

117TH CONGRESS
2D SESSION

S. 3819

To establish an Advanced Research Projects Authority for Health within
the National Institutes of Health.

IN THE SENATE OF THE UNITED STATES

MARCH 10 (legislative day, MARCH 7), 2022

Mrs. MURRAY (for herself and Mr. BURR) introduced the following bill; which
was read twice and referred to the Committee on Health, Education,
Labor, and Pensions

A BILL

To establish an Advanced Research Projects Authority for
Health within the National Institutes of Health.

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 “Advanced Research
5 Project Authority for Health Act” or the “ARPA–H Act”.

6 **SEC. 2. ADVANCED RESEARCH PROJECTS AUTHORITY FOR**
7 **HEALTH.**

8 Part E of title IV of the Public Health Service Act
9 (42 U.S.C. 287 et seq.) is amended by inserting after sub-
10 part 2 of such part the following:

1 **“Subpart 3—Advanced Research Projects Authority**
2 **for Health**

3 **“SEC. 483. ADVANCED RESEARCH PROJECTS AUTHORITY**
4 **FOR HEALTH.**

5 “(a) DEFINITIONS.—In this section:

6 “(1) ARPA–H.—The term ‘ARPA–H’ means
7 the Advanced Research Projects Authority for
8 Health established under subsection (b).

9 “(2) DIRECTOR.—The term ‘Director’ means
10 the Director of ARPA–H appointed under sub-
11 section (c).

12 “(3) OTHER TRANSACTIONS.—The term ‘other
13 transactions’ has the meaning given such term in
14 section 319L(a)(3).

15 “(b) ESTABLISHMENT OF THE ADVANCED RE-
16 SEARCH PROJECTS AUTHORITY FOR HEALTH.—There is
17 established within the National Institutes of Health the
18 Advanced Research Projects Authority for Health, for
19 purposes of—

20 “(1) supporting high-impact, cutting-edge re-
21 search in biomedicine and broadly applicable break-
22 through technologies that have the potential to sig-
23 nificantly transform and advance areas of biomedical
24 science and medicine in a manner that cannot read-
25 ily be accomplished through traditional biomedical
26 research or commercial activity; and

1 “(2) overcoming long-term and significant tech-
2 nological and scientific barriers to advancing such
3 technologies in order to improve the prevention, di-
4 agnosis, mitigation, treatment, and cure of health
5 conditions.

6 “(c) DIRECTOR.—

7 “(1) IN GENERAL.—ARPA–H shall be headed
8 by a Director, who shall be appointed by the Presi-
9 dent. The Director shall report to the Director of
10 NIH.

11 “(2) QUALIFICATIONS.—The Director shall be
12 an individual who, by reason of professional back-
13 ground and experience, is especially qualified to ad-
14 vise the Secretary on, and manage, research pro-
15 grams that advance the purposes of ARPA–H in
16 promoting biomedical and novel technology innova-
17 tion pursuant to this section, and who has a dem-
18 onstrated ability to identify and develop partnerships
19 to address strategic needs in meeting such purposes.

20 “(3) APPOINTMENT.—Notwithstanding section
21 405(a)(2), the Director shall be appointed for a pe-
22 riod of 4 years. The President may extend the term
23 of a Director for a period of up to 4 additional
24 years.

25 “(4) DUTIES.—The Director shall—

1 “(A) establish strategic goals, objectives,
2 and priorities for ARPA–H, pursuant to the
3 purposes of ARPA–H described in subsection
4 (b);

5 “(B) approve all new programs within
6 ARPA–H and terminate any program within
7 ARPA–H that is not achieving its goals;

8 “(C) establish criteria for funding and as-
9 sessing the success of programs through the es-
10 tablishment of technical milestones;

11 “(D) ensure that applications for funding
12 disclose current and previous research and de-
13 velopment efforts, and identify any challenges
14 associated with such efforts, including any sci-
15 entific or technical barriers encountered in the
16 course of such efforts or challenges in securing
17 sources of funding, as applicable and appro-
18 priate, in pursuit of the technology area for
19 which funding is requested;

20 “(E) facilitate coordination between the
21 Department of Health and Human Services,
22 relevant agencies within such Department, and
23 other relevant Federal departments and agen-
24 cies, with respect to research supported by
25 ARPA–H;

