

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)

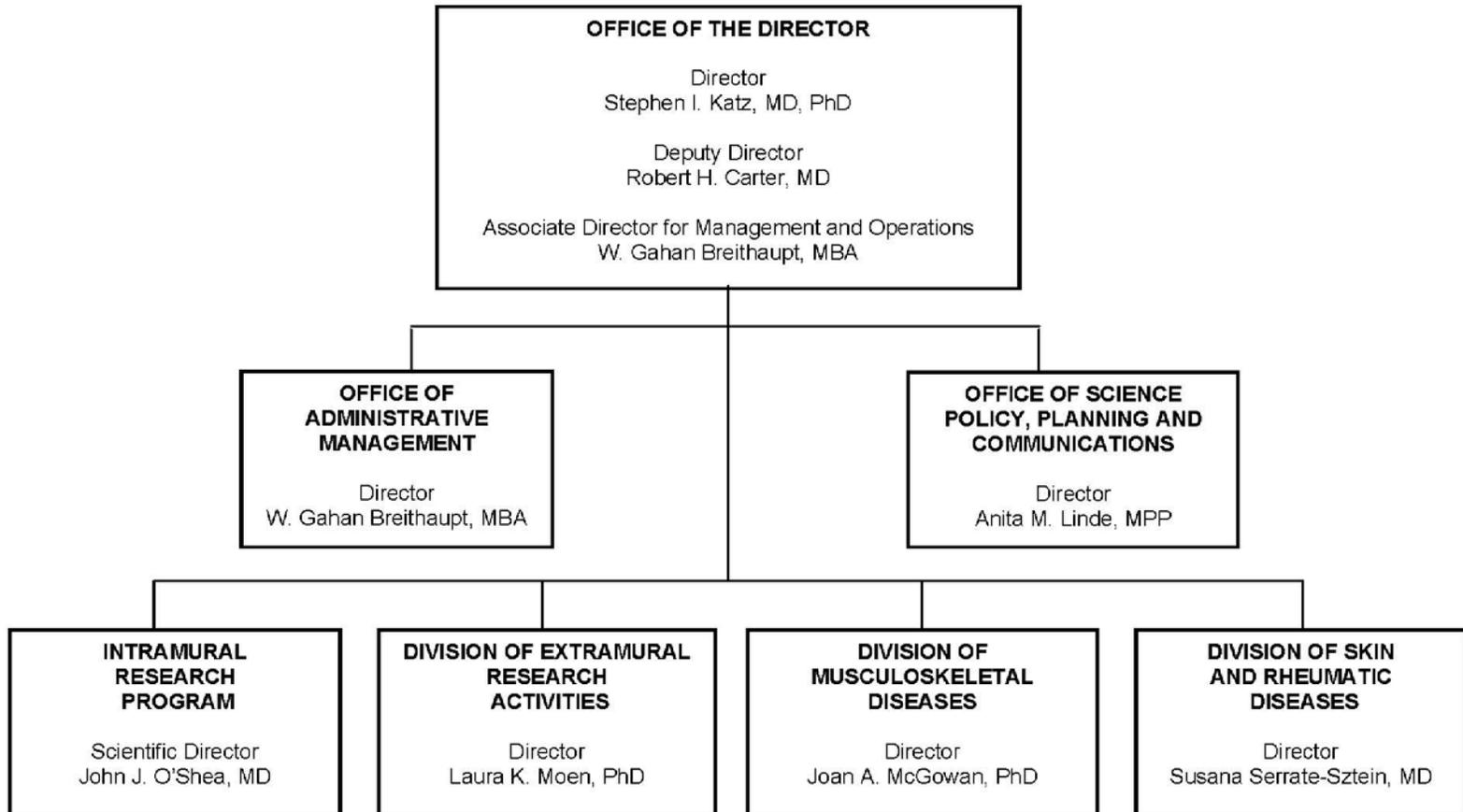
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NATIONAL INSTITUTES OF HEALTH

National Institute of Arthritis and Musculoskeletal and Skin Diseases

Organizational Structure



NATIONAL INSTITUTES OF HEALTH

National Institute of Arthritis and Musculoskeletal and Skin Diseases

For carrying out section 301 and title IV of the PHS Act with respect to arthritis and musculoskeletal and skin diseases, ~~【\$521,665,000】~~ \$533,232,000.

NATIONAL INSTITUTES OF HEALTH
National Institute of Arthritis and Musculoskeletal and Skin Diseases

Amounts Available for Obligation¹
(Dollars in Thousands)

Source of Funding	FY 2014 Actual	FY 2015 Enacted	FY 2016 President's Budget
Appropriation	\$520,053	\$521,665	\$533,232
Type 1 Diabetes	0	0	0
Rescission	0	0	0
Sequestration	0	0	0
FY 2014 First Secretary's Transfer	-1,305	0	0
FY 2014 Second Secretary's Transfer	-102	0	0
Subtotal, adjusted appropriation	\$518,646	\$521,665	\$533,232
OAR HIV/AIDS Transfers	0	-137	0
National Children's Study Transfers	1,709	0	0
Subtotal, adjusted budget authority	\$520,355	\$521,528	\$533,232
Unobligated balance, start of year	0	0	0
Unobligated balance, end of year	0	0	0
Subtotal, adjusted budget authority	\$520,355	\$521,528	\$533,232
Unobligated balance lapsing	-41	0	0
Total obligations	\$520,314	\$521,528	\$533,232

¹ Excludes the following amounts for reimbursable activities carried out by this account:

FY 2014 - \$2,811 FY 2015 - \$2,895 FY 2016 - \$2,982

NATIONAL INSTITUTES OF HEALTH
National Institute of Arthritis and Musculoskeletal and Skin Diseases

Budget Mechanism - Total¹

(Dollars in Thousands)

