

DEPARTMENT OF HEALTH AND HUMAN SERVICES

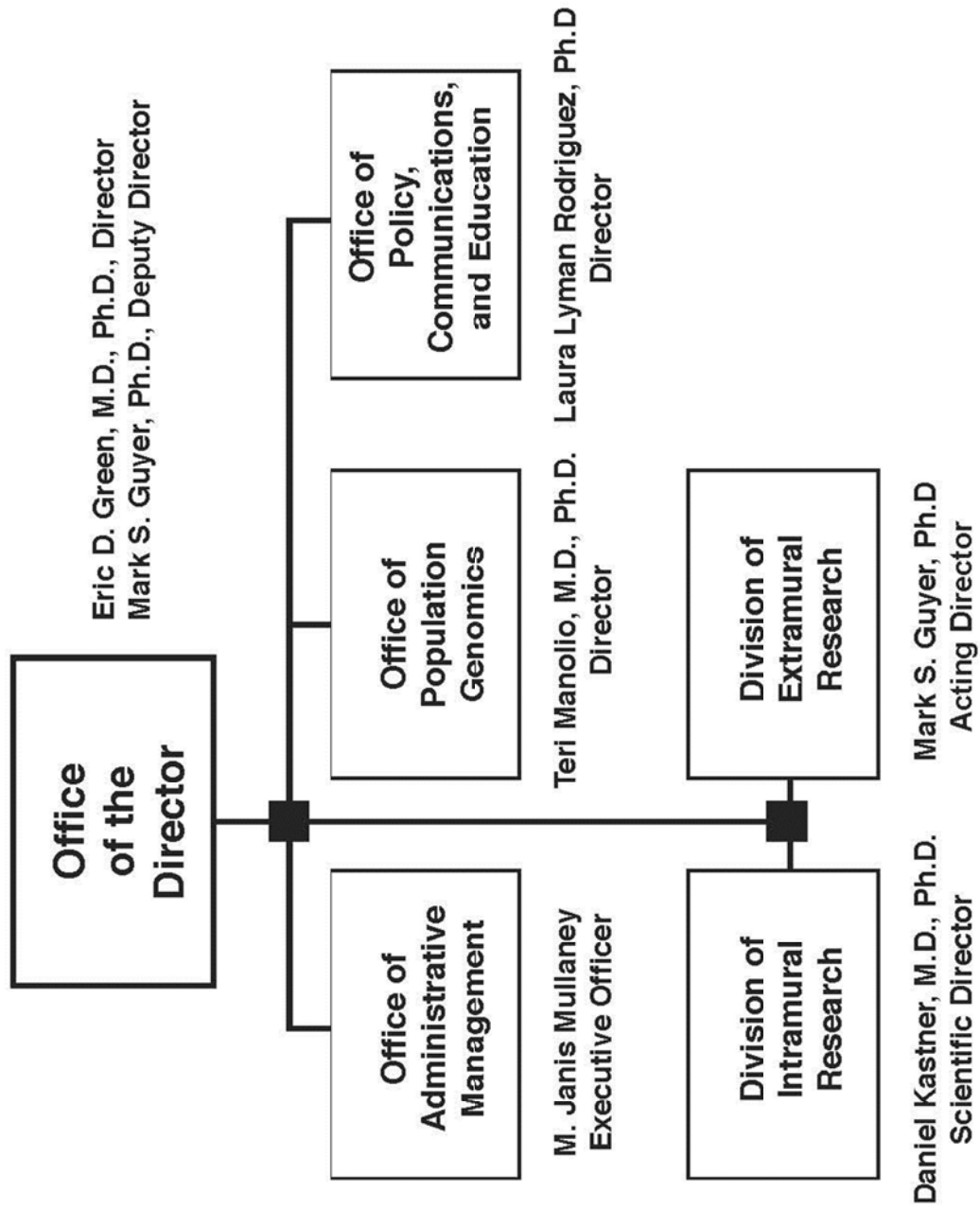
NATIONAL INSTITUTES OF HEALTH

National Human Genome Research Institute (NHGRI)

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# NATIONAL HUMAN GENOME RESEARCH INSTITUTE

## Organizational Structure



NATIONAL INSTITUTES OF HEALTH

National Human Genome Research Institute

For carrying out section 301 and title IV of the PHS Act with respect to human genome research,  
[\$513,844,000] \$511,370,000 (*Department of Health and Human Services Appropriations Act,  
2012.*)

**NATIONAL INSTITUTES OF HEALTH  
National Human Genome Research Institute**

**Amounts Available for Obligation <sup>1</sup>**  
(Dollars in Thousands)

<b>Source of Funding</b>	<b>FY 2011 Actual</b>	<b>FY 2012 Enacted</b>	<b>FY 2013 PB</b>
Appropriation	516,028	513,844	511,370
Type 1 Diabetes	0	0	0
Rescission	(4,531)	(971)	0
Supplemental	0	0	0
Subtotal, adjusted appropriation	511,497	512,873	511,370
Real transfer under Secretary's transfer authority	0	(146)	0
Comparative Transfers for NCATS reorganization	0	0	0
Comparative Transfers to NCATS for Therapeutics and Rare and Neglected Diseases (TRND)	(421)	0	0
Comparative Transfers to NLM for NCBI and Public Access	(439)	(464)	0
Subtotal, adjusted budget authority	510,637	512,263	511,370
Unobligated balance, start of year	0	0	0
Unobligated balance, end of year	0	0	0
Subtotal, adjusted budget authority	510,637	512,263	511,370
Unobligated balance lapsing	(28)	0	0
Total obligations	510,609	512,263	511,370

<sup>1</sup> Excludes the following amounts for reimbursable activities carried out by this account:

FY 2011 - \$80,363    FY 2012 - \$43,000    FY 2013 - \$43,031

Excludes \$157 in FY 2011, \$122 in FY 2012, and \$131 in FY 2013 royalties.

**NATIONAL INSTITUTES OF HEALTH**  
**National Human Genome Research Institute**  
**Budget Mechanism - Total** <sup>1/</sup>  
(Dollars in Thousands)