1 “(F) support transformative, translational,
2 applied, and advanced research in areas of bio-
3 medical science to address specific technical or
4 scientific questions by—

5 “(i) prioritizing investments based on
6 scientific potential and impact on the field
7 of biomedicine, as described in subsection
8 (b), especially in areas that require public-
9 private partnerships in order to effectively
10 advance research and development activi-
11 ties;

12 “(ii) translating scientific discoveries
13 and cutting-edge innovation into techno-
14 logical advancements;

15 “(iii) encouraging opportunities to de-
16 velop broadly applicable technologies, using
17 a multi-disciplinary approach; and

18 “(iv) making investments in high-risk,
19 high-reward research related to broadly ap-
20 plicable technologies, capabilities, and plat-
21 forms that may have an application for
22 medicine and health;

23 “(G) encourage strategic collaboration and
24 partnerships with a broad range of entities, in-
25 cluding institutions of higher education, indus-

1 try, nonprofit organizations, or consortia of
2 such entities, which may include federally fund-
3 ed research and development centers; and

4 “(H) ensure that the United States main-
5 tains global leadership in researching and devel-
6 oping health technologies.

7 “(d) PERSONNEL.—

8 “(1) IN GENERAL.—The Director shall establish
9 and maintain within ARPA–H a staff with appro-
10 priate qualifications and expertise to enable ARPA–
11 H to carry out the responsibilities under this section.

12 “(2) PROGRAM MANAGERS.—

13 “(A) IN GENERAL.—The Director shall
14 designate employees to serve as program man-
15 agers for the programs established or supported
16 pursuant to subsection (c)(4).

17 “(B) RESPONSIBILITIES.—A program
18 manager shall—

19 “(i) establish, in consultation with the
20 Director, research and development goals
21 for the program, including timelines and
22 milestones, and make such goals available
23 to the public;

1 “(ii) provide project oversight and
2 management of strategic initiatives to ad-
3 vance the purpose of the program;

4 “(iii) encourage research collabora-
5 tions, including by identifying and sup-
6 porting applicable public-private partner-
7 ships;

8 “(iv) select the projects to be sup-
9 ported under the program after consid-
10 ering—

11 “(I) the novelty, scientific, and
12 technical merit of the proposed
13 projects;

14 “(II) the demonstrated capabili-
15 ties of the applicants to successfully
16 carry out the proposed project and
17 achieve designated milestones within
18 the applicable timeline;

19 “(III) the potential future com-
20 mercial applications of the project
21 proposed by the applicant;

22 “(IV) the degree to which the
23 project addresses a scientific or tech-
24 nical question pursuant to subsection
25 (c)(4)(F) and has the potential to

1 transform biomedicine, as described in
2 subsection (b); and

3 “(V) other criteria as established
4 by the Director;

5 “(v) recommend program restructure,
6 expansion, or termination of research
7 projects or whole projects, as necessary
8 and appropriate; and

9 “(vi) communicate with leaders in the
10 health care and biomedical research and
11 development fields, including from both the
12 public and private sectors, representatives
13 of patient organizations, institutions of
14 higher education, and nonprofit organiza-
15 tions, to identify areas of need and sci-
16 entific opportunity with the potential to
17 transform biomedicine as described in sub-
18 section (b).

19 “(C) TERM.—The term of a program man-
20 ager shall be not more than 3 years, and, at the
21 discretion of the Director, may be renewed for
22 one additional period of up to 3 years.

23 “(3) CONSIDERATIONS.—The Director—

24 “(A) in designating employees to serve as
25 program managers under paragraph (1), shall

1 consider, as appropriate, individuals with dem-
2 onstrated scientific expertise and management
3 skills required to advance the purposes of
4 ARPA–H, and who represent a diverse set of
5 professional experiences or backgrounds, includ-
6 ing individuals with experience in academia, in-
7 dustry, government, nonprofit organizations, or
8 other sectors; and

9 “(B) in making appointments of personnel
10 to staff or support ARPA–H, may consider
11 other factors, as appropriate, such as popu-
12 lations that are traditionally underrepresented
13 in the biomedical research enterprise.

