DEPARTMENT OF HEALTH AND HUMAN SERVICES

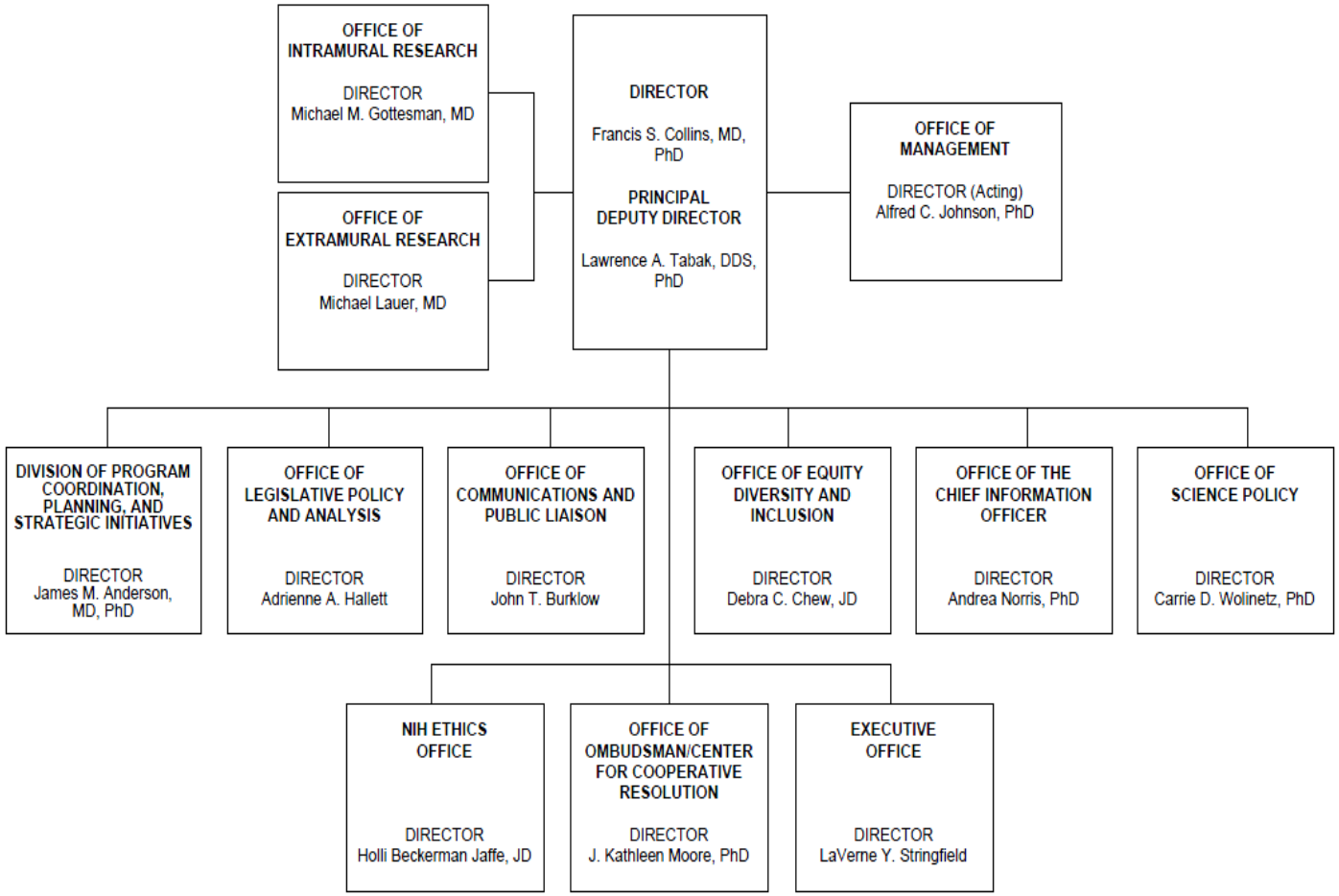
NATIONAL INSTITUTES OF HEALTH

Office of the Director (OD)

FY 2018 Budget — Page No.

NATIONAL INSTITUTES OF HEALTH

Office of the Director
Organization Structure



NATIONAL INSTITUTES OF HEALTH

Office of the Director

For carrying out the responsibilities of the Office of the Director, NIH, $1,329,833,000: Provided, That funding shall be available for the purchase of not to exceed 29 passenger motor vehicles for replacement only: Provided further, That all funds credited to the NIH Management Fund shall remain available for one fiscal year after the fiscal year in which they are deposited: Provided further, That $441,823,000 shall be available for the Common Fund established under section 402A(c)(1) of the PHS Act: Provided further, That of the funds provided, $10,000 shall be for official reception and representation expenses when specifically approved by the Director of the NIH: Provided further, That the Office of AIDS Research within the Office of the Director of the NIH may spend up to $4,000,000 to make grants for construction or renovation of facilities as provided for in section 2354(a)(5)(B) of the PHS Act:

In addition to other funds appropriated for the Common Fund established under section 402A(c) of the PHS Act, $12,600,000 is appropriated to the Common Fund from the 10-year Pediatric Research Initiative Fund described in section 9008 of title 26, United States Code, for the purpose of carrying out section 402(b)(7)(B)(ii) of the PHS Act (relating to pediatric research), as authorized in the Gabriella Miller Kids First Research Act.

NATIONAL INSTITUTES OF HEALTH
Office of the Director

Amounts Available for Obligation[1]

(Dollars in Thousands)

Source of Funding	FY 2016 Final	FY 2017 Annualized CR	FY 2018 President's Budget
Appropriation[2]	$1,571,200	$1,623,200	$1,452,433
Mandatory Appropriation: (non-add)			
Type 1 Diabetes	*(0)*	*(0)*	*(0)*
Other Mandatory financing	*(0)*	*(0)*	*(0)*
Rescission	0	-2,987	0
Sequestration	0	0	0
Zika Intra-NIH Transfer	-410	0	0
Subtotal, adjusted appropriation	$1,570,790	$1,620,213	$1,452,433
OAR HIV/AIDS Transfers	0	0	0
Subtotal, adjusted budget authority	$1,570,790	$1,620,213	$1,452,433
Unobligated balance, start of year	0	0	0
Unobligated balance, end of year	0	0	0
Subtotal, adjusted budget authority	$1,570,790	$1,620,213	$1,452,433
Unobligated balance lapsing	-105	0	0
Total obligations	$1,570,685	$1,620,213	$1,452,433

[1] Excludes the following amounts for reimbursable activities carried out by this account:
FY 2016 - $34,207 FY 2017 - $35,000 FY 2018 - $36,000

[2] Includes Innovation Fund appropriation in FY 2017 and FY 2018.

NATIONAL INSTITUTES OF HEALTH
Office of the Director

Budget Authority by Activity[1,2]
(Dollars in Thousands)

	FY 2016 Final	FY 2017 Annualized CR[4]	FY 2018 President's Budget[5]	FY 2018 +/- FY2017
OD Operations	143,323	143,290	177,330	34,040
NIH Director's Challenge Fund	*(1,413)*	*(1,410)*	*(1,361)*	*(-49)*
Division of Program Coordination, Planning and Strategic	13,074	13,250	11,945	-1,305
Office of Behavioral & Social Sciences Research	26,720	26,687	24,059	-2,629
Office of AIDS Research	62,222	61,805	58,348	-3,457
Office of Research on Women's Health	42,000	41,944	37,812	-4,131
Office of Disease Prevention	9,942	9,937	8,958	-979
Office of Dietary Supplements	25,278	25,249	22,245	-3,005
Office of Research Infrastructure Programs	277,243	276,868	220,811	-56,057
Science Education Partnership Awards/Office of Science	18,541	18,506	0	-18,506
Director's Discretionary Fund	9,989	9,981	8,998	-983
Foundation for the National Institutes of Health	1,000	998	900	-98
Intramural Loan Repayment and Scholarship	7,443	7,433	6,701	-732
Nuclear Radiological Chemical Countermeasures	93,392	93,214	74,385	-18,829
Environmental Influences on Child Health Outcomes	164,984	164,686	131,420	-33,267
BRAIN	0	10,000	0	-10,000
Reception and Representation Fund	0	10	9	-1
All of Us Research Program[3]	0	40,000	204,091	164,091
Regenerative Medicine	0	2,000	10,000	8,000
Common Fund	675,639	674,355	454,423	-219,932
Total	**$1,570,790**	**$1,620,213**	**$1,452,433**	**-$167,780**

[1] Includes FTEs whose payroll obligations are supported by the NIH Common Fund.

