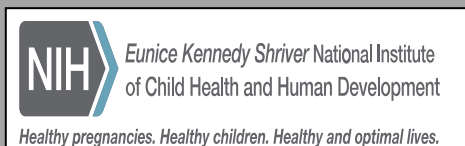


*Eunice Kennedy
Shriver* National
Institute of Child
Health and
Human
Development

CONGRESSIONAL JUSTIFICATION
FY 2022

Department of Health and Human Services
National Institutes of Health



DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)

<u>FY 2022 Budget Table of Contents</u>	<u>Page No.</u>
Director's Overview.....	3
IC Fact Sheet.....	9
Major Changes in Budget Request	11
Budget Mechanism Table	12
Appropriations Language.....	13
Summary of Changes.....	14
Budget Graphs	15
Organization Chart.....	16
Budget Authority by Activity	17
Justification of Budget Request	18
Program Descriptions	18
Appropriations History	27
Authorizing Legislation	28
Amounts Available for Obligation.....	29
Budget Authority by Object Class	30
Salaries and Expenses.....	31
Detail of Full-Time Equivalent Employment (FTE)	32
Detail of Positions.....	33

Director's Overview

On January 20, 2020 the first U.S. case was diagnosed with coronavirus disease 2019 (COVID-19), and the disease swept swiftly across the country. In less than a year, over half a million Americans died. The biomedical research community mobilized rapidly in response to the pandemic. Within weeks, scientists developed new protocols to analyze clinical data and pivoted existing experiments to contribute to the growing understanding of how the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) works and how best to slow its spread. The biomedical research infrastructure, built steadily over many years, facilitated this extraordinary response. Research networks, registries, data analysis methods, scientific collaborations, and a deep knowledge base in basic and clinical sciences are employed to meet this public health crisis. This robust infrastructure also supports the continuing research response to other longstanding and persistent public health issues.



Director: Diana W. Bianchi, M.D.

The *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) is the leading Federal agency for biomedical research focused on the health needs of women, children, and individuals with disabilities. NICHD's mission is to *“lead research and training to understand human development, improve reproductive health, enhance the lives of children and adolescents, and optimize abilities for all.”* NICHD's expertise and research infrastructure help to ensure that children, pregnant women, and people with disabilities are fully included in the rapid response to public health emergencies.

NICHD is using its clinical network infrastructure to rapidly initiate research projects to respond to the COVID-19 crisis. Scientists at NICHD's long-standing Maternal-Fetal Medicine Units (MFMU) Network,¹ established to support clinical trials in maternal-fetal medicine and obstetrics, are analyzing the medical records of up to 24,500 women to assess pregnancy outcomes related to COVID-19. Results indicate that pregnant women who were severely ill with COVID-19 had a higher incidence of cesarean delivery, postpartum hemorrhage, preeclampsia, and preterm birth.² Network scientists also found that transmission of SARS-CoV-2 from mother to child was rare, with one percent of newborns testing positive for the virus.² At eight sites within the NICHD-funded Global Network for Women's and Children's Health Research,³ researchers developed a study to estimate the prevalence of SARS-CoV-2 infection during pregnancy. Using antibody testing at delivery, the scientists will compare the maternal, fetal, and neonatal outcomes of infected women to those of non-infected women. NICHD's Perinatology Research Branch is studying the effects of COVID-19 on pregnant women who give birth at the Detroit Medical Center.⁴ They showed that placental cells lack the cellular receptor that is necessary for SARS-CoV-2 to enter a cell, which may explain why there are few cases of pregnant women transmitting COVID-19 to their fetuses.

¹ mfmunetwork.bsc.gwu.edu/PublicBSC/MFMU/MFMUPublic/

² www.nichd.nih.gov/newsroom/news/012821-GRAVID

³ www.nichd.nih.gov/research/supported/globalnetwork

⁴ irp.nih.gov/pi/roberto-romero

We do not yet fully understand how COVID-19 affects children. For some children, exposure to the SARS-CoV-2 virus leads to Multisystem Inflammatory Syndrome in Children (MIS-C), a severe and sometimes fatal inflammation of organs and tissues. NICHD and two other National Institutes of Health (NIH) Institute partners are supporting the Collaboration to Assess Risk and Identify loNG-term outcomes for Children with COVID (CARING⁵ for Children with COVID), which will assess both short- and long-term effects of MIS-C and other severe illness related to COVID-19 in children, including cardiovascular and neurodevelopmental complications. In addition, with support through NIH's Rapid Acceleration of Diagnostics Radical (RADxSM-rad) initiative,⁶ research studies are underway to identify predictive biomarkers to indicate which children may be at risk for later developing MIS-C.⁷ At the outset of the pandemic, researchers in NICHD's Pediatric Trials Network (PTN) (supported through the Best Pharmaceuticals for Children Act) quickly began researching the dosing and safety of drugs being used to treat children with COVID-19.⁸ Because many of these drugs were never previously tested in children, PTN investigators are collecting information on side effects and patient outcomes, as well as analyzing blood samples from routine medical procedures to understand how children of all ages metabolize these medications. The budget request includes funds for research on MIS-C and the spectrum of SARS-CoV-2 risks in children, which could augment current studies to enable increased enrollment, long-term follow up, and streamlined data sharing.



Although many children with COVID-19 experience a mild illness, the small number who develop MIS-C become seriously ill. Almost all require admission to the ICU. Because MIS-C does tend to occur several weeks after exposure to the virus, MIS-C seems to be associated with an over-active inflammatory response.

NICHD is working through the NIH-wide RADxSM-Underserved Populations (RADxSM-UP) initiative to understand the factors associated with disparities in COVID-19 morbidity and mortality. These efforts focus in part on increasing access to and use of testing among underserved populations, including individuals with intellectual and developmental disabilities (IDD). Funding from RADx-UP is supporting a team of NICHD researchers to help determine best practices for prevention, testing, and contact tracing for individuals with IDD in regional school systems. In addition, NICHD is leading a program through RADx-UP that will support researchers to develop and evaluate COVID-19 diagnostic testing approaches for children and staff in underserved and vulnerable communities, facilitating a safe return to in-person schooling. In April 2021, \$33 million in awards were made for this program, with additional awards anticipated in Summer 2021.⁹

While the COVID-19 crisis moved to the forefront of scientific research efforts, pregnant women, children, and people with disabilities continue to face other persistent public health

⁵ caring4kidswithcovid.nih.gov/

⁶ www.nih.gov/research-training/medical-research-initiatives/radx/radx-programs

⁷ www.nichd.nih.gov/newsroom/news/122120-prevail-kids

⁸ pediatrictrials.org/

⁹ www.nih.gov/news-events/news-releases/nih-funded-covid-19-testing-initiative-aims-safely-return-children-person-school

concerns. Maternal mortality is higher in the United States than in other industrialized nations, and many of these deaths may be preventable. Maternal death and severe maternal morbidity are significantly more likely to occur among women in racial and ethnic minority groups and women in rural areas. NICHD is co-leading a new trans-NIH initiative entitled Implementing a Maternal health and PRegnancy Outcomes Vision for Everyone (IMPROVE).¹⁰ IMPROVE is using an integrated approach to understand biological, behavioral, sociocultural, and structural factors contributing to maternal morbidity and mortality by building an evidence base for improved care and outcomes in specific populations and regions of the country. In September 2020, NIH made awards to institutions across the country to carry out the first phase of this multipronged, innovative research initiative. The President’s Budget requests additional funds to expand the IMPROVE initiative to support research to mitigate preventable maternal mortality, decrease severe maternal morbidity, and promote health equity.

Methodological innovation by scientists at the NICHD-funded Population Health Centers yielded early warnings of rising U.S. maternal mortality, including disparate impacts among some groups.¹¹ Researchers mobilized NICHD’s clinical research infrastructure to hasten the development of strategies to prevent placental complications, preeclampsia, thromboembolism, postpartum hemorrhage, and other serious conditions. For example, NICHD’s MFMU network is conducting a clinical trial of tranexamic acid, a drug used against hemorrhage in trauma and high-risk surgery patients, to prevent hemorrhage after cesarean delivery. In addition, NICHD’s new Maternal and Pediatric Precision in Therapeutics (MPRINT) Hub program will augment the research infrastructure by providing expertise, basic science research, and technology platforms for scientists conducting pharmacology research in pregnant women, lactating women, and children.¹²

NICHD-funded scientists are examining how key features of the context in which people live—such as income inequality, community violence, and geographic distribution—increase health risks and contribute to health disparities. One team of NICHD-supported researchers showed that a quality improvement initiative at 99 California hospitals was effective in reducing deaths (or complications) from obstetric hemorrhage by implementing evidence-based clinical practice recommendations. NICHD-funded researchers are also looking at the consequences of racial segregation and inequality in neonatal intensive care units. A recent cohort study of very low-birthweight and very preterm infants found that Neonatal Intensive Care Units (NICUs) (even in the same geographic area) varied widely in the proportions of minority families they served. Moreover, compared with White infants, Black infants were concentrated at NICUs with poorer health outcomes.

NICHD is also supporting several efforts to increase the diversity of the extramural workforce in the research community and to increase the scientific evidence needed to address health disparities. The Institute continues to support young scientists via the F31 predoctoral diversity fellowship and the diversity supplement program. NICHD routinely monitors the outcomes of diversity supplement recipients (e.g., subsequent application and receipt of NIH grants). The

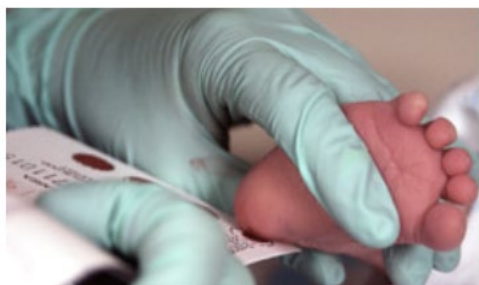
¹⁰ www.nih.gov/research-training/medical-research-initiatives/improve-initiative;
www.nichd.nih.gov/research/supported/IMPROVE

¹¹ www.nichd.nih.gov/research/supported/PDRIP

¹² www.nichd.nih.gov/about/org/der/branches/opptb/mprint

Institute uses a wide range of communications platforms to highlight the diversity of researchers and actively participates in outreach efforts to engage with diverse audiences.

