

DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH

COMMON FUND (CF)

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BUDGET MECHANISM

Budget Mechanism - Total^{1,2}

(Dollars in Thousands)

MECHANISM	FY 2018 Final		FY 2019 Enacted		FY 2020 President's Budget		FY 2020 +/- FY 2019 CR	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
<u>Research Projects:</u>								
Noncompeting	185	\$132,641	240	\$176,462	271	\$194,184	31	\$17,722
Administrative Supplements	(32)	6,762	(19)	4,375	(15)	3,469	(-4)	-906
<u>Competing:</u>								
Renewal	7	10,840	0	0	0	0	0	0
New	126	156,039	130	161,765	89	98,633	-41	-63,132
Supplements	2	1,128	0	0	0	0	0	0
Subtotal, Competing	135	\$168,007	130	\$161,765	89	\$98,633	-41	-\$63,132
Subtotal, RPGs	320	\$307,411	370	\$342,602	360	\$296,286	-10	-\$46,316
SBIR/STTR	0	0	0	0	0	0	0	0
Research Project Grants	320	\$307,411	370	\$342,602	360	\$296,286	-10	-\$46,316
<u>Research Centers:</u>								
Specialized/Comprehensive	29	\$33,128	29	\$33,524	15	\$16,896	-14	-\$16,628
Clinical Research	10	17,878	8	14,898	6	11,605	-2	-3,293
Biotechnology	1	577	1	565	0	0	-1	-565
Comparative Medicine	2	729	12	4,249	10	3,702	-2	-547
Research Centers in Minority Institutions	0	0	0	0	0	0	0	0
Research Centers	42	\$52,312	50	\$53,236	31	\$32,203	-19	-\$21,033
<u>Other Research:</u>								
Research Careers	1	\$201	0	\$0	0	\$0	0	\$0
Cancer Education	0	0	0	0	0	0	0	0
Cooperative Clinical Research	0	0	0	0	0	0	0	0
Biomedical Research Support	0	0	0	0	0	0	0	0
Minority Biomedical Research Support	0	0	0	0	0	0	0	0
Other	90	181,461	82	166,251	80	161,813	-2	-4,438
Other Research	91	\$181,662	82	\$166,251	80	\$161,813	-2	-\$4,438
Total Research Grants	453	\$541,384	502	\$562,089	471	\$490,302	-31	-\$71,787
<u>Ruth L. Kirchstein Training Awards:</u>								
	<u>FTTPs</u>		<u>FTTPs</u>		<u>FTTPs</u>		<u>FTTPs</u>	
Individual Awards	0	\$0	0	\$0	0	\$0	0	\$0
Institutional Awards	135	17,121	131	17,010	102	13,251	-29	-3,759
Total Research Training	135	\$17,121	131	\$17,010	102	\$13,251	-29	-\$3,759
Research & Develop. Contracts <i>(SBIR/STTR) (non-add)</i>	0 <i>(0)</i>	\$3,394 <i>(0)</i>	0 <i>(0)</i>	\$2,000 <i>(0)</i>	0 <i>(0)</i>	\$1,335 <i>(0)</i>	0 <i>(0)</i>	-\$665 <i>(0)</i>
Intramural Research	0	13,091	0	15,205	0	11,021	0	-4,184
Res. Management & Support <i>Res. Management & Support (SBIR Admin) (non-add)</i>	0 <i>(0)</i>	25,725 <i>(0)</i>	0 <i>(0)</i>	22,862 <i>(0)</i>	0 <i>(0)</i>	17,058 <i>(0)</i>	0 <i>(0)</i>	-5,804 <i>(0)</i>
Construction		0		0		0		0
Buildings and Facilities		0		0		0		0
Total, Common Fund	0	\$600,716	0	\$619,166	0	\$532,967	0	-\$86,199

¹ All items in italics and brackets are non-add entries.

² All Subtotal and Total numbers may not add due to rounding.

MAJOR CHANGES IN THE PRESIDENT'S BUDGET REQUEST

Major changes by budget mechanism and/or budget activity detail are briefly described below. Note that there may be overlap between budget mechanism and activity detail and these highlights will not sum to the total change for the FY 2020 President's Budget for the Common Fund, which is \$86.2 million less than the FY 2019 Enacted level, for a total of \$533.0 million. The FY 2020 President's Budget reflects the Administration's fiscal policy goals for the Federal Government. Within that framework, the Common Fund will pursue its highest research priorities through strategic investments and careful stewardship of appropriated funds.