[2] Items in italics are "non-adds"; for reference only (NIH Director's Challenge Fund amounts are already included in OD Operations budget.)

[3] The Common Fund includes funding for the *All of Us* Research Program in FY 2016 ($130,000,000) and FY 2017 ($129,753,000)

[4] The FY 17 CR level includes $52M for Cures/Innovation Account

[5] The FY18 level of funding includes *All of Us* Research Program and Regenerative Medicine

NATIONAL INSTITUTES OF HEALTH
Office of the Director

Authorizing Legislation

	PHS Act/ Other Citation	U.S. Code Citation	2017 Amount Authorized	FY 2017 Annualized CR[1]	2018 Amount Authorized	FY 2018 President's Budget[2]
Research and Investigation	Section 301	42§241	Indefinite	$1,568,213,000	Indefinite	$1,342,433,000
Office of the Director	Section 401(a)	42§281	Indefinite		Indefinite	
Innovation Account	Section 1001 21st Century Cures Act			$52,000,000		$110,000,000
Total, Budget Authority				$1,620,213,000		$1,452,433,000

[1] The FY 17 CR level includes $52M for Cures/Innovation Account

[2] The FY18 level of funding includes *All of Us* Research Program and Regenerative Medicine

NATIONAL INSTITUTES OF HEALTH
Office of the Director

Appropriations History

Fiscal Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
2008	$517,062,000	$1,114,422,000	$1,145,790,000	$1,109,099,000
Rescission				$19,720,000
2009	$1,056,797,000	$1,255,420,000	$1,275,281,000	$1,246,864,000
Rescission				$0
Supplemental				$2,636,000
2010	$1,182,777,000	$1,168,704,000	$1,182,777,000	$1,177,020,000
Rescission				$0
2011	$1,220,478,000		$1,268,580,000	$1,177,300,000
Rescission				$10,337,395
2012	$1,298,412,000	$1,198,412,000	$1,439,064,000	$1,461,880,000
Rescission				$2,762,953
2013	$1,429,161,000		$1,431,341,000	$1,528,181,000
Rescission				$3,056,362
Sequestration				($76,704,177)
2014	$1,473,398,000		$1,463,606,000	$1,400,134,000
Rescission				$0
2015	$1,451,786,000		$1,413,734,000	$1,413,734,000
Rescission				$0
2016	$1,442,628,000	$1,552,326,000	$1,523,537,000	$1,571,200,000
Rescission				$0
2017[1,2]	$1,571,200,000			$1,623,200,000
Rescission				$2,987,000
2018[3]	$1,452,433,000			

[1] Budget Estimate to Congress includes mandatory financing.
[2] The FY 17 CR level includes $52M for Cures/Innovation Account
[3] The FY18 Budget Estimate to Congress includes All of Us Research Program and Regenerative Medicine

Justification of Budget Request

Office of the Director

Authorizing Legislation: Section 301 and title IV of the Public Health Service Act, as amended.

Budget Authority:

	FY 2016 Final	FY 2017 Annualized CR[1]	FY 2018 President's Budget	FY 2018 +/- FY 2017
BA	$1,570,790,000	$1,620,213,000	$1,452,433,000	-$167,780,000
FTEs	686	752	770	18

[1]The FY 17 CR level includes $52M for Cures/Innovation Account

Program funds are allocated as follows: Competitive Grants/Cooperative Agreements; Contracts; Direct Federal/Intramural and Other.

Director's Overview

The Office of the Director (OD) provides scientific and administrative leadership to foster trans-NIH activities through planning, managing, and implementing policies and procedures to facilitate the coordination of cutting-edge biomedical research.[1] OD coordinates NIH's intramural and extramural research activities, science policy, health information dissemination, legislative activities, technology transfer, and oversight of NIH's stewardship of public funds. OD manages, prioritizes, and allocates funds for administrative services including budget and financial management, human resources, information technology, procurement services, property management, intramural and extramural support, ethics, and administration of equal employment and diversity management practices. Descriptions of the OD Offices and examples of their initiatives in support of the NIH mission are provided below:

- **Immediate Office of the Director (IMOD)** directly serves the NIH Director and Principal Deputy Director in a wide range of support functions.
- **The NIH Branch of the HHS Office of the General Counsel's (OGC) Public Health Division** provides advice, representation, and other legal services to NIH. OGC coordinates with the Department of Justice when NIH is involved in litigation, and advises and represents NIH on HHS-wide matters.
- **Office of Equity, Diversity, and Inclusion (EDI)** is a federally mandated policy portfolio whose purpose is to foster an inclusive culture at NIH, increase diversity representation,

[1] http://www.nih.gov/institutes-nih/nih-office-director

provide demographic diversity data analyses, and manage the agency's civil rights program.

- **Executive Secretariat (ES)** manages correspondence and documents on behalf of the NIH Director and Principal Deputy Director; facilitates clearance activities; provides information for FOIA requests; coordinates NIH congressional reports; and retains official records.
- **NIH Ethics Office (NEO)** provides leadership and oversight to the NIH Ethics Program to educate employees on and in compliance with ethics statutes, regulations, and policies.
- **Office of the Chief Information Officer (OCIO)** advises the NIH Director and IC leadership on the direction and management of NIH IT activities; establishes NIH-level IT plans, policies, and guidance; assures compliance with policies and promotes best practices in information and IT management across NIH. The OCIO also manages the NIH Security Program (cybersecurity).
- **Office of Communications and Public Liaison (OCPL)** communicates the NIH mission, scientific research results, and health information to the public; provides leadership and guidance to the communications offices at NIH's Institutes and Centers; and speaks for NIH.
- **Executive Office (ODEO)** provides planning and coordination of administrative management activities for the NIH OD on policy, finance, budget, human resources, performance management, property, internal controls, organizational development, IT support, management analysis.
- **The Office of Extramural Research (OER)** provides the corporate framework for NIH research administration, ensuring scientific integrity, public accountability, and effective stewardship of the NIH extramural research portfolio. It oversees activities related (but not limited) to high-profile digital platforms, grant compliance, peer review, communications with the extramural community, scientific misconduct, human subjects protection, and laboratory animal welfare.
- **The Office of Federal Advisory Committee Policy (OFACP)** is responsible for NIH-wide development and implementation of policies and procedures for the establishment, appointment of members, and management of 153 Federal advisory committees.
- **The Office of Intramural Research (IRP)** oversees policies that govern intramural research, as well as training conducted within the NIH Intramural Research Program. IRP approves the appointment of NIH principal investigators and is responsible for external scientific research review, human subjects research protections, animal care and use, research integrity, and technology transfer in the IRP.
- **Office of Legislative Policy and Analysis (OLPA)** provides essential information, advice, and guidance on congressional actions affecting NIH to the NIH community, and is the principal point-of-contact and liaison with members of Congress and their staff.
- **Office of Management (OM)** advises, provides leadership, and oversees NIH administration and management, including (but not limited to) areas of budget, human resources, facilities, support services, security operations, and logistics. OM represents the Director in working with the ICs on business management matters, except grants administration.
- **Office of the Ombudsman/Center for Cooperative Resolution (OOCCR)** serves as a confidential and informal information resource, communications channel, and dispute resolver for NIH employees.
- **Office of Science Policy (OSP)** is the primary advisor to the NIH Director on matters of biomedical research policy issues that are of significance to the agency, including biosafety and biosecurity, human subject protections, and technology transfer.
- **Office of the Chief Officer for Scientific Workforce Diversity (SWD)** leads NIH's effort

to diversify the national scientific workforce through expanded recruitment and retention.