MECHANISM	FY 2011 Actual		FY 2012 Enacted		FY 2013 PB		Change vs. FY 2012	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Grants								
<u>Research Projects</u>								
Noncompeting	138	\$78,109	146	\$76,911	152	\$76,556	6	(\$355)
Administrative Supplements	<i>41</i>	26,857	<i>43</i>	27,907	<i>43</i>	23,001	<i>0</i>	(4,906)
Competing:								
Renewal	17	8,604	17	8,604	20	9,806	3	1,202
New	71	30,753	71	30,753	71	30,487	0	(266)
Supplements	0	0	0	0	0	0	0	0
Subtotal, Competing	88	\$39,357	88	\$39,357	91	\$40,293	3	\$936
Subtotal, RPGs	226	\$144,323	234	\$144,175	243	\$139,850	9	(\$4,325)
SBIR/STTR	28	\$10,716	30	\$11,372	31	\$11,699	1	\$327
Research Project Grants	254	\$155,039	264	\$155,547	274	\$151,549	10	(\$3,998)
<u>Research Centers</u>								
Specialized/Comprehensive	29	\$158,836	29	\$158,836	29	\$158,518	0	(\$318)
Clinical Research	0	0	0	0	0	0	0	0
Biotechnology	14	36,199	14	36,199	14	36,127	0	(72)
Comparative Medicine	0	0	0	0	0	0	0	0
Research Centers in Minority Institutions	0	0	0	0	0	0	0	0
Research Centers	43	\$195,035	43	\$195,035	43	\$194,645	0	(\$390)
<u>Other Research</u>								
Research Careers	4	\$402	4	\$402	4	\$401	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	0	0	0	0	0	0	0
Other	20	1,262	20	1,262	20	1,259	0	(3)
Other Research	24	\$1,664	24	\$1,664	24	\$1,660	0	(\$4)
Total Research Grants	321	\$351,738	331	\$352,246	341	\$347,854	10	(\$4,392)
<u>Research Training</u>								
Individual Awards	<u>FTEs</u> 10	\$452	<u>FTEs</u> 10	\$461	<u>FTEs</u> 10	\$470	0	\$9
Institutional Awards	162	8,138	162	8,301	162	8,467	0	166
Total Research Training	172	\$8,590	172	\$8,762	172	\$8,937	0	\$175
Research & Development Contracts	8	\$20,150	8	\$20,675	8	\$24,054	0	\$3,379
<i>SBIR/STTR</i>	<i>0</i>	<i>\$16</i>	<i>0</i>	<i>\$16</i>	<i>0</i>	<i>\$16</i>	<i>0</i>	<i>\$0</i>
Intramural Research	<u>FTEs</u> 253	\$104,495	<u>FTEs</u> 253	\$104,916	<u>FTEs</u> 251	\$104,863	(2)	(\$53)
Research Management and Support	87	25,664	87	25,664	86	25,662	(1)	(2)
Construction		0		0		0		0
Buildings and Facilities		0		0		0		0
Total, NHGRI	340	\$510,637	340	\$512,263	337	\$511,370	(3)	(\$893)

1/ All items in italics are "non-adds"; items in parenthesis are subtractions.

## **Major Changes in Fiscal Year 2013 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 2013 President's Budget request for NHGRI, which is \$0.893 million less than the FY 2012 Enacted level, for a total of \$511.4 million.

In keeping with the vision articulated in NHGRI's 2011 strategic plan, as well as a desire to report NHGRI's research activities in a more holistic manner (one that includes an integrated view of intramural and extramural research activities), the institute has changed the reporting of Budget Authority by Activity in the Congressional Justification for FY 2013. Intramural and Extramural research activities are now grouped by their place within the Strategic Plan's five domains and three crosscutting elements (plus Intramural Research and Research Management Support):

- Understanding the Structure of Genomes
- Understanding the Biology of Genomes
- Using Genomics to Understand the Biology of Disease
- Using Genomics to Advance Medical Science
- Using Genomics to Improve the Effectiveness of Healthcare
- Bioinformatics and Computational Biology
- Education and Training
- Genomics and Society

**NATIONAL INSTITUTES OF HEALTH**  
**National Human Genome Research Institute**  
**Summary of Changes**  
(Dollars in Thousands)

<b>FY 2012 Enacted</b>				<b>\$512,263</b>
<b>FY 2013 President's Budget</b>				<b>\$511,370</b>
<b>Net change</b>				<b>(\$893)</b>
<b>CHANGES</b>	<b>2013 President's Budget</b>		<b>Change from FY 2012</b>	
	<b>FTEs</b>	<b>Budget Authority</b>	<b>FTEs</b>	<b>Budget Authority</b>
A. Built-in:				
1. Intramural Research:				
a. Annualization of January				
		2012 pay increase & benefits		\$2
		\$37,984		\$2
		37,984		119
		37,984		146
		37,984		0
		17,162		0
		49,717		0
Subtotal				\$267
2. Research Management and Support:				
a. Annualization of January				
		2012 pay increase & benefits		\$1
		\$11,452		\$1
		11,452		35
		11,452		44
		11,452		0
		1,143		0
		13,067		0
Subtotal				\$80
Subtotal, Built-in				\$347

**NATIONAL INSTITUTES OF HEALTH  
National Human Genome Research Institute**

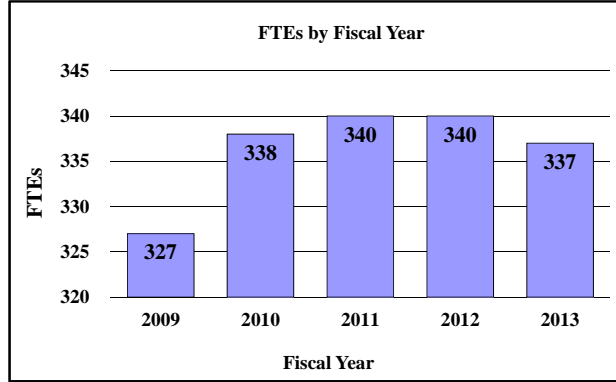
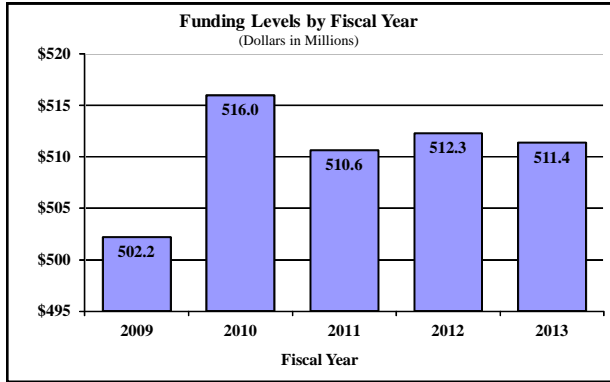
**Summary of Changes--continued**

CHANGES	2013 President's Budget		Change from FY 2012	
	No.	Amount	No.	Amount
B. Program:				
1. Research Project Grants:				
a. Noncompeting	152	\$99,557	6	(\$5,261)
b. Competing	91	40,293	3	936
c. SBIR/STTR	31	11,699	1	327
Total	274	\$151,549	10	(\$3,998)
2. Research Centers	43	\$194,645	0	(\$390)
3. Other Research	24	1,660	0	(4)
4. Research Training	172	8,937	0	175
5. Research and development contracts	8	24,054	0	3,379
Subtotal, Extramural		\$380,845		(\$838)
6. Intramural Research	<u>FTEs</u> 251	\$104,863	<u>FTEs</u> (2)	(\$320)
7. Research Management and Support	86	25,662	(1)	(82)
8. Construction		0		0
9. Buildings and Facilities		0		0
Subtotal, program	337	\$511,370	(3)	(\$1,240)
Total changes				(\$893)