MECHANISM	FY 2014 Actual		FY 2015 Enacted		FY 2016 President's Budget		FY 2016 +/- FY 2015	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Projects:								
Noncompeting	698	\$242,521	677	\$237,668	722	\$240,506	45	\$2,838
Administrative Supplements	(15)	771	(15)	1,090	(15)	1,090	(0)	0
Competing:								
Renewal	45	18,744	55	17,642	66	18,608	11	966
New	237	65,556	257	70,225	263	74,069	6	3,844
Supplements	6	1,722	6	1,794	7	1,893	1	99
Subtotal, Competing	288	\$86,021	318	\$89,661	336	\$94,570	18	\$4,909
Subtotal, RPGs	986	\$329,312	995	\$328,419	1,058	\$336,166	63	\$7,747
SBIR/STTR	43	13,832	45	14,452	48	15,507	3	1,055
Research Project Grants	1,029	\$343,144	1,040	\$342,871	1,106	\$351,673	66	\$8,802
Research Centers:								
Specialized/Comprehensive	42	\$42,688	42	\$41,560	44	\$43,388	2	\$1,828
Clinical Research	0	0	0	0	0	0	0	0
Biotechnology	0	0	0	0	0	0	0	0
Comparative Medicine	0	29	0	29	0	29	0	0
Research Centers in Minority Institutions	0	0	0	0	0	0	0	0
Research Centers	42	\$42,717	42	\$41,589	44	\$43,417	2	\$1,828
Other Research:								
Research Careers	150	\$18,923	156	\$19,490	156	\$19,491	0	\$1
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	195	0	195	0	195	0	0
Other	25	3,197	36	3,183	36	3,183	0	0
Other Research	175	\$22,315	192	\$22,868	192	\$22,869	0	\$1
Total Research Grants	1,246	\$408,176	1,274	\$407,328	1,342	\$417,959	68	\$10,631
Ruth L Kirchstein Training Awards:	<u>FTTPs</u>		<u>FTTPs</u>		<u>FTTPs</u>		<u>FTTPs</u>	
Individual Awards	62	\$2,998	61	\$3,046	61	\$3,095	0	\$49
Institutional Awards	224	11,915	224	12,106	224	12,300	0	194
Total Research Training	286	\$14,913	285	\$15,152	285	\$15,395	0	\$243
Research & Develop. Contracts	37	\$15,148	37	\$16,109	37	\$16,109	0	\$0
<i>(SBIR/STTR) (non-add)</i>	<i>(0)</i>	<i>(69)</i>	<i>(0)</i>	<i>(147)</i>	<i>(0)</i>	<i>(152)</i>	<i>(0)</i>	<i>(5)</i>
Intramural Research	135	53,602	135	54,138	135	54,680	0	542
Res. Management & Support	107	28,516	108	28,801	108	29,089	0	288
<i>Res. Management & Support (SBIR Admin) (non-add)</i>	<i>(0)</i>	<i>(0)</i>	<i>(0)</i>	<i>(0)</i>	<i>(0)</i>	<i>(0)</i>	<i>(0)</i>	<i>(0)</i>
Construction		0		0		0		0
Buildings and Facilities		0		0		0		0
Total, NIAMS	242	\$520,355	243	\$521,528	243	\$533,232	0	\$11,704

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

Major Changes in the Fiscal Year 2016 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 2016 President's Budget for NIAMS, which is \$11.567 million more than the FY 2015 Enacted level, for a total of \$533.232 million.

Research Project Grants (+\$8.802 million; total \$351.673 million):

NIAMS will support a total of 1,106 Research Project Grant (RPG) awards in FY 2016. Noncompeting awards will increase by 45 awards and \$2.838 million. Competing RPGs will increase by 18 awards and \$4.909 million. NIAMS continues to place a priority on support to new investigators.

Research Centers (+\$1.828 million; total \$43.417 million):

NIAMS will support a total of 44 Research Centers awards in FY 2016 which is an increase of 2 awards and \$1.828 million to help support the Precision Medicine Cohort Initiative. NIH proposes to launch a national research cohort of one million or more Americans – to propel our understanding of health and disease and set the foundation for a new way of doing research through engaged participants and open, responsible data sharing. Participants who voluntarily choose to join this effort will be able to share their genomic data, biological specimens, and behavioral data, and, if they choose, link it to their electronic health records (EHRs), taking advantage of the latest in social media and mobile applications, and with appropriate privacy protections in place. Bona fide researchers from across the country will have access to data voluntarily provided, thereby crowdsourcing rich data to the brightest minds in biomedical research. The cohort will be built largely by linking existing cohorts together taking advantage of infrastructure, data security and expertise already in place. NIH will help to connect these existing cohorts, but the current sponsors of the cohorts will maintain their ownership and management. Research on this scale promises to lead to new prevention strategies, novel therapeutics and medical devices, and improvements in how we prescribe drugs – on an *individual and personalized basis*.

Research Training (+\$0.243 million; total \$15.395 million):

NIAMS will support 285 pre- and postdoctoral trainees in full-time training positions, the same as the number funded in FY 2015. Support for NRSA training mechanism will be increased by \$0.243 million amount to cover the cost of increased stipends.

NATIONAL INSTITUTES OF HEALTH
National Institute of Arthritis and Musculoskeletal and Skin Diseases

Summary of Changes

(Dollars in Thousands)

FY 2015 Enacted		\$521,528		
FY 2016 President's Budget		\$533,232		
Net change		\$11,704		
CHANGES	FY 2016 President's Budget		Change from FY 2015	
	FTEs	Budget Authority	FTEs	Budget Authority
<u>A. Built-in:</u>				
<u>1. Intramural Research:</u>				
a. Annualization of January 2015 pay increase & benefits		\$19,203		\$46
b. January FY 2016 pay increase & benefits		19,203		139
c. One more day of pay (n/a for 2015)		19,203		73
d. Differences attributable to change in FTE		19,203		0
e. Payment for centrally furnished services		9,637		235
f. Increased cost of laboratory supplies, materials, other expenses, and non-recurring costs		25,840		366
Subtotal				\$859
<u>2. Research Management and Support:</u>				
a. Annualization of January 2015 pay increase & benefits		\$16,185		\$39
b. January FY 2016 pay increase & benefits		16,185		118
c. One more day of pay (n/a for 2015)		16,185		61
d. Differences attributable to change in FTE		16,185		0
e. Payment for centrally furnished services		3,765		92
f. Increased cost of laboratory supplies, materials, other expenses, and non-recurring costs		9,138		84
Subtotal				\$394
Subtotal, Built-in				\$1,253

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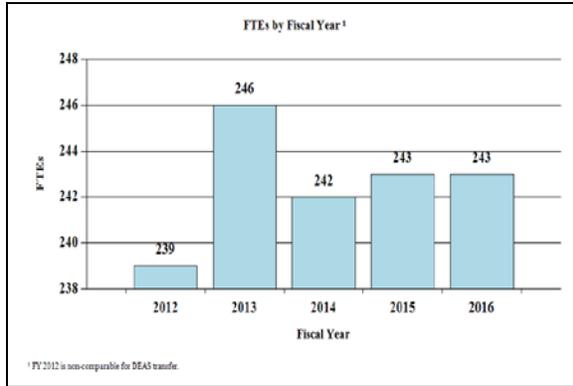
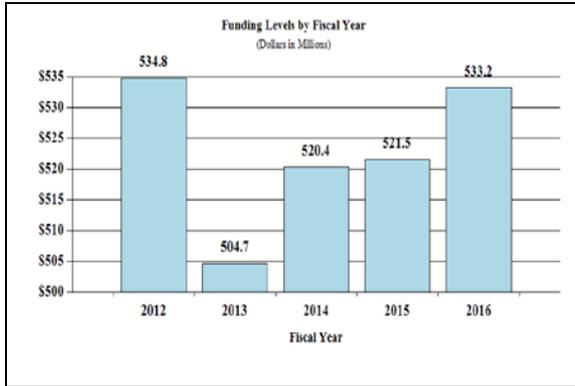
Summary of Changes

