

117TH CONGRESS  
2D SESSION

# H. R. 5585

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## AN ACT

To establish the Advanced Research Projects Agency-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,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Advanced Research  
3 Projects Agency–Health Act” or the “ARPA–H Act”.

4 **SEC. 2. ADVANCED RESEARCH PROJECTS AGENCY–**  
5 **HEALTH.**

6 Title IV of the Public Health Service Act (42 U.S.C.  
7 281 et seq.) is amended by adding at the end the fol-  
8 lowing:

9 **“PART J—ADVANCED RESEARCH PROJECTS**  
10 **AGENCY–HEALTH**  
11 **“SEC. 499A. ADVANCED RESEARCH PROJECTS AGENCY–**  
12 **HEALTH.**

13 “(a) ESTABLISHMENT.—

14 “(1) IN GENERAL.—There is established as an  
15 independent operating division within the Depart-  
16 ment of Health and Human Services, the Advanced  
17 Research Projects Agency–Health (in this part re-  
18 ferred to as ‘ARPA–H’). Not later than 180 days  
19 after the date of enactment of this part, the Sec-  
20 retary shall transfer all functions, personnel, mis-  
21 sions, activities, authorities, and funds of the Ad-  
22 vanced Research Projects Agency for Health within  
23 the National Institutes of Health, as in existence on  
24 the date of enactment of this part, to ARPA–H es-  
25 tablished by the preceding sentence.

26 “(2) ORGANIZATION.—

1                   “(A) IN GENERAL.—There shall be within  
2                   ARPA–H—

3                   “(i) an Office of the Director;

4                   “(ii) not more than 6 program offices;

5                   and

6                   “(iii) such special project offices as  
7                   the Director may establish.

8                   “(B) PROGRAM OFFICES DEDICATED TO  
9                   RESEARCH AND DEVELOPMENT.—Not fewer  
10                  than two-thirds of the program offices of  
11                  ARPA–H shall be exclusively dedicated to re-  
12                  search and development.

13               “(b) GOALS AND METHODS.—

14               “(1) GOALS.—The goals of ARPA–H shall be  
15               to—

16               “(A) foster the development of new, break-  
17               through capabilities, technologies, systems, and  
18               platforms to accelerate innovations in health  
19               and medicine that are not being met by Federal  
20               programs or private entities;

21               “(B) revolutionize detection, diagnosis,  
22               mitigation, prevention, treatment, and curing of  
23               serious diseases and medical conditions through  
24               the development of transformative health tech-  
25               nologies;

1 “(C) promote high-risk, high-reward inno-  
2 vation for the development and translation of  
3 transformative health technologies; and

4 “(D) contribute to ensuring the United  
5 States maintains—

6 “(i) global leadership in science and  
7 innovation;

8 “(ii) the highest quality of life and  
9 health for its citizens; and

10 “(iii) an aggressive agenda for innova-  
11 tions to address global health threats that  
12 place United States citizens at risk.

13 “(2) METHODS.—ARPA-H shall achieve the  
14 goals specified in paragraph (1) by—

15 “(A) discovering, identifying, and pro-  
16 moting revolutionary advances in health  
17 sciences;

18 “(B) translating scientific discoveries into  
19 transformative health technologies;

20 “(C) providing resources and support to  
21 create platform capabilities that draw on mul-  
22 tiple disciplines;

23 “(D) using researchers in a wide range of  
24 disciplines, including the life sciences, the phys-

1           ical sciences, engineering, and the computa-  
2           tional sciences;

3                 “(E) delivering advanced proofs of concept  
4           that demonstrate potentially clinically meaning-  
5           ful advances;

6                 “(F) developing new capabilities, advanced  
7           computational tools, predictive models, or ana-  
8           lytical techniques to identify potential targets  
9           and technological strategies for early disease  
10          detection and intervention;

11                “(G) accelerating transformational techno-  
12          logical advances in areas with limited technical  
13          certainty; and

14                “(H) prioritizing investments based on  
15          such considerations as—

16                   “(i) scientific opportunity and unique-  
17           ness of fit to the strategies and operating  
18           practices of ARPA-H;

19                   “(ii) the effect on disease burden, in-  
20           cluding unmet patient need, quality and  
21           disparity gaps, and the potential to pre-  
22           empt progression of serious disease; and

23                   “(iii) the effect on the fiscal liability  
24           of the Federal Government with respect to

1 health care and the ability to reduce the  
2 cost of care through innovation.