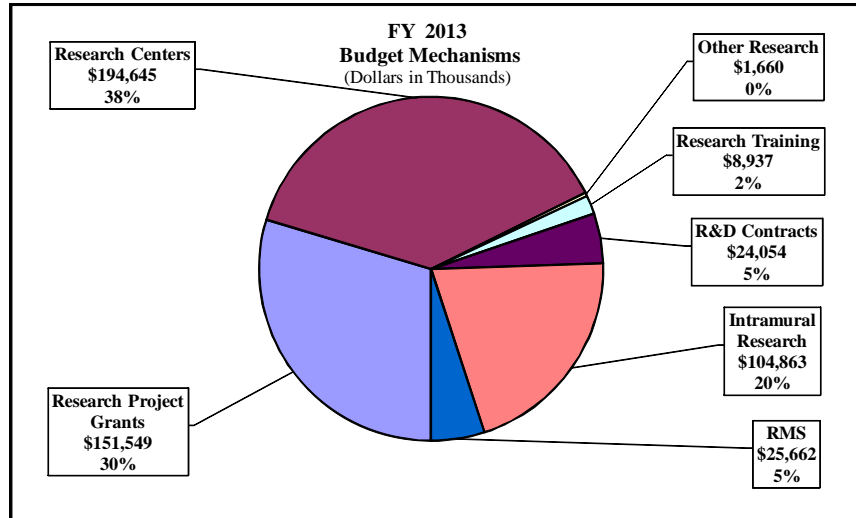


## Budget Graphs

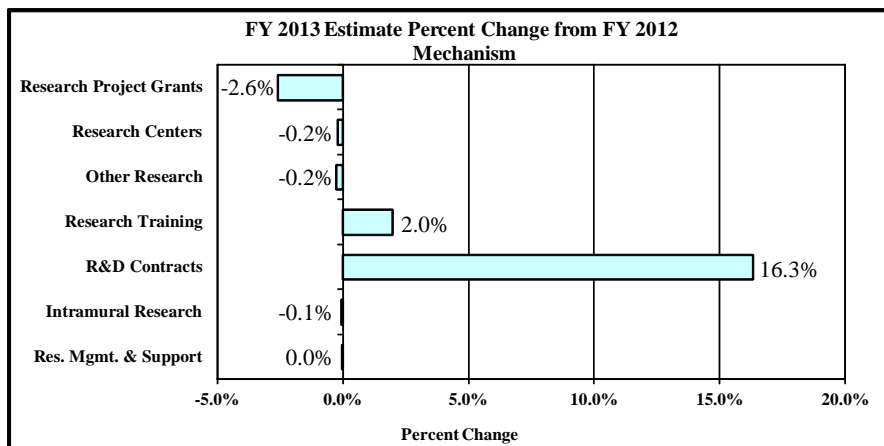
### History of Budget Authority and FTEs:



### Distribution by Mechanism:



### Change by Selected Mechanism:



**NATIONAL INSTITUTES OF HEALTH**  
**National Human Genome Research Institute**  
**Budget Authority by Activity**  
(Dollars in Thousands)

<b>Program Activity</b>	<b>FY 2011 Actual</b>		<b>FY 2012 Enacted</b>		<b>FY 2013 PB</b>		<b>Change vs. FY 2012 Enacted</b>	
	<b>FTEs</b>	<b>Amount</b>	<b>FTEs</b>	<b>Amount</b>	<b>FTEs</b>	<b>Amount</b>	<b>FTEs</b>	<b>Amount</b>
<u>Detail:</u>								
Understanding the Structure of Genomes		\$67,379		\$67,594		\$67,450		-\$144
Understanding the Biology of Genomes		113,575		113,951		113,732		-219
Using Genomics to Understand the Biology of Disease		139,639		140,111		139,862		-249
Using Genomics to Advance Medical Science		19,805		19,880		19,860		-20
Using Genomics to Improve the Effectiveness of Healthcare		11,710		11,752		11,738		-14
Bioinformatics and Computational Biology		81,846		82,116		81,956		-160
Education and Training		25,045		25,133		25,094		-39
Genomics and Society		25,974		26,062		26,016		-46
<b>Subtotal, Program Activity*</b>		<b>\$484,973</b>		<b>\$486,599</b>		<b>\$485,708</b>		<b>-\$891</b>
<i>Extramural Research (non-add)</i>		<i>\$380,478</i>		<i>\$381,683</i>		<i>\$380,845</i>		<i>-\$838</i>
<i>Intramural Research (non-add)</i>	253	<i>\$104,495</i>	253	<i>\$104,916</i>	251	<i>\$104,863</i>	-2	<i>-\$53</i>
<b>Research Management &amp; Support</b>	87	\$25,664	87	\$25,664	86	\$25,662	-1	-\$2
<b>TOTAL</b>	<b>340</b>	<b>\$510,637</b>	<b>340</b>	<b>\$512,263</b>	<b>337</b>	<b>\$511,370</b>	<b>-3</b>	<b>-\$893</b>

1. Includes FTEs which are reimbursed from the NIH Common Fund.

2. Includes Real Transfers and Comparable Adjustments as detailed in the "Amounts Available for Obligation" table.

\* The detail programs listed above include both extramural and intramural funding.

**NATIONAL INSTITUTES OF HEALTH  
National Human Genome Research Institute**

**Authorizing Legislation**

	<b>PHS Act/ Other Citation</b>	<b>U.S. Code Citation</b>	<b>2012 Amount Authorized</b>	<b>FY 2012 Appropriation</b>	<b>2013 Amount Authorized</b>	<b>FY 2013 PB</b>
Research and Investigation	Section 301	42§241	Indefinite	\$512,263,000	Indefinite	\$511,370,000
National Human Genome Research Institute	Section 401(a)	42§281	Indefinite		Indefinite	
<b>Total, Budget Authority</b>				<b>\$512,263,000</b>		<b>\$511,370,000</b>

**NATIONAL INSTITUTES OF HEALTH  
National Human Genome Research Institute**

**Appropriations History**

Fiscal Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
2004	\$478,072,000	\$478,072,000	\$482,372,000	\$482,222,000
Rescission				(\$3,149,000)
2005	\$492,670,000	\$492,670,000	\$496,400,000	\$492,670,000
Rescission				(\$4,062,000)
2006	\$490,959,000	\$490,959,000	\$502,804,000	\$490,959,000
Rescission				(\$4,910,000)
2007	\$482,942,000	\$482,942,000	\$486,315,000	\$486,491,000
Rescission				\$0
2008	\$484,436,000	\$493,996,000	\$497,031,000	\$495,434,000
Rescission				(\$8,655,000)
Supplemental				\$2,589,000
2009	\$487,878,000	\$504,603,000	\$501,411,000	\$502,367,000
Rescission				\$0
2010	\$509,594,000	\$520,311,000	\$511,007,000	\$516,028,000
Rescission				\$0
2011	\$533,959,000		\$533,127,000	\$516,028,000
Rescission				(\$4,531,033)
2012	\$524,807,000	\$524,807,000	\$505,738,000	\$513,844,000
Rescission				(\$971,165)
2013	\$511,370,000			

## Justification of Budget Request

### *National Human Genome Research Institute*

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

Budget Authority:

	FY 2011 Actual	FY 2012 Enacted	FY 2013 President's Budget	FY 2013 +/- FY 2012
BA	\$510,637,000	\$512,263,000	\$511,370,000	-\$893,000
FTE	340	340	337	-3

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

### Director's Overview

The National Human Genome Research Institute (NHGRI) funds and conducts research to advance knowledge about the genomic underpinnings of disease and to establish how genomic information can be used to improve the diagnosis and treatment of disease. As described in NHGRI's new strategic plan for genomics research published in the journal *Nature*<sup>1</sup> in February 2011, it is an extraordinary time for biomedical research in general and genomics research in particular. In FY 2013, NHGRI will capitalize on the remarkable opportunities afforded by prior research investments to advance our understanding of genome biology and to begin translating genomic science into genomic medicine on a broader scale than was previously possible.