14 “(4) HIRING.—

15 “(A) IN GENERAL.—The Director may—

16 “(i) make or rescind appointments of
17 scientific, medical, and professional per-
18 sonnel, without regard to any provision of
19 title 5, United States Code governing ap-
20 pointments under the civil service laws and
21 notwithstanding section 202 of the Depart-
22 ment of Health and Human Services Ap-
23 propriations Act, 1993 (Public Law 102–
24 394); and

1 “(ii) fix the compensation of such per-
2 sonnel at a rate to be determined by the
3 Director, up to the amount of annual com-
4 pensation (excluding expenses) specified in
5 section 102 of title 3, United States Code.

6 “(B) REPORTING.—The Director shall es-
7 tablish and maintain records regarding the use
8 of the authority under subparagraph (A)(i), in-
9 cluding—

10 “(i) the number of positions filled
11 through such authority;

12 “(ii) the types of appointments of
13 such positions;

14 “(iii) the titles, occupational series,
15 and grades of such positions;

16 “(iv) the number of positions publicly
17 noticed to be filled under such authority;

18 “(v) the number of qualified appli-
19 cants who apply for such positions;

20 “(vi) the qualification criteria for such
21 positions; and

22 “(vii) the demographic information of
23 individuals appointed to such positions.

24 “(C) REPORTS TO CONGRESS.—Not later
25 than one year after the date of enactment of

1 the Advanced Research Project Authority for
2 Health Act, and annually thereafter for each
3 fiscal year in which such authority is used, the
4 Director shall submit to the Committee on
5 Health, Education, Labor, and Pensions of the
6 Senate and the Committee on Energy and Com-
7 merce of the House of Representatives a report
8 describing the total number of appointments
9 filled under this subsection within the fiscal
10 year and how the positions relate to the pur-
11 poses of ARPA-H.

12 “(D) PRIVATE RECRUITING FIRMS.—The
13 Director may contract with private recruiting
14 firms for the hiring of qualified technical staff
15 to carry out this section.

16 “(E) CLARIFICATIONS.—

17 “(i) PREVIOUS POSITIONS.—The Di-
18 rector shall ensure that the personnel who
19 are appointed to staff or support ARPA-
20 H are individuals who, at the time of ap-
21 pointment and for 3 years prior to such
22 appointment, were not employed by the
23 National Institutes of Health.

24 “(ii) NUMBER OF PERSONNEL.—The
25 Director may appoint not more than 120

1 personnel under this section. The Director
2 shall submit a notification to Congress if
3 the Director determines that additional
4 personnel are required to carry out this
5 section.

6 “(F) GAO REPORT.—Not later than 2
7 years after the date of enactment of the Ad-
8 vanced Research Project Authority for Health
9 Act, the Comptroller General of the United
10 States shall submit to the Committee on
11 Health, Education, Labor, and Pensions of the
12 Senate and the Committee on Energy and Com-
13 merce of the House of Representatives a report
14 on the use of the authority provided under sub-
15 paragraph (A)(i). Such report shall, in a man-
16 ner that protects personal privacy, to the extent
17 required by applicable Federal and State pri-
18 vacy law, at a minimum, include information
19 on—

20 “(i) the number of positions publicly
21 noticed and filled under the authority
22 under this subsection;

23 “(ii) the occupational series, grades,
24 and types of appointments of such posi-
25 tions;

1 “(iii) how such positions related to ad-
2 vancing the purposes of ARPA-H;

3 “(iv) how the Director made appoint-
4 ment decisions under this subsection;

5 “(v) sources used to identify can-
6 didates for filling such positions;

7 “(vi) the number of individuals ap-
8 pointed;

9 “(vii) aggregated demographic infor-
10 mation related to individuals appointed;
11 and

12 “(viii) any challenges, limitations, or
13 gaps related to the use of the authority
14 under this subsection and any related rec-
15 ommendations to address such challenges,
16 limitations, or gaps.

17 “(e) FUNDING AWARDS.—

18 “(1) IN GENERAL.—In carrying out this sec-
19 tion, the Director may award grants, contracts, co-
20 operative agreements, cash prizes, and enter into
21 other transactions, as described in paragraph (2).