3 “(c) DIRECTOR.—

4 “(1) IN GENERAL.—The President shall ap-  
5 point a director of ARPA–H (in this part referred  
6 to as the ‘Director’).

7 “(2) QUALIFICATIONS.—The Director shall be  
8 an individual who, by reason of professional back-  
9 ground and experience, is especially qualified to  
10 manage—

11 “(A) research and advanced development  
12 programs; and

13 “(B) large-scale, high-risk initiatives with  
14 respect to health research and technology devel-  
15 opment across multiple sectors, including gener-  
16 ating transformative health technologies and  
17 improving health outcomes for patients.

18 “(3) RELATIONSHIP TO SECRETARY.—The Di-  
19 rector shall report directly to the Secretary.

20 “(4) DUTIES.—The duties of the Director shall  
21 include the following:

22 “(A) Approve and terminate the projects  
23 and programs of ARPA–H.

24 “(B) Set research and development prior-  
25 ities with respect to the goals specified in sub-

1 section (b) and manage the budget of ARPA–  
2 H.

3 “(C) Develop funding criteria and assess  
4 the success of programs through the establish-  
5 ment of technical milestones.

6 “(D) Advance the goals under subsection  
7 (b), through consideration of the advice of the  
8 ARPA–H Interagency Research Council estab-  
9 lished under subsection (q).

10 “(E) Solicit data, as needed, from the Na-  
11 tional Institutes of Health and other relevant  
12 entities.

13 “(F) Coordinate with the Director of the  
14 National Institutes of Health to ensure that the  
15 programs of ARPA–H build on, and are in-  
16 formed by, scientific research supported by the  
17 National Institutes of Health.

18 “(G) Coordinate with the heads of Federal  
19 agencies and, to the extent practicable, ensure  
20 that the activities of ARPA–H supplement (and  
21 do not supplant) the efforts of other Federal  
22 agencies.

23 “(H) Ensure ARPA–H does not provide  
24 funding for a project unless the program man-

1           ager determines that the project meets the  
2           goals described in subsection (b)(1).

3           “(5) TERM.—The Director—

4                   “(A) shall be appointed for a 5-year term;  
5           and

6                   “(B) may be reappointed for 1 consecutive  
7           5-year term.

8           “(6) AUTONOMY OF AGENCY REGARDING REC-  
9           OMMENDATIONS AND TESTIMONY.—No officer or  
10          agency of the United States shall have any authority  
11          to require the Director or any other officer of  
12          ARPA-H to submit legislative recommendations, or  
13          testimony or comments on legislation, to any officer  
14          or agency of the United States for approval, com-  
15          ments, or review prior to the submission of such rec-  
16          ommendations, testimony, or comments to the Con-  
17          gress, if such recommendations, testimony, or com-  
18          ments to the Congress include a statement indi-  
19          cating that the views expressed therein are those of  
20          the Director or such officer, and do not necessarily  
21          reflect the views of the President or another agency.

22          “(7) DELEGATION OF AUTHORITY.—The Direc-  
23          tor may delegate to any duly authorized employee,  
24          representative, or agent any power vested in the Di-  
25          rector by law, except that the Director may not dele-



1       gate the power to appoint the Deputy Director  
2       under paragraph (8).

3               “(8) DEPUTY DIRECTOR.—The Director shall  
4       appoint a deputy director to serve as the first assist-  
5       ant to the office.

6               “(d) APPLICATION OF PAPERWORK REDUCTION  
7       ACT.—The Director may waive the requirements of sub-  
8       chapter I of chapter 35 of title 44, United States Code  
9       (commonly referred to as the ‘Paperwork Reduction Act’)  
10      with respect to the methods described in subsection (b)(2).

11              “(e) PROTECTION OF INFORMATION.—The following  
12      types of information collected by ARPA–H from recipients  
13      of financial assistance awards shall be considered commer-  
14      cial and financial information obtained from a person and  
15      privileged or confidential and not subject to disclosure  
16      under section 552(b)(4) of title 5, United States Code:

17              “(1) Plans for commercialization of technologies  
18      developed under the award, including business plans,  
19      technology-to market plans, market studies, and cost  
20      and performance models.

21              “(2) Investments provided to an awardee from  
22      third parties (such as venture capital firms, hedge  
23      funds, and private equity firms), including amounts  
24      and the percentage of ownership of the awardee pro-  
25      vided in return for the investments.

1           “(3) Additional financial support that the  
2       awardee—

3                   “(A) plans to invest or has invested in the  
4           technology developed under the award; or

5                   “(B) is seeking from third parties.