(Dollars in Thousands)

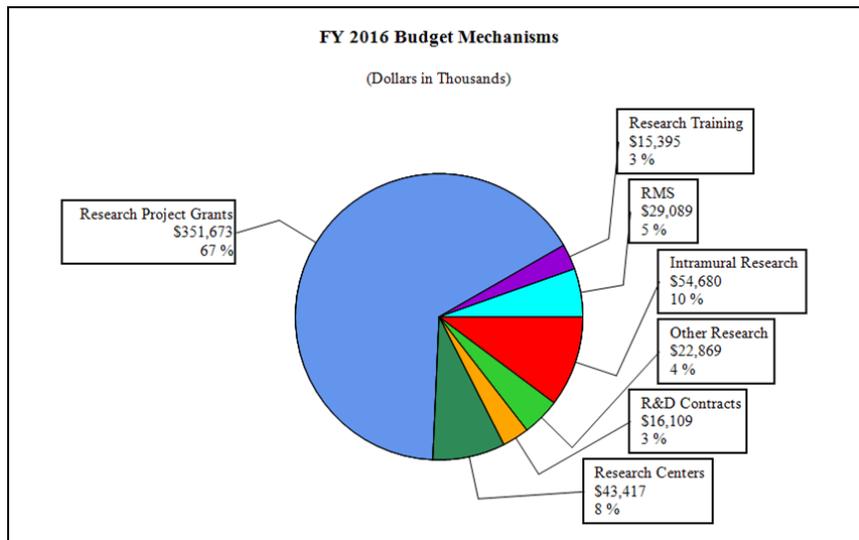
FY 2015 Enacted				\$521,528
FY 2016 President's Budget				\$533,232
Net change				\$11,704
CHANGES	FY 2016 President's Budget		Change from FY 2015	
	FTEs	Budget Authority	FTEs	Budget Authority
A. Built-in:				
1. Intramural Research:				
a. Annualization of January 2015 pay increase & benefits		\$19,203		\$46
b. January FY 2016 pay increase & benefits		19,203		139
c. One more day of pay (n/a for 2015)		19,203		73
CHANGES	FY 2016 President's Budget		Change from FY 2015	
	No.	Amount	No.	Amount
B. Program:				
1. Research Project Grants:				
a. Noncompeting	722	\$241,596	45	\$2,838
b. Competing	336	94,570	18	4,909
c. SBIR/STTR	48	15,507	3	1,055
Subtotal, RPGs	1,106	\$351,673	66	\$8,802
2. Research Centers	44	\$43,417	2	\$1,828
3. Other Research	192	22,869	0	1
4. Research Training	285	15,395	0	243
5. Research and development contracts	37	16,109	0	0
Subtotal, Extramural		\$449,463		\$10,874
6. Intramural Research	<u>FTEs</u>	135	<u>FTEs</u>	0
		\$54,680		-\$317
7. Research Management and Support	108	29,089	0	-106
8. Construction		0		0
9. Buildings and Facilities		0		0
Subtotal, Program	243	\$533,232	0	\$10,451
Total changes				\$11,704

Fiscal Year 2016 Budget Graphs

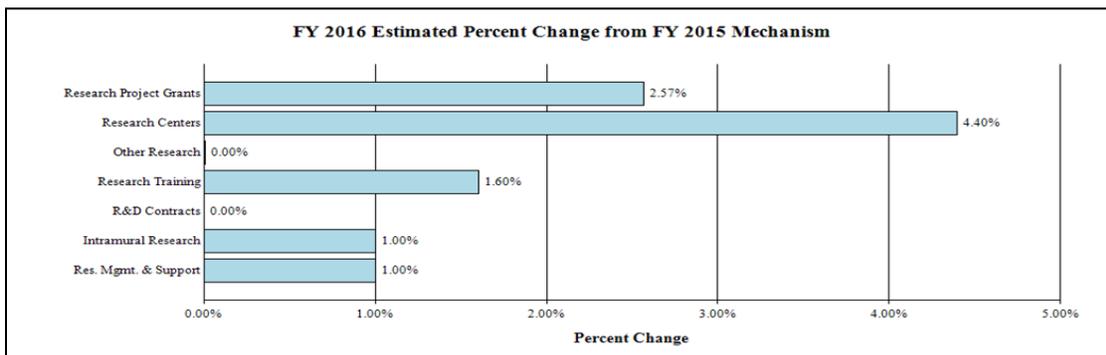
History of Budget Authority and FTEs:



Distribution by Mechanism:



Change by Selected Mechanism:



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National Institute of Arthritis and Musculoskeletal and Skin Diseases

Budget Authority by Activity¹
(Dollars in Thousands)

	FY 2014 Actual		FY 2015 Enacted ²		FY 2016 President's Budget		FY 2016 +/- FY 2015	
	<u>FTE</u>	<u>Amount</u>	<u>FTE</u>	<u>Amount</u>	<u>FTE</u>	<u>Amount</u>	<u>FTE</u>	<u>Amount</u>
Extramural Research								
<u>Detail</u>								
Arthritis and Rheumatic Diseases		\$103,430		\$103,514		\$106,082		\$2,568
Musculoskeletal Biology and Diseases		132,962		133,065		136,360		3,295
Bone Biology and Diseases		60,048		60,097		61,588		1,491
Muscle Biology and Diseases		68,786		68,842		70,550		1,708
Skin Biology and Diseases		73,011		73,071		74,883		1,812
Subtotal, Extramural		\$438,237		\$438,589		\$449,463		\$10,874
Intramural Research	135	\$53,602	135	\$54,138	135	\$54,680	0	\$542
Research Management & Support	107	\$28,516	108	\$28,801	108	\$29,089	0	\$288
TOTAL	242	\$520,355	243	\$521,528	243	\$533,232	0	\$11,704

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

¹ Items in italics are "non-adds"; for reference only (NIH Director's Challenge Fund amounts are already included in OD Operations budget.)

² The amounts in the FY 2014 column take into account funding reallocations, and therefore may not add to the total budget authority reflected herein.