NICHD's and NIH's foundational research is critical to understanding the typical neurocognitive, psychological, behavioral, physical, and social-emotional development of infants, children, and adolescents. Understanding typical development is essential to describing the differences seen in children with intellectual, developmental, and physical disabilities. For example, the NIH Toolbox Cognition Battery, a group of brief memory, executive function, processing speed, and language tests, was designed for use in the general population. Researchers tested this cognitive portion of the NIH Toolbox in children with intellectual disability and found that all the tests were feasible and reliable for a high percentage of individuals with intellectual disability, although adaptation may be required for younger children and children with lower cognitive functioning. NICHD also co-leads the trans-NIH INvestigation of Co-occurring conditions across the Lifespan to Understand Down syndrome (INCLUDE) Project. In FY 2022, management of the INCLUDE program will move from the Office of the NIH Director to NICHD, with continued commitment to addressing critical health and quality-of-life needs for individuals with Down syndrome.¹³



Newborn screening programs across the United States screen 4 million infants each year, often allowing treatment to begin before symptoms or permanent problems occur. NICHD research has been responsible for the development of many newborn screening tests, and research continues to add more tests for other rare conditions and improve screening methods.

CREDIT: U.S. Air Force, Staff Sgt Eric T. Sheler

NICHD is poised to respond effectively to public health challenges because of previous investments and scientific advances in basic, translational, and clinical sciences. For example, newborn screening tests can detect potentially dangerous disorders soon after a baby is born. Advances in newborn screening technology, such as the application of rapid whole-genome sequencing, automated phenotyping and interpretation, and data analysis with machine learning have allowed for faster diagnosis, improved accuracy, and reduced false positives. Recently, NICHD has supported research leading to new newborn screening tests and devices for spinal muscular atrophy, cystic fibrosis, Niemann-Pick Type C, Prader-Willi Syndrome, and lysosomal disorders.

Understanding the effects of environmental exposures on child health and development is also consistent with NICHD's mission and is the primary aim of NIH's Environmental influences on Child Health Outcomes (ECHO) program.¹⁴ In FY 2022, the ECHO program will move from the Office of the NIH Director to NICHD. ECHO will continue to focus on using pediatric cohort studies to discover developmental origins of health and disease and identify the effects of environmental exposures on child health. ECHO also will maintain support for the IDeA States Pediatric Clinical Trials Network (ISPCTN), which includes children and infants from rural

¹³ www.nih.gov/include-project

¹⁴ www.nih.gov/research-training/environmental-influences-child-health-outcomes-echo-program

areas in research while building pediatric research capacity through professional development and infrastructure support. The ECHO ISPCTN and NICHD currently collaborate on two Advancing Clinical Trials in Neonatal Opioid Withdrawal (ACT NOW) trials as part of NIH's Helping to End Addiction Long-term (HEAL) InitiativeSM. These trials will build evidence for best practices to care for newborns with opioid withdrawal syndrome. ISPCTN also supports trials to understand vitamin D pharmacokinetics and telehealth treatment of children with obesity.

Although NICHD is making significant strides to advance its mission, the potential for additional advances and the need for future investments remains enormous. Over the past year, the Institute worked diligently to implement the NICHD Strategic Plan that was released in September 2019.¹⁵ Over the next five years, NICHD plans to expand efforts to develop new tools for studying embryonic development and structural birth defects. The Institute will lead efforts to delineate the many factors underlying gynecologic and andrologic disorders. NICHD is committed to advancing understanding of typical and atypical child development in contemporary cohorts, with an emphasis on identifying sensitive time periods when prevention and treatment strategies will have the greatest impact. NICHD will also lead efforts to develop, test, and evaluate new and existing therapeutics and devices to find safe and effective solutions to meet the unique needs of pregnant and lactating women, children, and people with intellectual and physical disabilities.

Overall Budget Policy: The FY 2022 President's Budget request for NICHD is \$1,942.1 million, an increase of \$104.2 million compared with the FY 2021 Enacted level.¹⁶ This appropriation level will support the redirection of administrative responsibility for the ECHO and INCLUDE programs to NICHD from the NIH Office of the Director. Additional funds are also directed toward research to improve maternal health, reduce the risks associated with preterm birth, and address long-term consequences of the pandemic. This includes \$30.0 million for the IMPROVE program and \$15.0 million to augment research on the effects of SARS-CoV-2 infection in children.

¹⁵ www.nichd.nih.gov/sites/default/files/2019-09/NICHD_Strategic_Plan.pdf

¹⁶ The FY 2021 level is adjusted for the transfer of the ECHO and INCLUDE programs for comparability with the FY 2022 request.



Healthy pregnancies. Healthy children. Healthy and optimal lives.

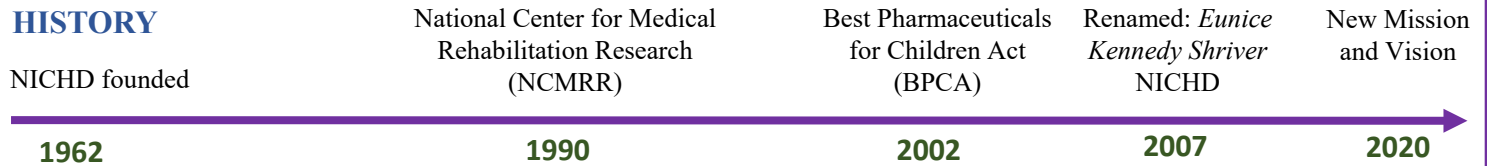


Director:
Diana W. Bianchi, M.D.

NICHD's mission is to lead research and training to understand human development, improve reproductive health, enhance the lives of children and adolescents, and optimize abilities for all.
<http://nichd.nih.gov>

Key populations: Children, Pregnant Women, People with Disabilities

HISTORY



RESEARCH HIGHLIGHTS, FY 2019-2020

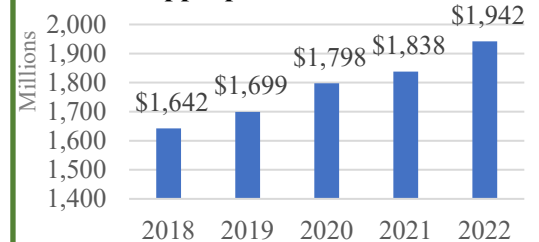
- ✓ Pregnant women who experienced severe symptoms of COVID-19 had a higher risk of complications during and after pregnancy.
- ✓ Over 700 women in the U.S. die each year because of pregnancy complications. Pravastatin may prevent preeclampsia, a pregnancy condition related to high blood pressure.
- ✓ Foundational research from NICHD led to FDA approval of the first pill to treat pain from endometriosis, a common gynecological disease that can cause pain and infertility.
- ✓ New devices, rapid genomic sequencing, and artificial intelligence improved the speed, accuracy, and impact of newborn screening.
- ✓ Due to physiological differences between children and adults, using an adult medicine in a child without proper dosing info can be dangerous or ineffective. NICHD research led to 6 FDA pediatric labeling changes.
- ✓ Imaging genetic activity can track how a cell develops into an entire body, a technological breakthrough for basic development research.
- ✓ Researchers discovered in mice a genetic mutation to improve cognitive flexibility—the ability to adapt to changing situations.

NICHD BY THE NUMBERS, FY 2020

# Full-Time Employees:	520
# Principal Investigators (PIs):	3,194
# Institutions:	438
# Awards (Total):	2,895
# Awards (Training):	349
# Nobel Prize Winners:	16

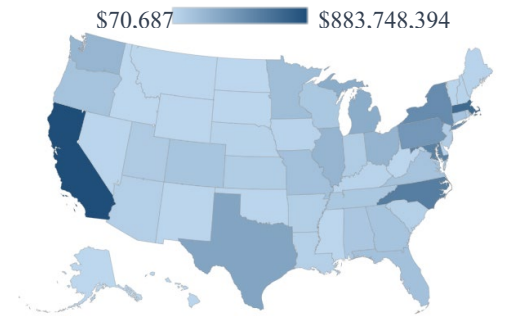
Note: excludes contracts and intramural projects, and includes co-funded awards.

NICHD Appropriations, FY 2018-2022



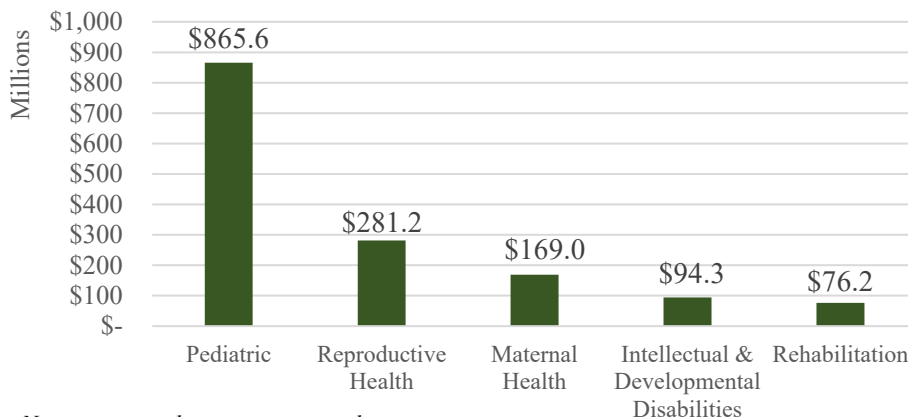
Note: Appropriations figures have been adjusted to reflect funds for programs transferred from NIH OD.