- **Environmental influences on Child Health Outcomes (ECHO)** is an extramural research program office supporting research to investigate how exposure to a range of environmental factors in fetal development and early childhood influences future health.
- **All of Us Research Program (formerly the Precision Medicine Initiative (PMI) Cohort Program)** oversees the planning, implementation, and evaluation of a research resource using data on one million or more U.S. volunteers.
- **Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI)** provides leadership for identifying, reporting, and funding trans-NIH research that represents areas of emerging scientific opportunities, rising public health challenges, or knowledge gaps meriting further research and benefiting from collaboration, strategic coordination, and planning. DPCPSI offices include:
  - **Office of AIDS Research (OAR)** coordinates the scientific, budgetary, legislative, and policy elements of HIV/AIDS-related research across NIH.
  - **Office of Behavioral and Social Sciences Research (OBSSR)** coordinates NIH's behavioral and social sciences research activities to promote health and prevent disease.
  - **Office of Disease Prevention (ODP)** enhances research, assesses health outcomes, and disseminates research results related to disease prevention. ODP includes the Office of Dietary Supplements which coordinates research and educates the public about dietary supplements.
  - **Office of Portfolio Analysis (OPA)** enhances the impact of NIH-supported research by developing tools to improve the evaluation and prioritization of current and emerging, areas of research.
  - **Office of Research Infrastructure Programs (ORIP)** provides research infrastructure and support through extramural awards and activities that include developing new animal models, and enhancing research training and career development of veterinary scientists.
  - **Office of Research on Women's Health (ORWH)** ensures that women's health research is part of the scientific framework at NIH and throughout the scientific community by fostering and supporting research on women's health and ensuring inclusion in research studies.
  - **Office of Strategic Coordination** manages the NIH Common Fund for strategic investments in science that are risky, but likely to have exceptional payoff if successful.
  - The two newest offices established in DPCPSI were: the **Sexual and Gender Minority Research Office** and the **Tribal Health Research Office** which coordinate research across NIH, represent and serve as point-of-contact for these communities, and leverage resources and develop initiatives with the ICs to support research involving these populations.

The FY 2018 President's Budget request is $1,452.433 million, a decrease of $167.780 million compared with the FY 2017 Annualized CR level. In FY 2018, the OD will continue to promote and foster NIH research and research training efforts in the prevention and treatment of disease through the policy oversight of both the extramural grant and contract award functions and the Intramural Research program.

The FY 2018 funding level will enable OD Operations to continue efforts to reduce vulnerabilities to risks that exist in all areas at the NIH, including both extramural and intramural

research, research information, program integrity, IT, finance and administration. In addition, OD Operations will support the continuation of several key activities formerly managed by the Fogarty lnternational Center (FIC) to include visa and passport services for all NIH international travel; services to maintain international relations by developing new partnerships between U.S. scientists, institutions and counterparts abroad to advance research and training in the biomedical and behavioral sciences; and to continue collaborative efforts with NIH Institutes and Centers to: 1) assess the state of the science on topics of U.S. and global importance; 2) identify research gaps and opportunities and produce high-impact publications and other resources to guide future investments and scientific directions; 3) create and maintain networks of researchers and other stakeholders to facilitate better translation of evidence into policy and practice; and 4) provide short-term training that addresses critical trans-NIH priorities (e.g., Household Air Pollution, mHealth).

The planned funding initiatives of the OD's research offices are described in detail as follows:

DPCPSI will coordinate trans-NIH research through the Common Fund, and Program Offices for research on HIV/AIDS, Women's Health, Behavioral and Social Sciences, Disease Prevention, Dietary Supplements, Infrastructure Resources, Sexual and Gender Minorities, and Tribal Health. In addition, the Division will continue its portfolio analysis efforts. Within the President's budget request, DPCPSI will be unable to fill several key vacancies and will reduce or eliminate other costs, including support for a planned scientific workshop. Examples of FY 2018 program area changes across the Division are included below.

The reduced level of funding will allow the Common Fund to pursue new scientific opportunities within 3 existing programs: Illuminating the Druggable Genome, Metabolomics, and the Undiagnosed Diseases Network, and to launch 2 new programs in FY 2018: the Transformative High Resolution Cryo-Electron Microscopy program and the Human BioMolecular Atlas Project. Steady support for the High-Risk, High-Reward program and continued support of the Gabriella Miller Kids First Research Program will be provided. For additional details, please see the Common Fund section.

The OAR will support initiatives that address the highest HIV/AIDS scientific priorities outlined in the NOT-OD-15-137[2] and the Trans-NIH Plan for HIV-Related Research,[3] including research: 1) to reduce the incidence of HIV/AIDS, including the development of safe and effective HIV/AIDS vaccines, microbicides, and pre-exposure prophylaxis; 2) to develop the next generation of HIV therapies with increased safety and ease of use; 3) toward a cure for HIV/AIDS; and 4) on prevention and treatment of HIV coinfections and comorbidities; and the cross-cutting areas of basic research, health disparities research, and research training.

To continue and further prioritize OBSSR's efforts in the opioid crisis, OBSSR will reduce efforts in other areas, e.g., OBSSR will continue to support the National Cooperative on Childhood Obesity Research[4] steering committee meetings and basic infrastructure, but will rely

[2] http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-137.html
[3] https://www.oar.nih.gov/strategic_plan/fy2018/OAR_18_StrategicPlan_P10_508.pdf
[4] http://www.nccor.org/about/

on non-federal partners for funding new initiatives. Based on its strategic plan,[5] OBSSR planned several initiatives, some of which have been released[6] while others will be deferred or reduced, e.g., OBSSR support for OppNet[7] will be reduced, and a new initiative to improve the standardization of behavioral research taxonomies and ontologies to increase efficiency and sharing of behavioral and social science research data will be deferred.

The ORWH, in partnership with NIH ICs, will implement the NIH women's health strategic plan[8] by: 1) providing support to expand consideration of sex/gender factors in basic, biomedical, and behavioral science studies; 2) facilitating the translation of basic science findings to clinical research and to clinical practice; 3) maximizing the domestic and global impact of women's health research; and 4) developing innovative career development models. With the reduced funding level, ORWH will be unable to support the High Priority, Short-Term Project Awards (R56) in FY 2018. The budget for the Administrative Supplements for Research on Sex/Gender Differences in Health and Disease program will be reduced less than the R56 program because these supplements are directly aligned with priorities in the new NIH-wide strategic plan.

ODP will continue its ongoing partnership with NIH ICs to build the prevention research evidence base and develop collaborative activities through the trans-NIH Prevention Scientific Interest Groups. ODP will maintain a database used by NIH Scientific Review Officers to identify experts in prevention science methods to improve the quality of prevention research supported by the NIH. With the reduced spending level, ODP will not be able to support a new P2P workshop in FY 2018. ODP will also be unable to support research co-funding and other interagency agreements focused on advancing and promoting prevention research.