22 “(2) OTHER TRANSACTIONS.—

23 “(A) LIMITATIONS ON ENTERING INTO
24 OTHER TRANSACTIONS.—

1 “(i) IN GENERAL.—To the maximum
2 extent practicable, competitive procedures
3 shall be used when entering into other
4 transactions to carry out projects under
5 this section.

6 “(B) WRITTEN DETERMINATIONS RE-
7 QUIRED.—The authority of this paragraph may
8 be exercised for a project if the project man-
9 ager—

10 “(i) submits a proposal to the Direc-
11 tor for each individual use of such author-
12 ity before conducting or supporting a
13 project, including why the use of such au-
14 thority is essential to promoting the suc-
15 cess of the project;

16 “(ii) receives approval for the use of
17 such authority from the Director; and

18 “(iii) for each year in which the pro-
19 gram manager has used such authority in
20 accordance with this paragraph, submits a
21 report to the Director on the activities of
22 the program relating to such project.

23 “(3) PRIZE COMPETITIONS.—The Director may
24 utilize the authorities and processes established
25 under section 24 of the Stevenson-Wydler Tech-

1 nology Innovation Act of 1980 (15 U.S.C. 3719) to
2 support prize competitions, in accordance with this
3 section.

4 “(4) FEDERAL DEMONSTRATION OF TECH-
5 NOLOGIES.—The Director may seek opportunities to
6 partner with procurement programs of Federal agen-
7 cies to demonstrate technologies resulting from ac-
8 tivities funded through ARPA–H.

9 “(5) CLARIFICATIONS.—Research supported by
10 this section shall not be subject to the requirements
11 of section 406(a)(3)(A)(ii) or 492.

12 “(f) COORDINATION, COLLABORATION, NONDUPLICA-
13 TION, AND CONSULTATION.—

14 “(1) COORDINATION.—To the maximum extent
15 practicable, the Director shall ensure that the activi-
16 ties of ARPA–H are coordinated with, and do not
17 duplicate the efforts of—

18 “(A) other programs within, or research
19 conducted or supported by, the Department of
20 Health and Human Services, including the Na-
21 tional Institutes of Health and the Biomedical
22 Advanced Research and Development Authority;
23 and

24 “(B) other relevant efforts or research and
25 development programs operated or overseen by

1 other departments, agencies, or offices of the
2 Federal Government.

3 “(2) FUNDING DETERMINATIONS.—The Direc-
4 tor shall ensure that ARPA–H does not provide
5 funding for a research program or project unless the
6 applicant for such funding demonstrates that—

7 “(A)(i) such applicant has made sufficient
8 unsuccessful attempts to secure private financ-
9 ing, and that there is a lack of significant pri-
10 vate support for the program or project; or

11 “(ii) such program or project is in the best
12 interests of the United States; and

13 “(B) such program or project has the po-
14 tential to significantly transform and advance
15 the field of biomedicine, as described in sub-
16 section (b).

17 “(3) CONSULTATION.—In carrying out this sec-
18 tion, the Director may seek input from—

19 “(A) the President’s Council of Advisors
20 on Science and Technology;

21 “(B) representatives of professional or sci-
22 entific organizations with expertise in specific
23 technologies under consideration or development
24 by ARPA–H; and

1 “(C) representatives of patient organiza-
2 tions, public health, innovators, and other pub-
3 lic and private entities.

4 “(4) ENHANCED COLLABORATION AND COMMU-
5 NICATION.—

6 “(A) IN GENERAL.—In order to facilitate
7 enhanced collaboration and communication with
8 respect to the most current priorities of ARPA-
9 H, the Food and Drug Administration may
10 meet with ARPA-H and any other appropriate
11 Federal partners, such as the Biomedical Ad-
12 vanced Research and Development Authority, at
13 appropriate intervals, to discuss the develop-
14 ment status, and actions that may be taken to
15 facilitate the development, of medical products
16 and projects that are the highest priorities to
17 ARPA-H.

18 “(B) RELATION TO OTHERWISE AUTHOR-
19 IZED ACTIVITIES OF THE FOOD AND DRUG AD-
20 MINISTRATION.—Utilizing interagency agree-
21 ments or other appropriate resource allocation
22 mechanisms available, the Director shall reim-
23 burse the Food and Drug Administration, as
24 appropriate, for activities identified by the
25 Commissioner of Food and Drugs and the Di-

1 rector as being conducted by the Food and
2 Drug Administration under the authority of
3 this section, using funds made available to
4 ARPA–H.