NICHD Funding by State, FY 2015-2020



From 2015-2020, NICHD has supported research in all 50 states and involving at least 135 countries across the globe.

NICHD Funding by Topic, FY 2019



Note: topics and amounts are overlapping.

Healthy pregnancies. Healthy children. Healthy and optimal lives.

RECENT ACCOMPLISHMENTS

Four million newborns are screened each year, so treatment can begin before permanent problems occur. New or improved screening tests for lysosomal storage disorders, spinal muscular atrophy, propionic acidemia, and cystic fibrosis.

Human Development



Scientists developed a prototype method to use drug-containing nanoparticles to reduce the size of fibroid tumors in mice. They plan to extend this research to humans through future studies.

Reproductive Health



Researchers developed a new imaging technique to track maternal blood flow to the placenta. This technology could help diagnose several common complications in early pregnancy.

Maternal Health



NICHD pioneered prenatal surgery for the most severe form of spina bifida. Years later, children who had the surgery prenatally walked independently more often than those who had the traditional operation after birth.

Child Health



Early interventions can help children with autism spectrum disorder (ASD). Researchers have developed smartphone apps, wearable devices, and other ways to assess children to enable a more accurate or earlier diagnosis.

Optimize Abilities for All



CURRENT ACTIVITIES

NICHD leads the birth defects portion of the Gabriella Miller Kids First Pediatric Research Program at NIH, to help researchers uncover new insights into the biology of structural birth defects and share these data.

The Centers to Advance Research in Endometriosis support basic, translational, and/or clinical studies of endometriosis, a chronic painful condition affecting 1 in 10 women of reproductive age.

NICHD's Study of Pregnancy and Neonatal Health will analyze data from more than 7,000 pregnant women and male partners to examine maternal risk factors, genomic associations, and optimal delivery time.

The Advancing Clinical Trials in Neonatal Opioid Withdrawal study is designed to improve clinical care for children with prenatal opioid exposure by determining the best methods of treatment.

NICHD aims to improve inclusion of populations frequently omitted from research, including pregnant women and individuals with disabilities. Researchers assessed the NIH Toolbox Cognitive Battery for use in individuals with intellectual disabilities, which could help support their participation in clinical studies.

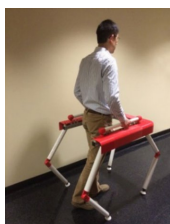
NEW AND FUTURE INITIATIVES



- Mobilizing the COVID-19 response:
 - Analyzing medical records of 24,500 women to assess pregnancy outcomes related to COVID-19
 - Tracking impact of infection among 16,000 women in 7 low- and middle-income countries
 - Working with other NIH ICs to identify risk factors for Multisystem Inflammatory Syndrome in Children (MIS-C), a severe pediatric condition resulting from SARS-CoV-2 infection
 - Maximizing testing for children with intellectual and developmental disabilities and school staff
 - Assessing impact of pandemic-related changes, including remote learning, on child development



- Through the NIH-wide IMPROVE initiative, identifying biological, behavioral, sociocultural, and structural factors that contribute to disparities in maternal mortality
- Providing pharmacology expertise, basic science research, and technology platforms for research in pregnant women, lactating women, and children
- Exploring how the use of electronic media, beginning in early childhood, affects multiple aspects of child health and development



- Establishing a new research initiative on role of nutrition in the care and development of preterm infants
- Studying how neurobehavioral factors, feeding practices, and early life food exposures affect diet and growth in 3- to 5-year old children
- Working with other NIH ICs to support centers of excellence in Fragile X/FMR-1 disorders and in Autism Spectrum Disorders
- Building infrastructure in medical rehabilitation research, focusing on areas such as tissue engineering, pediatric rehabilitation, technology development, and neuromodulation
- Expanding the intramural pediatric and adolescent gynecology program

Major Changes in the Fiscal Year 2022 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 mechanisms and activity detail and these highlights will not sum to the total change for the FY 2022 President's Budget for NICHD, which is an increase of 5.7 percent above the comparably adjusted FY 2021 Enacted level, for a total of \$1,942.1 million. Within the request level, NICHD will pursue its highest research priorities through strategic investments and careful stewardship of appropriated funds.

Research Project Grants (RPGs) (+\$75.1 million, total \$1,175.6 million):

NICHD will support a total of 1,964 Research Project Grant (RPG) awards in FY 2022, excluding SBIR/STTR awards. Non-competing RPGs will increase by 58 awards to an estimated level of 1,386 awards, while the amount to support the costs associated with the commitments of these prior year competing awards will increase by \$33.7 million compared to the FY 2021 Enacted level. Competing RPGs will increase by 34 grants compared to the FY 2021 Enacted level of 544 awards, and the amount to support the costs associated with new competing awards will increase by \$21.5 million compared to the FY 2021 Enacted level. In addition, awards under the Small Business Research programs will increase by 21 awards and \$12.4 million compared to the FY 2021 Enacted level.

Research Centers (-\$3.4 million, total \$75.1 million):

NICHD will support a total of 54 Research Centers awards in FY 2022, unchanged from the FY 2021 Enacted level but at a lower funding level than in FY 2021.

Other Research (+\$8.0 million, total \$180.4 million):

NICHD will support a total of 460 awards in the Other Research areas in FY 2022, an increase of 23 awards compared with the FY 2021 Enacted level of 437 awards. NICHD will continue to support Career awards and clinical trial networks within these funding amounts.

Research and Development Contracts (+7.4 million, total \$142.5 million):

NICHD will support a total of 133 contract awards in FY 22, three more than the FY 21 Enacted level. Additional funds will support Department of Health and Human Services initiatives and the implementation of the NICHD Strategic Plan.

Intramural Research (+\$8.4 million, total \$230.4 million):

NICHD will increase support for the Intramural Research program by \$8.4 million compared to the FY 2021 Enacted level, maintaining support for research and innovation at the Clinical Center and increasing support for cybersecurity efforts and existing staff and trainees.

Research Management and Support (+\$6.9M, total \$96.5 million):

NICHD will increase funding for the Research Management and Support program by \$6.9 million compared to the FY 2021 Enacted level, increasing support for cybersecurity efforts, clinical trials management and automation of business practices.

NATIONAL INSTITUTES OF HEALTH
National Institute of Child Health and Human Development

Budget Mechanism - Total ^{1 2}
(Dollars in Thousands)

MECHANISM	FY 2020 Final		FY 2021 Enacted		FY 2022 President's Budget		FY 2022 +/- FY 2021 Enacted	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
<u>Research Projects:</u>								
Noncompeting	1,366	\$772,221	1,328	\$760,283	1,386	\$793,980	58	\$33,697
Administrative Supplements	(84)	20,374	(70)	22,694	(88)	30,300	(18)	7,606
<u>Competing:</u>								
Renewal	43	26,519	46	29,266	49	31,579	3	2,313
New	449	215,104	496	241,895	529	261,011	33	19,116
Supplements	2	406	2	471	0	508	-2	37
Subtotal, Competing	494	\$242,029	544	\$271,632	578	\$293,098	34	\$21,466
Subtotal, RPGs	1,860	\$1,034,625	1,872	\$1,054,609	1,964	\$1,117,378	92	\$62,769
SBIR/STTR	81	47,011	81	45,898	102	58,257	21	12,359
Research Project Grants	1,941	\$1,081,636	1,953	\$1,100,507	2,066	\$1,175,635	113	\$75,128
<u>Research Centers:</u>								
Specialized/Comprehensive	49	\$68,717	50	\$72,309	50	\$68,939	0	-\$3,370
Clinical Research	0	0	0	0	0	0	0	0
Biotechnology	4	5,686	4	5,602	4	5,602	0	0
Comparative Medicine	0	513	0	513	0	513	0	0
Research Centers in Minority Institutions	0	0	0	0	0	0	0	0
Research Centers	53	\$74,915	54	\$78,424	54	\$75,054	0	-\$3,370
<u>Other Research:</u>								
Research Careers	238	\$43,057	229	\$43,139	250	\$44,431	21	\$1,292
Cancer Education	0	0	0	0	0	0	0	0
Cooperative Clinical Research	67	38,729	54	24,855	53	19,591	-1	-5,264
Biomedical Research Support	0	0	0	0	0	0	0	0
Minority Biomedical Research Support	0	0	0	0	0	0	0	0
Other	137	93,650	154	104,415	157	116,360	3	11,945
Other Research	442	\$175,436	437	\$172,409	460	\$180,382	23	\$7,973
Total Research Grants	2,436	\$1,331,986	2,444	\$1,351,340	2,580	\$1,431,071	136	\$79,731
<u>Ruth L Kirschstein Training Awards:</u>	<u>FTEPs</u>		<u>FTEPs</u>		<u>FTEPs</u>		<u>FTEPs</u>	
Individual Awards	257	\$12,662	261	\$13,181	279	\$14,662	18	\$1,481
Institutional Awards	438	25,172	455	26,777	439	26,962	-16	185
Total Research Training	695	\$37,834	716	\$39,958	718	\$41,624	2	\$1,666
Research & Develop. Contracts (SBIR/STTR) (non-add)	127 (3)	\$133,858 (482)	130 (3)	\$135,157 (482)	133 (3)	\$142,543 (482)	3 (0)	\$7,386 (0)
Intramural Research	296	215,216	296	221,949	296	230,365	0	8,416
Res. Management & Support ² SBIR Admin. (non-add)	224 (0)	78,885 (280)	265 (0)	89,568 (362)	306 (0)	96,514 (362)	41 (0)	6,946 (0)
Construction	-	0	-	0	-	0	-	0
Buildings and Facilities	-	0	-	0	-	0	-	0
Total, NICHD	520	\$1,797,780	561	\$1,837,972	602	\$1,942,117	41	\$104,145

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

² FY 2020 and FY 2021 have been comparably adjusted for the proposed transfer of ECHO and INCLUDE into NICHD in FY 2022.