ODS will be working under its Strategic Plan for 2017-2021.[9] With the reduced funding level, ODS will support the congressionally mandated Dietary Supplement Label Database and Analytical Methods and Reference Materials (AMRM) Program. In 2018, the model used for the ODS-led Vitamin D initiative will be applied to other nutrients such as iron. ODS, in partnership with NCCIH, will continue to support the NIH Botanical Research Centers program in 2018. With the reduced spending level, ODS will reduce its grant co-funding with NIH ICs and its contribution to Congressionally-supported resources such as the AMRM Program.

ORIP programs provide support for research and research infrastructure needs. ORIP's DCM programs will include: (1) the NPRC program; (2) the Mutant Mouse Resource and Research Centers and other resources for genetically-altered mammals; (3) non-mammalian models; and (4) National Research Service Awards. DCM will reduce the number of new awards proportionally across activities and programs. The DCI, ORIP will provide funding for shared instrumentation grants to enable, enhance, and accelerate NIH-funded basic, translational, and clinical research. DCI will reduce the number of awards proportionally in each category of supported technologies.

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[5] https://obssr.od.nih.gov/about-us/strategic-plan/
[6] https://grants.nih.gov/grants/guide/rfa-files/RFA-OD-17-004.html
[7] https://oppnet.nih.gov/
[8] https://orwh.od.nih.gov/research/strategic-plan/
[9] https://ods.od.nih.gov/About/StrategicPlan2017-2021.aspx

The Environmental influences on Child Health Outcomes (ECHO) program will continue to integrate multiple synergistic, longitudinal studies by leveraging existing and new data from maternal/pediatric cohorts. Working in concert with each other, these cohorts aim to examine the impact of a broad range of environmental exposures (e.g., physical, chemical, biological, behavioral, social) on child health. ECHO focuses on four key pediatric outcomes with high public health impact: pre-, peri-, and postnatal outcomes; upper and lower airway; obesity; and neurodevelopment; as well as a new fifth outcome, positive health. All ECHO cohort studies will use a standardized, targeted set of Common (core) Data Elements including demographics, typical descriptors of early health and development, genetic background, environmental factors, and patient/person reported outcomes. With the reduced funding level, the ECHO program will eliminate support for the Children's Health Exposure Analysis Resource (CHEAR), composed of a laboratory network to analyze exposures in bio and environmental specimens, a key component of ECHO research. Reductions would also occur to the program's Data Analysis Centers and Coordinating Centers as well as Cohort grants.

The All of Us Research Program will continue enrollment and retention activities, with a focus on engagement strategies that emphasize diversity, as well as begin enrollment of children. FY 2018 funds will be used to collect individual data and biospecimens from participants, and will ensure that the data is shared back with participants according to their preferences. The funding will support the development of analytic tools to allow reserachers to utilize the data for research, and to ensure that all types of researchers will be able to access the data through a secure enclave. The program will also assess whether improvements can be made or additional scientific and/or technological advances can be leveraged to achieve efficiencies and increase value to participants and researchers.

In FY 2018, the OD will support the Regenerative Medicine Innovation Project. Given the tremendous promise of Regenerative Medicine to enhance human health and treat disease, Congress included a provision in the 21st Century Cures Act for $30 million distributed over FY 2017 through FY 2020 for the funding of an Innovation Project aimed at "…clinical research to further the field of regenerative medicine using adult stem cells, including autologous cells." The Act stipulates that NIH, in coordination with FDA, award grants and contracts "…contingent upon the recipient making available non-Federal contributions…in an amount not less than $1 for each $1 of Federal funds provided in the award." The provision in the Act for a Regenerative Medicine Innovation Project offers an opportunity to galvanize the field and stimulate a comprehensive and coordinated effort to foster major scientific advances and ensure that regenerative medicine clinical studies are standardized, reproducible, and generalizable.

Program Description and Accomplishments

Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI): DPCPSI[10] provides leadership for identifying, reporting, and funding trans-NIH research that represents important areas of emerging scientific opportunities, rising public health challenges, or

[10] https://dpcpsi.nih.gov/

knowledge gaps that merit further research and would benefit from collaboration between two or more ICs, or from strategic coordination and planning.

Within DPCPSI, the Office of Portfolio Analysis (OPA) focuses on accurate quantitative assessment of the NIH portfolio and improvement of portfolio analysis methodology by developing and disseminating computational tools, training, and best practices that support the overall effort to help ensure the NIH research portfolio is balanced, free of unnecessary duplication, and takes advantage of collaborative, crosscutting research.[11] One example is a powerful, web-based tool, *iCite,*[12] which is publicly available and allows the calculation of Relative Citation Ratios (RCRs) for any unit of analysis, which can consist of a single publication or a large collection of publications. A publication describing the development of the RCR method[13] is already being recognized as an important new way to track biomedical scientists' influence on their respective fields.[14] DPCPSI also coordinates reporting on completed evaluation studies and performance reporting under the Government Performance and Results Modernization Act.

In FY 2018, DPCPSI will continue to coordinate trans-NIH research opportunities through the Common Fund, and Program Offices for research on HIV/AIDS, Women's Health, Behavioral and Social Sciences, Disease Prevention, Dietary Supplements, and Infrastructure Resources. DPCPSI's two newest offices—the Sexual and Gender Minority Research Office (SGMRO) [15] and the Tribal Health Research Office (THRO) [16] —are providing guidance for and coordination of research in their respective areas. The SGMRO facilitates sexual and gender minority (SGM) research across NIH through implementation of the NIH FY 2016-2020 Strategic Plan to Advance Research on the Health and Well-being of Sexual and Gender Minorities The SGMRO collaborates with the National Institute on Minority Health and Health Disparities to implement the designation of SGMs as a health disparity population for NIH research. The THRO coordinates NIH activities related to health research involving American Indian and Alaska Native populations and works to ensure NIH obtains input from tribal nations on NIH programs and activities. Input and feedback is solicited from the NIH Tribal Advisory Committee (TAC)through tribal consultations on topics of interest, and via outreach and engagement at events.

Common Fund (CF)/Office of Strategic Coordination (OSC): The CF supports the biomedical community by providing enabling technologies, databases, and programs; developing essential tools and methodologies; and fostering innovation through high risk/high reward programs.[17] CF programs tackle major challenges in biomedical research that affect many diseases or conditions or that broadly relate to human health. CF programs address challenges and opportunities identified as high priorities for the scientific research community and NIH.

[11] https://dpcpsi.nih.gov/opa
[12] https://iCite.od.nih.gov
[13] http://journals.plos.org/plosbiology/article?id=10.1371/journal.pbio.1002541
[14] http://www.nature.com/news/the-quiet-rise-of-the-nih-s-hot-new-metric-1.20957
[15] https://dpcpsi.nih.gov/sgmro
[16] https://dpcpsi.nih.gov/thro
[17] https://commonfund.nih.gov/

OSC oversees the management of CF, working with trans-NIH teams for each of the more than 25 CF programs to ensure that each program synergizes with IC-funded research.[18] Program outcome evaluations, along with additional assessments conducted throughout the lifetime of the programs, are expected to deliver lessons learned concerning trans-NIH program management in addition to information concerning the scientific products and utility of the programs to date. Communication and outreach is an important component of all the CF programs, as the products and data generated by each program become ready for dissemination to the community-at-large.