6           “(4) Revenue from the licensing or sale of new  
7       products or services resulting from research con-  
8       ducted under the award.

9       “(f) SHARING INFORMATION WITH THE CENTERS  
10   FOR MEDICARE & MEDICAID SERVICES.—The Director  
11   shall timely share relevant information with the Adminis-  
12   trator of the Centers for Medicare & Medicaid Services  
13   that may help to expedite determinations of coverage of  
14   transformative health technologies developed by ARPA–H.

15       “(g) EXPEDITING BREAKTHROUGHS THROUGH CO-  
16   OPERATION WITH THE FOOD AND DRUG ADMINISTRA-  
17   TION.—

18           “(1) IN GENERAL.—The Secretary, acting  
19       through the Commissioner of Food and Drugs and  
20       in consultation with the Director, may take actions  
21       to facilitate translation of transformative health  
22       technology into tangible solutions for patients and to  
23       expedite development of drugs, devices, and biologi-  
24       cal products, including through—

1           “(A) helping to ensure that drug, device,  
2           or biological product development programs, in  
3           as efficient a manner as possible, gather the  
4           nonclinical and clinical data necessary to ad-  
5           vancing the development of such products and  
6           to obtaining their approval, licensure, or clear-  
7           ance, as applicable, by the Food and Drug Ad-  
8           ministration under sections 505, 510(k), and  
9           515 of the Federal Food, Drug, and Cosmetic  
10          Act and section 351 of this Act;

11          “(B) expediting review of investigational  
12          new drug applications under section 505(i) of  
13          the Federal Food, Drug, and Cosmetic Act, re-  
14          view of investigational device exemptions under  
15          section 520(g) of such Act, and review of appli-  
16          cations for approval, licensure, and clearance of  
17          drugs, devices, or biological products under sec-  
18          tions 505, 510(k), and 515 of such Act, and  
19          section 351 of this Act; and

20          “(C) meeting at appropriate intervals with  
21          the Director and any member of the ARPA–H  
22          Interagency Research Council to discuss the de-  
23          velopment status of drugs, devices, or biological  
24          products and projects that are the highest pri-  
25          orities to ARPA–H, unless the Director and the

1 Commissioner of Food and Drugs determine  
2 that any such meetings are not necessary.

3 “(2) RELATION TO OTHERWISE AUTHORIZED  
4 ACTIVITIES OF THE FDA.—The authority specified in  
5 paragraph (1) shall not be construed as limiting the  
6 authority of the Secretary, acting through the Com-  
7 missioner of Food and Drugs, with respect to the re-  
8 view and approval, clearance, authorization for emer-  
9 gency use, or licensure of drugs, devices, or biologi-  
10 cal products under the Federal Food, Drug, and  
11 Cosmetic Act or section 351 of this Act.

12 “(3) REIMBURSEMENT.—The Director, using  
13 funds made available to ARPA–H, may reimburse  
14 the Food and Drug Administration for expenditures  
15 made by the Food and Drug Administration for ac-  
16 tivities carried out under this section that have been  
17 identified by the Commissioner of Food and Drugs  
18 and the Director as being carried out by the Food  
19 and Drug Administration.

20 “(h) AWARDS.—

21 “(1) IN GENERAL.—In carrying out this sec-  
22 tion, the Director may make awards including—

23 “(A) grants and cooperative agreements,  
24 which shall—

1 “(i) be subject to the uniform admin-  
 2 istrative requirements, cost principles, and  
 3 audit requirements for Federal awards  
 4 contained in part 200 of title 2, Code of  
 5 Federal Regulations (or successor regula-  
 6 tions); and

7 “(ii) include the total line-item and  
 8 itemized indirect facilities and administra-  
 9 tive costs that shall be made publicly avail-  
 10 able and published in a machine-readable  
 11 format;

12 “(B) contracts subject to the Federal Ac-  
 13 quisition Regulation;

14 “(C) multi-year contracts under section  
 15 3903 of title 41, United States Code;

16 “(D) prizes; and

17 “(E) other transactions.

18 “(2) EXEMPTIONS FOR CERTAIN REQUIRE-  
 19 MENTS.—Research funded by ARPA-H shall not be  
 20 subject to the requirements of section  
 21 406(a)(3)(A)(ii) or section 492.

22 “(i) FACILITIES AUTHORITY.—

23 “(1) IN GENERAL.—The Director may acquire  
 24 (by purchase, lease, condemnation, or otherwise),  
 25 construct, improve, repair, operate, and maintain

1 such real and personal property as may be necessary  
2 to carry out this section.