**NATIONAL INSTITUTES OF HEALTH
National Institute of Arthritis and Musculoskeletal and Skin Diseases**

Authorizing Legislation

	PHS Act/ Other Citation	U.S. Code Citation	2015 Amount Authorized	FY 2015 Enacted	2016 Amount Authorized	FY 2016 President's Budget
Research and Investigation	Section 301	42§241	Indefinite		Indefinite	
National Institute of Arthritis and Musculoskeletal and Skin Diseases	Section 401(a)	42§281	Indefinite	\$521,528,000	Indefinite	\$533,232,000
Total, Budget Authority				\$521,528,000		\$533,232,000

NATIONAL INSTITUTES OF HEALTH
National Institute of Arthritis and Musculoskeletal and Skin Diseases

Appropriations History

Fiscal Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
2006 Rescission	\$513,063,000	\$513,063,000	\$525,578,000	\$513,063,000 (\$5,131,000)
2007 Rescission	\$504,533,000	\$504,533,000	\$508,585,000	\$508,240,000 \$0
2008 Rescission Supplemental	\$508,082,000	\$516,044,000	\$519,810,000	\$517,629,000 (\$9,043,000) \$2,075,000
2009 Rescission	\$509,080,000	\$526,583,000	\$523,246,000	\$524,872,000 \$0
2010 Rescission	\$530,825,000	\$543,621,000	\$533,831,000	\$539,082,000 \$0
2011 Rescission	\$555,715,000		\$554,846,000	\$539,082,000 (\$4,733,461)
2012 Rescission	\$547,891,000	\$547,891,000	\$528,332,000	\$536,801,000 (\$1,014,454)
2013 Rescission Sequestration	\$535,610,000		\$537,233,000	\$535,786,446 (\$1,071,573) (\$26,892,795)
2014 Rescission	\$540,993,000		\$537,398,000	\$520,053,000 \$0
2015 Rescission	\$520,189,000			\$521,665,000 \$0
2016	\$533,232,000			

Justification of Budget Request

National Institute of Arthritis and Musculoskeletal and Skin Diseases

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

Budget Authority (BA):

	FY 2014 Actual	FY 2015 Enacted	FY 2016 President's Budget	FY 2016 +/- FY 2015
BA	\$520,355,189	\$521,528,000	\$533,232,000	+\$11,704,000
FTE	242	243	243	+0

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

Director's Overview

As the primary Federal agency for supporting medical research on diseases of the bones, joints, muscles, and skin, the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) touches the lives of nearly every American. Arthritis limits the activities of approximately 21 million adults in the United States each year; medical care and lost wages attributable to musculoskeletal conditions cost Americans an estimated \$950 billion annually; and skin conditions such as eczema and psoriasis affect more than 12 percent of people worldwide.¹ NIAMS is working to enhance health, lengthen life, and reduce illness and disability by supporting basic and translational research that will impact clinical practice, training the next generation of bone, joint, muscle, and skin scientists, and disseminating the findings and related health information from the studies it supports to all Americans. The activities described below highlight the Institute's many efforts to advance public health.

Investigator-initiated basic research is one of NIAMS' highest priorities. NIAMS-supported efforts to understand the basic mechanisms of disease provide a foundation for the development of new therapies and suggest new uses for existing drugs. For example, identification of the immune cells and signaling molecules responsible for destroying hair follicles in people with alopecia areata—a common autoimmune disease that causes disfiguring hair loss—led to a small clinical trial of a Food and Drug Administration-approved drug that targets similar pathways in

¹ Cheng YJ, et al. Prevalence of doctor-diagnosed arthritis and arthritis-attributable activity limitation—United States, 2007–2009. *MMWR* 2010;59(39):1261–1265

U.S. Department of Health and Human Services, Agency for Healthcare Research and Quality, Medical Expenditures Panel Survey, 1996 – 2006. Data analyzed and modeled by Edward H. Yelin, PhD, Institute for Health Policy Studies, University of California, San Francisco, San Francisco, CA, as cited in www.boneandjointburden.org/highlights/FactsinBrief.pdf, accessed October 3, 2014

Vos T, et al. Years lived with disability (YLDs) for 1160 sequelae of 289 diseases and injuries 1990–2010: a systematic analysis for the Global Burden of Disease Study 2010. *Lancet*. 2012 Dec 15;380(9859):2163–96. PMID: 23245607

other conditions. Each of three patients regrew their hair within five months of starting treatment; investigators are continuing the study to determine the drug's long-term success and safety.

In the NIAMS Intramural Research Program (IRP), investigators are finding treatments for children who have rare diseases, while learning how the body maintains a delicate balance between protective and destructive responses. They recently treated a seven-year-old girl who appeared to have a rare disease called macrophage activation syndrome (MAS). When the child's lab tests indicated that an unknown mechanism was triggering her life-threatening inflammation, the researchers used sophisticated genome sequencing tools to identify the mutation responsible for her illness. Not only did their finding reveal that the child would benefit from an existing drug, which reduced many of her symptoms, it pointed to an additional molecule that could be the target of future, better treatments for MAS and other conditions.

In addition to supporting basic research into disease mechanisms, NIAMS leads several projects with industry and non-profit partners to develop resources for translating discoveries into treatments, diagnostic approaches, and prevention strategies. In FY 2014, NIAMS, the National Institute of Allergy and Infectious Diseases (NIAID), the Foundation for NIH, six pharmaceutical companies, and five patient advocacy and professional societies established the Accelerating Medicines Partnership in Rheumatoid Arthritis and Lupus (AMP RA/Lupus) Network. Over five years, the Network will examine molecules and pathways involved in RA and lupus at the single-cell level, and will identify differences and similarities between people with and without disease, and among those at various disease stages. Identification of shared and disease-specific pathways is expected to reveal targets for drug development at an overall lower cost, and in less time, than could be done through individual studies. The Institute also continues to participate in other public-private partnerships, such as the Osteoarthritis Initiative and the Biomarkers Consortium's Bone Quality Initiative and Osteoarthritis Biomarkers Project, which are developing tools to improve the efficiency of future clinical studies.

As NIAMS looks to FY 2016, the Institute is planning to reissue a series of initiatives that will help investigators ask and answer the most important clinical questions facing health care providers and patients today. Building on discussions at the Institute's FY 2014 scientific planning retreat, NIAMS is considering strategies to encourage research ideas that challenge existing paradigms or uncover new directions related to the diagnosis, treatment, or prevention of diseases within the NIAMS mission.