³ The FTE level for FY 2022 includes FTEs associated with the transfer of the ECHO program from the NIH Office of the Director to NICHD. FTE levels for FY 2020 and FY 2021 are not adjusted for comparability.

**EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH AND
HUMAN DEVELOPMENT**

For carrying out section 301 and title IV of the PHS Act with respect to child health and human development, [\$1,590,337,000]*\$1,942,117,000*.

NATIONAL INSTITUTES OF HEALTH
National Institute of Child Health and Human Development

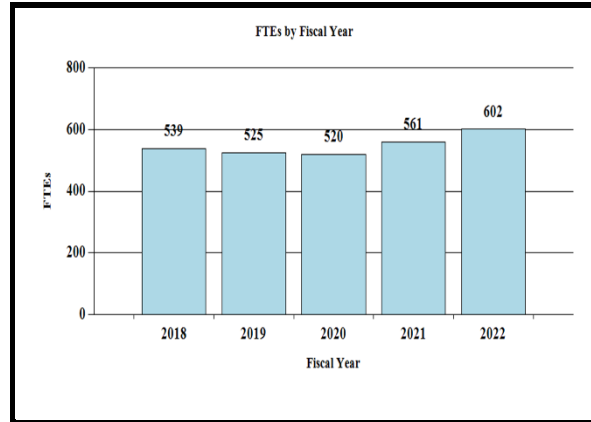
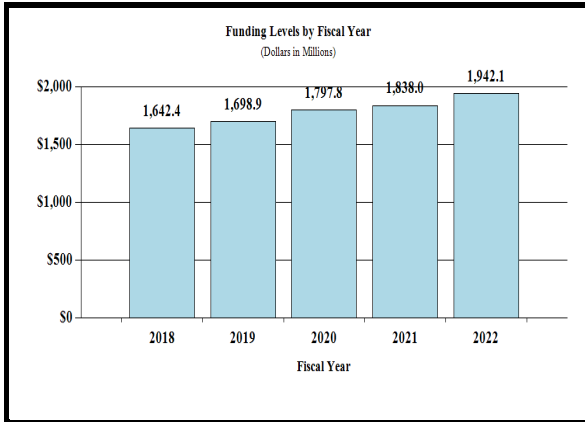
Summary of Changes
(Dollars in Thousands)

FY 2021 Enacted				\$1,837,972		
FY 2022 President's Budget				\$1,942,117		
Net change				\$104,145		
CHANGES	FY2021 Enacted		FY 2022 President's Budget		Built-In Change from FY 2021 Enacted	
	FTEs	Budget Authority	FTEs	Budget Authority	FTEs	Budget Authority
A. Built-in:						
1. Intramural Research:						
a. Annualization of January 2021 pay increase & benefits	-	\$70,928	-	\$73,035	-	\$189
b. January FY 2022 pay increase & benefits	-	70,928	-	73,035	-	1,918
c. Paid days adjustment	-	70,928	-	73,035	-	0
d. Differences attributable to change in FTE	-	70,928	-	73,035	-	-243
e. Payment for centrally furnished services	-	38,830	-	40,771	-	1,941
f. Cost of laboratory supplies, materials, other expenses, and non-recurring costs	-	112,191	-	116,559	-	3,128
Subtotal	-	-	-	-	-	\$6,934
2. Research Management and Support¹:						
a. Annualization of January 2021 pay increase & benefits	-	\$46,175	-	\$51,580	-	\$123
b. January FY 2022 pay increase & benefits	-	46,175	-	51,580	-	1,282
c. Paid days adjustment	-	46,175	-	51,580	-	0
d. Differences attributable to change in FTE	-	46,175	-	51,580	-	7,576
e. Payment for centrally furnished services	-	9,580	-	10,059	-	479
f. Cost of laboratory supplies, materials, other expenses, and non-recurring costs	-	33,813	-	34,875	-	1,110
Subtotal	-	-	-	-	-	\$10,570
Subtotal, Built-in	-	-	-	-	-	\$17,503
CHANGES	FY2021 Enacted		FY 2022 President's Budget		Program Change from FY 2021 Enacted	
	No.	Amount	No.	Amount	No.	Amount
B. Program:						
1. Research Project Grants:						
a. Noncompeting	1,328	\$782,977	1,386	\$824,280	58	\$41,303
b. Competing	544	271,632	578	293,098	34	21,466
c. SBIR/STTR	81	45,898	102	58,257	21	12,359
Subtotal, RPGs	1,953	\$1,100,507	2,066	\$1,175,635	113	\$75,128
2. Research Centers	54	\$78,424	54	\$75,054	0	-\$3,370
3. Other Research	437	172,409	460	180,382	23	7,973
4. Research Training	716	39,958	718	41,624	2	1,666
5. Research and development contracts	130	135,157	133	142,543	3	7,386
Subtotal, Extramural	-	\$1,526,455	-	\$1,615,238	-	\$88,783
6. Intramural Research	FTEs	-	FTEs	-	FTEs	-
	296	\$221,949	296	\$230,365	0	\$1,482
7. Research Management and Support ¹	265	89,568	306	96,514	41	-3,624
8. Construction	-	0	-	0	-	0
9. Buildings and Facilities	-	0	-	0	-	0
Subtotal, Program	561	\$1,837,972	602	\$1,942,117	41	\$86,642
Total built-in and program changes	-	-	-	-	-	\$104,145

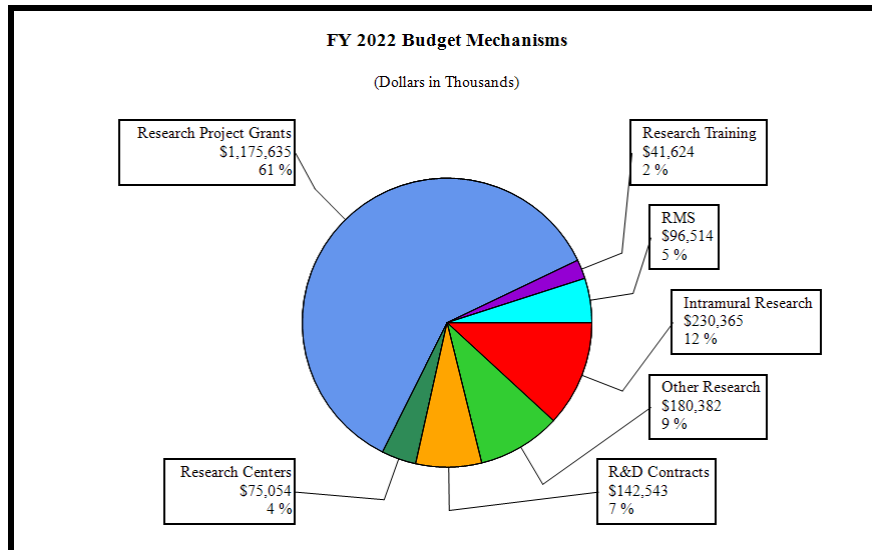
¹ The FTE level for FY 2022 includes FTEs associated with the transfer of the ECHO program from the NIH Office of the Director to NICHD. FTE levels for FY 2020 and FY 2021 are not adjusted for comparability.

Fiscal Year 2020 Budget Graphs

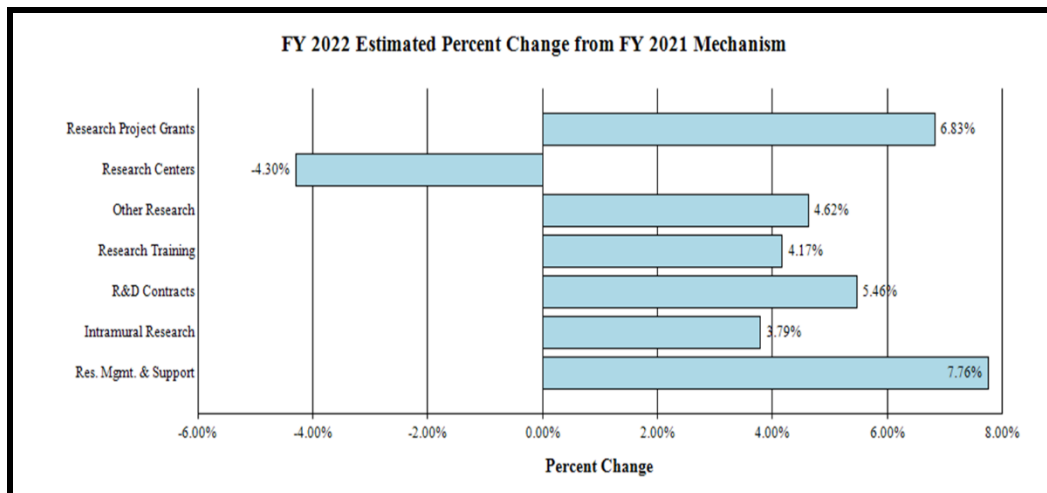
History of Budget Authority and FTEs:



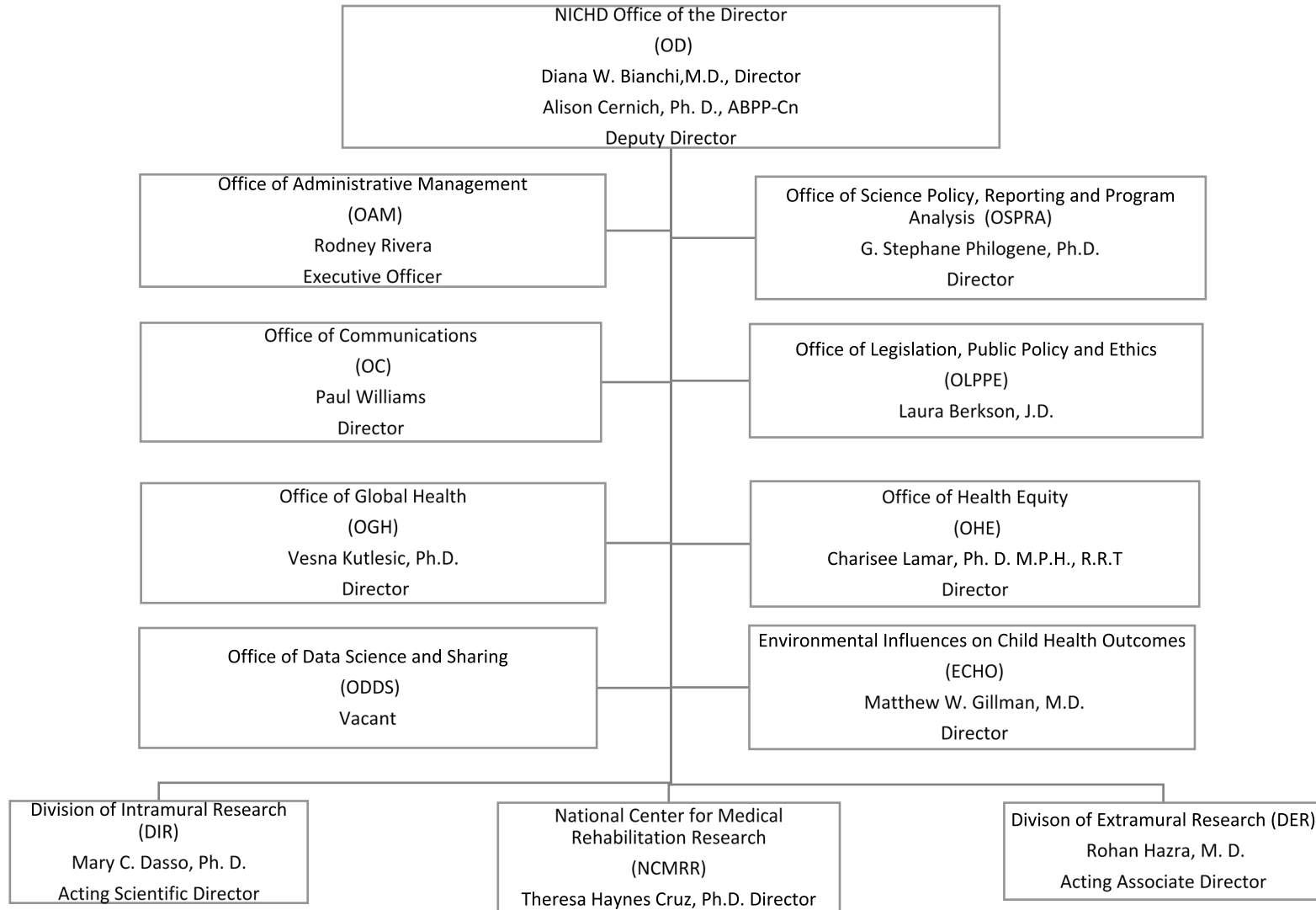
Distribution by Mechanism:



Change by Selected Mechanisms:



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Budget Authority by Activity ^{1,2}
(Dollars in Thousands)

	FY 2020 Final		FY 2021 Enacted		FY 2022 President's Budget		FY 2022 +/- FY 2021 Enacted	
	<u>FTE</u>	<u>Amount</u>	<u>FTE</u>	<u>Amount</u>	<u>FTE</u>	<u>Amount</u>	<u>FTE</u>	<u>Amount</u>
<u>Extramural Research</u>								
<u>Detail</u>								-
Reproductive Health, Pregnancy, and Perinatology	-	\$395,010	-	\$401,146	-	\$443,283	-	\$42,137
Child Health	-	583,003	-	588,197	-	618,789	-	30,591
Intellectual and Developmental Disabilities	-	198,436	-	204,799	-	210,861	-	6,063
Demography and Behavior	-	240,825	-	244,566	-	251,918	-	7,352
Rehabilitation	-	86,405	-	87,747	-	90,387	-	2,640
Subtotal, Extramural	-	\$1,503,679	-	\$1,526,455	-	\$1,615,238	-	\$88,783
Intramural Research	296	\$215,216	296	\$221,949	296	\$230,365	0	\$8,416
Research Management & Support³	224	\$78,885	265	\$89,568	306	\$96,514	41	\$6,946
TOTAL	520	\$1,797,780	561	\$1,837,972	602	\$1,942,117	41	\$104,145

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

² FY 2020 and FY 2021 have been comparably adjusted for the proposed transfer of ECHO and INCLUDE into NICHD in FY 2022.

³ The FTE level for FY 2022 includes FTEs associated with the transfer of the ECHO program from the NIH Office of the Director to NICHD.
FTE levels for FY 2020 and FY 2021 are not adjusted for comparability.

Justification of Budget Request

Eunice Kennedy Shriver National Institute of Child Health and Human Development

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

Budget Authority (BA):¹⁷

	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY 2021
BA	\$1,797,779,573	\$1,837,972,000	\$1,942,117,000	+\$104,145,000
FTE	520	561	602	+41

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

Program Descriptions and Accomplishments

Reproductive Health, Pregnancy, and Perinatology: The NICHD program in reproductive health, pregnancy, and perinatology supports basic, clinical, and translational research on gynecologic and andrologic disorders; contraception; fertility and infertility; pregnancy; and newborn care. NICHD manages a broad research portfolio to understand, treat, and prevent common, painful, and costly gynecologic health conditions, including endometriosis, uterine fibroids, chronic pelvic pain, and pelvic floor disorders. A recent genome-wide study of fibroid subtypes discovered multiple mutations that alter the expression of three genes. This research calls into doubt the long-standing characterization of fibroids as a single condition; instead, uterine fibroids may be more similar to breast cancers—a group of similar conditions that arise in a variety of ways. Such basic biology insights may lead to more targeted and more effective treatments. The new NICHD-supported centers of excellence in endometriosis research will also focus on understanding the basic biology of endometriosis to help scientists develop non-invasive diagnostics, improved treatment, and ultimately, a cure for this painful condition that affects 10 percent of women. Millions of couples across the United States have difficulty conceiving and establishing a healthy pregnancy, yet only limited information is available to understand the causes of infertility, minimize risk factors, and improve treatment options. Scientists recently discovered a key protein, SKP1, that drives a crucial step in the sperm production process. The discovery may inform strategies to treat certain forms of male infertility.

¹⁷ Budget authority for FY 2020 and FY 2021 is comparably adjusted to reflect the proposed transfer of the ECHO and INCLUDE programs from the NIH Office of the Director to NICHD in FY 2022. FTE levels are not comparably adjusted.

As NIH's leader in pregnancy research, NICHD supports scientific studies on clinical treatments to reduce the risk of pregnancy complications for both pregnant women and their offspring. For example, scientists found that negative pressure wound therapy—placing a low-pressure pump over a closed surgical wound to create negative air pressure—did not appear to lower the risk of infection for women with obesity after cesarean delivery. Scientists are also working on basic and translational studies to understand, and ultimately prevent, adverse pregnancy outcomes. For example, researchers recently found that high concentrations of platelet factor 4—a chemical released by small cell fragments in blood that start the first stage of chemical blood clotting—could serve as a predictor of risk of placenta-mediated pregnancy complications. NICHD led the Congressionally-mandated Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC), which sought to address gaps in understanding how to guide treatment decisions during pregnancy and breastfeeding. In September 2020, PRGLAC submitted its Implementation Plan to the HHS Secretary with pragmatic steps for carrying out the Task Force's earlier recommendations. NICHD is emphasizing obstetric pharmacology studies; in 2020-2021 NICHD is launching a new effort to provide more researchers with obstetric and pediatric pharmacology expertise, basic science research, and technology platforms to advance clinical research with pregnant and lactating women and children at all stages of development.

Male Reproductive Health

Reproductive health is an important component of men's overall health and well-being. Too often, males were overlooked in discussions of reproductive health, especially in the areas of contraception and infertility, which have more often been focused on females. Men have fewer contraceptive choices compared with women, and many men find their current choices unsatisfactory. When a couple experiences problems with fertility, the cause(s) can be multiple and overlapping. Problems in the male are just as likely as problems in the female, and it is equally likely that the cause of infertility is a combination of factors from both partners. Men, like women, may also experience disorders of their reproductive system, and for some of these andrologic conditions few treatment options exist. NICHD highlighted andrologic conditions in the Institute's most recent strategic plan, and research scientists have been energized to bring the power of scientific research to improving male reproductive health. Scientists recently developed and tested new contraceptive pills for men. These pills contain hormones that could prevent pregnancy by reducing a man's mature sperm count. Researchers wanted to know whether men would be willing to take a contraceptive pill and whether they would be satisfied with the method used for a specific type of pill. The scientists asked a group of men who participated in a study that tested a contraceptive pill to complete a survey. The results showed that 80 percent of the men were satisfied with the method, 77 percent would recommend it to others, and over half would use the method as their primary contraceptive if it were available. The findings indicate that a daily male contraceptive pill could provide a satisfactory alternative for preventing pregnancy.