3 “(2) LEASE OF NONEXCESS PROPERTY.—The  
4 Director may enter into a lease under this section  
5 with any person or entity (including another depart-  
6 ment or agency of the Federal Government or an en-  
7 tity of a State or local government) with regard to  
8 any nonexcess real property and related personal  
9 property under the jurisdiction of the Director.

10 “(3) UTILIZATION OF LEASE FUNDS.—The Di-  
11 rector shall deposit amounts of cash consideration  
12 received for a lease entered into under this sub-  
13 section in the ‘Advanced Research Projects Agency  
14 for Health’ account as discretionary offsetting collec-  
15 tions, and such amounts shall be available only to  
16 the extent and in the amounts provided in advance  
17 in appropriations Acts—

18 “(A) to cover the full costs to ARPA–H in  
19 connection with the lease;

20 “(B) for maintenance, capital revitaliza-  
21 tion, and improvements of the real property as-  
22 sets and related personal property under the ju-  
23 risdiction of the Director; and

24 “(C) for maintenance, capital revitaliza-  
25 tion, and improvements of the real property as-

1 sets and related personal property at the re-  
2 spective center or facility of ARPA–H engaged  
3 in the lease, subject to the concurrence of the  
4 Director.

5 “(4) LOCATIONS.—

6 “(A) IN GENERAL.—ARPA–H, including  
7 its headquarters, shall not be located on any  
8 part of the existing National Institutes of  
9 Health campuses.

10 “(B) CONSIDERATIONS.—In determining  
11 the location of facilities, the Director shall  
12 make a fair and open consideration of—

13 “(i) the characteristics of the intended  
14 location; and

15 “(ii) the extent to which such location  
16 will facilitate advancement of the goals and  
17 methods specified in subsection (b).

18 “(j) PERSONNEL.—

19 “(1) IN GENERAL.—The Director may—

20 “(A) make and rescind appointments of  
21 scientific, engineering, medical, and professional  
22 personnel, which may include temporary or  
23 time-limited appointments as determined by the  
24 Director to fulfill the mission of ARPA–H,  
25 without regard to any provision in title 5,

1 United States Code, governing appointments  
2 and removals under the civil service laws, and  
3 fix the base pay compensation of such personnel  
4 at a rate to be determined by the Director, up  
5 to the amount of annual compensation (exclud-  
6 ing expenses) specified in section 102 of title 3,  
7 United States Code; and

8 “(B) contract with private recruiting firms  
9 for the hiring of qualified staff referenced in  
10 subparagraph (A).

11 “(2) ADDITIONAL STAFF.—The Director may  
12 use, to the same extent and in the same manner as  
13 the Secretary, all authorities in existence on the date  
14 of the enactment of this section that are provided to  
15 the Secretary to hire administrative, financial, con-  
16 tracts, legislative affairs, information technology,  
17 ethics, and communications staff, and such other  
18 staff as may be identified by the Director as nec-  
19 essary to carry out this section.

20 “(3) ADDITIONAL CONSIDERATIONS.—In ap-  
21 pointing personnel under this subsection, the Direc-  
22 tor—

23 “(A) may contract with private entities;

24 “(B) shall make efforts to recruit and re-  
25 tain a diverse workforce, including individuals



1 underrepresented in science and medicine and  
2 racial and ethnic minorities (as long as such ef-  
3 forts comply with applicable Federal civil rights  
4 law); and

5 “(C) shall recruit program managers with  
6 expertise in a wide range of relevant disciplines,  
7 including life sciences, the physical sciences, en-  
8 gineering, and the computational sciences.

9 “(4) ADDITIONAL HIRING AUTHORITY.—To the  
10 extent needed to carry out the authorities vested by  
11 paragraph (1), the Director may utilize hiring au-  
12 thorities under sections 3371 through 3376 of title  
13 5, United States Code, to staff ARPA–H with em-  
14 ployees from other Federal agencies, State and local  
15 governments, Indian Tribes and Tribal organiza-  
16 tions, institutions of higher education, and other or-  
17 ganizations, as described in such sections.

18 “(5) EXISTING AUTHORITIES.—The authorities  
19 granted by this section are—

20 “(A) in addition to existing authorities  
21 granted to the Secretary; and

22 “(B) are not intended to supersede or  
23 modify any existing authorities.