NHGRI's 2011 strategic plan identifies five distinct domains that together comprise a progressive continuum of research endeavors. This continuum begins with fundamental basic research to understand the *structure of genomes*, the *biology of genomes*, progresses to include the use of genomics to *understand the biology of disease*, to *advance medical science*, and to *improve the effectiveness of healthcare*.

In FY 2013, NHGRI is increasing its research efforts to apply basic knowledge about the structure and function of the human genome to the third research domain—investigating the genomic basis for human disease. In the future, the focus will expand toward translating new insights about disease into genomic-based clinical advances.

**Genomic Science:** Many of the most impressive genomic advances in the past decade have been fueled by NHGRI's long-term investment in technology development aiming to reduce the cost of DNA sequencing. NHGRI set a goal to reduce the fully loaded cost of generating a high-

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<sup>1</sup> Green ED, Guyer MS, and National Human Genome Research Institute. (2011). Charting a course for genomic medicine from base pairs to bedside. *Nature*. 470(7333): 204-213. Available at <http://www.genome.gov/Pages/About/Planning/2011NHGRIStrategicPlan.pdf>.

quality human genome sequence to \$25,000 by the end of FY 2011—a 40,000-fold reduction over what the Human Genome Project accomplished in 2003. By end of FY 2011, even this ambitious goal was surpassed, with a sequenced human genome costing approximately \$7,700. The extraordinary advances in DNA sequencing technologies are accelerating discoveries across all areas of biomedical research and are now invigorating genomics-oriented translational research.

The Large-Scale Genome Sequencing Centers supported by NHGRI for many years remain a prominent and vital part of the Institute's research portfolio. These centers conduct genomic studies in support of NHGRI flagship programs, such as The Cancer Genome Atlas (TCGA, which explores the genomic basis underlying different types of cancer) and the 1000 Genomes project (which aims to improve our understanding of human genomic variation). These Centers will increasingly conduct collaborative research projects with other investigators, providing the opportunity to broaden the application of the sequencing centers' technologies and expertise in the pursuit of important and cutting-edge research questions.

In addition to continuing highly successful programs like TCGA, NHGRI is expanding its application genome sequencing to include new large-scale studies of rare, Mendelian (single-gene) diseases through the establishment of Mendelian Disorders Genome Centers. These new Centers will seek to discover the genomic basis for thousands of Mendelian disorders that affect approximately 25 million Americans.

**Genomic Medicine:** NHGRI's expansion into more translational genomics research is still in a relatively early phase. The Electronic MEDical Records and GENomics (eMERGE) Network is integrating genomic information into electronic medical record systems and investigating how this information can be used by healthcare providers to improve clinical care. For example, genomic data could help identify patients who would benefit from increased monitoring for specific conditions and/or from a tailored selection of drug treatments to enhance effectiveness and reduce adverse reactions.

As an extension of NHGRI's broader Large-Scale Genome Sequencing Program, a new Clinical Sequencing Exploratory Research program aims to study how best to apply genome sequencing in clinical settings. These investigator-initiated projects will apply the foundational knowledge, skills, and practices gained from prior NHGRI genome-sequencing activities to the care of individual patients—bridging the gap between genomic discoveries and patient care. These projects will also integrate genomic, clinical, and psychosocial research components, with the latter being important for understanding the attitudes and social consequences associated with the implementation of genomic medicine.

Fundamental to the success of the research continuum detailed in NHGRI's 2011 strategic plan are three cross-cutting elements: Bioinformatics and Computational Biology, Education and Training, and Genomics and Society. NHGRI is committed to its investment in these areas, as each is crucial to realizing the Institute's long-term vision for genomics. The benefits of genomic medicine will only be realized if there are robust bioinformatic and computational tools for manipulating the large data sets generated by high-throughput genomic methods; a workforce

with the requisite interdisciplinary skills and training; and a public ready to embrace new genomic knowledge about themselves as an element of their clinical care.

**Genomics and the Economy:** In addition to improving human health, the federal investment in genomics research is also a stimulant for the U.S. economy. The independently commissioned Battelle report (2011)<sup>2</sup> showed that every dollar invested by the U.S. Government in genomics has generated \$141 in the nation's economy. In 2010 alone, the genomics sector directly supported more than 51,000 jobs and indirectly supported another 310,000, adding \$67 billion to the U.S. economy (including \$20 billion in personal income).

While the full potential of enhancing Americans' health through the application of genomics will not be realized for many years, research and investment in this field of biomedical research is already significantly benefiting the nation. By pursuing the genomics research agenda detailed in NHGRI's 2011 strategic plan, not only will the financial benefits continue, but they will be further enhanced in the long run as a byproduct of genomics positive impact on medicine.

Overall Budget Policy: The FY 2013 President's Budget request for NHGRI is \$511.4 million, a decrease of \$0.893 million or -0.17 percent less than the FY 2012 Enacted level. Funds are included in R&D contracts to support trans-NIH initiatives, such as the Basic Behavioral and Social Sciences Opportunity Network (OppNet).

### **Program Descriptions and Accomplishments**

**Understanding the Structure of Genomes:** Understanding the structure of genomes remains fundamental to NHGRI's research portfolio. The Institute's DNA Sequencing Technology Development Program is among its most successful endeavors to date, supporting the design of a wide variety of methodological approaches to DNA sequencing since its inception in 2003. As a result, the fully loaded cost of sequencing a human genome has fallen by many orders of magnitude, quickly approaching the 10-year goal set in 2004 of \$1,000.

Other NHGRI research activities in this domain include the 1000 Genomes project, which has benefited from ever-decreasing DNA sequencing costs and is now analyzing the genomes of about 2,500 people from 27 populations around the world; these efforts are providing key information about millions of genomic variants, information which is important to identifying the genetic causes of disease. The catalogued variants range from single-base differences among people to large genomic insertions and deletions, and these reflect both rare variants as well as common ones. A small subset of these variants contributes to an increased risk (or protection) for specific diseases and to differences in drug response. The data from the 1000 Genomes project is accelerating the field of human genetics, and many researchers are already using the ever-growing informational resource created by the project for their disease studies. There is clear evidence that these efforts are leading to the successful identification of genetic mutations accounting for both rare and common diseases. The 1000 Genomes data are also being used to develop affordable technologies for individual genome analysis, which will eventually enable physicians to predict a person's risk for various diseases and to choose effective drugs and drug dosages.

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<sup>2</sup> <http://www.battelle.org/publications/humangenomeproject.pdf>

Budget Policy: The FY 2013 President's Budget request for Understanding the Structure of Genomes is \$67.5 million, a decrease of \$0.144 million or 0.21 percent less than the FY 2012 Enacted level. The activity in Understanding the Structure of Genomes will continue NHGRI's signature efforts to decrease the cost of DNA sequencing and the 1000 Genomes Project. NHGRI will continue in FY 2013 its ground-breaking efforts to reduce the cost of DNA sequencing so that this technology, which has increasingly become central to biomedical research, can become a widely disseminated research tool and, beyond that, a tool for clinical application and individual healthcare. Additionally, in FY 2013 this program will continue with the full-scale implementation of the 1000 Genomes Project. New directions will include the analysis of the role of variation in understanding gene expression. The Institute also will continue to fund meritorious investigator-initiated applications submitted in response to announcements that encourage new technologies and new approaches to the analysis of genome structure, and the role that genome structure plays in the determination of human disease, disease susceptibility, and environmental sensitivities.