Preeclampsia

Preeclampsia is a pregnancy-related high blood pressure disorder. In preeclampsia, a pregnant woman's high blood pressure reduces the blood supply to the fetus, which may get less oxygen and fewer nutrients. Women with preeclampsia are at increased risk for organ damage/failure, preterm birth, pregnancy loss, and stroke. Risks to the fetus include lack of oxygen and nutrients, preterm birth, and stillbirth. Infants born preterm due to preeclampsia are at higher risk of some long-term health issues. The causes of preeclampsia are not known. To learn more, NICHD-funded scientists are studying the placental, genetic, environmental, nutritional, and immunological factors that may lead to preeclampsia. For example, NICHD intramural researchers discovered how key placental molecules become impaired in preeclampsia. Intramural scientists are continuing work towards developing non-invasive biomarkers of placental function and early identification of women at risk of preterm preeclampsia and other placenta-mediated pregnancy complications. Scientists supported by NICHD's Human Placenta Project used recent techniques to isolate and analyze placental proteins in the blood serum of pregnant women who developed preeclampsia. Focusing on a specific type of cell particles in blood plasma, researchers were able to identify differences in how microRNAs were expressed in women with preeclampsia. These types of insights into the disease process will form the evidence base needed to develop new ways to diagnose, prevent, and treat preeclampsia.

Perinatal research supported by NICHD continues to yield important advances, including early detection of and protection against disorders that threaten the survival and development of newborns. Scientists showed that in children born between 22-26 weeks of gestation, a combination of antenatal treatment with both corticosteroids and magnesium sulfate was associated with lower rates of severe neurodevelopmental impairment or death compared with antenatal corticosteroids alone. Researchers recently developed a new imaging system, Electromyometrial Imaging (EMMI), to model fetal kicks, contractions, and fetal/maternal movements in utero. The system uses individualized body-uterus geometry mapped by Magnetic Resonance Imaging (MRI), a large number of electrodes placed around the abdomen, and specialized software for 3D mapping of electrical activation signals across the entire surface of the uterus during labor.

Budget Policy: The budget request for this program is \$443.3 million, an increase of \$42.1 million or 10.5 percent compared with

the FY 2021 Enacted level. Addressing maternal morbidity and mortality will remain a very high priority for this program. The President's Budget requests \$30.0 million to expand the IMPROVE initiative to support research to mitigate preventable maternal mortality, decrease severe maternal morbidity, and promote health equity. The program also aims to prioritize pharmacological studies to improve the evidence base for treatment of pregnant women, research on preterm birth and newborn health, and support for endometriosis research.

Child Health: Research on child health explores basic biological processes that control healthy or atypical development, translational research from the bench to the bedside, behavioral and social science research, and clinical studies in pediatric pharmacology, infectious diseases, nutrition, endocrinology, trauma and critical illness, and other aspects of pediatric medicine.

As described above, children infected with the SARS-CoV-2 virus are vulnerable to serious complications like MIS-C. NICHD’s longstanding expertise in pediatric critical care and pediatric pharmacology has positioned the Institute to lead efforts to accelerate understanding of how COVID-19 affects children. Additional funds in the FY 2022 budget request will facilitate expansion of these efforts. Moreover, the COVID-19 pandemic affects many aspects of child health and development for children who remain uninfected. One of the greatest upheavals caused by the COVID-19 pandemic was the sudden shutdown of elementary, middle, and high schools to prevent the spread of the virus. Across the country, as many as three-quarters of large school districts were employing a fully-online learning model over some period. The move to online learning raised concerns about access to computers and the internet, potential increases in food insecurity for children who received free or reduced-price lunches, changes in physical activity, and lack of social interactions with peers. Suspension of classroom time disproportionately affects children with intellectual and developmental disabilities, who often require special educational services, increased teacher-student ratios, and specialized interventions, many of which need to be administered in person by skilled professionals. Beyond educational changes, children have been affected by pandemic-related changes in family and social interaction (e.g., less time with peers and grandparents), nutrition, and other changes. NICHD-supported researchers are assessing the impact of these changes on child development. For example, one group of scientists is researching the impact of prolonged school closures from COVID-19 on health, nutrition and weight of low-income children, and determining the effects of emergency food programs.

Adolescent Transition to Adult Health Care

As adolescents gain independence, they must transition to taking full responsibility for their own adult health care; often, this means leaving their pediatrician’s care and working with new adult health care providers. For children with pediatric chronic health conditions or disabilities, this process is often especially difficult because few adult subspecialists may be available with expertise on their specific conditions. Even for typically developing children, population research has shown that young adults may miss out on needed medical care during the transition process. Working with other NIH ICs, NICHD has led efforts to prioritize improvements in the transition to adult health care to improve health outcomes for adolescents and young adults. A recent scientific workshop on this topic brought together researchers and clinicians, representing a broad range of pediatric diseases and conditions, to learn from each other and define the current state of health care transition research. The hundreds of experts discussed issues such as defining and measuring successful transition to adult care, key challenges in the transition process, and interventions to improve transition outcomes. Research projects underway, including those at NICHD’s Adolescent Trials Network for HIV/AIDS Interventions, are focused on the process of improving self-management among youth undergoing the transition to adult health care.

NICHD’s basic research portfolio on developmental biology has led to a better understanding of normal embryonic development, as well as mechanisms that underlie causes of structural and functional birth defects. For example, scientists have long suggested that neural tube defects like spina bifida can be associated with multiple developmental “signaling pathways,” genetically controlled processes in cell interactions that lead to organ formation. However, mutations in such pathways have been identified in few cases of neural tube defects, leaving the underlying causes unclear. Scientists recently identified eight rare genetic variants associated with spina bifida and are exploring ways to enhance the functions that are critical for normal neural tube closure.

Pediatric clinical researchers recognize that children are not small adults – often, children react differently than adults do to both disease and to treatment. For example, children’s growing bodies and changing metabolism affect how the body processes and reacts to medications. Ongoing activities under the Best Pharmaceuticals Act for Children (BPCA) include identifying off-patent drugs in need of further study of dosing, safety, and efficacy for pediatric indications, prioritizing needs in pediatric therapeutics, and sponsoring clinical studies of prioritized drugs, with a goal of the U.S. Food and Drug Administration (FDA) labeling for use in children. Recent FDA label changes supported by this research provide clinicians with evidence-based prescribing information on the antibiotics doxycycline and clindamycin to treat serious infections in children. The NICHD-supported Pediatric Trials Network (PTN) quickly began collecting data on COVID-19 drugs that clinicians at approximately 40 PTN sites are using to treat infants, children, and adolescents, including a group of children with Down syndrome.

Budget Policy: The budget request for this program is \$618.8 million, an increase of \$30.6 million or 5.2 percent compared with the FY 2021 Enacted level. This funding level reflects the transfer of the ECHO program from the NIH Office of the Director to NICHD. The budget request also includes \$15.0 million for research into MIS-C and the spectrum of SARS-CoV-2 risks in children, which could augment current studies to facilitate increased enrollment, long-term follow up, and data sharing. As described in NICHD’s strategic plan, other high priority areas for this program include studies on the transition from adolescence to adulthood, pediatric pharmacology research, and research designed to help address health disparities and improve health equity. NICHD also will support research on the impact of exposure and use of technology and digital media on child and adolescent development.

Intellectual and Developmental Disabilities: Intellectual and developmental disabilities (IDDs) were once thought to be permanent and untreatable, but new science discoveries have challenged this belief, inspiring renewed efforts to improve the lives of individuals with IDDs. NICHD’s program on IDDs supports research and research training aimed at preventing and ameliorating both common and rare disorders, such as Down syndrome (DS), Fragile X syndrome (FXS), Rett syndrome, and muscular dystrophy; inborn errors of metabolism; autism spectrum disorders (ASD); congenital conditions currently or potentially detectable through newborn screening; and IDDs that have no identified cause or are not associated with a specific syndrome.



NICHD research led to the discovery of the gene that causes Rett syndrome. Today, NICHD’s work enables diagnosis and effective treatments for kids like Alyssa, shown with her mother, Susan.

CREDIT: SARAH COOK, COOKWIRE PHOTOGRAPHY

NICHD’s IDD portfolio includes a broad array of investigator-initiated research and also incorporates key programs that support larger-scale innovative projects. For example, the trans-NIH Autism Centers of Excellence supports large-scale multidisciplinary studies on ASDs, with the goal of determining the disorders' causes and potential treatments. The Centers for

Collaborative Research on Fragile X will study FMR1-associated conditions, as well as the FMR1 gene, the role of the gene in development and progression of these conditions, and other aspects of the NIH Strategic Plan for Research on FMR1-Associated Conditions. NICHD's *Eunice Kennedy Shriver* Intellectual and Developmental Disabilities Research Centers offer a wide range of research services to scientists, including informatics and biostatistics; genomic, proteomic, and metabolomics facilities; cellular neuroimaging and optogenetic services; neuroimaging; and animal and human behavioral testing. The INCLUDE program, to be transferred from the NIH OD to NICHD, is designed to support targeted, high-risk, high-reward basic science and clinical studies to address the needs of individuals with DS. In FY 2022, INCLUDE will continue to support promising research and will update the INCLUDE Research Plan, integrating it with the NIH Research Plan on Down Syndrome (for release in 2021), signifying INCLUDE's important role in continuing a trans-NIH approach to DS.

A priority for NICHD is advancing the inclusion of individuals with IDD in clinical research from which they typically are excluded, even though their developmental disability may co-exist with cardiovascular, metabolic, and other disorders and health risks of the general population. For example, a recent NICHD grant supports research on the most effective way to optimize weekly COVID-19 testing of students with IDDs and staff. Prompted by challenges in recruiting an adequate research cohort of infants and toddlers with tuberous sclerosis complex (TSC), researchers developed a remote model for research participation. A rare, multi-system genetic disease, TSC affects the central nervous system, resulting in combinations of symptoms including ASD, seizures, impaired intellectual development, behavioral issues, and physical symptoms. Working with TSC children's caregivers, researchers modified their experimental intervention so that caregivers could provide the intervention to children at home, alongside weekly videoconferences with researchers. Within a year, study enrollment increased tenfold and the cohort of affected infants was more diverse and clinically representative. Through the INCLUDE program and NICHD's Down Syndrome Registry (DS-Connect™), expanded opportunities for individuals with Down syndrome to participate in research are now available. Lessons from the success of these programs can be applied to other IDD conditions.