Office of AIDS Research (OAR): Major scientific accomplishments and preclinical research have driven advances in the development and testing of safe and efficacious treatment regimens, successful prevention interventions, and strategies to halt the further spread of the AIDS pandemic. These successes have resulted from the comprehensive and coordinated NIH HIV/AIDS research program. OAR serves a critical role in coordinating and managing the comprehensive trans-NIH AIDS research program, supported by nearly all the NIH ICs and encompassing all areas of biomedical, behavioral, and social sciences research on HIV/AIDS and its associated coinfections, comorbidities, and other complications.[19] OAR uses its legislative authorities to identify the highest priority areas of scientific opportunity, enhance collaboration, minimize duplication, and ensure that HIV/AIDS research dollars are invested effectively and efficiently. OAR has implemented new trans-NIH planning, portfolio analysis, and budgeting processes to ensure that AIDS dollars are supporting the highest HIV/AIDS research priorities. OAR plans, coordinates, evaluates, and manages the trans-NIH HIV/AIDS research program budget, which is linked directly to the annual Strategic Plan it develops. OAR also identifies specific funding for emerging scientific opportunities in HIV/AIDS research and public health needs; manages and facilitates multi-IC and trans-NIH activities to address those needs; stimulates research by designating funds to support pilot program areas; facilitates international AIDS research and training; disseminates information about HIV/AIDS research advances and best practices; and sponsors workshops to identify cutting-edge initiatives.

Office of Research on Women's Health (ORWH): The mission of ORWH is to advance and expand research on women's health and increase the consideration of sex and gender factors in health and disease, to ensure the inclusion of women in NIH clinical research, and to promote the career development of women in biomedical research.[20] ORWH activities are guided by the 2010 NIH Strategic Plan for Women's Health Research[21] which outlines six goals to maximize the impact of NIH research efforts: 1) Increase sex differences research in basic science; 2) Consider sex/gender differences in the development and delivery of new devices, technologies, and therapeutics; 3) Actualize personalized prevention, diagnostics, and therapeutics for girls and women; 4) Create strategic partnerships, domestically and globally; 5) Fully utilize new communication and social networking technologies; and 6) Increase diversity in the research workforce. The ORWH will be an active participant in the implementation of the 21st Century Cures Act.

[18] https://dpcpsi.nih.gov/osc/
[19] https://www.oar.nih.gov/
[20] https://orwh.od.nih.gov/
[21] https://orwh.od.nih.gov/research/strategicplan/index.asp

Program Portrait: Administrative Supplements for Research on Sex/Gender Differences in Health and Disease

FY 2017 Level: $3.5 million
FY 2018 Level: $2.4 million
Change: - $1.1 million

Sex – being male or female – is an important biological determinant of health and is a fundamental variable in biomedical research. The over-reliance on male animals, and neglect of attention to the sex of cells in some fields, can lead to a failure to detect key sex differences that should be guiding clinical studies, and ultimately, clinical practice. The May 14, 2014 comment in Nature[22] by Drs. Janine A. Clayton and Francis S. Collins first outlined changes in NIH policy to address this issue. The formalization of this policy ensures that men and women receive the full benefit of medical research. The policy states that:

NIH expects that sex as a biological variable (SABV) will be factored into research designs, analyses, and reporting in vertebrate animal and human studies. Strong justification from the scientific literature, preliminary data, or other relevant considerations must be provided for applications proposing to study only one sex.

The consideration of SABV can have a profound impact on the development of safe and effective drugs and medical devices. FDA and drug manufacturers have removed drugs from the market that have been shown to have unacceptable health risks after they were already in widespread use.

Office of Behavioral and Social Sciences Research (OBSSR): OBSSR furthers the mission of NIH by facilitating research on the behavioral and social determinants of health which account for over half of premature deaths in the United States and contribute to disease trajectories and management.[23] In November 2016, the OBSSR Strategic Plan (Fiscal Years 2017-2021)[24] was released focusing on three scientific priorities: 1) improve the synergy of basic and applied behavioral and social sciences research, 2) enhance and promote the research infrastructure, methods, and measures needed to support a more cumulative and integrated approach to behavioral and social sciences research, and 3) facilitate the adoption of behavioral and social sciences research findings in health research and in practice. Drs. Francis S. Collins and William T. Riley published an editorial in Science Translational Medicine[25] accompanying this strategic plan that describes the transformational research opportunities in the behavioral and social sciences including neuroscience integration, measurement science advances, digital intervention platforms, and large-scale data integration. To address these scientific priorities and the broader NIH efforts in the behavioral and social sciences, OBSSR identifies research gaps, develops new initiatives, provides targeted research grant co-funding, and coordinates and integrates the behavioral and social sciences research efforts across the NIH ICs to leverage resources and minimize redundancy.

[22] http://www.nature.com/news/policy-nih-to-balance-sex-in-cell-and-animal-studies-1.15195
[23] https://obssr.od.nih.gov
[24] https://obssr.od.nih.gov/about-us/2017-strategic-plan/
[25] http://stm.sciencemag.org/content/8/366/366ed14

Program Portrait: Opioid Abuse as a Behavioral and Social Systems Problem

FY 2017 Level: $0.3 million
FY 2018 Level: $1.2 million
Change: + $0.9 million

Opioid abuse has rapidly become a public health epidemic. The CDC reports that while the amount of overall pain that patients report has not changed, the amount of prescription opioids sold in the U.S. has quadrupled since 1999. Deaths from opioid overdose increased 200% between 2000 and 2014, and opioids are the leading cause of drug overdose in this country. From the behavior of opioid prescribing to nonpharmacologic interventions for substance abuse and chronic disease management, behavioral and social sciences research have and will continue to make significant contributions to addressing this crisis. Over three years ago, OBSSR, through the NIH Pain Consortium and with NIDA, co-led a Pathways to Prevention (P2P)[18] effort that outlined the current state of research on pain management and opioid abuse. This effort led to federal partners meetings to coordinate opioid abuse research and the implementation of this research in practice. For FY 2017, OBSSR is working with NIDA and other partners on a series of meetings addressing key research needs to address this crisis, including a meeting on best social and behavioral practices for reducing opioid prescribing, preventing and treating substance abuse, and managing chronic pain to rapidly disseminate this knowledge into practice.

For FY 2018, OBSSR plans to conduct additional research workshops and develop rapid-funding research initiatives to improve the effectiveness and implementation of nonpharmacologic approaches for treating opioid abuse and managing chronic pain as well as systems-based strategies that encourage more appropriate prescribing practices. With reduced funding, OBSSR will prioritize resources to this effort and will continue to serve an integral coordination function for a comprehensive, biopsychosocial approach to opioid abuse research but will have to prioritize initiatives and the funding possible from OBSSR for these efforts.

Office of Disease Prevention (ODP): The mission of ODP is to improve the public health by increasing the scope, quality, dissemination, and impact of prevention research supported by NIH.[26] ODP activities are guided by its Strategic Plan for FYs 2014–2018, which outlines the six priorities that the Office will focus on and highlights our role in advancing prevention research at NIH. To achieve its goals, ODP collaborates with other Federal agencies, academic institutions, the private sector, and non-governmental organizations in formulating prevention research initiatives. For example, ODP is the primary liaison with the U.S. Preventive Services Task Force (USPSTF) and provides input on draft research plans, evidence reports, and clinical practice recommendations. Additionally, ODP directs the Pathways to Prevention (P2P) program which includes workshops designed to identify research gaps, identify methodological and scientific weaknesses, suggest research needs, and move these fields forward through an unbiased, evidence-based assessment. ODP also coordinates several trans-NIH Prevention Scientific Interest Groups to develop new initiatives to address important gaps in prevention research identified through the P2P program and other collaborative activities. Additionally, ODP provides training resources to NIH program and review staff and to extramural researchers to promote the use of the best available methods in prevention research.

ODP also provides scientific leadership and oversight for the continued implementation of the NIH-FDA Tobacco Regulatory Science Program which addresses priority areas of the Family Smoking Prevention and Tobacco Control Act including the manufacture, distribution, and marketing of tobacco products. The Office of Dietary Supplements also is included as an

[26] https://prevention.nih.gov/

administrative unit within ODP and promotes scientific research in the area of dietary supplements.

