DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

Office of the Director (OD)

FY 2019 Budget

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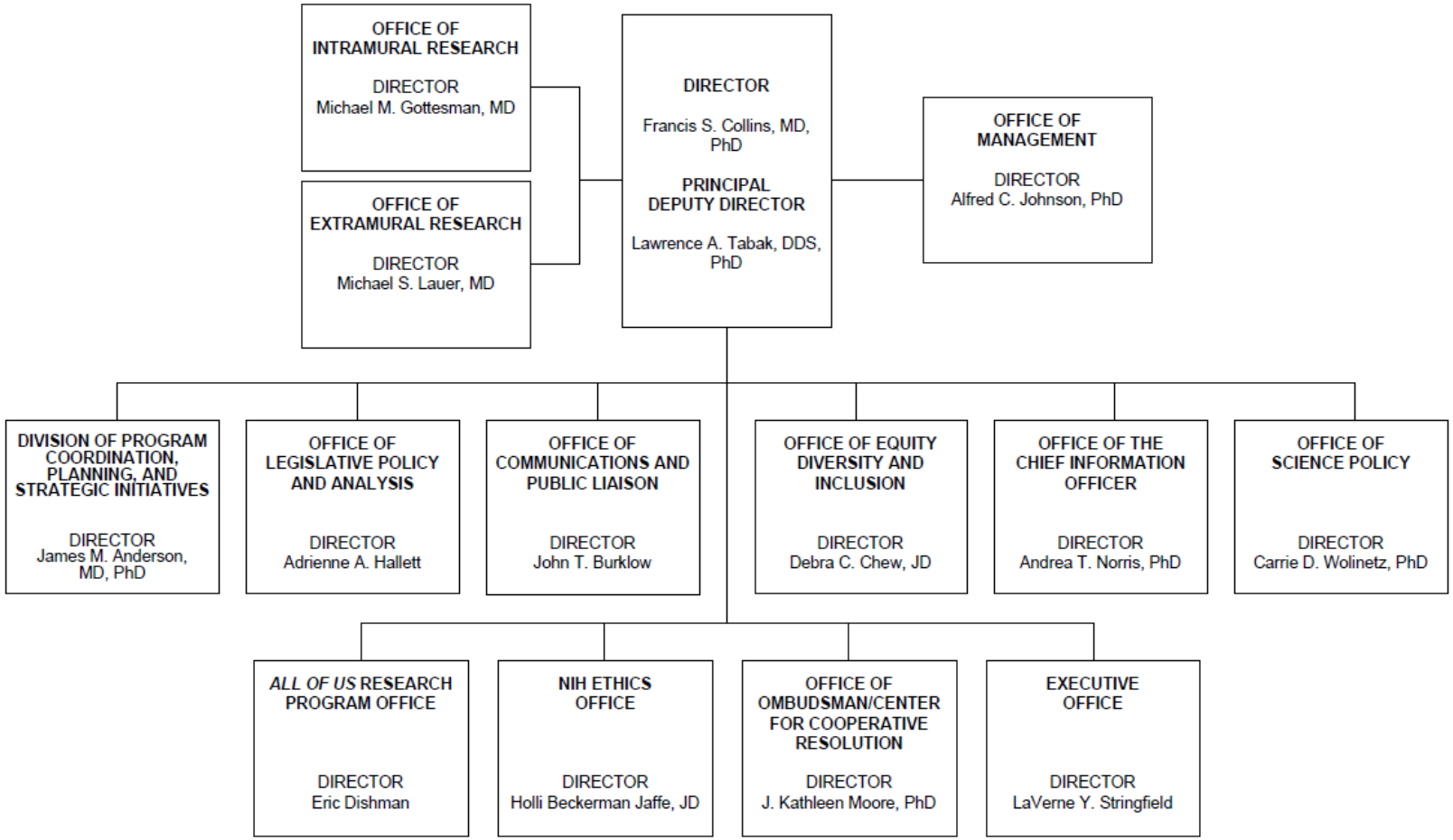
NATIONAL INSTITUTES OF HEALTH

Office of the Director
Organization Structure



NATIONAL INSTITUTES OF HEALTH

Office of the Director

(INCLUDING TRANSFER OF FUNDS)

For carrying out the responsibilities of the Office of the Director, NIH, $1,795,706,000: 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 $586,181,000 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 $8,000,000 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, 2]
(Dollars in Thousands)

Source of Funding	FY 2017 Final	FY 2018 Annualized CR	FY 2019 President's Budget
Appropriation	$1,728,603	$1,718,036	$2,004,306
Mandatory Appropriation: (non-add)			
Type 1 Diabetes	*(0)*	*(0)*	*(0)*
Other Mandatory financing	*(0)*	*(0)*	*(0)*
Rescission	0	-11,904	0
Sequestration	0	0	0
Secretary's Transfer	-3,607	0	0
Subtotal, adjusted appropriation	$1,724,996	$1,706,132	$2,004,306
OAR HIV/AIDS Transfers	2,427	0	0
Subtotal, adjusted budget authority	$1,727,423	$1,706,132	$2,004,306
Unobligated balance, start of year	0	0	0
Unobligated balance, end of year[3]	-39,805	0	0
Subtotal, adjusted budget authority	$1,687,618	$1,706,132	$2,004,306
Unobligated balance lapsing	-179	0	0
Total obligations	$1,687,439	$1,706,132	$2,004,306

[1] Excludes the following amounts (in thousand) for reimbursable activities carried out by this account:
FY 2017 - $46,704 FY 2018 - $50,000 FY 2019 - $50,000

[2] OD Cures - FY 2019 includes $196,000 million derived by transfer from the NIH Innovation Account.