24 “(6) AUTHORITY TO ACCEPT FEDERAL  
25 DETAILEES.—The Director may accept officers or

1 employees of the United States or members of the  
2 uniformed service on a detail from an element of the  
3 Federal Government on a reimbursable or a nonre-  
4 imburseable basis, as jointly agreed to by the heads  
5 of the receiving and detailing elements, for a period  
6 not to exceed 3 years.

7 “(k) PROGRAM MANAGERS.—

8 “(1) IN GENERAL.—The Director shall appoint  
9 program managers for 3-year terms (and may re-  
10 appoint such program managers for 1 consecutive 3-  
11 year term) for the programs carried out by ARPA-  
12 H.

13 “(2) DUTIES.—A program manager shall—

14 “(A) establish, in consultation with the Di-  
15 rector or Deputy Director, research and devel-  
16 opment goals for programs, including timelines  
17 and milestones, and make such goals available  
18 to the public;

19 “(B) collaborate with experts from the Na-  
20 tional Institutes of Health and other Federal  
21 agencies and experts in relevant scientific fields  
22 to identify research and development gaps and  
23 opportunities;

24 “(C) convene workshops and meetings, as  
25 needed, with entities such as patients, patient

1       advocacy groups, practitioners, professional so-  
2       cieties, and other stakeholders to solicit input  
3       on programs and goals;

4               “(D) manage applications and proposals,  
5       through the appropriate officials for making  
6       grants, cooperative agreements, contracts,  
7       prizes, and other transaction awards for ad-  
8       vanced research that may show particular  
9       promise, especially in areas in which the private  
10      sector and the Federal Government have not  
11      undertaken sufficient research;

12              “(E) issue funding opportunity announce-  
13      ments, using uniform administrative processes,  
14      as appropriate;

15              “(F) select, on the basis of merit, each of  
16      the projects to be supported under a program  
17      carried out by ARPA-H, and taking into con-  
18      sideration—

19                      “(i) the scientific and technical merit  
20                      of the proposed project;

21                      “(ii) the capabilities of the applicants  
22                      to successfully carry out the proposed  
23                      project;

1 “(iii) the unmet needs or ability to  
2 improve health outcomes within patient  
3 populations;

4 “(iv) future commercial applications  
5 of the project or the feasibility of  
6 partnering with one or more commercial  
7 entities;

8 “(v) the potential for  
9 interdisciplinarity of the approach of the  
10 project; and

11 “(vi) such other criteria as established  
12 by the Director;

13 “(G) conduct project reviews within 18  
14 months of funding awards to identify milestones  
15 and monitor progress of such milestones with  
16 respect to each project and prior to disburse-  
17 ment of new funds;

18 “(H) provide recommendations to the Di-  
19 rector with respect to advancing the goals speci-  
20 fied in subsection (b);

21 “(I) cultivate opportunities for the com-  
22 mercial application or community use of suc-  
23 cessful projects, including through the establish-  
24 ment of partnerships between or among award-  
25 ees;

1           “(J) identify innovative cost-sharing ar-  
2 rangements for ARPA–H projects;

3           “(K) provide recommendations to expand,  
4 restructure, or terminate research partnerships  
5 or projects; and

6           “(L) ensure that—

7               “(i) animal studies meet the Federal  
8 animal research requirements pursuant of  
9 the Public Health Service Policy on Hu-  
10 mane Care and Use of Laboratory Ani-  
11 mals; and

12               “(ii) applications apply statistical  
13 modeling approaches and appropriately  
14 justify animal sample sizes to meet project  
15 goals.

16       “(l) REPORTS AND EVALUATION.—

17           “(1) ANNUAL REPORT.—

18               “(A) IN GENERAL.—Beginning not later  
19 than 1 year after the date of enactment of this  
20 section, and each fiscal year thereafter, the Di-  
21 rector shall submit a report on the actions un-  
22 dertaken, and results generated, by ARPA–H,  
23 including—

24               “(i) a description of projects sup-  
25 ported by ARPA–H in the previous fiscal

1 year and whether such projects are meet-  
2 ing the goals developed by the Director  
3 pursuant to subsection (c)(4)(C);

4 “(ii) a description of projects termi-  
5 nated in the previous fiscal year, and the  
6 reason for such termination;

7 “(iii) a description of programs start-  
8 ing in the next fiscal year, as available;

9 “(iv) activities conducted in coordina-  
10 tion with other Federal agencies;

11 “(v) an analysis of the extent of co-  
12 ordination conducted pursuant to sub-  
13 sections (c)(4)(F) and (f), including suc-  
14 cesses and barriers with respect to achiev-  
15 ing the goals under subsection (b);

16 “(vi) a description of the demographic  
17 (including racial and gender) diversity if  
18 available of direct recipients and per-  
19 formers in funded projects and of the  
20 ARPA–H workforce; and

21 “(vii) a disclosure by the reward re-  
22 cipients of whether the principal investiga-  
23 tors named on the award participate in  
24 foreign talent programs, including the pro-  
25 vision of copies of all grants, contracts, or

1 other agreements related to such pro-  
2 grams, and other supporting documenta-  
3 tion related to such programs, as a condi-  
4 tion of receipt of Federal extramural bio-  
5 medical research funding awarded.

