ensure that—

1           “(A) research proposals are reviewed by at  
2           least one person who has expertise in non-animal  
3           research methods; and

4           “(B) reviewers of the research proposals  
5           have access to a reference librarian with expertise  
6           in evaluating the adequacy of the searches  
7           for non-animal methods described in the research  
8           proposals.

9           “(5) Establish and maintain research proposal  
10          guidelines for conducting thorough searches for non-  
11          animal alternatives to the use of animals for biomedical  
12          and behavioral research.”; and

13          (2) in subsection (c)(1)—

14                (A) in subparagraph (A), by striking  
15                “and” at the end; and

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

17                   “(C) a statement of assurance that a scientifically  
18                   satisfactory non-animal method of  
19                   obtaining the result sought is not available;  
20                   and”.

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