[3] NIH Innovation Fund, Cures Act Account carryover that is available for obligation in FY 2018

NATIONAL INSTITUTES OF HEALTH
Office of the Director

Authorizing Legislation

	PHS Act/ Other Citation	U.S. Code Citation	2018 Amount Authorized	FY 2018 Annualized CR	2019 Amount Authorized	FY 2019 President's Budget
Research and Investigation	Section 301	42§241	Indefinite	$1,706,132,211	Indefinite	$2,004,306,000
Office of the Director	Section 401(a)	42§281	Indefinite		Indefinite	
Total, Budget Authority				$1,706,132,211		$2,004,306,000

NATIONAL INSTITUTES OF HEALTH
Office of the Director

Appropriations History

Fiscal Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
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]	$1,571,200,000			$1,729,783,000
Rescission				$0
2018	$1,452,433,000			$1,717,879,000
Rescission				$11,746,956
2019	$2,004,306,000			

[1] Budget Estimate to Congress includes mandatory financing.

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 (BA):

	FY 2017 Final	FY 2018 Annualized Continuing Resolution level	FY 2019 President's Budget	FY 2019 +/- FY 2018
BA	$1,728,603,000	$1,706,132,211	$2,004,306,000	+$298,173,789
FTE	785	781	781	0

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] The OD coordinates NIH's extramural and intramural research activities, health information dissemination, science policy, legislative activities, technology transfer, and oversight of NIH's stewardship of public funds. The OD manages, prioritizes, and allocates funds for administrative services including budget and financial management, information technology, procurement services, property management, ethics, human resources, intramural and extramural support, 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[2] 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 (ICs); 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.
- **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, biomedical research workforce, and laboratory animal welfare.
- **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.
- **Office of Intramural Research (OIR)** oversees policies that govern intramural research, as well as training conducted within the NIH Intramural Research Program. OIR approves the appointment of NIH principal investigators and is responsible for external review of intramural research, human subjects research protections, animal care and use, research integrity, and technology transfer in the intramural research program.
- **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, logistics and strategic planning. 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.

[2] https://ethics.od.nih.gov/

- **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 clinical research, data sharing, biosafety and biosecurity, and technology innovation.
- **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*** **(AOURP)** 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)** assesses, facilitates, and stimulates research in disease prevention and health promotion, and disseminates the results of this research to improve public health.
  - ODP includes the **Office of Dietary Supplements (ODS)** 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 models of human diseases, providing access to state-of-the art instrumentation, and enhancing research training and career development of veterinary scientists.
  - **Office of Research on Women's Health (ORWH)** serves as the focal point for women's health research at NIH and coordinates across the agency to help ensure the inclusion of women in clinical research and female animals in preclinical studies. The Office also fosters the recruitment, retention, reentry, and advancement of women in biomedical careers.
  - **Office of Strategic Coordination (OSC)** manages the NIH Common Fund, a portfolio of short-term, goal-driven, trans-NIH research programs that represent strategic investments aimed at solving problems or building resources to affect research throughout the entire biomedical research enterprise.
  - **Office of Program Evaluation and Performance (OPEP)** coordinates and manages agency-wide activities that support implementation of Government Performance and Results Act and coordinates reporting to HHS on evaluation activities.
  - The **Office of Administrative Management and Communications (OAMC)** provides administrative management support for the offices within DPCPSI, and coordinates communications activities for selected DPCPSI offices.

- The two newest offices established in DPCPSI are: the **Sexual and Gender Minority Research Office (SGMRO)** and the **Tribal Health Research Office (THRO)** 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.

Program Description and Accomplishments

Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI)
DPCPSI[3] provides leadership for identifying, reporting, and funding trans-NIH research that represents important areas of emerging scientific opportunities, rising public health challenges, or knowledge gaps that merit further research and would benefit from collaboration between two or more ICs, or from strategic coordination and planning.

Within the division, the Office of Portfolio Analysis (OPA) provides leadership and facilitates individual Institute and Center as well as trans-NIH portfolio analysis efforts. The OPA developed a standardized metric of scientific influence, the Relative Citation Ratio[4],[5],[6] and a website, *iCite*, [7] which provides open access to this metric. Training in the use of the iCite tool is provided to NIH staff along with user manuals, FAQs, and instructional videos. OPA also develops computational tools to retrieve and clean data used to analyze information about NIH investments, funded collaborations, publication records, and bench-to-bedside translation; and to leverage advanced data mining and knowledge discovery techniques to link people, funding, and research outputs across data sets and to analyze the content of grant applications, awards, publications, and patents. Newer OPA analytics are designed to identify duplication and improve strategic planning, including *iSearch*, the OPA NextGen portfolio analysis platform. *iSearch* provides NIH scientific staff comprehensive, easy-to-use access to carefully curated, extensively linked datasets encompassing publications, clinical trials, patents, approved drugs, investigators, and awards made by other funders, both domestic and international. These tools can help identify overlapping investments, emerging areas of science, and research gaps to help ensure that the NIH research portfolio is balanced, free of unnecessary duplication, and takes advantage of collaborative, cross-cutting research. DPCPSI also coordinates reporting on completed evaluation studies and performance reporting under the Government Performance and Results Modernization Act.