Budget Policy: The budget request for this program is \$210.9 million, an increase of \$6.1 million or 3.0 percent compared with the FY 2021 Enacted level. This funding level reflects the transfer of the INCLUDE program from NIH OD to NICHD. Within the IDD program, NICHD plans to prioritize efforts to include individuals with disabilities in clinical research studies, support high-risk high-reward basic science projects, and research to help develop therapies and treatments for IDDs and comorbid conditions. NICHD will continue the INCLUDE project and apply the lessons from INCLUDE to studying co-morbid conditions that affect individuals with ASD, Down syndrome, and other IDDs as well as the general population. Moreover, in FY 2022 NICHD plans to join with other NIH Institutes and Centers in the renewal of the Autism Centers of Excellence program.

Demography and Behavior: The program in demography and behavior incorporates NICHD's strong portfolio on behavioral and social influences on health. For example, one NICHD-funded study assessed whether stricter state standards for school nutritional programs were associated with improved eating habits and obesity in more than 2,000 adolescents. Teens in states with strong "farm-to-school" laws to increase the amount of fresh produce in schools consumed more whole fruits, fewer snacks, and less soda than those in states with weak or no such laws.

A key priority for child development and behavior research at the NICHD is to investigate the impact of the digital age on child development. When researchers studied children’s “screen time” behavior at one to three years of age and at eight years of age, the scientists found that the amount of screen time greatly exceeded levels recommended by the American Academy of Pediatrics. The research results also showed that patterns of screen time behavior developed at early ages, often as early as infancy. Over 85 percent of the children in the study had higher screen use than recommended for their age, and the average time the children spent in front of screens increased as they grew, from nearly 1 hour per day at 12 months to nearly 2 hours a day at 3 years. This study was conducted prior to the COVID-19 pandemic, and child use of digital media has increased significantly during the past year.

NICHD also supports behavioral research related to reproductive health. For example, in response to Delaware reporting the highest rate of unintended pregnancies in the United States, NICHD-funded researchers assessed the impact of a public-private partnership initiative to increase women’s use of contraceptives. The program was designed to ensure free, same-day access for all women to all contraceptive options and address provider inexperience in inserting and removing long-acting reversible contraceptives. The program was associated with a 40 percent increase in the use of recommended, long-acting contraception.

Budget Policy: The budget request for this program is \$251.9 million, an increase of \$7.4 million or 3.0 percent compared with the FY 2021 Enacted level. As described in the NICHD Strategic Plan, this program will place a high priority on supporting research designed to help address health disparities and improve health equity. Particular areas of focus will include research to understand social determinants of health to inform strategies to mitigate health disparities. The program plans to continue support for highly successful population centers.

Rehabilitation: The NICHD’s National Center for Medical Rehabilitation Research (NCMRR) fosters research and research training to enhance the health, productivity, independence, and quality of life of people with physical disabilities. With its leadership role in trans-NIH and broader medical rehabilitation research collaborations, NCMRR takes a collaborative approach to advance a broad range of research and research training, including efforts to understand the underlying biology of injury and disability and the body’s own mechanisms of recovery and adaptation.

Bioelectronic devices that can modulate nervous system functioning have shown promise in treating neurological disorders. However, the use of these devices in children has been limited, because of the need to adapt devices as children grow. Recently, NCMRR-supported scientists designed and implanted a “morphing” bioelectronics device, MorphE, under the sciatic nerve of experimental rats in their most rapid period of growth, adolescence. A series of tests indicated that MorphE was capable of actively adapting to the animals’ tissue growth. Further evaluation over longer duration of implantation of the new technology could pave the way to better efficacy and reduced complications of implantable bioelectronic devices for young patients.

Through basic, translational, and clinical research, NCMRR aims to foster development of scientific knowledge needed to create and refine real-world interventions. The Medical Rehabilitation Research Resource (MR3) Network is funded through NCMRR with support from

NICHD and five other NIH ICs. The MR3 Network builds research infrastructure in medical rehabilitation by providing researchers with access to expertise, technologies, and resources to foster clinical and translational research in medical rehabilitation. The network focuses on several key areas, including pediatric rehabilitation, technology to improve real-world outcomes, regenerative rehabilitation promoting tissue engineering and function, stimulation of nerve activity to restore function and relieve pain, and translational/dissemination.

Budget Policy: The budget request for this program is \$90.4 million, an increase of \$2.6 million or 3.0 percent compared with the FY 2021 Enacted level. In FY 2022, NCMRR efforts will be guided by the newly updated NIH Research Plan on Rehabilitation, which lays out priorities in medical rehabilitation research to benefit individuals with temporary or chronic limitations in physical, cognitive, or sensory function. Among the focus areas for NICHD will be advancing knowledge and improving outcomes in reproductive and pregnancy care for women with disabilities. Building on successful collaborations with the research and disability communities, NCMRR also plans to expand research on home and community-based physical activity interventions for wheelchair users.

Intramural Research: NICHD's Division of Intramural Research (DIR) conducts laboratory and clinical research programs to seek fundamental knowledge about the nature and behavior of living systems through basic, clinical, and population-based research.

DIR scientists use a range of model systems to discover answers to fundamental biomedical research questions that can ultimately be used to address a broad array of difficult clinical problems. For example, DIR researchers developed a new strategy to stop tumors from stimulating the growth of new blood vessels, a process called angiogenesis. Normally when angiogenesis is blocked, tumor cells respond by producing more stimulatory molecules. Using gene modification in human cell cultures and zebrafish embryos, as well as drug treatments in mice, researchers overcame this limitation by disabling several key enzymes that tumor cells need to initiate the sequence of chemical reactions that ultimately drives blood vessel growth. This new approach successfully reduces tumor and tumor blood vessel growth and may inform future cancer treatment strategies.

DIR has created a multidisciplinary environment for scientists to develop new insights into the physics, chemistry, and biology of cells, the processes that govern cellular function, and the impact on the body when these processes fail. Difficulty with cognitive flexibility—the ability to adapt to changing situations—occurs in many people with neurological disorders. DIR researchers have discovered in mice what they believe is the first known genetic mutation to improve cognitive flexibility. The researchers found that altering a single base pair in the *KCND2* gene enhanced the ability of the protein to dampen nerve impulses. Mice with this mutation performed better than mice without the mutation on a cognitive task. The researchers plan to investigate whether the mutation will affect neural networks in the animals' brains. Studying the gene and its protein may ultimately lead to insights on the nature of cognitive flexibility in people.

A recent series of intramural studies in population health have focused on identifying methods to predict pregnancy complications and outcomes. In one study, researchers found that women who had higher levels of leptin before pregnancy were more likely to develop gestational

diabetes and preeclampsia (a high blood pressure disorder). These results may help explain why women with obesity are at higher risk for pregnancy complications. Postpartum hemorrhage, or severe bleeding after childbirth, can cause serious complications and even death. However, identifying specific at-risk patients remains challenging. Researchers recently analyzed a dataset of nearly 25,000 vaginal births, which included 1,167 cases of postpartum hemorrhage. Although women with more complex labor had a higher rate of postpartum hemorrhage, a large majority of postpartum hemorrhage cases were among women with few labor complications.

NICHD's intramural program also is engaged in a new collaboration with the Department of Obstetrics and Gynecology at Howard University, a historically black university. In addition to partnering on research projects, this collaboration will provide mentorship, training, professional development, and career exploration opportunities for Howard students and trainees.

Budget Policy: The budget request for this program is \$230.4 million, an increase of \$8.4 million or 3.8 percent compared with the FY 2021 Enacted level. DIR's FY 2022 priorities will emphasize support for implementation of NICHD's Strategic Plan, such as the program in pediatric and adolescent gynecology and additional collaborative efforts in developmental biology research. NICHD also will continue support for the NIH Clinical Center as well as pregnancy and perinatology research to improve maternal and newborn health outcomes.

Research Management and Support:

Research Management and Support (RMS) activities include administrative and technical functions that support and enhance the effectiveness of NICHD's research investments. Included among these functions are public communications; budget, contracts, and grants management; peer review; reporting; program evaluation; public policy; and information technology. NICHD anticipates increased investment in information technology development to support remote work by Institute staff, keep pace with the need for cybersecurity measures, conduct sophisticated data analysis for research, take advantage of advanced technologies to support administration and reporting, and expand and modernize program monitoring systems. To support responsible stewardship of valuable resources, NICHD will continue to support systematic evaluations of NICHD's scientific and administrative programs, helping to identify ways to ensure program effectiveness.

Budget Policy: The budget request for this program is \$96.5 million, an increase of \$6.9 million or 7.8 percent compared with the FY 2021 Enacted level. Priorities for RMS will emphasize information technology development and cybersecurity, along with efforts to maintain excellent stewardship of federal resources as outlined in the NICHD Strategic Plan 2020. To address these stewardship and accountability goals, such as improving clinical trials management and automating business practices, NICHD will continue to increase investment in human resources in FY 2022. In FY 2022, NICHD also will incorporate support costs related to integrating ECHO and INCLUDE into the institute.

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National Institute of Child Health and Human Development

Appropriations History

Fiscal Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
2013	\$1,320,600,000	-	\$1,324,603,000	\$1,321,397,829
Rescission	-	-	-	\$2,642,796
Sequestration	-	-	-	(\$66,325,085)
2014	\$1,339,360,000	-	\$1,330,459,000	\$1,282,595,000
Rescission	-	-	-	\$0
2015	\$1,283,487,000	-	-	\$1,286,571,000
Rescission	-	-	-	\$0
2016	\$1,318,061,000	\$1,305,586,000	\$1,345,355,000	\$1,339,802,000
Rescission	-	-	-	\$0
2017 ¹	\$1,338,348,000	\$1,373,408,000	\$1,395,811,000	\$1,380,295,000
Rescission	-	-	-	\$0
2018	\$1,032,029,000	\$1,401,727,000	\$1,426,092,000	\$1,452,006,000
Rescission	-	-	-	\$0
2019	\$1,339,592,000	\$1,469,346,000	\$1,507,251,000	\$1,506,458,000
Rescission	-	-	-	\$0
2020	\$1,296,732,000	\$1,580,084,000	\$1,587,278,000	\$1,556,879,000
Rescission	-	-	-	\$0
2021	\$1,416,366,000	\$1,582,269,000	\$1,657,606,000	\$1,590,337,000
Rescission	-	-	-	\$0
2022	\$1,942,117,000	-	-	-

¹ Budget Estimate to Congress includes mandatory financing.

