

117TH CONGRESS
1ST SESSION

H. R. 4211

To amend the Public Health Service Act to require full inspection, and complete transparency, with respect to entities receiving financial assistance from the National Institutes of Health, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JUNE 28, 2021

Mr. TURNER introduced the following bill; which was referred to the
Committee on Energy and Commerce

A BILL

To amend the Public Health Service Act to require full inspection, and complete transparency, with respect to entities receiving financial assistance from 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 “Enabling More Pene-
5 trating Oversight When Examining Research for NIH Act
6 of 2021” or the “EMPOWER NIH Act of 2021”.

1 **SEC. 2. ONSITE INSPECTIONS REQUIRED OF NIH AWARD**
2 **RECIPIENTS.**

3 Part A of title IV of the Public Health Service Act
4 (42 U.S.C. 281 et seq.) is amended by adding at the end
5 the following:

6 **“SEC. 404O. ONSITE INSPECTIONS OF AWARD RECIPIENTS.**

7 “(a) SCOPE.—

8 “(1) IN GENERAL.—This section applies with
9 respect to any financial assistance from the National
10 Institutes of Health to any non-Federal entity for
11 research-related activities, whether the assistance is
12 made available directly or indirectly, including
13 through the award of a subgrant or other subaward.

14 “(2) SPECIAL RULE.—This section applies even
15 where an entity described in paragraph (1) is located
16 or operates at—

17 “(A) a site that is in a foreign country
18 whose government—

19 “(i) prevents inspectors from reaching
20 the site;

21 “(ii) impedes or impairs inspection; or

22 “(B) a site that restricts or delays the
23 entry of the inspectors for any reason.

24 “(b) CONDITION ON RECEIPT.—As a condition on re-
25 ceipt of any financial assistance described in subsection

1 (a), an entity shall agree to undergo an annual in-person
2 inspection pursuant to this section.

3 “(c) INSPECTION REQUIREMENTS.—The Director of
4 NIH shall conduct an annual inspection of each entity re-
5 ceiving financial assistance described in subsection (a) in
6 accordance with the following:

7 “(1) The inspection shall be unannounced.

8 “(2) The timing of the inspection shall vary
9 each year.

10 “(3) The inspection shall take place at all the
11 sites at which activities are being funded through
12 the financial assistance.

13 “(4) The inspection shall examine—

14 “(A) whether the funded research is con-
15 sistent with the description and assurances in
16 the relevant proposal;

17 “(B) whether each site at which the re-
18 search is conducted, and the research itself, is
19 in compliance with all applicable standards and
20 requirements of the National Institutes of
21 Health; and

22 “(C) whether each entity receiving the fi-
23 nancial assistance keeps detailed and updated
24 records of the research conducted.

25 “(5) The inspection shall include—

1 “(A) the facility at the research site;

2 “(B) the materials used to conduct the re-
3 search;

4 “(C) any electronic or hard-copy materials
5 relevant to the research; and

6 “(D) photographic and video evidence of
7 the inspection.

8 “(6) Each team of inspectors shall consist of at
9 least three individuals, each of whom shall have no
10 affiliation with any of the entities receiving the fi-
11 nancial assistance.

12 “(7) Each team of inspectors shall certify in
13 writing that they have no financial conflict of inter-
14 est with respect to the operations, researchers, or
15 potential findings involved.

16 “(8) Each inspector upon arrival at the site to
17 be inspected shall present officials of the entity to be
18 inspected with credentials confirming the inspector’s
19 identity and authority to inspect the entity.

20 “(d) PENALTIES.—

21 “(1) IN GENERAL.—If an entity fails an inspec-
22 tion under this section—

23 “(A) the entities receiving the financial as-
24 sistance involved shall, collectively, return the

1 full amount of such assistance to the Treasury;
2 and

3 “(B) each entity receiving the financial as-
4 sistance involved, including each entity that re-
5 ceives the assistance directly from the National
6 Institutes of Health and each entity that re-
7 ceives the assistance indirectly, shall be ineli-
8 gible to receive financial assistance from the
9 National Institutes of Health for a period of—

10 “(i) not less than 5 years; and

11 “(ii) in the case of an entity that is
12 determined by the Director of NIH to have
13 failed the inspection for a violation de-
14 scribed in paragraph (2), not less than 15
15 years.

16 “(2) VIOLATIONS DESCRIBED.—A violation re-
17 ferred to in paragraph (1)(B)(ii) is—

18 “(A) without regard to whether the con-
19 duct is knowing or not—

20 “(i) denial of entry by the entity to in-
21 spectors;

22 “(ii) maintaining incomplete or fal-
23 sified research records;

24 “(iii) damaging or destroying research
25 records;

1 “(iv) withholding research records
2 from inspectors; or

3 “(v) relocating research materials to
4 alternate sites to avoid inspection; or

5 “(B) any action taken knowingly to pre-
6 vent a full and complete inspection.

7 “(3) RELATION TO OTHER PENALTIES.—The
8 penalties specified in this subsection are in addition
9 to any other penalties applicable to an act or omis-
10 sion causing an entity to fail an inspection under
11 this section.

12 “(e) ANNUAL REPORT TO CONGRESS.—

13 “(1) IN GENERAL.—Not later than October 1,
14 2024, and annually thereafter, The Director of NIH
15 shall submit an annual report on the implementation
16 of this section to the following congressional commit-
17 tees:

18 “(A) The Committee on Homeland Secu-
19 rity and Governmental Affairs of the Senate.

20 “(B) The Committee on Finance of the
21 Senate.

22 “(C) The Select Committee on Intelligence
23 of the Senate.

24 “(D) The Committee on Oversight and Re-
25 form of the House of Representatives.

1 “(E) The Committee on Energy and Com-
2 merce of the House of Representatives.

3 “(F) The Permanent Select Committee on
4 Intelligence of the House of Representatives.

5 “(2) CONTENTS.—Each report under para-
6 graph (1) shall, with respect to the period covered
7 by the report, include—

8 “(A) the full text of each proposal receiv-
9 ing financial assistance from the National Insti-
10 tutes of Health;

11 “(B) data regarding whether research con-
12 ducted using financial assistance from the Na-
13 tional Institutes of Health is consistent with the
14 substance of the corresponding proposal;

15 “(C) data regarding whether each site at
16 which research is conducted using financial as-
17 sistance from the National Institutes of Health,
18 and the research itself, is in compliance with all
19 applicable standards and requirements of the
20 National Institutes of Health;

21 “(D) data regarding whether each entity
22 receiving financial assistance from the National
23 Institutes of Health keeps detailed and updated
24 records of the research conducted;

1 “(E) a final assessment of whether each
2 entity receiving financial assistance from the
3 National Institutes of Health remains eligible to
4 continue receiving such assistance; and

5 “(F) a plan for the National Institutes of
6 Health to enforce the penalties under sub-
7 section (d) with respect to each entity fails an
8 inspection under this section.

9 “(3) PUBLICATION.—The Director of NIH shall
10 post each report under paragraph (1) in its entirety
11 on the public website of the National Institutes of
12 Health.

13 “(f) APPLICABILITY.—This section applies beginning
14 on October 1, 2023, irrespective of whether the financial
15 assistance involved is awarded before or after such date.”.

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