The DPCPSI Sexual and Gender Minority Research Office (SGMRO) and the Tribal Health Research Office (THRO) provide leadership for and coordination of research in their respective areas. The Sexual & Gender Minority Research Office (SGMRO) continues to coordinate and encourage sexual and gender minority (SGM) research across NIH. SGMRO works with all of the NIH ICs to ensure that SGM-related research is considered in large cohort studies and in

[3] https://dpcpsi.nih.gov/
[4] Hutchins, B.I., Yuan, X., Anderson, J.M., and Santangelo, G.M. (2016). Relative Citation Ratio (RCR): A New Metric That Uses Citation Rates to Measure Influence at the Article Level. PLoS biology 14, e1002541.
[5] Naik, G. (2016). The quiet rise of the NIH's hot new metric. Nature 539, 150.
[6] Santangelo, G.M. (2017) Article-level assessment of influence and translation in biomedical research. Mol. Biol. Cell 28, 11 1401-1408
[7] https://icite.od.nih.gov/

Funding Opportunity Announcements across disease areas and health conditions. SGMRO leads NIH's efforts to implement the SGM research-related provisions included in the 21st Century Cures Act. SGMRO will continue to collaborate with the National Institute on Minority Health and Health Disparities to ensure that the designation of SGMs as a health disparity population for NIH research is incorporated throughout the work of the agency. SGMRO also facilitates implementation of the NIH FY 2016-2020 Strategic Plan to Advance Research on the Health and Well-being of Sexual and Gender Minorities. Additionally, SGMRO continues to serve as a resource to the NIH community at-large (including intramural researchers), extramural researchers, colleagues across government, and the SGM stakeholder community.

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.[8] The NIH Tribal Advisory Committee (TAC) provides a forum for meetings between Tribal leaders and NIH officials to exchange views, share information, and seek advice related to NIH programs. The NIH holds tribal consultations annually on health research topics proposed by the TAC and/or tribal communities. The office is working with the Tribal Health Research Coordinating Committee at the NIH and with the tribal community to development a THRO Strategic Plan.

In FY 2019, DPCPSI will continue to coordinate trans-NIH research opportunities through the Common Fund, and 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 aimed at optimizing future research investments by the ICs and the OD.

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.[9] 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.

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.[10] 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.

The FY 2019 President's Budget request reflects the transition of the *All of Us* Research Program out of the Common Fund but still within the Office of the Director. The level of funding will

[8] https://dpcpsi.nih.gov/thro
[9] https://commonfund.nih.gov/
[10] https://dpcpsi.nih.gov/osc/

allow the Common Fund to pursue high impact scientific opportunities within several programs. The Big Data to Knowledge program will continue support for the NIH Data Commons, launched in FY 2017. This project is testing ways to store, access, and share biomedical big data and associated tools in a shared cloud environment. It will also support a program on Somatic Cell Genome Editing, launched in FY 2018, which aims to improve the efficacy and specificity of tools to precisely change specific sequences in the human genome to catalyze a fundamentally new approach to treat diseases. The Common Fund plans to launch a new Prize Program in FY 2019 to accelerate research in defined areas of need across the NIH. Finally, this request also includes funds for continued support of the Gabriella Miller Kids First Research Program. For additional details, please see the Common Fund section.

Office of AIDS Research (OAR)

The OAR is Congressionally-mandated to plan, coordinate, evaluate, and manage the trans-NIH HIV/AIDS research program.[11] Each year, the OAR oversees the development of the comprehensive *Trans-NIH Plan for HIV-Related Research*, commonly known as the *Strategic Plan*. This Plan establishes the NIH HIV/AIDS research agenda in the following scientific priority areas: 1) research to reduce the incidence of HIV/AIDS, including the development of safe and effective HIV/AIDS vaccines, microbicides, and pre-exposure prophylaxis; 2) the development of the next generation of HIV therapies with increased safety and ease of use; 3) research toward a cure for HIV/AIDS; and 4) prevention and treatment of HIV coinfections and comorbidities. The Plan also includes basic research, clinical research, epidemiologic research, health disparities research, research training, behavioral and social sciences research, and information dissemination.

To maximize support for the highest priority science, the OAR has continued the portfolio review and analysis process which allows the OAR to identify and redirect funding to support the highest priority HIV/AIDS research projects. 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 innovative pilot program areas; cultivates international AIDS research and training; and sponsors workshops to identify cutting-edge initiatives.

The OAR will continue to use the expertise of Office of AIDS Research Advisory Council (OARAC) to assist in setting the future research agenda. In addition, the OAR will convene external expert panels to provide advice and guidance to OAR and the ICs regarding emerging research opportunities. These panels will identify gaps in the research agenda that should be undertaken within the next few years. These efforts will allow OAR to focus the NIH HIV/AIDS research agenda on the most compelling science.

In FY 2019, OAR will continue to direct funds to the highest priority HIV/AIDS research to build on scientific progress and push for discovery and breakthroughs in the key research areas of prevention, including microbicides and vaccines; novel therapeutics to achieve durable viral suppression and improve treatment modalities; addressing comorbidities of aging, neurological impairment, cancer, and cardiovascular complications with HIV; and research toward a cure.

[11] https://www.oar.nih.gov/

Office of Research on Women's Health (ORWH)

The mission of the 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.[12] Presently, ORWH activities are guided by the 2010 NIH Strategic Plan for Women's Health Research,[13] 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.