Research Project Grants (-\$46.3 million; total \$296.3 million): The Common Fund expects to support a total of 360 Research Project Grant (RPG) awards in FY 2020. Estimated awards for FY 2020 include 271 Noncompeting RPGs and the award of 89 Competing RPGs.

Research Centers (-\$21.0 million; total \$32.2 million): The estimated decrease in Common Fund support for Research Centers reflects a planned ramp down of initiatives within the 4D Nucleome and Library of Integrated Network-based Cellular Signatures programs.

Intramural Programs (-\$4.2 million; total \$11.0 million): The estimated decrease in support for Intramural Programs reflects a planned reduction in the Stem Cell Translation Laboratory within the Regenerative Medicine Program, as well as the intramural site of the Undiagnosed Diseases Network.

Research Management and Support (-\$5.8 million; total \$17.1 million): The estimated decrease in Research Management and Support reflects decreased need for these activities as the 4D Nucleome and Library Integrated Network-based Cellular Signatures programs wind down.

Budget by Initiative

**National Institutes of Health
Common Fund by Initiative
(Dollars in Thousands)**

Common Fund Program	FY 2018 Final	FY 2019 Enacted	FY 2020 President's Budget
4D Nucleome	28,629	27,811	203
Technology Development, Biological Validation, Modeling and Pilot Mapping	10,456	9,939	203
Nucleomic, Imaging, and Computational Tool Development	10,588	10,038	0
4D Nucleome Coordination and Integration	7,584	7,834	0
Acute to Chronic Pain Signatures	0	2,402	14,365
Clinical Observation of Pain	0	1,659	8,084
Omics Data Generation Centers	0	200	3,561
Data Integration and Resource	0	543	2,720
All of Us Research Program	67	0	0
Big Data to Knowledge (BD2K)	2,208	109	97
Enhancing the Diversity of the NIH-Funded Workforce	50,603	52,675	47,818
BUILD Initiative	47,581	40,900	31,960
National Research Mentoring Network (NRMN)	1,784	10,100	8,992
Coordination and Evaluation Center (CEC)	1,239	1,675	6,867
Epigenomics	45	0	0
Extracellular RNA Communication	6,555	6,869	5,204
Data Management and Resource/Repository (DMRR)	2,429	1,633	609
Reference Profiles of Human Extracellular RNA	4,007	0	0
Extracellular RNA Biogenesis, Biodistribution, Uptake, and Effector Function	52	0	0
Clinical Utility of Extracellular RNAs as Biomarkers and Therapeutic Agents	66	0	0
Separating exRNA Carrier Subclasses	0	2,620	2,296
Phenotyping Single Vesicle-Associated exRNAs	0	2,617	2,299
Gabriella Miller Kids First Pediatric Research	14,043	13,028	12,956
Genotype-Tissue Expression (GTEx) Resources	577	565	0
Global Health	16,750	15,459	10,296
Medical Education Partnership Initiative (MEPI)	3,000	3,000	0
Human Heredity and Health in Africa (H3Africa)	11,405	10,126	8,653
Cookstove Initiative	2,346	2,333	1,643
Glycoscience	20,327	19,480	11,896
Health Care Systems Research Collaboratory	6,397	1,750	1,558
NIH-HMORN Coordinating Center	2,396	1,750	1,558
Expansion Activities	4,001	0	0
Health Economics	60	0	0
Changing Incentives for Consumers, Insurers, and Providers	44	0	0
Data Infrastructure to Enable Research on Health Reform	17	0	0
High-Risk Research	188,232	183,250	171,908
NIH Director's Pioneer Award	35,698	44,297	48,260
NIH Director's New Innovator Award Program	103,328	88,466	70,938
Transformative Research Award	27,884	29,642	33,075
NIH Director's Early Independence Award Program	21,322	20,845	19,635
Human BioMolecular Atlas Project (HuBMAP)	7,442	15,006	24,065
Technology Development	1,663	4,205	8,141
Human Tissue Mapping	2,756	7,162	11,820
Data Coordination and Integration	3,023	3,639	4,104
Illuminating the Druggable Genome	9,395	12,400	11,920
Knowledge Management Network	1,571	3,598	3,212
Data and Resource Generation Centers	7,284	8,236	8,222
Dissemination and Outreach Hub	541	566	485
Knockout Mouse Phenotyping Program	11,542	11,000	9,793
Data Coordination	1,256	1,262	1,123
Production, Characterization, Cryopreservation, Phenotyping, and Data Release	10,286	9,738	8,669