Genome-wide association studies (GWAS) have led to significant advances in understanding complex musculoskeletal, rheumatic, and skin disorders by facilitating identification of common genetic variants that influence disease risk. A growing body of data generated through efforts such as the Encyclopedia of DNA Elements (ENCODE) Project and the NIH Epigenomics Program has enabled researchers to extend results of GWAS studies through genome-wide analysis of transcription, chromatin organization, and epigenetic markers. The Institute's activities for FY 2016 include continuing to consider ways in which bone, joint, muscle, and skin researchers can leverage these data for studies that will lead to better diagnostic, preventive, and treatment strategies. NIAMS also will continue its participation in trans-NIH activities to support the nation's biomedical, behavioral, and clinical research needs in Big Data Science.

NIAMS is committed to ensuring that a sufficient number of well-trained basic scientists and clinical researchers are prepared to conduct cutting-edge studies related to musculoskeletal, skin, and rheumatic diseases. The Institute funds a combination of institutional training grants and individual fellowships for this purpose. Building on a successful effort to encourage clinician scientists as they transition from mentored research to full independence, NIAMS began meeting with clinical and patient-oriented research career development awardees in both the first and third years of their grants. These interactions identify challenges that the investigators face and ways to better support them and future awardees. In addition, NIAMS is participating in an NIH-wide effort to increase the number of grants made to investigators with meritorious ideas who previously have not had a substantial independent NIH award and is developing a program that would provide sustained support for scientists who have received their first competitive renewal, or type 2, research project grant. This Supplements to Advance Research (STAR) program focuses on a particularly vulnerable time when investigators no longer qualify for new-investigator status, but have not yet developed the robust research portfolio that places them on even ground with long-established faculty members. Other plans for FY 2016 include continuing a small grant program that supports new investigators as they generate the preliminary data necessary for a larger NIH research project grant.

Overall Budget Policy:

The FY 2016 President's Budget request for NIAMS is \$533.232 million, an increase of \$11.704 million or 2.2 percent above the FY 2015 Enacted level.

Program Descriptions and Accomplishments

Arthritis and Rheumatic Diseases: This program advances high-quality basic, translational, and clinical biomedical and biopsychosocial research to treat, cure, and prevent arthritis and autoimmune diseases. It supports the application of new insights in the fields of genetics, genomics, proteomics, immunology, and imaging to understand how the immune system interacts with various tissues in normal and pathological conditions, and to ensure a continuous supply of new targets on which therapies can be based. Many of the diseases covered by this program vary with respect to the severity of the symptoms that patients experience and the damage done to tissues and organs. Where treatments exist, clinicians lack the ability to differentiate between patients who should be treated conservatively because their conditions are stable and those who might benefit from additional, more aggressive therapies. Numerous research teams are addressing this need by searching for predictive markers that could be easily measured as part of an office visit; some recently have made progress toward identifying molecules from patients' blood samples that correlate with the severity of conditions including lupus and scleroderma. The program also managed the Patient-Reported Outcomes Measurement Information System (PROMIS®) initiative for the NIH Common Fund and continues to support the development and use of PROMIS technologies. NIAMS-funded researchers recently published a set of PROMIS questions that accurately evaluates patient function across a wider range of physical abilities. This expansion is compatible with the World Health Organization's increased emphasis on health as a state of well-being rather than simply an absence of disease.

Budget Policy:

The FY 2016 budget estimate for this program is \$106.082 million, an increase of \$2.568 million or 2.5 percent above the FY 2015 Enacted level. Program plans for FY 2016 include encouraging investigators to explore the signaling pathways within and between immune cells and their target tissues, with the goal of identifying potential drug targets or diagnostic strategies for autoimmune diseases. In addition, as lead of the Lupus Federal Working Group, NIAMS will continue to facilitate collaborations among the NIH Institutes and Centers, other Federal agencies, voluntary and professional organizations, and pharmaceutical companies with an interest in lupus.

Musculoskeletal Biology and Diseases: This program focuses on understanding the fundamental biology of tissues that constitute the musculoskeletal system and on translating and applying this knowledge to a variety of diseases and conditions, including osteoarthritis (OA). One recent advance supported by this program comes from a research team that developed a mouse model of the disease pseudoachondroplasia (PSACH), a severe form of dwarfism that starts to manifest as children approach their second birthday; not only have the findings shed light on the pathology of the disease, the research identified a window during which treatments may be most effective. The program also supports the development of technologies such as bone and joint imaging, tissue engineering, and regenerative medicine to improve the diagnosis and treatment of skeletal disorders, or to facilitate repair of damage caused by trauma to otherwise healthy tissue. It oversees clinical research into the treatment and prevention of acute and chronic bone and joint injuries and orthopaedic conditions.

Program Portrait: The Spine Patient Outcomes Research Trial (SPORT) for Low Back Pain

FY 2015 level: \$0.828 million

FY 2016 level: \$0.775 million

Change: -\$0.053 million

World-wide, low back pain is the leading cause of disability, as measured by years lived with disability (YLDs), and it is the sixth greatest source of disease burden as measured in disability-adjusted life years (DALYs).² Although clinicians quickly can identify some of their patients who require surgery for their low back pain – and others who will recover without it – guidance about how best to care for patients who are not at either extreme would be beneficial.

For the past decade, NIH-funded researchers have been monitoring the health of people who have low back pain due to one of three specific diagnoses: intervertebral disc herniation, lumbar spinal stenosis, or degenerative spondylolisthesis. Early findings from the study, called SPORT, showed that, in general, otherwise healthy people who have surgery for one of these three conditions are likely to fare better than those who receive non-operative care. However, people who are reluctant to have surgery may also recover with non-operative treatments if their conditions are not progressing and their pain is tolerable. And, importantly, delaying or avoiding surgery does not cause additional damage in most cases.

Benefits from surgical intervention occurred for all conditions at four years and for disc herniation at eight years. Eight-year results for the other two conditions are pending. Continued follow-up of SPORT participants has created a rich database of traits that are associated with a surgery's success. Although the current NIAMS commitment to the SPORT trial runs through FY 2015, program plans for FY 2016 and beyond include supporting an effort to incorporate the findings into a decision tool that will inform patients and their health care teams about likely improvements in physical activity, pain, and overall health after surgical or non-surgical treatment for low back pain.

Budget Policy:

The FY 2016 budget estimate for this program is \$136.360 million, an increase of \$3.295 million or 2.5 percent above the FY 2015 Enacted level. Program plans for FY 2016 include continuing an effort, begun in FY 2013, to promote the use of data and images collected as part of the Osteoarthritis Initiative in studies of the epidemiology and natural history of OA and its risk factors. NIAMS also will continue to encourage identification of molecular and cellular mechanisms underlying progressive deterioration of joint structure and function in OA. The goal is to accelerate the development of strategies to predict who will experience OA, how OA can be prevented, and how it can be treated once joint degeneration has begun.