Recent evidence reveals a growing consensus regarding the health disparity between U.S. men and women.[14] While the life expectancy of U.S. men continues to improve, the life expectancy of U.S. women is falling far behind that of women in high-income peer countries.[15,16] The health of women in the U.S. is also significantly worse than the health of women in similar high-income countries. [15] The probability of U.S. women surviving to age 50 is lower than that of women in these peer countries. [16] As a result, more and more daughters in the U.S. may not live as long as their mothers. ORWH is reviewing these findings to influence the development of the new NIH-wide Strategic Plan for Women's Health Research (2018 – 2023).[17] These findings, along with feedback from across the NIH and additional stakeholders, will guide the NIH in its mission to improve the health of women.

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

ORWH supports a program to catalyze exploratory research on sex/gender influences by providing administrative supplements to ongoing NIH-funded research. In keeping with the NIH Director's themes, ORWH is broadening the focus of the Administrative Supplements Program to include understudied, underreported, and underrepresented (U_3) populations that suffer from a disproportionate burden of disease in research. The U_3 Program applies a translational and interdisciplinary research approach to investigate women's health in the context of relevant biological and social influences on health and disease.

In 2015, the NIH introduced the NIH Policy on Consideration of Sex as a Biological Variable (SABV) in NIH-funded research (NOT-OD-15-102). To maximize the value of publicly funded research for everyone, the NIH expects that 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.

[12] https://orwh.od.nih.gov/
[13] https://orwh.od.nih.gov/research/strategic-plan/
[14] Wang et al. 2013. Left behind: widening disparities for males and females in US county life expectancy, 1985–2010. Population Health Metrics 11: 8
[15] National Academies of Sciences, Engineering, and Medicine. 2016. Improving the Health of Women in the United States: Workshop Summary. Washington, DC: The National Academies Press
[16] National Research Council. 2011. Explaining Divergent Levels of Longevity in High-Income Countries. Washington, DC: The National Academies Press
[17] https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-102.html

The ORWH, in partnership with NIH ICs, will implement the NIH strategic plan, *Moving into the Future with New Dimensions and Strategies: A Vision for 2020 for Women's Health Research*, by: 1) providing support to expand consideration of sex/gender factors in basic, biomedical, and behavioral science studies through ORWH research initiatives, policy initiatives, programs and co-funding; 2) facilitating the translation of basic science findings to clinical research and to clinical practice through ORWH programs such as the Specialized Centers of Research on Sex Differences; 3) maximizing the domestic and global impact of women's health research through alliances with Federal government programs charged with prevention and policy in areas of public health significance such as violence against women and the intersection of violence and HIV/AIDS; and 4) developing innovative career development models, such as the Building Interdisciplinary Research Careers in Women's Health program to ensure the continued supply of scientists with the skills necessary to be productive in emerging multidisciplinary fields of women's health research.

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.[18] Guided by the OBSSR Strategic Plan (Fiscal Years 2017-2021), the office has led or coordinated a number of initiatives. Working with the National Institute on Drug Abuse (NIDA) and other NIH partners, OBSSR held workshops on social and behavioral factors contributing to the opioid crisis. Applications to the "Intensive Longitudinal Analysis of Health Behaviors: Leveraging New Technologies to Understand Health Behaviors" will be reviewed and awarded in FY 2018. This cooperative agreement will seek to explain underlying mechanisms and predict health behaviors within individuals over time utilizing intensive longitudinal, within-person protocols that leverage recent advances in mobile and wireless sensor technologies and big data analytics. Working with the BRAIN Initiative, OBSSR has developed initiatives to improve the precision and temporal density of behavior characterization in humans to improve the linkages between neurobiological and behavioral processes. OBSSR helps support trans-NIH basic behavioral and social sciences research critical to the translation of innovative behavior change strategies. OBSSR also is developing behavioral ontology efforts to improve the standard terminologies needed to facilitate scientific communication and data sharing. Training efforts of OBSSR include Summer Training Institutes (R25s) on various emerging methodologies, K18 awards(short-term awards to experienced scientists who wish to broaden their scientific capabilities) to assist investigators in expanding their transdisciplinary expertise, and the development of training awards in computational and big data analytic approaches for behavioral and social scientists.

Program Portrait: Research to Improve Behavioral and Social Interventions for Opioid Abuse

The Centers for Disease Control and Prevention 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. For FY 2018, OBSSR is working with NIDA and other NIH partners to hold meetings addressing key research needs to address this crisis, including best social and behavioral practices for reducing opioid prescribing, preventing and treating substance abuse, and managing chronic pain to rapidly disseminate this knowledge into

[18] https://obssr.od.nih.gov/

practice. Studies indicate that social and economic pressures, particularly on working class Whites, laid the foundation for "diseases of despair" such as opioid abuse.[19] In addition, prescribing patterns made these drugs more readily available, and current social and behavioral treatments have been inadequate to prevent or treat opioid abuse, or chronic pain syndromes that often co-occur with opioid abuse.[20]

For FY 2019, OBSSR plans to develop and release funding opportunity announcements to address research gaps identified from these meetings 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. These efforts will be integrated within a comprehensive biopsychosocial effort across the NIH to address the opioid crisis, and will include leveraging potential private sector partnerships for conducting this research and encouraging implementation of effective programs.