5 “(g) ADVISORY COMMITTEE.—

6 “(1) IN GENERAL.—There is established an
7 ARPA–H Interagency Advisory Committee (referred
8 to in this subsection as the ‘Advisory Committee’) to
9 coordinate efforts and provide advice and assistance
10 on specific program or project tasks and the overall
11 direction of ARPA–H.

12 “(2) MEMBERS.—The Advisory Committee es-
13 tablished under paragraph (1) shall consist of the
14 heads of the following agencies or their designees:

15 “(A) The National Institutes of Health.

16 “(B) The Centers for Disease Control and
17 Prevention.

18 “(C) The Food and Drug Administration.

19 “(D) The Office of the Assistant Secretary
20 for Preparedness and Response.

21 “(E) The Office of the Assistant Secretary
22 of Health.

23 “(F) The Defense Advanced Research
24 Projects Agency.

1 “(G) The Office of Science of the Depart-
2 ment of Energy.

3 “(H) The National Science Foundation.

4 “(I) Any other agency with subject matter
5 expertise that the Director of ARPA–H deter-
6 mines appropriate to advance programs or
7 projects under this section.

8 “(3) NONAPPLICABILITY OF FACCA.—The Fed-
9 eral Advisory Committee Act (5 U.S.C. App.) shall
10 not apply to the Advisory Committee.

11 “(4) ADVISORY NATURE.—The functions of the
12 Advisory Committee shall be advisory in nature, and
13 nothing in this subsection shall be construed as
14 granting such Committee authority over the activi-
15 ties authorized under this section.

16 “(5) PERFORMANCE MEASURES FRAMEWORK.—
17 The Director, in consultation with the Advisory
18 Committee, shall develop a performance measures
19 framework for programs or projects supported by
20 ARPA–H in order to inform and facilitate the eval-
21 uation required under subsection (m), including
22 identification of any data needed to perform such
23 evaluation, consistent with subsection (l).

24 “(h) FACILITIES.—

1 “(1) AUTHORITIES.—The Director is author-
2 ized to—

3 “(A) acquire (by purchase, lease, con-
4 demnation or otherwise), construct, improve, re-
5 pair, operate, and maintain such real and per-
6 sonal property as are necessary to carry out
7 this section; and

8 “(B) lease an interest in property for not
9 more than 20 years, notwithstanding section
10 1341(a)(1) of title 31, United States Code.

11 “(2) LOCATIONS.—

12 “(A) IN GENERAL.—ARPA–H, including
13 its headquarters, shall not be located, including
14 headquartered, inside of, or in close proximity
15 to, the National Capital region, and shall not be
16 located on any part of the National Institutes
17 of Health campuses.

18 “(B) CONSIDERATIONS.—In determining
19 the location of facilities, the Director shall con-
20 sider the characteristics of the intended location
21 and the extent to which such location will facili-
22 tate advancement of the ARPA–H purposes
23 pursuant to subsection (b).

24 “(i) RULE OF CONSTRUCTION.—The authorities
25 granted by this section—

1 “(1) are in addition to existing authorities
2 granted to the Secretary; and

3 “(2) shall not be construed to modify or super-
4 sede any existing authorities.

5 “(j) PROTECTION OF INFORMATION.—

6 “(1) IN GENERAL.—Nothing in this section
7 shall be construed as authorizing the Secretary to
8 disclose any information that is a trade secret, or
9 other privileged or confidential information subject
10 to section 552(b)(4) of title 5, United States Code,
11 or section 1905 of title 18, United States Code.

12 “(2) REPORTING.—One year after the date of
13 enactment of the Advanced Research Project Au-
14 thority for Health Act, and annually thereafter, the
15 Director shall report to the Committee on Health,
16 Education, Labor, and Pensions of the Senate and
17 the Committee on Energy and Commerce of the
18 House of Representatives on—

19 “(A) the number of instances in which the
20 Secretary has used the authority under this
21 subsection to withhold information from disclo-
22 sure; and

23 “(B) the nature of any request under sec-
24 tion 552 of title 5, United States Code, or sec-

1 tion 1905 of title 18, United States Code, that
2 was denied using such authority.