6 “(B) SUBMISSION TO CONGRESS.—The re-  
7 port under subparagraph (A) shall be submitted  
8 to—

9 “(i) the Committee on Energy and  
10 Commerce and the Committee on Appro-  
11 priations of the House of Representatives;  
12 and

13 “(ii) the Committee on Health, Edu-  
14 cation, Labor, and Pensions and the Com-  
15 mittee on Appropriations of the Senate.

16 “(2) EVALUATION.—

17 “(A) IN GENERAL.—Not later than 5 years  
18 after the date of the enactment of this section,  
19 the Secretary shall enter into an agreement  
20 with the National Academies of Sciences, Engi-  
21 neering, and Medicine under which the National  
22 Academies agree to study and evaluate whether  
23 ARPA–H is meeting the goals specified in sub-  
24 section (b).

1                   “(B) SUBMISSION OF RESULTS.—The  
2                   agreement entered into under subparagraph (A)  
3                   shall require the National Academies of  
4                   Sciences, Engineering, and Medicine to submit  
5                   the results of the evaluation conducted under  
6                   such agreement to the Secretary, the Com-  
7                   mittee on Energy and Commerce of the House  
8                   of Representatives, and the Committee on  
9                   Health, Education, Labor, and Pensions of the  
10                  Senate.

11               “(m) STRATEGIC PLAN.—Not later than 1 year after  
12 the date of the enactment of this section, and every 3  
13 years thereafter, the Director shall provide to the relevant  
14 committees of Congress a strategic plan describing how  
15 ARPA–H will carry out investments each fiscal year in  
16 the following 3-year period.

17               “(n) INDEPENDENT REVIEW.—Not later than 1 year  
18 after the date of the enactment of this section, and every  
19 3 years thereafter, the Comptroller General of the United  
20 States shall conduct an independent review of the research  
21 portfolio of the Department of Health and Human Serv-  
22 ices, including ARPA–H, the National Institutes of  
23 Health, the Food and Drug Administration, and the Bio-  
24 medical Advanced Research and Development Authority—



1 “(1) to assess the degree of unnecessary dupli-  
2 cation of existing Federal programs and projects;  
3 and

4 “(2) to make recommendations regarding any  
5 potential reorganization, consolidation, or termi-  
6 nation of such programs and projects.

7 “(o) PRIORITIZATION.—The Director shall—

8 “(1) prioritize awarding grants, cooperative  
9 agreements, contracts, prizes, and other transaction  
10 awards to domestic recipients conducting the re-  
11 search on transformative health technology in the  
12 United States;

13 “(2) as appropriate and practicable, ensure that  
14 nondomestic recipients of any grants, cooperative  
15 agreements, contracts, prizes, and other transactions  
16 under this section are conducting research in col-  
17 laboration with a domestic recipient;

18 “(3) not award any grants, cooperative agree-  
19 ments, contracts, prizes, and other transactions to  
20 nondomestic recipients organized under the laws of  
21 a covered foreign country (as defined in section  
22 119C of the National Security Act of 1947); and

23 “(4) in accordance with the requirements of  
24 chapter 33 of title 41, United States Code, and the  
25 Federal Acquisition Regulation, only award grants,

1 cooperative agreements, contracts, prizes, and other  
2 transactions to individual persons that do not have  
3 more than 3 ongoing concurrent grants, cooperative  
4 agreements, contracts, prizes, and other transactions  
5 under this section.

6 “(p) ADDITIONAL CONSULTATION.—In carrying out  
7 this section, the Director may consult with—

8 “(1) the President’s Council of Advisors on  
9 Science and Technology;

10 “(2) peers in the scientific community, includ-  
11 ing academia and industry;

12 “(3) an existing advisory committee providing  
13 advice to the Secretary or the head of any operating  
14 or staff division of the Department;

15 “(4) a new interagency research council orga-  
16 nized to support the programs of ARPA–H and to  
17 provide advice and assistance on—

18 “(A) specific program tasks; or

19 “(B) the overall direction of ARPA–H; and

20 “(5) any other entity the Director may deem  
21 appropriate.