The FY 2019 President's Budget will prioritize OBSSR's efforts in the opioid crisis, including rapid dissemination of current best practices and new research initiatives to improve social and behavioral interventions to address opioid abuse and pain management. We will continue to support the National Cooperative on Childhood Obesity Research (NCCOR), a collaboration of federal partners and private entities to support research to reduce childhood obesity and will depend on private partners for any new initiatives in FY 2018. Based on the recently completed strategic plan, OBSSR planned a number of initiatives to improve the development of novel intervention approaches from basic science findings, to advance novel measurement, methodology, and data infrastructure efforts, and to facilitate the adoption of effective social and behavioral interventions in practice. Some of these initiatives, such as the Intensive Longitudinal Analysis of Health Behaviors: Leveraging New Technologies to Understand Health Behaviors (U01) are to be awarded in FY 2018 with out year obligations in FY 2019. OBSSR will continue to support planned and existing projects that we have obligated to support and will defer development of any new projects based on the strategic plan.

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.[21] 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.

[19] Case A, Deaton A. Rising morbidity and mortality in midlife among White, non-Hispanic Americans in the 21st century. PNAS 2015; 112: 15078-83.
[20] Dugosh K, Abraham A, Seymour B, McLoyd K, Chalk M, Festinger D. A systematic review on the use of psychosocial interventions in conjunction with medications for the treatment of opioid addiction. J Addict Med 2016; 10:91-101.
[21] https://prevention.nih.gov/

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

In FY 2019, ODP will release its second strategic plan. The first ODP strategic plan was released in February 2014 and charted new directions and, at the same time, built upon and expanded existing programs. The Office has made considerable progress on the priorities identified in the initial plan, and the ODP remains committed to playing an integral role in advancing trans-NIH prevention-related activities. The final FY 2019–2023 Strategic Plan will outline activities coordinated by the ODP to further assess, facilitate, and stimulate research in disease prevention, and disseminate the results of this research to improve public health. Activities will include the coordination of an annual survey to identify activities supported by NIH Institutes, Centers, and Offices related to areas of insufficient evidence identified by the USPSTF. The survey provides an opportunity for Institutes and Centers to consider how their current and planned activities are sufficient, or whether additional activity may be warranted to better inform the development of USPSTF clinical guideline recommendations. The Office will also be able to fully leverage data made available through new portfolio analysis tools created by ODP to identify patterns and trends in the NIH prevention research portfolio, as well as research areas that may benefit from targeted efforts by the NIH Institutes, Centers, and Offices. Furthermore, ODP will continue to coordinate trans-NIH Prevention Scientific Interest Groups to address gaps in prevention research through the development of targeted initiatives such as new funding opportunity announcements, workshops, and research resources.

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 foster an enhanced quality of life and health for the U.S. population.[22] Toward this end, ODS co-funds research grants with NIH 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.

Program Portrait: Vitamin D Standardization Program

The NIH Office of Dietary Supplements (ODS) established the Vitamin D Standardization Program (VDSP) in November 2010. Part of the ODS Vitamin D Initiative,[23] VDSP is an international collaborative effort to promote the standardized laboratory measurement of vitamin D levels to improve clinical and public health practice worldwide. A standardized laboratory measurement is one that is accurate and comparable over time, location, and laboratory procedure. Serum total 25-hydroxyvitamin D [25(OH)D] concentration is used to assess an individual's vitamin D status. Research has consistently shown that there is a great deal of variation in 25(OH)D assays. This assay variation impedes pooling of 25(OH)D results from different studies in systematic reviews for the specific purpose of determining dose-response and/or clinical cut points and to make public health recommendations about

[22] https://ods.od.nih.gov/
[23] https://ods.od.nih.gov/Research/VitaminD.aspx

vitamin D intake. The VDSP was established to correct this problem and has resulted in significant advances in the field (see VDSP News).[24]

Accomplishments include development of a reference measurement system in collaboration with the National Institute of Standards and Technology (NIST); collaboration with CDC to create a Vitamin D Standardization-Certification Program; development of methods to standardize vitamin D values in previously conducted studies; and over 40 publications including these articles.[25],[26]

This ongoing collaboration involves the coordinated efforts of ODS; NIST; CDC; the Vitamin D External Quality Assessment Scheme (DEQAS); the College of American Pathologists (CAP); the American Association for Clinical Chemistry (AACC); the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC); the Laboratory for Analytical Chemistry; Faculty of Pharmaceutical Sciences; Ghent University, Ghent, Belgium; plus national surveys and collaborators around the world. Since the inception of this program, ODS has enlisted the participation of national health surveys from Australia, Canada, Germany, Ireland, Mexico, South Korea, the United Kingdom, and the United States.

The ODS will be working under its new Strategic Plan for 2017-2021. In addition to co-funding research grants on dietary supplements, this budget will support a number of major activities including the congressionally mandated Dietary Supplement Label Database (DSLD), a database of label information from dietary supplements sold in the United States. ODS will continue to support its Analytical Methods and Reference Materials (AMRM) program, also congressionally mandated, in the development, validation, and dissemination of analytical methods and reference materials that are critical tools for quality assurance of dietary supplements. ODS leads efforts to advance knowledge of vitamin D's importance to health and to accurately measure levels of this nutrient in the U.S. population through its Vitamin D Initiative and its Vitamin D Standardization Program (see Portrait of a Program). In 2019, the model used for this initiative will be applied to other nutrients of public health concern such as iron. ODS, in partnership with NCCIH, will continue to support the NIH Botanical Research Centers (BRC) program in 2019.