**Understanding the Biology of Genomes:** Since completion of the Human Genome Project, NHGRI-funded research has continued to lead the field of genomics by studies that expand our understanding of human genome function. The ENCyclopedia of DNA Elements (ENCODE) project (which is focused on the human genome) and the companion modENCODE project (which uses the same approach on a few select model organisms) have successfully generated a wealth of data about the functional elements in genomes, such as genes and sequences that turn those genes on or off at the proper times during development and in the proper cell types. This information is critical to understanding normal biological processes and the perturbations in biological pathways that manifest in disease.

NHGRI's Centers of Excellence in Genomic Science (CEGS) program supports interdisciplinary research efforts that have been instrumental in developing new ways to use genomic approaches to derive novel biological and biomedical insights. The CEGS will continue to develop and test new approaches for producing, analyzing, and using genomic data. They will also generate new insights into how genomes function and how genomic variants among individuals influence that function. The U.S. biomedical research enterprise will continue to benefit from this investment as genomic tools, techniques, and trainees make their way from the CEGS to the broader biomedical research community.

Budget Policy: The FY 2013 President's Budget request for Understanding the Biology of Genomes is \$113.7 million, a decrease of \$0.219 million or 0.19 percent less than the FY 2012 Enacted level. In FY 2013, NHGRI will continue to support the CEGS program in its efforts to stimulate highly innovative research approaches that will substantially advance genomic approaches to the study of a biological problem, and to foster the wider application of comprehensive, high-throughput genomics methods to the study of human biology and disease. The Institute also will continue to fund meritorious investigator-initiated applications submitted in response to announcements that encourage new technologies and new approaches to the analysis of genome biology.



**Using Genomics to Understand the Biology of Disease:** NHGRI's research portfolio is expanding its focus on utilizing genomics to better understand the biology of disease, as described in the Institute's 2011 Strategic Plan. This research builds upon work conducted in the above two programs and will be used to inform scientists working in more translational areas. NHGRI's Large-Scale Genome Sequencing Program has shifted its major focus from sequencing the genomes of many different organisms to provide data for comparative genomic analyses to sequencing large numbers of human genomes as part of large disease studies.

Genome-wide association studies (GWAS) have identified many genetic variants related to common diseases, as disseminated by the online NHGRI GWAS Catalog (<http://www.genome.gov/gwastudies/>). To date, most of these studies have been performed in populations of European origin; further exploration in non-European populations is critical for the entire population to benefit from such research. The Population Architecture using Genomics and Epidemiology (PAGE) project is a consortium of U.S. studies that analyzes relationships between genetic variants and a range of common diseases and traits in well-characterized populations. Importantly, PAGE includes approximately 100,000 study participants to investigate whether these genetic associations are generalizable to non-European individuals or if they are modified by lifestyle or other factors. NHGRI is also creating tools that investigators can use to expand GWAS efforts beyond their primary genetic research focus. The Consensus Measures for Phenotypes and eXposures (PhenX) project is creating a toolkit that provides *standard* measures related to complex diseases, phenotypic traits, and environmental exposures; these standards have been largely lacking until now.

NHGRI's Intramural Research Program is also supporting research to advance our knowledge of the genetic contributors to disease. For common diseases, the ClinSeq project is examining the clinical strategies that will be needed for widespread genome sequencing in a clinical context, initially focusing on cardiovascular disease. At the other end of the spectrum, rare diseases are the focus of the Undiagnosed Diseases Program (see program portrait), which draws on the resources and wealth of expertise at the NIH Clinical Center to address medical mysteries, ideally arriving at diagnoses or possible treatment options for patients whose conditions have stumped medical experts.

**Budget Policy:** The FY 2013 President's Budget request for Using Genomics to Understand the Biology of Disease is \$139.9 million, a decrease of \$0.249 million or 0.18 percent less than the FY 2012 Enacted level. The Institute will continue to fund meritorious investigator-initiated applications that will increase the ability of genomics to have a major impact on the progress of biomedical and translational research.

### **Program Portrait: NIH Undiagnosed Diseases Program**

FY 2012 Level: \$3.5 million

FY 2013 Level: \$3.5 million

Change: \$0 million

The Undiagnosed Diseases Program (UDP) is a trans-NIH initiative with programmatic and administrative support from NHGRI, the NIH Clinical Center, and the NIH Office of Rare Diseases Research. In February 2011, three years after its launch, the program reported its first diagnosis of a new rare disease in the *New England Journal of Medicine*.\*

The UDP has two goals—to provide answers to patients with mysterious conditions that have long eluded diagnosis and to advance medical knowledge about human diseases. Patients are referred to the UDP by their clinicians and, if accepted, travel to the NIH Clinical Center in Bethesda. There, a team of medical and scientific experts conducts a multi-day, comprehensive clinical work up; this that includes consults from numerous senior physicians with expertise in medical specialties from across NIH institutes and centers, including endocrinology, immunology, oncology, dermatology, dentistry, cardiology, and genetics. Not all of the patients accepted into the UDP will receive a diagnosis, but cases are chosen that offer a reasonable potential for NIH doctors to identify a previously unrecognized rare disease, suggest new ways to treat that illness, and/or determine promising options for continued research.

The UDP team is exceptionally dedicated, reviewing approximately 140 applications a month and seeing 180 patients a year for intensive weeklong evaluations. In fact, the UDP has received such an overwhelming response that in July 2011, the program had to suspend accepting new applications temporarily in order to allow the team to work through the backlog of several hundred cases.

The program has captured the imagination of the public, and has been featured in numerous media reports. William Gahl, M.D., Ph.D.—NHGRI's Clinical Director and the founding Director of the UDP—and the UDP team have won a number of prestigious awards as a result of their work.

\*St Hilaire, et al. (2011). NT5E Mutations and Arterial Calcifications. *The New England journal of medicine*, 364(5), 432–442. doi:10.1056/NEJMoa0912923

**Using Genomics to Advance Medical Science:** With increasing frequency, genomic information in the form of individual patient's personal genome sequences will be used to guide physicians' therapeutic decisions and to improve the practice of medicine. Work in this research domain is still at an early stage, but significant advances are anticipated in the coming decade. The widespread use of genome sequencing as a clinical tool will require more than just clinically affordable genome sequencing methods. Rather, sequencing a patient's genome, analyzing the resulting data, and then providing the relevant genomic information in an easy-to-understand format to his/her healthcare provider (who most likely will not be an expert in genomics) will require new developments at multiple levels, involving many different aspects of NHGRI's research portfolio.

To anticipate these needs, the Institute is beginning to fund translational research that will facilitate the application of genomics to clinical care. This work is exemplified by the recently launched Clinical Sequencing Exploratory Research program, which began in FY 2012. This program is a valuable 'test bed' for exploring and developing the capacities necessary to obtain a patient's whole-exome sequence (just the protein-coding components) or whole-genome sequence (the entire genome) and to derive the necessary information for enhancing clinical decision-making. The collaborative nature of this program will facilitate the development,

standardization, and integration of best practices and common approaches for clinical genome sequencing. Integral to the specific projects in this program are studies examining the significant bioethical issues relevant to acquiring large amounts of genome sequence data from patients as part of their medical care, to deciding what genomic findings to return to patients, and to deciding when and how to communicate such findings to patients and their families.