22 “(q) ARPA–H INTERAGENCY RESEARCH COUN-  
23 CIL.—

24 “(1) IN GENERAL.—The Director shall establish  
25 an interagency advisory committee to be known as

1 the ARPA–H Interagency Research Council (re-  
2 ferred to in this subsection as the ‘Research Coun-  
3 cil’).

4 “(2) MEMBERSHIP.—The Research Council  
5 may include any or all of the following members, or  
6 designees:

7 “(A) The Director of the National Insti-  
8 tutes of Health.

9 “(B) The Director of National Center for  
10 Advancing Translational Sciences.

11 “(C) The Director of Office of Science and  
12 Technology Policy.

13 “(D) The Commissioner of Food and  
14 Drugs.

15 “(E) The Director of the Biomedical Ad-  
16 vanced Research and Development Authority.

17 “(F) The Director of the Centers for Dis-  
18 ease Control and Prevention.

19 “(G) The Administrator of the Centers for  
20 Medicare & Medicaid Services.

21 “(H) The Director of the Agency for  
22 Healthcare Research and Quality.

23 “(I) The Director of the Office of Minority  
24 Health.

1           “(J) The Administrator of the Health Re-  
2 sources and Services Administration.

3           “(K) The Director of the Defense Ad-  
4 vanced Research Projects Agency.

5           “(L) The Director of the National Science  
6 Foundation.

7           “(M) The Director of the Office of Science  
8 of the Department of Energy.

9           “(N) The Director of the Advanced Re-  
10 search Projects Agency–Energy.

11           “(O) The Assistant Secretary for Pre-  
12 paredness and Response.

13           “(P) Representatives of any Federal agen-  
14 cy with subject matter expertise that the Direc-  
15 tor determines is necessary for the successful  
16 completion of a project carried out pursuant to  
17 this section.

18           “(Q) Any other entity the Director may  
19 deem appropriate.

20           “(3) DUTIES.—The Research Council shall ad-  
21 vise the Director, including by—

22           “(A) making recommendations on—

23           “(i) research priorities that will pro-  
24 vide the greatest return on investment with  
25 respect to improving human health;

1                   “(ii) avoiding duplication of efforts in  
2                   the Federal Government; and

3                   “(iii) improving coordination with  
4                   other Federal agencies; and

5                   “(B) identifying and developing strategies  
6                   to address regulatory, reimbursement, and mar-  
7                   ket barriers to commercialization or adoption of  
8                   transformative health technologies, including  
9                   technologies intended to preempt serious dis-  
10                  ease.

11                 “(4) ADVISORY NATURE.—The function of the  
12                 Research Council shall be advisory in nature. Noth-  
13                 ing in this subsection shall be construed as granting  
14                 the Research Council authority over any activities or  
15                 functions of ARPA-H.

16                 “(5) MEETINGS.—Not later than 1 year after  
17                 the date of the enactment of this section, and every  
18                 fiscal year thereafter, the Director shall convene  
19                 meetings of the Research Council, including con-  
20                 ferences or workshops, as needed. The Research  
21                 Council may function through established or ad hoc  
22                 committees, task forces, or interagency groups to—

23                   “(A) share information on health innova-  
24                   tions funded by ARPA-H; and

1                   “(B) receive input on areas of particular  
2                   promise for ARPA–H projects.

3           “(r) TECHNOLOGY TRANSFER OFFICE.—The Direc-  
4   tor may establish within ARPA–H an Office of Technology  
5   Transfer to facilitate, where appropriate, the transfer of  
6   federally-owned or federally-originated technology to re-  
7   cipients of an award under this section (other than Fed-  
8   eral Government entities).

9           “(s) FOLLOW-ON PRODUCTION AWARD AUTHOR-  
10   ITY.—

11           “(1) IN GENERAL.—An other transaction en-  
12   tered into by the Director under subsection (h)(1)  
13   for a project may provide for the award of a follow-  
14   on production contract or transaction to the partici-  
15   pants in the transaction by ARPA–H or another  
16   Federal agency. For purposes of this paragraph,  
17   such an other transaction includes all individual sub-  
18   projects awarded under the transaction to a consor-  
19   tium of United States industry and academic institu-  
20   tions.