**National Institutes of Health
Common Fund by Initiative
(Dollars in Thousands)**

Common Fund Program	FY 2018 Final	FY 2019 Enacted	FY2020 President's Budget
Library of Integrated Network-Based Cellular Signatures (LINCS)	10,175	10,000	0
Metabolomics	12,387	12,403	11,040
Metabolomics Data Sharing and Program Coordination Core	4,580	4,896	4,401
Metabolomics Data Analysis	7,807	7,507	6,639
Molecular Transducers of Physical Activity	28,720	36,336	41,064
Study Coordination and Data Management	7,637	4,448	4,374
Molecular Transducers of Physical Activity in Humans – Clinical Study	9,390	12,149	14,736
Chemical Analysis of Biological Samples	10,262	18,311	19,344
Characterization of Human Molecular Transducers of Physical Activity in Model Systems	1,431	1,428	2,610
New Models of Data Stewardship	39,152	27,153	15,031
NIH Data Commons Pilot Phase	18,147	17,153	15,031
Science Technology Research Infrastructure for Discovery, Experimentation, and Sustainability (STRIDES)	21,005	10,000	0
NIH Center for Regenerative Medicine (NCRM)	5,600	7,600	5,074
Cell Therapy Projects	600	600	534
Stem Cell Translation Laboratory (SCTL)	5,000	7,000	4,540
Protein Capture	1,332	0	0
Production of anti-TF antibodies	1,327	0	0
New Reagent Technology Development and Piloting	5	0	0
Science of Behavior Change	12,215	12,617	198
Somatic Cell Genome Editing	14,153	35,785	34,663
S.P.A.R.C. - Stimulating Peripheral Activity to Relieve Conditions	48,842	51,268	42,080
Functional and Anatomical Mapping of Five Organ Systems	25,483	25,405	18,611
Next Generation Tools	13,588	10,079	5,412
Off-Label Use of Existing Market-Approved Technology for Small Markets	2,054	9,205	8,195
Data Coordination	7,717	6,579	5,857
Leveraging SPARC in support of HEAL	0	0	4,006
Strengthening the Biomedical Research Workforce	2,567	0	0
Transformative High Resolution Cryo-Electron Microscopy (CryoEM)	26,263	14,900	33,652
National Centers for Cryo-Electron Microscopy	25,745	14,366	33,182
Training Cryo-electron Microscopists	518	534	470
Undiagnosed Diseases Network	28,948	28,900	21,099
Strategic Planning Funds	7,490	9,829	6,988
Subtotal Common Fund	600,716	608,593	532,967
New Initiatives in Common Fund	0	10,573	0
Total Common Fund	600,716	619,166	532,967

Justification of Budget Request

Common Fund

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

Budget Authority (BA):

	FY 2018 <u>Final</u>	FY 2019 <u>Enacted Level</u>	FY 2020 President's <u>Budget</u>	FY 2020 +/- <u>FY 2019</u>
BA	\$600,716,000	\$619,166,000	\$532,967,000	-\$86,199,000
FTE	0	0	0	0

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

Common Fund Narrative

Overview

The NIH Common Fund (CF) supports research in areas of emerging scientific opportunities, rising public health challenges, and knowledge gaps that deserve special emphasis; that would benefit from strategic coordination and planning across NIH Institutes and Centers (ICs); and that are designed to address specific, high-impact goals and milestones within a 5- to 10-year timeframe.¹ Collectively, these programs represent strategic investments aimed at solving problems or building resources to affect research throughout the entire biomedical research enterprise. CF programs attempt to change the way science is conducted through the establishment of new scientific fields or paradigms, the development of new and innovative technologies that change the way scientists approach their work, or the generation of comprehensive data sets or other resources that catalyze all research and enable discovery.

CF programs capitalize on some of the most exciting and promising scientific opportunities in biomedical research today, all of which require creative and innovative approaches to overcome challenges and foster new discoveries. Therefore, the CF is an excellent example of how NIH supports and promotes science that addresses the NIH Director's theme for FY 2020, *From Inspiration to Innovation*. Within this theme, many CF programs address the priority areas for NIH. Each of these programs is described in more detail within the Selected Program Descriptions and Accomplishments section.

- *Transformational Tools and Technologies*: Transformational tools and technologies are an integral part of many CF programs. Some of the cutting-edge tools and technologies currently being developed with CF support will allow researchers to perform safe and effective precision genome editing to treat human diseases, or precisely stimulate

¹ <https://commonfund.nih.gov/>

peripheral nerves to control organ function and relieve symptoms of many different conditions. Another program is pioneering new models and approaches for storing, accessing, and analyzing vast amounts of biomedical data to benefit all researchers and catalyze discovery. CF is also enabling wide-spread access to potentially transformative but prohibitively expensive tools and technologies, such as cryo-electron microscopy for determining protein structure.