Bone Biology and Diseases: This program covers a broad spectrum of research designed to better understand genetic and cellular mechanisms involved in the build-up and breakdown of bone. It supports studies of the regulation of bone remodeling; bone formation, bone resorption, and mineralization; and the effects of hormones, growth factors, and other signals on bone cells. One project, supported in a partnership with the National Aeronautics and Space Administration and the Center for the Advancement of Science in Space on board the International Space Station, is exploring how bone cells respond to the absence of gravity and how those changes relate to the bone loss that millions of people experience each year because of illness or injury. The program also supports several large epidemiologic cohorts for characterization of the natural history of osteoporosis and for identification of genetic and environmental risk factors that contribute to bone disease. Building on the knowledge that bone adapts to exercise by getting bigger, heavier and stronger, and that bones respond best during childhood and adolescence,

many NIAMS-funded research teams are studying bone health in pediatric populations. One group recently demonstrated that bone-building activities during youth provide benefits that last a lifetime. Another identified characteristics of childhood fractures that are associated with underlying bone health problems; whereas children who break their arms after moderately forceful accidents (e.g., falling off a bicycle) likely have healthy bones, those who fracture following a mild trauma (e.g., a fall while running on a playground) might benefit from nutritional and exercise interventions to improve bone health.

Budget Policy:

The FY 2016 budget estimate for this program is \$61.588 million, an increase of \$1.491 million or 2.5 percent above the FY 2015 Enacted level. Program plans for FY 2016 include encouraging investigators to study the cell and mineral changes that lead to atypical femoral fractures—breaks in the upper part of the leg bone that are thought to be a rare side-effect of long-term bisphosphonate treatment for osteoporosis. NIAMS also will promote collaborations and the exchange of information at the agency level through the Federal Working Group on Bone Diseases—an interagency committee led by the Institute.

Muscle Biology and Diseases: This program supports a wide range of basic, translational, and clinical research projects in skeletal muscle biology and diseases. It focuses on the fundamental biology of muscle development, physiology, and muscle imaging. The overarching objective is to advance the understanding of the role that muscle plays in musculoskeletal and whole body health and, ultimately, to treat or prevent skeletal muscle diseases and disorders, including the muscular dystrophies, inflammatory myopathies, muscle ion channel diseases, disuse atrophy, skeletal muscle injury, and loss of muscle mass associated with aging and diseases. For example, a team of researchers recently linked genetic mutations that alter muscle cells' ability to process calcium with a common side effect of cholesterol-lowering drugs called statins. The connection between statin-induced muscle damage and these mutations, which also are associated with a potentially fatal condition called malignant hyperthermia, suggests health care providers should carefully monitor people known to have malignant hyperthermia who take statins for cholesterol control. The findings also could have implications for people with a history of statin-induced myopathy, as the condition may be a sign that they are harboring malignant hyperthermia mutations.

Budget Policy:

The FY 2016 budget estimate for this program is \$70.550 million, an increase of \$1.708 million or 2.5 percent above the FY 2015 Enacted level. Plans include continued participation in the Senator Paul D. Wellstone Muscular Dystrophy Cooperative Research Centers Program, collaborations with other NIH components and Federal agencies to advance research objectives in the new Action Plan for the Muscular Dystrophies, and efforts to encourage researchers to investigate the molecular processes by which skeletal muscle influences other organ systems.

² Brauer CA, et al. Incidence and mortality of hip fractures in the United States. JAMA. 2009 Oct 14;302(14):1573-9. PMID: 19826027

Skin Biology and Diseases: This program's support for basic, translational, and clinical research includes work on the developmental and molecular biology of skin, the study of skin as an immune organ, and the genetics of skin diseases. One emerging area of research into skin's sensory functions focuses on understanding the biological basis of chronic itch, a symptom associated with many skin diseases and with responses to certain drugs. Chronic itch, which affects millions of Americans, can be difficult to treat and manage, potentially leading to severe deterioration of a person's quality of life. Although the underlying cellular and molecular mechanisms of itch are not well understood, a number of NIAMS-funded research teams recently identified cells, molecules, and pathways involved in chronic itch and have developed new tools to study the condition. The Skin Biology and Diseases program also supports research into ways to prevent skin damage due to ultraviolet (UV) light. Despite the well-known link between skin cancer and chronic UV light exposure from the sun or tanning beds, people have been slow to adopt measures that will protect their skin, and skin cancer incidence continues to rise. NIAMS-funded investigators recently demonstrated that UV exposure causes skin cells to produce molecules that resemble opioids; prolonged exposure leads to addiction-like responses that likely contribute to UV-seeking behavior and the increase in skin cancer cases reported each year.

Program Portrait: Studying Stem Cells to Help the Body Heal

FY 2015 Level: \$71.286 million

FY 2016 Level: \$72.855 million

Change: +\$1.569 million

Dividing stem cells can take two paths; they can generate more stem cells or mature into other cell types. NIAMS-funded research into the signals that control stem cell behavior is answering several questions that have puzzled investigators for decades. For example, salamanders and newts are well known for their ability to regenerate lost limbs; but people can only regenerate the tips of fingers and toes, and only if part of the nail remains. In FY 2014, investigators discovered that a signaling pathway triggers fingertip regeneration by stimulating the formation of new nail from stem cells found at the base of the nail. The regenerating nail then draws nerve cells into the wound site. These nerve cells – by promoting the release of a growth factor – help form the other tissues that comprise the finger, such as bone, muscle, and tendons.

Other groups are exploring methods to grow new tissue from stem cells in the laboratory, with the goal of developing functional material that could replace tissue that was damaged by injury or disease. One group has found a way to isolate muscle stem cells from rats and turn them into an elongated bundle of muscle fibers that spontaneously twitch. When stimulated with electric pulses, the fibers contract like natural muscles. And, the tissue developed its own blood supply and continued to function when implanted into rats whose muscles had been injured. The next step is to see if the fibers can connect to the animals' nervous system and work in tandem with the remaining healthy muscle tissue.

A third example of the healing power of stem cells comes from a team that showed how muscle stem cells can be turned into brown fat – an energy-burning type of fat. This entailed altering the amount of one of the many molecules that regulate genes. When tested in mice, the increased production of brown fat made the animals more resistant to diet-induced obesity and better able to process sugar. Four months later, they also burned more calories than their untreated counterparts. This finding could have implications for treating obesity and the health risks associated with it, such as Type 2 Diabetes, osteoarthritis, and other disorders.