Office of Dietary Supplements (ODS): The mission of ODS is to strengthen knowledge and understanding of dietary supplements by evaluating scientific information, stimulating and supporting research, disseminating research results, and educating the public to enhance quality of life and health for the U.S. population.[27] ODS co-funds research grants with ICs on dietary supplements and sponsors systematic reviews in relevant areas as well as projects to enhance the incorporation of these reviews into nutrition research. Recently, the USPSTF determined that there is insufficient evidence to assess the benefits and harms associated with screening pregnant women and infants (6-24 months) for iron deficiency as well as routine iron supplementation for pregnant women. In September 2016, ODS hosted a workshop to identify the specific research needs related to these topics. ODS also has developed an iodine initiative in response to concerns that some pregnant women may have inadequate intakes of this nutrient at a time of high physiologic demand. ODS continues to support the Dietary Supplement Label Database (DSLD), a joint project of ODS and the NLM.

Portrait of a Program: Dietary Supplement Label Database

FY 2017 Level: $1.0 million
FY 2018 Level: $1.0 million
Change: $ .0 million

The Office of Dietary Supplements (ODS), in partnership with the National Library of Medicine (NLM), has developed a Dietary Supplement Label Database (DSLD),[28] a free web-based resource that is compiling all information from the labels of dietary supplements marketed in the United States provided by the seller. This includes contents, ingredient amounts, and any health-related product statements, claims, and cautions. It also provides a downloadable photo of each label. Research scientists, for example, can use the DSLD to determine total nutrient intakes from food and supplements in populations they study. Health care providers can learn the content of products their patients are taking. An app for smartphones has just been released which makes it easy for consumers to use the DSLD to search for and compare products of interest.

The DSLD currently contains 63,000 labels, and it is expected to grow rapidly over the next three years to include most of the dietary supplement products sold to American consumers. The DSLD is updated regularly to include any formulation changes and label information in a product. It also includes the labels of products that have been discontinued and are no longer on the market. More information about the DSLD and its current capabilities is available online[29] and at Dwyer et al., 2014.[30]

In October 2016 ODS published a Federal Register Notice requesting ideas and suggestions for how the DSLD might evolve, including what features might be added, improved, or enhanced—for example, in capabilities related to search, sorting, organization, and downloading of information—that would make it a more valuable tool for users. A Federal stakeholder panel for the DSLD is working with developers to make key changes to improve functionality.

Office of Research Infrastructure Programs (ORIP): ORIP advances the NIH mission by making grant awards that support research infrastructure and research-related resources

[27] https://ods.od.nih.gov/
[28] https://ods.od.nih.gov/Research/Dietary_Supplement_Label_Database.aspx
[29] http://www.dsld.nlm.nih.gov
[30] http://www.sciencedirect.com/science/article/pii/S2212267214004584

programs.[31] Specifically, ORIP: 1) awards grants to support research resources such as animal models of human disease and state of the art biomedical instrumentation; 2) plans, organizes, and conducts workshops, both independently and in collaboration with NIH ICs, to identify and pursue scientific opportunities; and 3) supports research-training opportunities for veterinary scientists that capitalize on their distinct perspective and expertise based in a deep understanding of comparative medicine and insight into animal models of human disease.

Division of Comparative Medicine (DCM): DCM provides critical resources for scientists using animal models for basic and biomedical research and supports the development of specialized technologies involving human disease models.[32] DCM also funds research to safeguard the health and welfare of the full range of laboratory animal models.

DCM provides training and career development opportunities in translational science and in comparative/laboratory animal medicine and pathology for biomedical researchers who have degrees in veterinary medicine. These programs enhance the value of translational research teams when veterinarians join with other scientists and physicians, thus strengthening and sustaining the biomedical research workforce.

Continuing areas of emphasis in FY 2018 will include among other activities: 1) developing and characterizing animal models to study basic aspects of Zika virus infection and pathogenesis; 2) developing new "precision animal models" to address the unique requirements of individual patients or groups of patients; 3) revitalizing veterinarian-scientist, a subset of clinician-scientist, training to further strengthen and sustain the biomedical research workforce; and 4) enhancing rigor and reproducibility of NIH research involving disease models through consideration of biological variables such as the sex of research animals and cultured cells as well as environmental influences such as the microbiome (the community of microorganisms living on, and inside, humans and animals).

DCM supports the National Primate Research Centers (NPRCs), which facilitate the use of non-human primates (NHPs) as models of human health and disease for basic and translational biomedical research. In FY 2016, the NPRCs facilitated approximately 1,000 individual research projects involving roughly 1,500 researchers. Major areas of research benefiting from the resources of the NPRCs include: vaccine development and treatment of infectious agents, neuroscience and mental health, metabolic diseases, aging, and women's health. Research supported by the NPRCs in FY 2016 included significant advances in HIV/AIDS therapy, infectious diseases genetic model development, and regenerative medicine.

The NIH Chimpanzee Management Program,[33] managed by DCM, supports long-term, cost-effective housing and maintenance at NIH-supported facilities for chimpanzees. ORIP provides programmatic oversight of the facilities and ensures they comply with the Animal Welfare Act and PHS policies. The Chimpanzee Health Improvement, Maintenance, and Protection Act[34], signed into law in December 2000, required the establishment of a sanctuary system for

[31] https://dpcpsi.nih.gov/orip/index
[32] https://dpcpsi.nih.gov/orip/CM/index
[33] https://dpcpsi.nih.gov/orip/cm/chimpanzee_management_program
[34] http://www.gpo.gov/fdsys/pkg/PLAW-106publ551/html/PLAW-106publ551.htm

federally-owned or supported chimpanzees that are no longer needed for research. In November 2015, the NIH announced it will no longer support biomedical research on chimpanzees, and all NIH-owned and NIH-supported chimpanzees that reside outside of the Federal Sanctuary are eligible for retirement and relocation to the sanctuary[35]. Efforts are being made to relocate the animals as safely and quickly as possible while allowing for optimal transition of each individual chimpanzee with careful consideration of their welfare, including their health and social grouping. The NIH chimpanzee retirement plan[36] outlines the sequence and approximate time line of the chimpanzees' transition to the Federal Sanctuary. As needed, NIH will revise the plan and communicate updates to the Facility Directors. Annually, NIH will update its website to reflect any modifications in the plan and animal numbers at each facility.

Division of Construction and Instruments (DCI): DCI supports programs that improve and expand the Nation's capacity to conduct biomedical research by funding grants for the acquisition of expensive state-of the-art instrumentation and to improve existing animal research facilities, or to construct new research facilities, when funds are available.[37]

The Shared Instrumentation (SIG) and the High-End Instrumentation (HEI) Grant Programs (Instrumentation Programs) promote advances in biomedical research that would be impossible without access to the appropriate tools and instruments. New and improved technologies emerge continuously, necessitating updates to the research instrumentation infrastructure to permit NIH-supported investigators to continue the discovery process. DCI's Instrumentation Programs are unique among the NIH grant programs in that they give groups of NIH-funded investigators the funds needed to purchase and share cutting-edge instruments. The Instrumentation Programs address critical needs across all disciplines and all NIH ICs. The fact that the programs require sharing of the instrument among multiple research projects assures a higher return on the initial investment. In FY 2016, the Instrumentation Programs funded 107 grants at academic and research institutions coast-to-coast and supported more than 1,000 NIH research projects, which collectively represent the majority of NIH ICs.

The Extramural Research Facilities Improvement Program focuses on the needs of the animal research community for modern scientific equipment and instruments. Such instruments, when specifically configured to support well-defined areas of animal research, enable innovative and potentially transformative investigations which otherwise would not be possible. DCI has, in the past, supported construction of new buildings and laboratory space for NIH-funded research. DCI manages such NIH-funded facilities for biomedical or behavioral research purposes which must be utilized for 10 or 20 years following completion and occupancy.