- *Building on Basic Science:* Many CF programs build foundational resources and establish fundamental biological principles, which can then catalyze research broadly. As one example, CF is creating a data resource to catalogue all known information about understudied proteins within several important protein families and is beginning to elucidate their functions. This investment in basic science is anticipated to spur additional research and accelerate drug discovery.
- *Exploring the Next Frontier:* CF programs are exploring newly emerging, cutting-edge areas of science that may lead to entirely new ways to promote health and treat or cure diseases. One CF program is leading the way in understanding how DNA is arranged in the nucleus of a cell over time and how that organization affects development and disease. The Common Fund's High Risk, High Reward awards support exceptionally creative scientists proposing innovative and transformative research; many of these awards are investigating questions that push the boundaries of science in a variety of biomedical research disciplines.

To date, many CF programs have had notable achievements. The Human Microbiome Program, completed in FY 2017, is an excellent example of a CF program that aimed to transform research capabilities and develop new biological paradigms. Largely as a result of this program and collaborative international efforts, our understanding of the human body has been transformed. We now understand that each of us is an ecosystem in which our microbial cells far outnumber our human cells and that our microbes have a profound impact on our health. The Epigenomic Roadmap Program, also completed in FY 2017, provided foundational information about the ways in which genes are turned on or turned off in many different human cell types. The Epigenomics program has changed the way that we understand gene regulation and its impact on health, with many epigenetic changes occurring early in life but contributing to disease years or decades later.

Significant efforts are being made to evaluate programs during their lifetime, and outcomes are assessed as programs end. Continuous evaluation during program implementation allows flexibility to modify program management and/or budgets in response to rapidly evolving scientific landscapes, technical challenges, or other unforeseen challenges or opportunities. Funds will be available in FY 2020 for new challenges and opportunities as programs end, move to other sources of support, or require decreased support as indicated by evaluative data.

Over the next five years, priorities for the CF collectively address three overarching goals:

- Invest in broadly useful, high impact data, methods, and tools that are expected to yield new scientific paradigms, solve cross-cutting challenges, and catalyze further research across the NIH
- Develop and test new models for effective data stewardship that can be adopted NIH-wide to increase the impact and extend the value of data

- Establish and evaluate new funding mechanisms that foster innovation and discovery across the workforce, particularly for early stage investigators

Overall Budget Policy: The FY 2020 President's Budget Request for the CF is \$533.0 million, a decrease of \$86.2 million or 13.9 percent compared to the FY 2019 Enacted level. This decrease reflects the planned ramping down of several programs and initiatives, and allows for the expansion of several high-priority activities within existing programs, including the Transformative Cryo-Electron Microscopy Program, Human BioMolecular Atlas Project (HuBMAP), and Molecular Transducers of Physical Activity Consortium (MoTrPAC).

Selected Program Descriptions and Accomplishments

The CF supports approximately 30 programs, most of which consist of a series of integrated initiatives that collectively address a set of goals aiming to transform the way research is conducted, the way that health and disease are understood, and/or the way that diseases are diagnosed or treated. These programs span a wide range of biomedical research fields, and encompass basic, translational, and clinical research. Highlighted below are programs that exemplify the science to be supported in FY 2020, and/or which involve significant budget shifts compared to FY 2019. Also included are CF programs that have achieved the goals set when program plans were originally developed and are now identifying additional scientific challenges and opportunities that may be addressed in a second stage of support. Two CF programs -- Library of Integrated Network-Based Cellular Signatures (LINCS) and Genotype-Tissue Expression Resources (GTEx) -- will receive their final year of support in FY 2019; funds are therefore not requested in FY 2020. Information on these programs and their accomplishments can be found on the program websites.²

4D Nucleome (4DN)