Office of Research Infrastructure Programs (ORIP)

ORIP advances the NIH mission by making grant awards that support research infrastructure and research-related resources programs[27] to provide a platform for innovation in basic research and translational and clinical studies. 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. ORIP has two scientific divisions, the Division of Comparative Medicine and the Division of Construction and Instruments, which play essential roles in supporting and accelerating biomedical discovery.

[24] https://ods.od.nih.gov/Research/VDSPNews.aspx

[25] Makowski AJ, Rathmacher JA, Horst RL, Sempos CT. Simplified 25-Hydroxyvitamin D Standardization and Optimization in Dried Blood Spots by LC-MS/MS. J AOAC Int. 2017 May 11. doi: 10.5740/jaoacint.17-0086. [Epub ahead of print]

[26] Brooks SPJ, Sempos CT. The Importance of 25-Hydroxyvitamin D Assay Standardization and the Vitamin D Standardization Program. J AOAC Int. 2017 May 11. doi: 10.5740/jaoacint.17-0129. [Epub ahead of print]

[27] https://orip.nih.gov

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.[28] Many major medical advances of the last century involved the use of animal models. Because it would neither be cost effective nor feasible to reproduce these specialized animal resources and expertise at every research institution, these DCM programs are a valuable resource to the entire research community.

DCM also funds research to safeguard the health and welfare of the full range of laboratory animal models from invertebrates to mammals. Non-mammalian models such as fish, worms, and fruit flies are often used to advance the understanding of gene function, protein interactions, and metabolic processes related to human health and disease. Genetically-altered mammals such as mice, rats, and pigs enable the discovery of molecular targets and biomarkers (indicators of biological condition) that are both valuable for pre-clinical testing and as potential therapeutic targets for human diseases models.

DCM supports development of a clinician-scientist workforce by providing training and career development opportunities in translational science and in comparative/laboratory animal medicine and pathology for veterinary scientists, 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, sustaining, and diversifying the biomedical research workforce.

DCM supports the National Primate Research Centers (NPRC) program, which facilitate the use of non-human primates (NHPs) as models of human health and disease for basic and translational biomedical research. In FY 2017, the NPRCs facilitated over 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 2017 included significant advances in HIV/AIDS therapy, other infectious diseases, genetic model development, and regenerative medicine. For example, the NRPCs are actively engaged in creating genetic models of human disease which is critical part of advancing precision medicine. Preclinical studies have addressed long-term safety with lentiviral and adeno-associated virus (AAV) vectors, and have led to new clinical trials for inherited diseases such as Pompe disease, which can lead to death from heart failure in the first year of life.

The NIH Chimpanzee Management Program,[29] managed by DCM, supports long-term 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[30], signed into law in December 2000, required the establishment of a sanctuary system for federally-owned or supported chimpanzees. In November 2015, the NIH announced it will no longer support

[28] https://orip.nih.gov/comparative-medicine
[29] https://dpcpsi.nih.gov/orip/cm/chimpanzee_management_program
[30] http://www.gpo.gov/fdsys/pkg/PLAW-106publ551/html/PLAW-106publ551.htm

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[31]. 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[32] 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 by improving existing animal research facilities or constructing new research facilities, when funds are available.[33]

The Shared Instrumentation (SIG), the High-End Instrumentation (HEI), and the Shared Instrumentation for Animal Research (SIFAR) Grant Programs promote advances in biomedical research that would otherwise be impossible to achieve without access to state-of-the-art instruments. In FY 2017, the Instrumentation Programs funded 109 grants to 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 currently focuses on the needs of the animal research community for modern scientific instruments (SIFAR Grant Program). Such instruments, when specifically configured to support well-defined areas of animal research, enable innovative and potentially transformative investigations. In the past, DCI has supported construction of new buildings and laboratory space for NIH-funded biomedical research. DCI continues to oversee the usage of these NIH-funded facilities, which must be utilized for biomedical research for 10 or 20 years following completion and initial 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.

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)

[31] https://www.nih.gov/about-nih/who-we-are/nih-director/statements/nih-will-no-longer-support-biomedical-research-chimpanzees
[32] https://orip.nih.gov/comparative-medicine/programs/nih-plan-retire-all-nih-owned-and-supported-chimpanzees
[33] https://orip.nih.gov/construction-and-instruments

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.

ORIP's DCI plans to continue to support the Nation's capacity for the conduct of biomedical research. DCI Instrumentation Programs will 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. DCI Programs aligned with several research initiatives as outlined in NIH Director's Themes "Supporting Basic Research to Drive New Understanding of Health and Disease in Living Systems" and "Investing in Translational and Clinical Research to Improve Health".

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).

During FY 2017 the distribution of ILRP awards was as follows:

- 62 awards for the General LRP – 25 new and 37 renewals; and
- Two awards for AIDS LRP – two renewals.

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 15 new recipients for the UGSP Scholarship award and 6 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 2017, funds were used to support trans-NIH initiatives such as Myalgic Encephalomyelitis/Chronic Fatigue Syndrome, Electronic Research Administration (eRA) IT Upgrades, Treatment and Study of Opioid Use Disorders, Pain Management Best Practices Inter-Agency Task Force and RNA-Sequencing in the Undiagnosed Disease Network.

In FY 2019, the DDF will continue funding projects to help uncover new knowledge that prevents, detects, diagnosed, and treats disease and disability, from the common cold to the treating of genetic disorders.