The ORIP programs provide support for research and research infrastructure needs, including animal research models and biological materials; training and career development for veterinarian scientists; acquisition of state-of-the-art and shared instrumentation; and grants to modernize biomedical research facilities when construction funds are appropriated.

[35] https://www.nih.gov/about-nih/who-we-are/nih-director/statements/nih-will-no-longer-support-biomedical-research-chimpanzees
[36] https://dpcpsi.nih.gov/orip/cm/chimpanzeeretirement
[37] https://dpcpsi.nih.gov/orip/diic/index

ORIP's DCM will continue to interact with NIH partners and the scientific community to maintain scientific priorities that best meet the broad needs of the multidisciplinary biomedical research continuum. DCM programs will include, but are not limited to: (1) the NPRCs program with the goal to facilitate the use of non-human primates as models of human health and disease for basic and translational biomedical research; (2) the Mutant Mouse Resource and Research Centers and other Resources for genetically-altered mammals such as rats and pigs; (3) non-mammalian models such as fish, worms, and fruit flies which are used to advance the understanding of gene function or metabolic processes; and (4) the National Research Service Awards, including plans to fund approximately 150 full-time training positions. The proposed budget will result in an approximately 15% reduction in funding levels of current (continuing) and new awards. To keep up with the program priorities of benefiting all areas of research funded by the NIH ICs, DCM will reduce the number of new awards proportionally across activities and programs.

ORIP's DCI plans to continue to support the Nation's capacity for the conduct of biomedical research. Specifically, these programs provide funding for shared instrumentation grants to enable, enhance, and accelerate NIH-funded research in a broad array of basic, translational, and clinical research. Further, DCI programs provide support for improvements of infrastructure of biomedical research facilities; by providing access to modern instruments and tools, these programs enhance scientific rigor of animal research. The proposed budget will result in a smaller number of awards. To keep up with the program priorities of benefiting all areas of research funded by the NIH ICs, DCI will reduce the number of awards, proportionally in each category of the supported technologies.

Intramural Loan Repayment and Scholarship Programs (ILRSP): The mission of ILRSP is to develop and manage programs that offer financial incentives and other benefits to attract highly-qualified physicians, nurses, and scientists into careers in biomedical, behavioral, and clinical research as employees of NIH. There are two education programs offered. The Intramural Loan Repayment Program (ILRP) and the NIH Undergraduate Scholarship Program (UGSP).

ILRP repays outstanding eligible educational debt for postgraduates, and in return, participants must enter into a contractual agreement to conduct qualified research as NIH employees. During FY 2016 the distribution of ILRP awards was as follows:

- 63 awards for the General LRP – 28 new and 35 renewals; and
- Four awards for AIDS LRP –2 new and 2 renewals.

FY 2016 ILRP awards (67) decreased by 2.9 percent compared to FY 2015 awards (69). It must be noted that there were no Clinical Research LRP applicants during the 2016 cycle. UGSP offers competitive scholarships to exceptional college students from disadvantaged backgrounds that are committed to biomedical, behavioral, and social science health-related research careers at NIH. For every year of UGSP scholarship support, recipients are obligated to participate in a ten-week summer internship and one year as a full-time paid employee in an NIH research laboratory. UGSP selected 16 new recipients for the UGSP Scholarship award and 4 UGSP

Scholars received scholarship award renewals. In addition, 21 UGSP scholars conducted their yearlong service obligation and 19 completed their summer internship during this same period.

Director's Discretionary Fund (DDF): The DDF allows the NIH Director to respond quickly to new and emerging high-priority research opportunities and health priorities. In FY 2016, funds were used to support trans-NIH initiatives such as the Clinical Center Patient Safety and Good Manufacturing Practice (GMP) Compliance Assessment, Anonymization Study Contract, Assessing the Implementation of the NIH Rigor and Reproducibility Policy, Genomic Determinants of Altered Fetal Growth and Metabolism, Sexual and Gender Minority Research Administrative Supplements, and the National Academies Study on Sexual Harassment.

Research for Countermeasures against Nuclear/Radiological/Chemical Threats: The Radiation and Nuclear Countermeasures Program (RNCP), managed by NIH/NIAID, funds the development of medical countermeasures (MCMs) to mitigate and treat injuries caused by exposure radiation due to terrorist incidents or accidents. The RNCP also supports development of drugs to remove internal radionuclide contamination from the body as well as biomarker studies and biodosimetry approaches for mass casualty triage. The multi-element program funds initiatives that support basic, translational, and product development services to provide capabilities for drug development toward FDA licensure. The NIAID encourages collaborative efforts between academic, industry, and federal laboratories. Five MCM candidates have progressed to the Investigational New Drug (IND) submission stage and two MCM candidates (Neupogen and Neulasta) have been granted FDA approval for a radiation public health emergency indication. These are the first MCMs to be licensed by FDA specifically for treatment of the acute radiation syndrome. RNCP accomplishments since initiation of the program in FY 2005 include over 1,000 scientific articles, more than 45 patents, and over 150 medical countermeasure candidates in discovery and early development phases. The targeted SBIR program for radiological/nuclear MCMs and biodosimetry has funded thirty-seven awards since FY 2009, including eleven grants that transitioned from SBIR Phase I to SBIR Phase II.

The Chemical Countermeasures Research Program (CCRP) is designed to prevent, diagnose, and treat the conditions caused by exposure to potential and existing chemical agents of terrorism and chemicals that may be released from transportation and storage facilities by industrial accidents or during a natural disaster. The program includes collaborative efforts with academia and industry, as well as agencies of the Federal Government to include the U.S. Army Medical Research Institute of Chemical Defense, the Defense Technical Information Center, and seven participating NIH ICs. A comprehensive research network has been established which includes 4 center grants (U-54) focused on countermeasures against chemical threats, 24 individual research grants and projects (U-01), 10 exploratory research projects (R21), 4 SBIR grants, contracts, and 8 Interagency Agreements. Accomplishments include patents, and more than 30 MCM candidates in discovery and research phases, transitioned compounds to the Biomedical Advanced Research and Development Authority (BARDA) including Midazolam (countermeasure against nerve agents), Galantamine (nerve agent antidote), Tissue Plasminogen Activator (for sulfur mustard injuries), and R107 Radical which transitioned in September 2016 (for chlorine acute lung injury). Products positioned for future transition include Cobinamide (for cyanide exposure), AEOL10150 (for pulmonary edema / pulmonary stress), and Doxycycline (for ocular exposure to sulfur mustard). The CCRP has published over 800 manuscripts since FY 2006.

Foundation for the National Institutes of Health (FNIH): The Congress created the FNIH, a 501(c) (3) public charity, to support the mission of NIH. Since 1996, the FNIH has raised over $900 million, generating $86 per $1 of NIH support, dramatically leveraging the modest NIH yearly contribution. Because of its charter, the FNIH serves as a critical and trusted convener of multiple constituencies and has pioneered novel public-private partnerships that have been widely emulated in the United States and abroad. For more than a decade, Charity Navigator, a prominent charity watchdog in the United States, has rated the FNIH as an organization that consistently exceeds industry standards for effective management and efficient use of resources. In addition, NIH continues to provide $1 million annually to FNIH to support direct salary and overhead costs incurred for operations.

As one example of a partnership, the FNIH Biomarkers Consortium launched a new project in May 2016 to determine whether liquid biopsies can be used instead of traditional solid tumor biopsies for diagnosing and monitoring metastatic colorectal cancer, the third leading cause of cancer death in the United States. The Biomarkers Consortium is the ideal platform for this project as it has broad participation from stakeholders across the health field, including government, industry, academia, and patient advocacy and other non-profit private sector organizations.