**Budget Policy:** The FY 2013 President's Budget request for Using Genomics to Advance Medical Science is \$19.9 million, a decrease of \$0.020 million or 0.10 percent less than the FY 2012 Enacted level. Medical sequencing continues to be an area of growth for NHGRI. With large-scale sequencing now completely transitioned to the next-generation sequencing instruments, many new opportunities have been created to apply genomic tools to the study of human disease and the application of that information to the development of new approaches to disease management. Many of the new opportunities will be pursued in collaboration with other NIH ICs.

**Program Portrait: Clinical Genome-Sequencing Program**

FY 2012 Level: \$9.5 million  
FY 2013 Level: \$9.5 million  
Change: \$0 million

The cost and time needed to sequence a human genome has decreased precipitously since the completion of the Human Genome Project in 2003, and it is now feasible to use high-throughput DNA sequencing as a diagnostic tool in certain clinical settings. At the same time, because of advances in genomics research more broadly, scenarios can realistically be envisioned whereby whole-genome sequencing may become a routine component of medical care in the coming years. Indeed, there have been a number of recent cases in which genome sequencing has been used both to identify the genetic cause of a disease and to guide a patient's treatment. For example, an unresolved case of extreme inflammatory bowel disease threatened the life of a 4-year-old boy until genome sequencing identified his underlying mutation, leading to a change in his treatment that probably may have saved his life.

The integration of state-of-the-art genome-analysis technologies into clinical practice is nevertheless still in its infancy. A tremendous amount still needs to be learned about how to overcome barriers to adopting these technologies and how to integrate them in a way that maximizes their clinical utility. Also needed are studies that rigorously explore the many ethical and social issues that will arise upon the widespread introduction of genome sequencing in medical settings.

To address these needs, NHGRI has launched the Clinical Sequencing Exploratory Research program, a new component of the Institute's Large-Scale Genome Sequencing Program. The new projects, which began in FY2012, are looking at the myriad critical aspects of integrating genomics into patient care, including how to provide meaningful genomic information to healthcare providers, how to integrate genomic data into health records, and how to give appropriate informed consent and subsequently genomic results to patients.

**Using Genomics to Improve the Effectiveness of Healthcare:** Using genomics to improve the effectiveness of healthcare is the most patient-relevant of the five research domains described in the 2011 NHGRI strategic plan. A robust research portfolio in this area requires a broad foundation built upon research accomplishments within the first four domains; it may not be until the next decade that we see a significant proportion of NHGRI's research initiatives focusing on

this domain. Even at this very early stage, however, NHGRI is funding research in this area, notably within the Electronic Medical Records and GENomics (eMERGE) Network. Currently consisting of a seven-member consortium of research centers and healthcare providers, eMERGE is investigating the integration of patients' genomic information with their electronic medical records. The combined phenotypic and genomic information enables novel approaches to clinical research as well as to the patient's ongoing clinical care. The eMERGE Network is also exploring the complex ethical, legal, and social issues involved with the use of electronic medical records for genomics research and developing best practices for data sharing.

Budget Policy: The FY 2013 President's Budget request for Using Genomics to Improve the Effectiveness of Healthcare is \$11.7 million, a decrease of \$0.014 million or 0.12 percent less than the FY 2012 Enacted level. NHGRI will continue in FY 2013 to support this area of research as the combination of advances in genomics with cutting-edge approaches to population studies remains of very high programmatic interest as an important strategy for addressing problems of using genomics to improve healthcare. The Institute also will continue to fund meritorious investigator-initiated applications, and to collaborate with other NIH Institutes/Centers in the area of translational genomics.

**Bioinformatics and Computational Biology:** As a result of NHGRI's DNA Sequencing Technology Development Program, genome sequencing is now cheaper and faster than ever, with improvements to streamline and enhance available methodologies continuously being developed and implemented. Although further cost reductions are desired, the major bottleneck in genomics is no longer the generation of sequence data. Rather, it is the challenge of computationally analyzing all of these data because of the nature of contemporary genomics, which is now regarded as "data-intensive research." The challenging elements include managing and storing large data files, analyzing the primary data to extract the essential genomic information, and visualizing the data in ways that minimize the burden on the researcher. NHGRI is funding bioinformatics and computational researchers through both unsolicited awards and more focused programs, such as the Informatics Tools for High-Throughput Sequence Data Analysis program and related projects. The goals for this area of the Institute's research portfolio include:

- Develop and optimize new informatics tools for the analysis of genome-sequence data that can be used by the broad community of biomedical and clinical researchers;
- Reduce the specialized skill level needed to interpret genome sequences;
- Transform "localized" computational tools of proven value into robust, distributable software;
- Use innovative software engineering to improve access and reduce the data-analysis bottleneck;
- Develop new methods for the visualization of genomic data;
- Enable data integration across diverse types of genomic and clinical data; and
- Provide essential knowledge bases for the genomics and medical genetics communities.

Budget Policy: The FY 2013 President's Budget request for Bioinformatics and Computational Biology is \$81.9 million, a decrease of \$0.160 million or 0.19 percent less than the FY 2012

Enacted level. Activity in Computational Genomics will remain essentially constant, maintaining the proportion of the NHGRI extramural budget devoted to this area. Effort will be directed to increasing the efficiency of data storage and distribution mechanisms, as the amount of data that needs to be processed has increased significantly with the introduction of next-generation sequencing and other new genomic technologies. In FY 2013, NHGRI will continue its support for the essential biomedical research resource represented by genomic databases. The Institute also will continue to fund meritorious investigator-initiated applications submitted in response to announcements that encourage new technologies and new approaches to the rapidly emerging issue of public access to large genomic datasets.

**Program Portrait: Bioinformatics and Computational Biology**

FY 2012 Level: \$82.1 million]

FY 2013 Level: \$81.9 million

Change: - \$0.2 million

NHGRI's past investments and continuing strong commitment to supporting research on new DNA sequencing technologies continue to pay great dividends across the entire NIH research portfolio. A new generation of genome-sequencing instruments capable of producing vast amounts of high-quality data now makes it possible for investigators outside of large sequencing centers to generate enormous amounts of sequence data in their own laboratories. Often, however, these researchers then face a serious challenge due to the lack of access to readily usable versions of software tools needed to analyze such large amounts of data, nor the informatics expertise necessary to take best advantage of them. There is thus an acute need for robust, well-documented, and well-supported software tools for processing and analyzing the genomic data that individual laboratories can now generate. The demand for such computational tools will only grow with the increasing uptake of large-scale genome sequencing and the development of new applications for genome-sequencing data, including clinical studies.

Data generated by projects such as ENCODE and 1000 Genomes are most valuable when they can be readily accessed and used by the broader biomedical research community. Therefore, NHGRI funds the development, refinement, and maintenance of readily accessible computational and bioinformatics resources, including collections of genomic data, new data-analysis tools, and community data standards.