21           “(2) RELATION TO COMPETITIVE PROCE-  
22   DURES.—A follow-on production contract or trans-  
23   action under paragraph (1) may be awarded to the  
24   participants in the transaction without the use of  
25   competitive procedures (as defined in section 152 of

1 title 41, United States Code), notwithstanding the  
2 requirements of division C of subtitle I of such title  
3 41, if—

4 “(A) competitive procedures were used for  
5 the selection of parties for participation in the  
6 other transaction; and

7 “(B) the participants in the other trans-  
8 action successfully completed the project pro-  
9 vided for in the transaction.

10 “(3) PRECONDITION.—A follow-on production  
11 contract or transaction may be awarded pursuant to  
12 this subsection when the Director determines that  
13 an individual project or subproject as part of a con-  
14 sortium is successfully completed by the partici-  
15 pants.

16 “(4) CLARIFICATION.—Award of a follow-on  
17 production contract or transaction pursuant to this  
18 subsection shall not be made contingent upon the  
19 successful completion of all activities within a con-  
20 sortium as a condition for an award for follow-on  
21 production of a successfully completed project or  
22 subproject within that consortium.

23 “(5) OTHER AUTHORITIES.—Contracts and  
24 transactions entered into by ARPA-H pursuant to  
25 this subsection may be awarded pursuant to division

1 C of subtitle I of title 41, United States Code, or  
2 under such procedures, terms, and conditions as the  
3 Director or head of such agency may establish by  
4 regulation.

5 “(t) RULE OF CONSTRUCTION.—The authorities  
6 under this section, with respect to the Director, are addi-  
7 tional authorities that do not supersede or modify any ex-  
8 isting authorities.

9 “(u) DEFINITIONS.—In this part:

10 “(1) ADVANCED PROOFS OF CONCEPT.—The  
11 term ‘advanced proofs of concept’ means data, a  
12 prototype, or other experimental evidence that—

13 “(A) may precede the development of  
14 transformative health technologies; and

15 “(B) demonstrates the feasibility of a new  
16 concept.

17 “(2) BIOLOGICAL PRODUCT.—The term ‘bio-  
18 logical product’ has the meaning given such term in  
19 section 351(i).

20 “(3) DEPARTMENT.—The term ‘Department’  
21 means the Department of Health and Human Serv-  
22 ices.

23 “(4) DRUG; DEVICE.—The terms ‘drug’ and  
24 ‘device’ have the meanings given such terms in sec-



1       tion 201 of the Federal Food, Drug, and Cosmetic  
2       Act.

3           “(5) FEDERAL ACQUISITION REGULATION.—  
4       The term ‘Federal Acquisition Regulation’ means  
5       the Federal Acquisition Regulation issued pursuant  
6       to section 1303(a)(1) of title 41, United States  
7       Code.

8           “(6) FEDERAL AGENCY.—The term ‘Federal  
9       agency’ has the meaning given such term in section  
10      3371 of title 5, United States Code.

11          “(7) PRIZE.—The term ‘prize’ means a prize as  
12      such term is used in section 24 of the Stevenson-  
13      Wydler Technology Innovation Act of 1980.

14          “(8) TRANSFORMATIVE HEALTH TECH-  
15      NOLOGY.—The term ‘transformative health tech-  
16      nology’ means a drug, biological product, interven-  
17      tion, platform, tool, or device—

18           “(A) that should be prioritized to detect,  
19      diagnose, mitigate, prevent, cure, or treat a se-  
20      rious disease or medical condition for which  
21      there are unmet needs; and

22           “(B) for which—

23           “(i) significant scientific uncertainty  
24      and regulatory risk exist; or

1                   “(ii) incentives in the commercial  
2                   market are unlikely to result in the ade-  
3                   quate or timely development of such drug,  
4                   biological product, intervention, platform,  
5                   tool, or device.

6           “(v) AUTHORIZATION OF APPROPRIATIONS.—

7                   “(1) IN GENERAL.—To carry out this section,  
8                   there is authorized to be appropriated \$500,000,000  
9                   for each of fiscal years 2023 through 2027, to re-  
10                  main available until expended.

11                  “(2) ADMINISTRATIVE EXPENSES.—Not more  
12                  than 15 percent of the amounts made available to  
13                  carry out this section for any fiscal year may be  
14                  used for administrative expenses to operate ARPA-  
15                  H.”.

Passed the House of Representatives June 22, 2022.

Attest:

*Clerk.*



117<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

**H. R. 5585**

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**AN ACT**

To establish the Advanced Research Projects  
Agency-Health, and for other purposes.