Budget Policy:

The FY 2016 budget estimate for this program is \$74.883 million, an increase of \$1.812 million or 2.5 percent above the FY 2015 Enacted level. Building on the significant gains in understanding itch sensation in recent years, NIAMS will continue to encourage basic and translational research that will lead to more discoveries about the mechanisms of itch sensation and the development of interventions to modulate and control itch in disease. Other FY 2016 activities include efforts to help the scientific community continue to expand its knowledge about how skin communicates with the brain and responds to changes in other organ systems. Ongoing programs that NIAMS will continue to support include a clinical trial of an antibody against a key signaling pathway in moderate and severe atopic dermatitis (a type of eczema).

Intramural Research Program: The mission of IRP is to conduct innovative basic, translational, and clinical research relevant to the health concerns of the Institute and to provide training for investigators who are interested in related research careers. IRP conducts basic scientific and clinical studies on the genetics, etiology, pathogenesis, and treatment of a variety of rheumatic, autoimmune, inflammatory, bone, skin, and muscle diseases. IRP consists of basic researchers and physician-scientists who have contributed many noteworthy discoveries. In addition to the MAS advance mentioned above, 2014 findings include the identification of a gene that underlies a very rare but devastating autoinflammatory condition, which the researchers named STING-associated vasculopathy with onset in infancy (SAVI). Several existing drugs have shown therapeutic potential in laboratory studies, and one is currently being studied in children with the disease. Because some of SAVI's characteristics appear in other diseases such as lupus, the work could lead to novel insights and new treatments that reach far beyond a single rare disease. As part of its commitment to providing a world-class training experience for future clinician scientists, NIAMS continued to participate in the NIH IRP Medical Research Scholars Program in FY 2014. This activity complements other NIAMS IRP training opportunities for investigators who have completed their degrees or are interested in other fields within the NIAMS mission, such as the Adult Rheumatology Fellowship Program and a pediatric rheumatology training program in partnership with Children's National Medical Center in Washington, D.C.

Budget Policy:

The FY 2016 budget estimate for this program is \$54.680 million, an increase of \$0.542 million or 1.0 percent above the FY 2015 Enacted level. NIAMS plans for FY 2016 include maintaining a focus on translational research in order to facilitate patient-oriented studies in the areas of arthritis, musculoskeletal, and skin diseases, including their genetic, inflammatory, and immune underpinnings. NIAMS will also continue a long-standing commitment to multidisciplinary training of rheumatology research fellows to strengthen the pipeline of highly qualified physician-scientists in this field. Both efforts will continue to synergize with the NIAMS Community Health Center facility in Silver Spring, Maryland. NIAMS is also continuing participation in an NIH Funding Opportunity Announcement to promote collaborations between intramural and extramural investigators in order to leverage the unique research opportunities and resources available at the NIH Clinical Center.

Program Portrait: Growing Muscle and Bone Portfolios in the NIAMS IRP

FY 2015 Level: \$1.382 million
FY 2016 Level: \$1.382 million
Change: \$0.000 million

In FY 2014, NIAMS added two research teams to its existing cadre of bone, joint, and muscle scientists. In partnership with the Johns Hopkins University’s Myositis Center, the Muscle Disease Unit focuses on understanding the underlying mechanisms of inflammatory muscle diseases such as dermatomyositis, polymyositis, statin-triggered necrotizing myopathy, and inclusion body myositis. The Laboratory of Muscle Stem Cells and Gene Regulation’s new RNA Molecular Biology Group is explaining how defects in proteins that interact with RNA can disrupt translation of genetic messages and lead to neuromuscular diseases that include myotonic dystrophy and oculopharyngeal muscular dystrophy.

While the Laboratory of Muscle Stem Cells and Gene Regulation explores the molecular basis of disease, investigators in the Clinical Trials Outcomes Branch are conducting comparative effectiveness research into how patients respond to treatments that are routinely used in clinical practice. They have mined an international database of medical records to compare the risks and benefits of two anticoagulants – warfarin and low-molecular-weight heparin – that are commonly prescribed after total joint replacement. Warfarin is taken in the form of a pill, but the patient is required to undergo blood tests and monitoring while taking it, whereas low molecular weight heparin, administered via an injection, requires no monitoring or blood tests. The researchers found low-molecular-weight heparin increases the risk for bleeding and superficial infections post-surgery, while warfarin is associated with reduced risk of postoperative infection despite its more complicated monitoring regimen. Other work includes examining large clinical databases to understand the occurrence of rare fractures of the thigh bone following prolonged use of a class of commonly prescribed osteoporosis drugs, as well as a clinical trial that will help primary care physicians and other health care providers identify women who are at high risk for this rare but devastating complication.

Research Management and Support (RMS): The NIAMS RMS budget supports the scientific, administrative management, and information technology activities associated with the Institute’s day-to-day operations. In FY 2014, the Institute managed more than 1,246 research grants and centers, as well as 37 research and development contracts and 286 individual and institutional full-time research training positions. NIAMS supported 540 clinical research studies, including 74 clinical trials. The Institute worked with researchers, healthcare professionals, and health advocacy organizations to update the Institute’s Long-Range Plan, a broad outline of scientific opportunities and challenges that will guide the Institute’s priority-setting for FYs 2015-2019. As part of the Institute’s efforts to engage with patients and the general public, NIAMS launched a new page on the social media site Google Plus and a dedicated channel on the video sharing site YouTube to provide a single, convenient platform to view video resources and other NIAMS content. Complementing the Institute’s existing Facebook and Twitter pages, Google Plus and YouTube broaden NIAMS’ reach to members of the “millennial generation.” NIAMS regularly posts messages in Spanish on its social media channels. When NIAMS publications in Chinese, Korean, and Vietnamese are available, the Institute’s communications in English include links to those materials as well as to English-language resources.

Budget Policy:

The FY 2016 budget estimate for this program is \$29.089 million, an increase of \$0.288 million or 1.0 percent above the FY 2015 Enacted level. Plans for FY 2016 include working with national and community partners to develop and disseminate meaningful health information for racial and ethnic minority populations through its National Multicultural Outreach Initiative (NMOI). NIAMS also will continue to enhance its social media presence through outlets such as Facebook and Twitter, and expects to implement a content management system that will tailor the information displayed on the Institute's website to the interests of different audiences.