Quality standards for genome-sequencing data must necessarily be higher for clinical care compared to research uses. Therefore, the routine and widespread use of genome sequencing in the practice of medicine will require the development of new computational and bioinformatics tools that are able to meet the specific regulatory standards required by the Food and Drug Administration and other oversight groups. These tools must be designed for use by healthcare professionals who likely will not have extensive training in genomics or bioinformatics. NHGRI is engaging in efforts to advance this specialized area of genomics, including the development of robust clinical genomics informatics systems.

**Education and Training:** Realizing the benefits of genomics will require more than the research tools and clinical practices under development across the NHGRI research portfolio. It will also require healthcare professionals that are appropriately trained to understand genomic data and how to apply them to advance medical care; it will further require a public that understands genomics in general terms and is comfortable with the use of genetic and genomic data for making their healthcare decisions. Therefore, appropriate education and training of healthcare professionals and the general public will be key to the ultimate success of genomic medicine. To support these needs, NHGRI fosters many education and training activities aimed at teaching genomics to different core audiences: the next generation of genomics and genomic medicine researchers, healthcare providers, the general public through the incorporation of genomics into primary and secondary education, and lifelong learning outreach.

**Budget Policy:** The FY 2013 President's Budget request for Education and Training is \$25.1 million, a decrease of \$0.039 million or 0.16 percent less than the FY 2012 Enacted level. NHGRI will continue in FY 2013 its support for training the next generation of genomics researchers as well as programs aimed at bringing genomics to healthcare professionals and the general public.

**Genomics and Society:** Since its inception, NHGRI has funded research that examines the social, ethical, and legal implications of genomic advances and the increasing availability of genomic information. This research area continues to be a vital component of the Institute's strategic vision. In July 2011, a new set of research priorities for the NHGRI Ethical, Legal, and Social Implications (ELSI) Research Program were issued that focus on the following four areas:

- Genomes to Research
- Genomes to Health
- Genomes to Society
- Ethical, Legal, Regulatory, and Public Policy Issues

Together, these research programs will continue to examine issues that arise in the design and conduct of genomic research, such as questions about informed consent, data sharing, and privacy; when and how best to return individual genomic results to research participants; and whether and how to provide information about incidental genomic findings to participants. Other research supported by the Institute will examine how advances in genomic technologies are influencing healthcare delivery and, more importantly, affecting the population's health. Research that examines more fundamental questions, such as how we conceptualize and understand the health-disease continuum and individual responsibility for health and behavior, is also vital for the development of effective regulations and public policies.

The Institute's Intramural Social and Behavioral Research Branch (SBRB) conducts leading-edge research at the intersection of genomics and society. SBRB scientists are focused in four highly relevant conceptual domains:

- Testing the effectiveness of strategies for communicating information about genetic risks
- Developing and evaluating behavioral interventions relevant to genomics
- Using genomic discoveries in clinical practice
- Understanding the social, ethical, and policy implications of genomics research

Through these collective research initiatives, NHGRI remains at the forefront of bioethics research and training, accounting for approximately one-third of all bioethics research funding at the NIH.

Budget Policy: The FY 2013 President's Budget request for Genomics and Society is \$26.0 million, a decrease of \$0.046 million or 0.18 percent less than the FY 2012 Enacted level. The ELSI budget is legislatively mandated at 5.0 percent of the total NHGRI extramural budget. In FY 2013, NHGRI will continue to support the ELSI research program and the Intramural Social and Behavioral Research Branch in their efforts to anticipate and address the social, legal, and ethical issues that will arise from new information about the human genome and the genetic contribution to human disease, and new approaches to applying that information to the improvement of human health.

**Research Management and Support:** The NHGRI's Office of the Director, part of the Research Management and Support program, oversees the operation of the Institute and includes a number of component parts. Major ongoing initiatives for which the Office of the Director provides key leadership and financial support include National DNA Day and other educational outreach activities, community genomics programs, and the development of genetics education resources for health professionals. Through these activities, the Office of the Director supports a suite of innovative communication tools to convey the NIH and NHGRI messages to the public and the media. Recent activities aimed at increasing public fluency with genomics have included a workshop on how best to improve genomic literacy among the public, the creation of a mobile application version of the NHGRI Talking Glossary of Genetic Terms, and the development of an exhibition on genomics in conjunction with the Smithsonian Natural History Museum. NHGRI also continues to provide leadership in the area of healthcare professional education, with web-based resources such as the Genetics/Genomics Competency Center (G2C2, [www.g-2-c-2.org](http://www.g-2-c-2.org)), and the Global Genetics and Genomics Community (G3C, [www.g-3-c.com](http://www.g-3-c.com)). G2C2 is a centralized repository for health professional education resources and aims to help the development of standardized curriculums. G3C is a bilingual collection of virtual case studies that provide students with a self-guided learning experience.

Budget Policy: The FY 2013 President's Budget request for the Research Management and Support program is \$25.7 million, no change from the FY 2012 Enacted level. In FY 2013, NHGRI will continue to increase efficiencies in travel and conferences in an effort to reduce costs. NHGRI also plans to continue addressing the challenges and opportunities that exist in strategically managing a research portfolio that addresses areas of critical research.

**NATIONAL INSTITUTES OF HEALTH  
National Human Genome Research Institute**

**Budget Authority by Object**  
(Dollars in Thousands)

	<b>FY 2012 Enacted</b>	<b>FY 2013 PB</b>	<b>Increase or Decrease</b>
Total compensable workyears:			
Full-time employment	340	337	(3)
Full-time equivalent of overtime and holiday hours	1	1	0
Average ES salary ( <i>in dollars</i> )	\$173,633	\$173,633	\$0
Average GM/GS grade	12.2	12.2	0.0
Average GM/GS salary ( <i>in dollars</i> )	\$97,786	\$98,158	\$372
Average salary, grade established by act of July 1, 1944 (42 U.S.C. 207) ( <i>in dollars</i> )	\$102,333	\$104,277	\$1,944
Average salary of ungraded positions ( <i>in dollars</i> )	135,170	135,683	513
<b>OBJECT CLASSES</b>	<b>FY 2012 Enacted</b>	<b>FY 2013 PB</b>	<b>Increase or Decrease</b>
Personnel Compensation:			
11.1 Full-time permanent	\$16,886	\$16,801	(\$85)
11.3 Other than full-time permanent	15,741	15,686	(55)
11.5 Other personnel compensation	642	639	(3)
11.7 Military personnel	640	637	(3)
11.8 Special personnel services payments	5,230	5,230	0
<b>Total, Personnel Compensation</b>	<b>\$39,139</b>	<b>\$38,993</b>	<b>(\$146)</b>
12.0 Personnel benefits	\$9,957	\$10,003	\$46
12.2 Military personnel benefits	465	465	0
13.0 Benefits for former personnel	0	0	0
<b>Subtotal, Pay Costs</b>	<b>\$49,561</b>	<b>\$49,461</b>	<b>(\$100)</b>
21.0 Travel and transportation of persons	\$1,485	\$1,462	(\$23)
22.0 Transportation of things	125	125	0
23.1 Rental payments to GSA	0	0	0
23.2 Rental payments to others	10	10	0
23.3 Communications, utilities and miscellaneous charges	535	537	2
24.0 Printing and reproduction	54	56	2
25.1 Consulting services	585	585	0
25.2 Other services	16,021	16,033	12
25.3 Purchase of goods and services from government accounts	67,321	69,769	2,448
25.4 Operation and maintenance of facilities	605	606	1
25.5 Research and development contracts	3,136	4,112	976
25.6 Medical care	963	963	0
25.7 Operation and maintenance of equipment	1,969	1,970	1
25.8 Subsistence and support of persons	0	0	0
<b>25.0 Subtotal, Other Contractual Services</b>	<b>\$90,600</b>	<b>\$94,038</b>	<b>\$3,438</b>
26.0 Supplies and materials	\$6,642	\$6,643	\$1
31.0 Equipment	2,243	2,247	4
32.0 Land and structures	0	0	0
33.0 Investments and loans	0	0	0
41.0 Grants, subsidies and contributions	361,008	356,791	(4,217)
42.0 Insurance claims and indemnities	0	0	0
43.0 Interest and dividends	0	0	0
44.0 Refunds	0	0	0
<b>Subtotal, Non-Pay Costs</b>	<b>\$462,702</b>	<b>\$461,909</b>	<b>(\$793)</b>
<b>Total Budget Authority by Object</b>	<b>\$512,263</b>	<b>\$511,370</b>	<b>(\$893)</b>