It is estimated that each human cell contains approximately 2 meters (6.5 feet) of linear DNA, squeezed inside the cell's microscopic nucleus. We now know that DNA is not randomly arranged within the nucleus; instead, the organization of the nucleus is tightly controlled, and early observations suggests that this organization plays an important role in cell function. However, specific consequences of this organization are not well understood. The Common Fund's 4D (four dimensional) Nucleome program aims to understand principles underlying nuclear organization in space (three dimensions) and time (the fourth dimension), the role nuclear organization plays in gene expression and cellular function, and how changes in nuclear organization affect normal development as well as various diseases.³ This program is developing technologies, resources, and data that enable the study of the 4D Nucleome, including novel tools to explore the dynamics of nuclear architecture and its role in gene expression programs, and computer models to examine the relationship between nuclear organization and function in both normal development and disease. It will also develop reference maps of nuclear architecture in a variety of cells and tissues. Comparing these maps between healthy and diseased cells is expected to lead to new clues about genomic changes that

² <https://commonfund.nih.gov/LINCS>, <https://commonfund.nih.gov/GTEx>

³ <https://commonfund.nih.gov/4Dnucleome>

occur in various pathologies. Funding for the 4DN program began in FY 2015 and funding for the first stage will end in FY 2019.

Budget Policy: The FY 2020 President’s Budget Request is \$0.2 million for the 4DN program, a decrease of \$27.6 million or 99.3 percent compared to the FY 2019 Enacted level. This decrease reflects a planned ramping down as stage 1 is closed out, with stage 2 anticipated to launch in FY 2021.

Acute to Chronic Pain Signatures (A2CPS)

In many individuals, acute pain from injury, surgery, or disease persists beyond the initial insult and may last for months, years, or throughout life. The mechanisms driving the transition from acute pain to a chronic state are poorly understood. The Acute to Chronic Pain Signatures (A2CPS) program focuses on identifying “signatures” predictive of the transition from acute to chronic pain.⁴ Understanding and identifying at-risk patients could result in preventive treatment plans that may greatly reduce the prevalence of chronic pain and reduce reliance on opioids. Although supported via the Common Fund, the program is part of the trans-NIH HEAL (Helping to End Addiction Long-term) Initiative, an aggressive effort to speed scientific solutions to stem the national opioid public health crisis.⁵ The program therefore represents an additional investment on the part of NIH to address pain and opioid addiction. A2CPS will support two clinical studies that follow patients after an acute pain event related to a surgical procedure or musculoskeletal trauma. The studies will use advances in imaging, high-throughput biomedical measurements, sensory testing, and psychosocial assessments to identify potential signatures of the transition from acute to chronic pain or resilience to chronic pain. After a planning year in FY 2019, A2CPS will scale up in FY 2020 as it implements the two clinical studies and begins recruiting study participants.

Budget Policy: The FY 2020 President’s Budget Request is \$14.4 million for the A2CPS program, an increase of \$12.0 million or 498.1 percent compared to the FY 2019 Enacted level. This increase will support the launch of two clinical trials to follow patients after an acute pain event.

Big Data to Knowledge (BD2K)

As biomedical tools and technologies rapidly improve, researchers are producing and analyzing an ever-expanding amount of complex biological data called “big data.” As one component of an NIH-wide strategy, the CF, in concert with NIH ICs, is supporting the Big Data to Knowledge (BD2K) program.⁶ BD2K has focused on facilitating broad use of biomedical big data, developing and disseminating analysis methods and software, enhancing training relevant for large-scale data analysis, and establishing centers of excellence for big data. The remaining activities within these initiatives will focus on making the products of research usable, discoverable, and disseminated to intended end-users. In FY 2020, the BD2K budget will decrease due to the planned ramping down of several initiatives. In addition, funding for the

⁴ <https://commonfund.nih.gov/pain>

⁵ <https://www.nih.gov/research-training/medical-research-initiatives/heal-initiative>

⁶ <https://commonfund.nih.gov/bd2k>

NIH Data Commons Pilot Phase is requested under a new programmatic title, “New Models of Data Stewardship.” As described below, this reflects the substantial shift from BD2K goals that the Data Commons Pilot encompasses as well as new goals that have been established via the Science and Technology Research Infrastructure for Discovery, Experimentation, and Sustainability (STRIDES) initiative.

Budget Policy: The FY 2020 President’s Budget Request is \$0.1 million for the BD2K program, a decrease of \$12,000 or 10.8 percent compared to the FY 2019 Enacted level. This decrease reflects the planned ramping down of BD2K activities as funds for data science are shifted to the New Models of Data Stewardship program.