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/treat injuries caused by radiation exposure due to a radiological or nuclear incident. The RNCP also supports drugs to remove internal radionuclide contamination from the body as well as biomarker studies and biodosimetry approaches for mass casualty triage. The RNCP funds initiatives that support basic, translational, and product development services to advance promising MCMs toward FDA licensure, and fosters collaborative efforts between academic, industry, and federal laboratories. Two MCM candidates (Neupogen and Neulasta) have been granted FDA approval for a radiation public health emergency indication, and five MCMs have been granted Investigational New Drug (IND) status. There are currently over 200 MCMs under study in the funded research portfolio.

The Chemical Countermeasures Research Program (CCRP) is designed to prevent and treat injuries caused by acute exposure to potential and existing chemical agents of terrorism and those that may be released from transportation and storage facilities during industrial accidents or natural disasters. The CCRP is a comprehensive collaborative network of academic, industry, and federal laboratories, and leverages the expertise of seven participating NIH ICs to manage the research and development pipeline. Since its inception in 2006, the CCRP researchers have identified more than 100 potential therapeutics to treat injuries caused by various chemicals, obtained numerous patents, published over 1,000 peer-reviewed scientific articles, and has transitioned five products to the HHS Biomedical Advanced Research and Development Authority (BARDA) for advanced development including the anticonvulsant drug midazolam (Versed), which is poised for delivery to the Strategic National Stockpile in 2018.

The Radiation and Nuclear Countermeasures Program will continue to support basic and translational research for the development of promising safe and effective therapeutic and diagnostic candidates towards IND and licensure. Basic research will focus on elucidating mechanisms of radiation injuries and identifying potential new medical countermeasure (MCM) candidates for measuring, minimizing, mitigating and treating the effects of exposure to external radiation sources. The Chemical Countermeasures Research Program will continue to support basic and translational research directed at the development of promising safe and effective therapeutics and antidotes for nerve agents, metabolic poisons, pulmonary agents, toxic industrial chemicals, and vesicating (blistering) agents.

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 $955 million, generating $81 per $1 of NIH support, dramatically leveraging the 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 October 2017, the FNIH, NIH and 11 leading biopharmaceutical companies launched the Partnership for Accelerating Cancer Therapies (PACT), a five-year public-private research

collaboration that is part of the Cancer Moonshot. PACT will initially focus on efforts to identify, develop and validate robust biomarkers - standardized biological markers of disease and treatment response - to advance new immunotherapy treatments that harness the immune system to attack cancer. PACT exemplifies the kind of multi-stakeholder collaboration the FNIH was founded to implement.

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, Federal Advisory Committee Policy, Chief Information Officer, Equity, Diversity and Inclusion, Chief Officer for Scientific Workforce Diversity, Executive Office, Executive Secretariat, NIH Ethics Office, and the Immediate Office of the Director.

Funding will be used to continue efforts to reduce vulnerabilities to risks that exist in all areas at the NIH, including both extramural and intramural research, research information, IT, finance and administration.

OD Operations will continue to support the NIH Director's Challenge Fund. The Office of Intramural Research will use these funds to foster innovation, accelerate intramural science, and encourage trans-NIH collaboration. Initial funding support to the ICs is limited to two years for a pilot project, renewable for up to two more years with additional required support from the host IC depending on progress and competing new applications.

Environmental Influences on Child Health Outcomes (ECHO)

NIH launched the Environmental Influences on Child Health Outcomes (ECHO) program in FY 2016 to enhance the health of children for generations to come. ECHO supports multiple synergistic, longitudinal studies by leveraging, harmonizing, combining, and performing innovative analyses from extant and new maternal/pediatric cohorts' data. The ECHO-wide Cohort consists of standardized data from 83 cohorts of mothers and children to address the effects of a broad range of early life environmental exposures (e.g., physical/chemical, societal, psychosocial, behavioral, biological) on four key pediatric outcomes with high public health impact, including pre-, peri-, and postnatal outcomes; upper and lower airway; obesity; and neurodevelopment; as well as an innovative fifth outcome, positive health, which reflects the positive attributes of healthy growth and development. An additional, primary component of ECHO is the IDeA States Pediatric Clinical Trials Network, whose goal is to provide access for rural and medically underserved children to participate in state-of-the-art clinical trials. This network also builds institutional capacity, provides professional development to researchers, and leverages partnerships with outside academic institutions. In FY 2019, having built its infrastructure, ECHO Cohorts will disseminate research findings, and the IDeA States Pediatric Network will continue to conduct one or more trials, all with the goal of informing programs, practices, and policies to improve the health of children and adolescents in the United States.

The FY 2019 President's Budget request will continue to support Environmental Influences on Child Health Outcomes (ECHO), established in FY 2016 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. An equally important component, the IDeA States Pediatric Clinical Trials Network, embeds clinical trials experts at IDeA state locations and facilitates partnerships among academic institutions, to provide rural and underserved children access to participate in state-of-the-art pediatric clinical trials. ECHO, with awardees in 44 states plus Puerto Rico and District of Columbia, is designed to take full advantage of existing resources, and is intended to be a multi-year program that continues beyond FY 2018.