Includes FTEs which are reimbursed from the NIH Common Fund.



**NATIONAL INSTITUTES OF HEALTH  
National Human Genome Research Institute**

**Salaries and Expenses  
(Dollars in Thousands)**

<b>OBJECT CLASSES</b>	<b>FY 2012 Enacted</b>	<b>FY 2013 PB</b>	<b>Increase or Decrease</b>
<b>Personnel Compensation:</b>			
Full-time permanent (11.1)	\$16,886	\$16,801	(\$85)
Other than full-time permanent (11.3)	15,741	15,686	(55)
Other personnel compensation (11.5)	642	639	(3)
Military personnel (11.7)	640	637	(3)
Special personnel services payments (11.8)	5,230	5,230	0
<b>Total Personnel Compensation (11.9)</b>	<b>\$39,139</b>	<b>\$38,993</b>	<b>(\$146)</b>
Civilian personnel benefits (12.1)	\$9,957	\$10,003	\$46
Military personnel benefits (12.2)	465	465	0
Benefits to former personnel (13.0)	0	0	0
<b>Subtotal, Pay Costs</b>	<b>\$49,561</b>	<b>\$49,461</b>	<b>(\$100)</b>
Travel (21.0)	\$1,485	\$1,462	(\$23)
Transportation of things (22.0)	125	125	0
Rental payments to others (23.2)	10	10	0
Communications, utilities and miscellaneous charges (23.3)	535	537	2
Printing and reproduction (24.0)	54	56	2
<b>Other Contractual Services:</b>			
Advisory and assistance services (25.1)	585	585	0
Other services (25.2)	16,021	16,033	12
Purchases from government accounts (25.3)	54,499	53,527	(972)
Operation and maintenance of facilities (25.4)	605	606	1
Operation and maintenance of equipment (25.7)	1,969	1,970	1
Subsistence and support of persons (25.8)	0	0	0
<b>Subtotal Other Contractual Services</b>	<b>\$73,679</b>	<b>\$72,721</b>	<b>(\$958)</b>
Supplies and materials (26.0)	\$6,642	\$6,643	\$1
<b>Subtotal, Non-Pay Costs</b>	<b>\$82,530</b>	<b>\$81,554</b>	<b>(\$976)</b>
<b>Total, Administrative Costs</b>	<b>\$132,091</b>	<b>\$131,015</b>	<b>(\$1,076)</b>

**NATIONAL INSTITUTES OF HEALTH  
National Human Genome Research Institute**

**Details of Full-Time Equivalent Employment (FTEs)**

OFFICE/DIVISION	FY 2011 Actual			FY 2012 Enacted			FY 2013 PB		
	Civilian	Military	Total	Civilian	Military	Total	Civilian	Military	Total
Office of the Director									
Direct:	6	0	6	6	0	6	6	0	6
Reimbursable:	0	0	0	0	0	0	0	0	0
Total:	6	0	6	6	0	6	6	0	6
Office of Administrative Management									
Direct:	24	0	24	24	0	24	23	0	23
Reimbursable:	0	0	0	0	0	0	0	0	0
Total:	24	0	24	24	0	24	23	0	23
Office of Population Genomics									
Direct:	6	0	6	6	0	6	6	0	6
Reimbursable:	0	0	0	0	0	0	0	0	0
Total:	6	0	6	6	0	6	6	0	6
Office of Policy, Communications and Education									
Direct:	11	0	11	11	0	11	11	0	11
Reimbursable:	0	0	0	0	0	0	0	0	0
Total:	11	0	11	11	0	11	11	0	11
Division of Intramural Research									
Direct:	219	8	227	219	8	227	218	8	226
Reimbursable:	26	0	26	26	0	26	25	0	25
Total:	245	8	253	245	8	253	243	8	251
Division of Extramural Research									
Direct:	36	1	37	36	1	37	37	0	37
Reimbursable:	3	0	3	3	0	3	3	0	3
Total:	39	1	40	39	1	40	40	0	40
<b>Total</b>	<b>331</b>	<b>9</b>	<b>340</b>	<b>331</b>	<b>9</b>	<b>340</b>	<b>329</b>	<b>8</b>	<b>337</b>
Includes FTEs which are reimbursed from the NIH Common Fund.									
FTEs supported by funds from Cooperative Research and Development Agreements	0	0	0	0	0	0	0	0	0
<b>FISCAL YEAR</b>	<b>Average GS Grade</b>								
2009	12.1								
2010	12.1								
2011	12.2								
2012	12.2								
2013	12.2								

**NATIONAL INSTITUTES OF HEALTH  
National Human Genome Research Institute**

**Detail of Positions**

<b>GRADE</b>	<b>FY 2011 Actual</b>	<b>FY 2012 Enacted</b>	<b>FY 2013 PB</b>
Total, ES Positions	2	2	2
Total, ES Salary	347,265	347,265	347,265
GM/GS-15	29	29	30
GM/GS-14	20	20	20
GM/GS-13	59	59	58
GS-12	49	49	48
GS-11	18	18	18
GS-10	3	3	3
GS-9	7	7	7
GS-8	19	19	19
GS-7	3	3	3
GS-6	0	0	0
GS-5	0	0	0
GS-4	0	0	0
GS-3	1	1	1
GS-2	1	1	1
GS-1	0	0	0
Subtotal	209	209	208
Grades established by Act of July 1, 1944 (42 U.S.C. 207):			
Assistant Surgeon General	0	0	0
Director Grade	5	5	4
Senior Grade	3	3	3
Full Grade	1	1	1
Senior Assistant Grade	0	0	0
Assistant Grade	0	0	0
Subtotal	9	9	8
Ungraded	150	150	149
Total permanent positions	218	218	216
Total positions, end of year	370	370	367
Total full-time equivalent (FTE) employment, end of year	340	340	337
Average ES salary	173,633	173,633	173,633
Average GM/GS grade	12.2	12.2	12.2
Average GM/GS salary	97,786	97,786	98,158

Includes FTEs which are reimbursed from the NIH Common Fund.