Gabriella Miller Kids First Pediatric Research

The Gabriella Miller Kids First Pediatric Research program (Kids First) aims to catalyze pediatric research by making large amounts of high-quality genetic and clinical data from pediatric patient cohorts widely available and easy to use for the entire biomedical research community.⁷ The Kids First program supports a data resource that integrates data from patients with childhood cancer or structural birth defects; these conditions have profound, lifelong effects on patients and their families. The information in the Kids First Data Resource consists of genetic and clinical information from patients, and genetic information from their parents. Researchers analyze these data to understand how genetic mutations lead to birth defects or to cancer, and to discover whether there are shared contributions to both conditions. There is considerable scientific evidence that examining childhood cancer and structural birth defects data together will uncover new connections between them that would not have been discovered if they were examined independently. Having these data sets together in a single, widely accessible resource is anticipated to facilitate new discoveries and novel ways of thinking about these conditions. Importantly, the Kids First Data Resource is poised to accept many additional existing data sets, increasing researchers’ ability to detect genetic changes that contribute to many different conditions. To date, funds for the Kids First program have been used to support research centers to perform genetic sequencing of samples from over 30 patient cohorts representing a wide range of diseases and conditions, as well as support to build the Kids First Data Resource. In accordance with Gabriella Miller Kids First Research Act, all appropriated Kids First funds have been used to support pediatric research. In FY 2020, support for the Kids First Data Resource will be used to enable collaboration with the NIH Data Commons Pilot to establish a Pediatric Data Commons, providing a pathway to efficiently share and analyze trans-NIH pediatric data.

Budget Policy: The FY 2020 President’s Budget Request is \$13.0 million for the Kids First program, a decrease of \$0.1 million or 0.6 percent compared to the FY 2019 Enacted level. Programmatic funding from the Pediatric Research Initiative Fund remains constant at the \$12.6 million statutory level in both FY 2019 and FY 2020, with the overall \$0.1 million decrease resulting from a reduction in funds requested in the regular Common Fund appropriation to support research management activities.

High-Risk, High-Reward Research (HRHR)

⁷ <https://commonfund.nih.gov/KidsFirst>

Research that aims to transform science is inherently difficult and risky but necessary to accelerate the pace of scientific discovery and advance human health. While all CF programs encourage risk-taking to overcome significant challenges in biomedical research, most programs designate funds for particular high-risk objectives or methods. The High-Risk, High-Reward Research (HRHR) program takes a different approach by supporting exceptionally creative scientists proposing innovative and transformative research in any scientific area within the NIH mission through four complementary initiatives: the Pioneer Award, New Innovator Award, Transformative Research Award, and Early Independence Award.⁸ The Pioneer Award supports extraordinarily creative scientists who propose bold approaches to addressing major challenges in biomedical and behavioral research. The New Innovator Award supports exceptionally creative, early career investigators who propose innovative, high-impact projects. The Transformative Research Award supports unconventional, paradigm-shifting research projects that are inherently risky and untested and allows teams of principal investigators when appropriate. The Early Independence Award bypasses the traditional post-doctoral training period by helping establish independent scientific careers for newly graduated scientists with the intellect, creativity, drive, and maturity to flourish independently.

Budget Policy: The FY 2020 President's Budget Request is \$171.9 million for the HRHR program, a decrease of \$11.3 million or 6.2 percent compared to the FY 2019 Enacted level. This level of support will allow NIH to continue to invest in high risk research with the potential for extraordinary impact.

Human BioMolecular Atlas Project (HuBMAP)

In living organisms consisting of multiple cell types, diverse cells with different functions and structures develop as we grow and age. The Human BioMolecular Atlas Project (HuBMAP) aims to catalyze development of an open, global framework for comprehensively mapping the human body at the level of individual cells.⁹ HuBMAP will show proof of principle via preliminary mapping activities of a few organs and distributed systems with existing and emerging technologies, it will establish and validate innovative technologies, and it will demonstrate the utility of these data. HuBMAP will only map a small percentage of the human body (tens of millions of cells out of the trillions in the human body), but it will work with the broader community to establish the tools, infrastructure, and standards with the expectation that the research community will continue to build upon these maps in the future. Ultimately, these maps will form part of a resource conceptually like Google Maps for the human body and, as this data resource grows over time, will result in a complete human body map at the cellular level. If successful, these maps will enable and encourage future studies and new insights into inter-individual variation and tissue changes across the lifespan and health/disease continuum. This program is expected to leverage close partnership with companies and international funding agencies so that multiple funding sources are applied to this global challenge. HuBMAP started in FY 2018 and entered a scale-up phase in FY 2019 that will continue through FY 2020. Support for technology development, tissue mapping, and data coordination will continue to ramp up as improvements are made to generate high quality tissue maps.