3 “(k) REPORTS AND STRATEGIC PLANS.—

4 “(1) ANNUAL REPORT.—As part of the annual
5 budget request submitted for each fiscal year, the
6 Director shall provide to the Committee on Health,
7 Education, Labor, and Pensions and the Committee
8 on Appropriations of the Senate and the Committee
9 on Energy and Commerce and the Committee on
10 Appropriations of the House of Representatives a re-
11 port that describes—

12 “(A) projects supported by ARPA–H dur-
13 ing the previous fiscal year, and, with respect to
14 each such project, the stage of development and
15 details as to whether the project is meeting
16 project milestones;

17 “(B) projects supported by ARPA–H in
18 the previous fiscal year that were terminated,
19 and the reasons for termination;

20 “(C) projects supported by ARPA–H dur-
21 ing the previous fiscal year that examine topics
22 and technologies closely related to other activi-
23 ties funded by the Department of Health and
24 Human Services, including an analysis of
25 whether in supporting such projects, the Direc-

1 tor is in compliance with the requirements of
2 this section; and

3 “(D) current, proposed, and planned
4 projects to be carried out.

5 “(2) STRATEGIC PLAN.—Not later than 180
6 days after the appointment of the first Director pur-
7 suant to subsection (c), and every 4 years thereafter,
8 the Director shall provide to the Committee on
9 Health, Education, Labor, and Pensions and the
10 Committee on Appropriations of the Senate and the
11 Committee on Energy and Commerce and the Com-
12 mittee on Appropriations of the House of Represent-
13 atives a plan describing the strategic plan that
14 ARPA–H will use to guide future investments over
15 the following 4 fiscal years. Every 2 years after the
16 date of submission of the initial plan, the Director
17 shall submit a supplemental strategic plan that de-
18 tails any changes to such strategic vision, as appro-
19 priate. The requirements regarding individual insti-
20 tute and center strategic plans under section
21 402(m), including paragraph (3) of such subsection,
22 shall not apply to ARPA–H.

23 “(1) NATIONAL ACADEMIES OF SCIENCES, ENGI-
24 NEERING, AND MEDICINE EVALUATION.—

1 “(1) IN GENERAL.—Not later than 3 years
2 after the date of enactment of the Advanced Re-
3 search Project Authority for Health Act, the Direc-
4 tor shall seek to enter into a contract with the Na-
5 tional Academies of Sciences, Engineering, and Med-
6 icine under which the National Academies conducts
7 an evaluation of ARPA–H regarding the goals and
8 purposes of ARPA–H and the degree to which the
9 activities of ARPA–H support, and align with, such
10 goals and purposes.

11 “(2) INCLUSIONS.—The evaluation under para-
12 graph (1) may include—

13 “(A) recommendations on how to improve
14 upon the operation of, and projects carried out
15 by, ARPA–H, which may include lessons
16 learned from other advanced research and de-
17 velopment agencies or authorities within the
18 Department of Health and Human Services and
19 in other departments, agencies, or offices of the
20 Federal Government;

21 “(B) a description of lessons learned from
22 the establishment and operation of ARPA–H,
23 and the manner in which those lessons may
24 apply to the operation of other programs of the

1 Department of Health and Human Services;
2 and

3 “(C) an analysis of whether any projects
4 supported by ARPA–H were duplicative of
5 other research programs supported by the De-
6 partment of Health and Human Services or
7 other another relevant Federal department or
8 agency.

9 “(3) AVAILABILITY.—Upon completion of the
10 evaluation, the evaluation shall be submitted by the
11 Director to the Committee on Health, Education,
12 Labor, and Pensions and the Committee on Appro-
13 priations of the Senate and the Committee on En-
14 ergy and Commerce and the Committee on Appro-
15 priations of the House of Representatives and made
16 publicly available.

17 “(m) AUTHORIZATION OF APPROPRIATIONS.—To
18 carry out this section, there are authorized to be appro-
19 priated such sums as may be necessary for each of fiscal
20 years 2023 through 2027.

21 “(n) ADDITIONAL BUDGET CLARIFICATION.—Any
22 budget request for ARPA–H shall be separate from the
23 other budget requests of the National Institutes of
24 Health.”.

○