All of Us Research Program

The *All of Us* Research Program[34], a key component of the Precision Medicine Initiative (PMI) and the 21st Century Cures Act (P.L. 114-255), is building a national research cohort of one million or more U.S. volunteers, in an ambitious effort to improve health. By taking into account individual differences in lifestyle, environment, and biology, researchers will uncover paths toward delivering precision medicine, a revolutionary approach for disease prevention and treatment. In June 2017, the program launched its beta phase and proceeded with an expanded beta phase in November 2017 and will launch nationally in FY 2018. In FY 2018, the consortium to support this transformative approach is present in more than 25 states and comprises more than 200 sites, including ten Regional Medical Centers' networks, six Federally Qualified Health Centers, a network of "direct volunteer" enrollment centers, and several Department of Veterans Affairs medical centers. The sites will engage the public, enroll interested individuals as participants, and collect essential health data and biological specimens. The consortium also includes the Participant Center to enroll direct volunteers, the Participant Technology Systems Center to develop applications and websites for volunteers to participate in the program and ensure security of all participant-facing systems, and the Data and Research Center to acquire, organize, and provide researchers of all types with secure access to datasets and analytic tools. Additionally, the program enhanced its engagement activities with four engagement partner awards in FY 2017 and expanded its efforts in FY 2018 to help motivate the diverse communities they serve to join and remain in the program, with a focus on those historically underrepresented in biomedical research. The FY 2019 budget reflects continued enrollment and retention of participants from across the country, including children; enhancing and increasing capacity for new data types, including genetics and mHealth; building a robust dataset and research platform for researchers, including citizen scientists, young investigators, and researchers from all sectors; catalyzing innovations in research; and implementing groundbreaking return of information practices for participants.

The FY 2019 President's Budget will be used to continue enrollment and retention activities, with a focus on engagement strategies that emphasize diversity, as well as the enrollment of children. FY 2019 funds will be used to collect individual data and biospecimens from

[34] https://allofus.nih.gov/

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 researchers 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 pilot genomic sequencing and the return of genetic information to participants. The program will continue to 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.

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 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.

Next Generation Researchers Initiative

The Next Generation Researchers Initiative (NGRI) began in FY 2017 to address longstanding challenges faced by researchers trying to embark upon and sustain independent research careers. Its goal is to increase funding available for the most promising early-stage investigators, and to provide support for those at risk of losing all NIH funding.

In FY 2019, the Office of the Director will manage a dedicated pool of $100 million that Institutes and Centers will be able to draw on to supplement the NGRI efforts undertaken with their own appropriations. NGRI is one of NIH's highest priorities, and was authorized by Congress in Section 2021 of the 21st Century Cures Act (adding Section 404M to the Public Health Service Act).

Advancing Data Science

In 2012, NIH established the Big Data to Knowledge (BD2K) initiative and created a new Associate Director for Data Science (ADDS) position. In the years since, NIH has established extramural Centers of Excellence, is piloting a "Data Commons," and supports enhanced training of data scientists and bioinformaticians. In FY 2019, NIH would begin the next phase of its data science activities with a $30 million fund, managed by the NIH Chief Data Strategist, who will

replace the position of ADDS and be responsible for coordinating implementation of the first Congressionally required NIH Data Science Strategic Plan. As the Common Fund supports a pilot phase of the NIH Data Commons and establishes a process for trans-NIH data management, the long term support of this infrastructure will reside with the Office of Data Science Strategy (ODSS). While the pilot phase is ongoing, the ODSS budget will support the movement of additional datasets to the cloud environment and will coordinate policies and practices surrounding data management. It will also support novel internship mechanisms to bring additional computational expertise to biomedical research.

NATIONAL INSTITUTES OF HEALTH
Office of the Director

Detail of Full-Time Equivalent Employment (FTE)

OFFICE/DIVISION	FY 2017 Final			FY 2018 Annualized CR			FY 2019 President's Budget		
	Civilian	Military	Total	Civilian	Military	Total	Civilian	Military	Total
Appropriated									
Direct:	715	7	722	734	7	741	734	7	741
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	715	7	722	734	7	741	734	7	741
Reimbursable									
Direct:	-	-	-	-	-	-	-	-	-
Reimbursable:	40	-	40	40	-	40	40	-	40
Total:	40	-	40	40	-	40	40	-	40
Total	755	7	762	774	7	781	774	7	781
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**								
2015	13.0								
2016	12.9								
2017	12.9								
2018	12.9								
2019	12.9								

NATIONAL INSTITUTES OF HEALTH
Office of the Director

Detail of Positions[1]

GRADE	FY 2017 Final	FY 2018 Annualized CR	FY 2019 President's Budget
Total, ES Positions	12	12	12
Total, ES Salary	2,198,108	2,248,445	2,293,414
GM/GS-15	117	120	120
GM/GS-14	154	158	158
GM/GS-13	228	234	234
GS-12	108	111	111
GS-11	45	46	46
GS-10	1	1	1
GS-9	19	20	20
GS-8	2	2	2
GS-7	12	13	13
GS-6	2	2	2
GS-5	1	1	1
GS-4	4	4	4
GS-3	1	1	1
GS-2	2	2	2
GS-1	3	3	3
Subtotal	699	718	718
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	2
Senior Grade	3	3	3
Full Grade	1	1	1
Senior Assistant Grade	0	0	0
Assistant Grade	0	0	0
Subtotal	7	7	7
Ungraded	62	62	62
Total permanent positions	644	663	663
Total positions, end of year	759	778	778
Total full-time equivalent (FTE) employment, end of year	762	781	781
Average ES salary	183,176	187,370	191,118
Average GM/GS grade	12.9	12.9	12.9
Average GM/GS salary	113,466	116,064	118,386

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