⁸ <https://commonfund.nih.gov/highrisk>

⁹ <https://commonfund.nih.gov/HuBMAP>

Budget Policy: The FY 2020 President’s Budget Request is \$24.1 million for the HuBMAP program, an increase of \$9.1 million or 60.4 percent compared to the FY 2019 Enacted level. This increase will support the planned ramp up of technology development, tissue mapping, and data coordination efforts.

Molecular Transducers of Physical Activity

Physical activity has been demonstrated to contribute to health via a wide variety of measures, and lack of physical activity is at the root of many common chronic health problems. Despite this, we have a poor understanding of the molecular mechanisms by which the benefits of physical activity are realized. A better understanding of the molecules that underlie the benefits of physical activity could lead to the development of improved, personalized exercise recommendations as well as therapies for individuals who are unable to exercise due to illness or disability. The development of a molecular map of physical activity is a daunting task but is now made possible because of recent advances in several powerful high-throughput analytic approaches, including metabolomics, proteomics, genomics, transcriptomics, and epigenomics. The Molecular Transducers of Physical Activity in Humans Consortium (MoTrPAC) will leverage these advances to improve our understanding of the molecular mechanisms by which physical activity improves health.¹⁰ This program will extensively catalogue the biological molecules affected by physical activity in people, identify some of the key molecules that underlie the systemic effects of physical activity, and characterize the function of these key molecules. Support for MoTrPAC will increase in FY 2020 as clinical studies of exercise in humans will continue to ramp up.

Budget Policy: The FY 2020 President’s Budget Request is \$41.1 million for MoTrPAC, an increase of \$4.7 million or 13.0 percent compared to the FY 2019 Enacted level. This increase in support will allow continued growth of clinical studies to identify key molecules that contribute to health benefits of physical activity.

Program Portrait: New Models of Data Stewardship (NMDS)

FY 2019 Level: \$27.2 million
FY 2020 Level: \$15.0 million
Change: -\$12.2 million

The New Models of Data Stewardship (NMDS) program encompasses goals that began as part of the BD2K program but which have expanded as a result of extensive strategic planning at NIH and as a result of the early work of the NIH Data Commons Pilot. The NMDS program is designed to enhance biomedical discovery and improve efficiency through new digital data management strategies.¹¹ These strategies contribute to NIH efforts to develop and sustain a modern biomedical data ecosystem as described in the NIH Strategic Plan for Data Science¹² by making data for research findable, accessible, interoperable, and reusable (FAIR) in the cloud environment. NMDS includes two integrated initiatives, the NIH Data Commons Pilot Phase and Science and Technology Research Infrastructure for Discovery, Experimentation, and Sustainability (STRIDES). The overarching goal of the NIH Data Commons Pilot Phase is to accelerate new biomedical discoveries by developing and testing a cloud-based platform where investigators can store, share, access, connect, and interact with digital objects (data, software, etc.)

¹⁰ <https://commonfund.nih.gov/MolecularTransducers/>

¹¹ <https://commonfund.nih.gov/data>

¹² <https://datascience.nih.gov/strategicplan>

generated from biomedical and behavioral research. The STRIDES initiative was launched in FY 2018 and established partnerships with commercial cloud service providers (CSPs) to reduce economic and technological barriers to accessing and computing on large biomedical data sets to accelerate biomedical advances. STRIDES supports NIH Data Commons Pilot Phase investigators and staff to provide cloud storage and services for data sets used as test cases to develop the Data Commons; data sets that are made available via STRIDES will conform to community-endorsed technical standards that will make them FAIR. Partnerships with CSPs through the STRIDES initiative will be leveraged by non-Common Fund programs across NIH to reduce economic and technological barriers to access, store, and compute on large biomedical data sets in the digital cloud ecosystem. Plans for these activities continue in FY 2020, with funds used to support migration of additional data sets to a cloud environment. No funding is requested for STRIDES in FY 2020 pending an assessment of community uptake of cloud computing.