OD Operations: OD Operations is comprised of several OD Offices that provide advice to the NIH Director, policy direction and oversight to the NIH research community, and administer centralized support services essential to the NIH mission. These include the Offices of Extramural Research, Intramural Research, Science Policy, Management, Budget, Communications and Public Liaison, Legislative Policy and Analysis, Equal Opportunity and Diversity Management, Chief Information Officer, Immediate Office of the Director, Associate Director for Data Science, Chief Officer of Scientific Workforce Diversity, Executive Office, Executive Secretariat, and the NIH Ethics Office.

OD Operations will support the continuation of several key activities formerly managed by the Fogarty lnternational Center (FIC) to include visa and passport services for all NIH international travel; services to maintain international relations by developing new partnerships between U.S. scientists, institutions and counterparts abroad to advance research and training in the biomedical and behavioral sciences; and to continue collaborative efforts with NIH Institutes and Centers to: 1) assess the state of the science on topics of U.S. and global importance; 2) identify research gaps and opportunities and produce high-impact publications and other resources to guide future investments and scientific directions; 3) create and maintain networks of researchers and other stakeholders to facilitate better translation of evidence into policy and practice; and 4) provide short-term training that addresses critical trans-NIH priorities (e.g., Household Air Pollution, mHealth).

Environmental Influences on Child Health Outcomes (ECHO): NIH launched the Environmental Influences on Child Health Outcomes (ECHO) program in FY 2016 to advance research at the intersection of pediatric and environmental health and to capitalize on existing participant populations (cohorts). ECHO supports multiple synergistic, longitudinal studies by leveraging, harmonizing, combining, and performing innovative analyses from extant and new

maternal/pediatric cohorts' data. ECHO consists of 84 cohorts of mothers and children with a broad range of early life environmental exposures (e.g., chemical, biological, behavioral). ECHO focuses on four key pediatric outcomes with high public health impact, including upper and lower airway; obesity; pre-, peri-, and postnatal outcomes; and neurodevelopment. To advance knowledge about what and how early life exposures impact child health, ECHO will collect standardized data (Core Elements) across all the cohorts, in addition to cohort-specific data. The ECHO IDeA States Pediatric Clinical Trials Network, an important component of ECHO, will enable clinical trials experts at IDeA state locations with advanced professional development and training in state of the art clinical research and facilitate partnership with outside academic institutions. In FY 2018, ECHO will continue to evaluate early research findings and determine what improvements the program can make, including leveraging scientific or technological advances.

***All of Us* Research Program (formerly the Precision Medicine Initiative (PMI) Cohort Program)**

The *All of Us* Research Program[38], formerly the PMI Cohort Program, is building a national research cohort of one million or more U.S. volunteers, providing a transformative platform for expanding our knowledge of precision medicine approaches. Precision medicine is an approach to disease prevention and treatment that seeks to maximize effectiveness by taking into account individual variability in genes, environment, and lifestyle. Precision medicine seeks to redefine our understanding of disease onset and progression, effective prevention, treatment response, and health outcomes through the more precise measurement of molecular, environmental, and behavioral factors that contribute to health and disease. Ultimately, this understanding can lead to more accurate diagnoses, more rational disease prevention strategies, better treatment selection, and the development of novel therapies. Coupled to advances in science and technology is a changing culture in which research participants want to be engaged as active partners – not just as patients or research subjects. The combination of a highly engaged population and rich biological, health, behavioral, and environmental data will usher in new and more effective ways of preventing and treating disease. FY 2016 marked the start of the *All of Us* Research Program and the budget reflects partial year funding in a pilot (startup) phase. Support for the program increased in FY 2017 as awardees move toward full implementation of the required infrastructure and programmatic operations needed to support initial enrollees. The FY 2018 budget reflects continued enrollment and retention of participants across the country, and initiating the inclusion of children; building capacity for new data types, including genetics and mHealth; and implementing groundbreaking return of information practices.

Regenerative Medicine (RM): Regenerative medicine holds the promise to repair or replace cells and tissues damaged by injury, disease, or aging. RM strategies focus on the delivery of therapeutic cells that restore normal structure and function as well as on leveraging and enhancing the body's own innate healing capacity. These strategies include a wide range of technologies such as engineered biomaterials and tissues as well as gene editing or replacement. Preclinical studies have demonstrated the possibility of these approaches to treat both chronic disease as well as acute injury in a wide range of contexts, including vision loss; hearing loss; developmental disorders/conditions; heart, lung, and blood disorders; and acute

[38] https://www.nih.gov/precision-medicine-initiative-cohort-program

injury to spinal cord, kidney, muscle, and connective tissues. Given the tremendous promise of RM to enhance human health and treat disease, Congress included a provision in the 21st Century Cures Act for $30 million distributed over FY 2017 through FY 2020 for the funding of an Innovation Project aimed at "…clinical research to further the field of regenerative medicine using adult stem cells, including autologous cells." The Act stipulates that NIH, in coordination with FDA, award grants and contracts "…contingent upon the recipient making available non-Federal contributions…in an amount not less than $1 for each $1 of Federal funds provided in the award." The provision in the Act for a Regenerative Medicine Innovation Project offers an opportunity to galvanize the field and stimulate a comprehensive and coordinated effort to foster major scientific advances and ensure that regenerative medicine clinical studies are standardized, reproducible, and generalizable.

NATIONAL INSTITUTES OF HEALTH
Office of the Director

Detail of Full-Time Equivalent Employment (FTE)

OFFICE/DIVISION	FY 2016 Final			FY 2017 Annualized CR			FY 2018 President's Budget		
	Civilian	Military	Total	Civilian	Military	Total	Civilian	Military	Total
Appropriated									
Direct:	635	4	639	701	4	705	718	5	723
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	635	4	639	701	4	705	718	5	723
Reimbursable									
Direct:	-	-	-	-	-	-	-	-	-
Reimbursable:	47	-	47	47	-	47	47	-	47
Total:	47	-	47	47	-	47	47	-	47
Total	682	4	686	748	4	752	765	5	770
Includes FTEs whose payroll obligations are supported by the NIH Common Fund.									
FTEs supported by funds from Cooperative Research and Development Agreements.	0	0	0	0	0	0	0	0	0

FISCAL YEAR	Average GS Grade
2014	12.7
2015	13.0
2016	12.9
2017	12.9
2018	12.9

NATIONAL INSTITUTES OF HEALTH
Office of the Director

Detail of Positions[1]

GRADE	FY 2016 Final	FY 2017 Annualized CR	FY 2018 President's Budget
Total, ES Positions	11	11	11
Total, ES Salary	1,986,185	2,025,909	2,066,427
GM/GS-15	116	119	122
GM/GS-14	140	154	160
GM/GS-13	200	229	230
GS-12	97	111	114
GS-11	38	41	42
GS-10	2	2	2
GS-9	24	26	27
GS-8	1	1	1
GS-7	8	9	11
GS-6	3	3	3
GS-5	2	2	2
GS-4	4	4	4
GS-3	3	3	3
GS-2	1	1	1
GS-1	1	1	1
Subtotal	640	706	723
Grades established by Act of July 1, 1944 (42 U.S.C. 207)	0	0	0
Assistant Surgeon General	1	1	1
Director Grade	2	2	3
Senior Grade	1	1	1
Full Grade	0	0	0
Senior Assistant Grade	0	0	0
Assistant Grade	0	0	0
Subtotal	4	4	5
Ungraded	64	64	64
Total permanent positions	564	630	648
Total positions, end of year	694	760	778
Total full-time equivalent (FTE) employment, end of year	686	752	770
Average ES salary	180,562	184,174	187,857
Average GM/GS grade	12.9	12.9	12.9
Average GM/GS salary	115,723	118,037	120,398

[1] Includes FTEs whose payroll obligations are supported by the NIH Common Fund.