NATIONAL INSTITUTES OF HEALTH
National Institute of Child Health and Human Development

Authorizing Legislation

-	PHS Act/ Other Citation	U.S. Code Citation	2021 Amount Authorized	FY 2021 Enacted	2022 Amount Authorized	FY 2022 President's Budget
Research and Investigation	Section 301	42§241	Indefinite	\$1,837,972,000	Indefinite	\$1,942,117,000
National Institute of Child Health and Human Development	Section 401(a)	42§281	Indefinite		Indefinite	
Total, Budget Authority	-	-	-	\$1,837,972,000	-	\$1,942,117,000

NATIONAL INSTITUTES OF HEALTH
National Institute of Child Health and Human Development

Amounts Available for Obligation¹
(Dollars in Thousands)

Source of Funding	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget
Appropriation	\$1,556,879	\$1,590,337	\$1,942,117
Secretary's Transfer	0	0	0
OAR HIV/AIDS Transfers	30	2,635	0
Comparative Transfer (ECHO/INCLUDE)	240,871	245,000	0
Subtotal, adjusted budget authority	\$1,797,780	\$1,837,972	\$1,942,117
Unobligated balance, start of year	0	0	0
Unobligated balance, end of year	0	0	0
Subtotal, adjusted budget authority	\$1,797,780	\$1,837,972	\$1,942,117
Unobligated balance lapsing	-68	0	0
Total obligations	\$1,797,712	\$1,837,972	\$1,942,117

¹ Excludes the following amounts (in thousands) for reimbursable activities carried out by this account:

FY 2020 - \$30,604 FY 2021 - \$35,000 FY 2022 - \$37,000

NATIONAL INSTITUTES OF HEALTH
National Institute of Child Health and Human Development

Budget Authority by Object Class¹
(Dollars in Thousands)

	FY 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY 2021 Enacted
Total compensable workyears:			
Full-time equivalent ²	561	602	41
Full-time equivalent of overtime and holiday hours	0	0	0
Average ES salary	\$194	\$199	\$5
Average GM/GS grade	12.6	12.6	0.0
Average GM/GS salary	\$119	\$121	\$3
Average salary, Commissioned Corps (42 U.S.C. 207)	\$133	\$136	\$3
Average salary of ungraded positions	\$144	\$147	\$3
OBJECT CLASSES	FY 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY 2021
11.1 Personnel Compensation			
11.1 Full-Time Permanent	44,477	48,377	3,900
11.3 Other Than Full-Time Permanent	27,070	27,686	616
11.5 Other Personnel Compensation	2,263	2,315	51
11.7 Military Personnel	429	440	12
11.8 Special Personnel Services Payments	14,827	15,164	337
11.9 Subtotal Personnel Compensation	\$89,066	\$93,982	\$4,916
12.1 Civilian Personnel Benefits	27,841	30,431	2,590
12.2 Military Personnel Benefits	196	202	5
13.0 Benefits to Former Personnel	0	0	0
Subtotal Pay Costs	\$117,103	\$124,615	\$7,512
21.0 Travel & Transportation of Persons	784	998	214
22.0 Transportation of Things	159	162	3
23.1 Rental Payments to GSA	0	0	0
23.2 Rental Payments to Others	0	0	0
23.3 Communications, Utilities & Misc. Charges	1,865	1,899	34
24.0 Printing & Reproduction	0	0	0
25.1 Consulting Services	57,233	59,412	2,179
25.2 Other Services	25,092	25,544	452
25.3 Purchase of goods and services from government accounts	119,088	134,703	15,615
25.4 Operation & Maintenance of Facilities	452	453	1
25.5 R&D Contracts	115,833	118,388	2,555
25.6 Medical Care	1,118	1,160	41
25.7 Operation & Maintenance of Equipment	5,371	4,900	-471
25.8 Subsistence & Support of Persons	0	0	0
25.0 Subtotal Other Contractual Services	\$324,187	\$344,559	\$20,372
26.0 Supplies & Materials	10,447	9,816	-631
31.0 Equipment	8,539	7,506	-1,033
32.0 Land and Structures	708	721	13
33.0 Investments & Loans	0	0	0
41.0 Grants, Subsidies & Contributions	1,374,156	1,451,817	77,661
42.0 Insurance Claims & Indemnities	0	0	0
43.0 Interest & Dividends	25	25	0
44.0 Refunds	0	0	0
Subtotal Non-Pay Costs	\$1,720,869	\$1,817,502	\$96,633
Total Budget Authority by Object Class	\$1,837,972	\$1,942,117	\$104,145

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

² The FTE level for FY 2022 includes FTEs associated with the transfer of the ECHO program from the NIH Office of the Director to NICHD. FTE levels for FY 2020 and FY 2021 are not adjusted for comparability.

NATIONAL INSTITUTES OF HEALTH
National Institute of Child Health and Human Development

Salaries and Expenses
(Dollars in Thousands)

OBJECT CLASSES	FY 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY 2021
Personnel Compensation			
Full-Time Permanent (11.1)	\$44,477	\$48,377	\$3,900
Other Than Full-Time Permanent (11.3)	27,070	27,686	616
Other Personnel Compensation (11.5)	2,263	2,315	51
Military Personnel (11.7)	429	440	12
Special Personnel Services Payments (11.8)	14,827	15,164	337
Subtotal Personnel Compensation (11.9)	\$89,066	\$93,982	\$4,916
Civilian Personnel Benefits (12.1)	\$27,841	\$30,431	\$2,590
Military Personnel Benefits (12.2)	196	202	5
Benefits to Former Personnel (13.0)	0	0	0
Subtotal Pay Costs	\$117,103	\$124,615	\$7,512
Travel & Transportation of Persons (21.0)	\$784	\$998	\$214
Transportation of Things (22.0)	159	162	3
Rental Payments to Others (23.2)	0	0	0
Communications, Utilities & Misc. Charges (23.3)	1,865	1,899	34
Printing & Reproduction (24.0)	0	0	0
Other Contractual Services:			
Consultant Services (25.1)	57,233	59,412	2,179
Other Services (25.2)	25,092	25,544	452
Purchases from government accounts (25.3)	73,827	80,818	6,992
Operation & Maintenance of Facilities (25.4)	452	453	1
Operation & Maintenance of Equipment (25.7)	5,371	4,900	-471
Subsistence & Support of Persons (25.8)	0	0	0
Subtotal Other Contractual Services	\$161,974	\$171,127	\$9,153
Supplies & Materials (26.0)	\$10,447	\$9,816	-\$631
Subtotal Non-Pay Costs	\$175,229	\$184,001	\$8,772
Total Administrative Costs	\$292,331	\$308,616	\$16,285

NATIONAL INSTITUTES OF HEALTH
National Institute of Child Health and Human Development

Detail of Full-Time Equivalent Employment (FTE)

OFFICE/DIVISION	FY 2020 Final			FY 2021 Enacted			FY 2022 President's Budget		
	Civilian	Military	Total	Civilian	Military	Total	Civilian	Military	Total
Division of Extramural Research									
Direct:	116	-	116	141	1	142	163	1	164
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	116	-	116	141	1	142	163	1	164
Division of Intramural Programs									
Direct:	291	2	293	290	2	292	289	2	291
Reimbursable:	3	-	3	4	-	4	5	-	5
Total:	294	2	296	294	2	296	294	2	296
National Center for Medical Rehabilitation Research									
Direct:	8	-	8	9	-	9	9	-	9
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	8	-	8	9	-	9	9	-	9
Office of the Director									
Direct:	92	-	92	105	-	105	125	-	125
Reimbursable:	8	-	8	9	-	9	8	-	8
Total:	100	-	100	114	-	114	133	-	133
Total	518	2	520	558	3	561	599	3	602
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								
2018	12.3								
2019	12.5								
2020	12.5								
2021	12.6								
2022	12.6								

NATIONAL INSTITUTES OF HEALTH
National Institute of Child Health and Human Development

Detail of Positions¹

GRADE	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget
Total, ES Positions	1	1	1
Total, ES Salary	176,490	193,963	199,103
General Schedule			
GM/GS-15	54	59	66
GM/GS-14	76	85	93
GM/GS-13	90	97	107
GS-12	67	71	78
GS-11	24	31	32
GS-10	2	2	2
GS-9	10	15	23
GS-8	14	14	14
GS-7	13	14	14
GS-6	3	3	3
GS-5	1	1	1
GS-4	0	0	0
GS-3	1	1	1
GS-2	0	0	0
GS-1	0	0	0
Subtotal	355	393	434
Commissioned Corps (42 U.S.C. 207)			
Assistant Surgeon General	0	0	0
Director Grade	2	2	2
Senior Grade	0	1	1
Full Grade	0	0	0
Senior Assistant Grade	0	0	0
Assistant Grade	0	0	0
Subtotal	2	3	3
Ungraded	207	211	215
Total permanent positions	356	395	438
Total positions, end of year	565	608	653
Total full-time equivalent (FTE) employment, end of year	520	561	602
Average ES salary	176,490	193,963	199,103
Average GM/GS grade	12.5	12.6	12.6
Average GM/GS salary	115,676	118,741	121,472

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