Program Portrait: Stimulating Peripheral Activity to Relieve Conditions (SPARC)

FY 2019 Level: \$51.3 million

FY 2020 Level: \$42.1 million

Change: -\$9.2 million

Electrical manipulation of nerve signals (called neuromodulation) that control organ function has been recognized as a potentially powerful way to treat many diseases and conditions, such as hypertension, heart failure, gastrointestinal disorders, type II diabetes, inflammatory disorders, and more. However, neural control of end-organ function is poorly understood. Consequently, efficacy of neuromodulation therapies has been inconsistent and side effects are difficult to predict. The Stimulating Peripheral Activity to Relieve Conditions (SPARC) program is a high-risk, goal-driven basic research endeavor to develop foundational knowledge and technologies for an entirely new class of therapeutic devices that have the potential to precisely treat a wide variety of diseases and conditions.¹³ Launched in FY 2015, the SPARC program supports interdisciplinary teams of investigators to deliver neural circuit maps and models that illustrate how peripheral nerves control organ function, along with technologies to isolate, measure, and manipulate nerve-organ interactions. Through partnerships with industry and physicians, the program supports human clinical studies that will serve to validate or refine neural circuit maps built from animal data. The mapping data, models, technologies, and protocols generated will be publicly available through an online resource to share tools and advancements. The program is designed to be iterative and dynamic, with the novel technologies informing mapping efforts, and mapping results defining new technology requirements. This program uses Other Transaction Authority for selected initiatives, which allows high levels of flexibility, responsiveness to adjust program components, and ability to engage with non-traditional partners as needed to address specific, high-risk goals within this complex, interdisciplinary, and rapidly evolving area of science. In FY 2020, SPARC will develop and refine neural circuit maps and models of the innervation of five organs. This will include efforts launched in FY 2019 in support of the HEAL Initiative to study pain pathways.

Program Portrait: Transformative High Resolution Cryo-Electron Microscopy

FY 2019 Level: \$14.9 million

FY 2020 Level: \$33.7 million

Change: \$18.8 million

Knowing the structure of a molecule reveals important information about how it functions and can provide insight into potential drug targets for fighting disease. Cryo-electron microscopy (cryo-EM) is a method used to image frozen biological molecules without the use of chemicals that can alter protein structure, providing a more accurate picture of the molecules and greater understanding of biological function. Additionally, recent technological advances have extended cryo-EM resolution to the atomic level, making it possible to image small molecules in great detail. However, the high cost of cryo-EM limits the method's availability to researchers. The Transformative High Resolution Cryo-Electron Microscopy program aims to provide nationwide access for researchers to cryo-EM through the creation of national service centers, improvement of technology, and the development of an expert workforce.¹⁴ In FY 2020, the Transformative High Resolution Cryo-Electron Microscopy program will increase

¹³ <https://commonfund.nih.gov/sparc>

¹⁴ <https://commonfund.nih.gov/CryoEM>

support for national service centers to provide biomedical researchers access to state-of-the-art equipment, technical support, and instruction for the production and analysis of high-resolution cryo-EM data.

Strategic Planning and Evaluation

The CF's 10-year restriction on support for any given program is designed to create a churn of funds so that new challenges and opportunities may be addressed each year. Strategic planning is therefore a critical activity for the CF. Conducted annually, the strategic planning process allows the CF to be nimble and adaptive to the changing scientific landscape. This process is a collaborative activity between the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI)/Office of Strategic Coordination (OSC) and the ICs. CF strategic planning encompasses both the identification of broadly relevant scientific challenges and opportunities for strategic investments using the CF (Phase 1 planning), and the articulation of specific goals, milestones, and implementation plans for each broadly defined potential program topic identified in Phase 1 (Phase 2 planning). Phase 1 strategic planning often involves gathering broad input from external stakeholders with diverse expertise as well as internal discussions about shared challenges and emerging opportunities. Phase 2 strategic planning often involves more specific consultations with external experts, analysis of NIH and worldwide portfolios of research on the given topic, and literature reviews to articulate specific gaps and areas of research where opportunities for transformative progress are possible.

Planning for new activities in FY 2020 involved discussions with NIH Leadership, NIH Institute and Center Directors, and DPCPSI Leadership about high-priority ideas that may be suitable for CF support. These discussions revealed enthusiasm for developing high-priority initiatives in FY 2020 that extend from existing CF programs and leverage previous investments. Collectively, these new activities capitalize on emerging scientific opportunities, leverage novel technologies, and address urgent public health needs.

Since CF programs are goal driven, evaluation is critical and increasingly important as more programs near the end of their support period. Evaluation is conducted as a partnership between DPCPSI/OSC and the ICs, and it includes both formal and informal evaluative activities. Informal evaluation involves convening grantees and NIH-wide teams to review progress, discuss new challenges, and develop strategies to adapt as part of routine program management. It also involves gathering input from external consultants and using their input, together with internal analysis, to help guide the implementation of the program. Formal evaluations involve the development of baseline data for new programs and the development of multiple metrics of outcomes. The utility of data, resources, technologies, and other program outputs is assessed through surveys, expert opinion, and the analysis of bibliometric data such as citation analyses.