NATIONAL INSTITUTES OF HEALTH
National Institute of Arthritis and Musculoskeletal and Skin Diseases

Budget Authority by Object Class¹
(Dollars in Thousands)

	FY 2015 Enacted	FY 2016 President's Budget	FY 2016 +/- FY 2015
Total compensable workyears:			
Full-time employment	243	243	0
Full-time equivalent of overtime and holiday hours	0	0	0
Average ES salary	\$182	\$182	\$0
Average GM/GS grade	12.1	12.1	0.0
Average GM/GS salary	\$101	\$101	\$1
Average salary, grade established by act of July 1, 1944 (42 U.S.C. 207)	\$98	\$99	\$1
Average salary of ungraded positions	\$117	\$117	\$0
OBJECT CLASSES	FY 2015 Enacted	FY 2016 President's Budget	FY 2016 +/- FY 2015
Personnel Compensation			
11.1 Full-Time Permanent	\$14,323	\$14,740	\$417
11.3 Other Than Full-Time Permanent	9,129	9,429	300
11.5 Other Personnel Compensation	623	642	19
11.7 Military Personnel	347	357	10
11.8 Special Personnel Services Payments	2,307	2,385	79
11.9 Subtotal Personnel Compensation	\$26,728	\$27,553	\$825
12.1 Civilian Personnel Benefits	\$7,406	\$7,606	\$200
12.2 Military Personnel Benefits	223	229	7
13.0 Benefits to Former Personnel	0	0	0
Subtotal Pay Costs	\$34,357	\$35,388	\$1,031
21.0 Travel & Transportation of Persons	\$642	\$628	-\$13
22.0 Transportation of Things	142	140	-2
23.1 Rental Payments to GSA	13	12	-1
23.2 Rental Payments to Others	0	0	0
23.3 Communications, Utilities & Misc. Charges	595	587	-8
24.0 Printing & Reproduction	0	0	0
25.1 Consulting Services	\$1,486	\$1,403	-\$83
25.2 Other Services	3,623	3,531	-91
25.3 Purchase of goods and services from government accounts	48,661	52,358	3,697
25.4 Operation & Maintenance of Facilities	\$24	\$23	\$0
25.5 R&D Contracts	3,718	1,619	-2,099
25.6 Medical Care	4,351	4,356	5
25.7 Operation & Maintenance of Equipment	1,128	1,120	-8
25.8 Subsistence & Support of Persons	0	0	0
25.0 Subtotal Other Contractual Services	\$62,990	\$64,411	\$1,420
26.0 Supplies & Materials	\$4,686	\$4,262	-\$424
31.0 Equipment	2,652	2,449	-203
32.0 Land and Structures	0	0	0
33.0 Investments & Loans	0	0	0
41.0 Grants, Subsidies & Contributions	415,451	425,354	9,903
42.0 Insurance Claims & Indemnities	0	0	0
43.0 Interest & Dividends	0	0	0
44.0 Refunds	0	0	0
Subtotal Non-Pay Costs	\$487,171	\$497,844	\$10,673
Total Budget Authority by Object Class	\$521,528	\$533,232	\$11,704

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

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Salaries and Expenses
(Dollars in Thousands)

OBJECT CLASSES	FY 2015 Enacted	FY 2016 President's Budget	FY 2016 +/- FY 2015
Personnel Compensation			
Full-Time Permanent (11.1)	\$14,323	\$14,740	\$417
Other Than Full-Time Permanent (11.3)	9,129	9,429	300
Other Personnel Compensation (11.5)	623	642	19
Military Personnel (11.7)	347	357	10
Special Personnel Services Payments (11.8)	2,307	2,385	79
Subtotal Personnel Compensation (11.9)	\$26,728	\$27,553	\$825
Civilian Personnel Benefits (12.1)	\$7,406	\$7,606	\$200
Military Personnel Benefits (12.2)	223	229	7
Benefits to Former Personnel (13.0)	0	0	0
Subtotal Pay Costs	\$34,357	\$35,388	\$1,031
Travel & Transportation of Persons (21.0)	\$642	\$628	-\$13
Transportation of Things (22.0)	142	140	-2
Rental Payments to Others (23.2)	0	0	0
Communications, Utilities & Misc. Charges (23.3)	595	587	-8
Printing & Reproduction (24.0)	0	0	0
Other Contractual Services:			
Consultant Services (25.1)	52	41	-11
Other Services (25.2)	3,623	3,531	-91
Purchases from government accounts (25.3)	34,600	35,327	727
Operation & Maintenance of Facilities (25.4)	24	23	0
Operation & Maintenance of Equipment (25.7)	1,128	1,120	-8
Subsistence & Support of Persons (25.8)	0	0	0
Subtotal Other Contractual Services	\$39,426	\$40,042	\$616
Supplies & Materials (26.0)	\$4,686	\$4,262	-\$424
Subtotal Non-Pay Costs	\$45,491	\$45,659	\$169
Total Administrative Costs	\$79,848	\$81,048	\$1,200

NATIONAL INSTITUTES OF HEALTH
National Institute of Arthritis and Musculoskeletal and Skin Diseases

Detail of Full-Time Equivalent Employment (FTE)

OFFICE/DIVISION	FY 2014 Actual			FY 2015 Est.			FY 2016 Est.		
	Civilian	Military	Total	Civilian	Military	Total	Civilian	Military	Total
Intramural Research Program									
Direct:	125	1	126	125	1	126	125	1	126
Reimbursable:	9	-	9	9	-	9	9	-	9
Total:	134	1	135	134	1	135	134	1	135
Office of Extramural Activities									
Direct:	50	2	52	51	2	53	51	2	53
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	50	2	52	51	2	53	51	2	53
Office of the Director									
Direct:	55	-	55	55	-	55	55	-	55
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	55	-	55	55	-	55	55	-	55
Total	239	3	242	240	3	243	240	3	243
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								
2012	11.8								
2013	11.6								
2014	12.1								
2015	12.1								
2016	12.1								

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Detail of Positions¹

GRADE	FY 2014 Actual	FY 2015 Enacted	FY 2016 President's Budget
Total, ES Positions	1	1	1
Total, ES Salary	181,500	181,500	181,500
GM/GS-15	18	18	18
GM/GS-14	31	31	31
GM/GS-13	43	43	43
GS-12	27	28	28
GS-11	10	10	10
GS-10	0	0	0
GS-9	11	11	11
GS-8	10	10	10
GS-7	6	6	6
GS-6	4	4	4
GS-5	0	0	0
GS-4	0	0	0
GS-3	0	0	0
GS-2	0	0	0
GS-1	0	0	0
Subtotal	160	161	161
Grades established by Act of July 1, 1944 (42 U.S.C. 207)	0	0	0
Assistant Surgeon General	1	1	1
Director Grade	1	1	1
Senior Grade	2	2	2
Full Grade	0	0	0
Senior Assistant Grade	0	0	0
Assistant Grade	0	0	0
Subtotal	4	4	4
Ungraded	99	99	99
Total permanent positions	164	165	165
Total positions, end of year	263	264	264
Total full-time equivalent (FTE) employment, end of year	242	243	243
Average ES salary	181,500	181,500	181,500
Average GM/GS grade	12.1	12.1	12.1
Average GM/GS salary	100,338	100,516	101,395

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