DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

Common Fund

NATIONAL INSTITUTES OF HEALTH
Common Fund
Budget Mechanism – Total[1]
Dollars in Thousands

	FY2010 Actual		FY 2011 Estimate		FY 2012 Estimate		Change	
MECHANISM	**No.**	**Amount**	**No.**	**Amount**	**No.**	**Amount**	**No.**	**Amount**
Research Grants								
Research Projects								
Noncompeting	210	$127,739	280	$149,107	267	$165,057	57	$37,318
Administrative Supplements	*35*	5,341	*9*	1447	*9*	1447	*-26*	-3894
Competing:								
Renewal	0	0	0	0	0	0	0	0
New	198	152,299	211	165,806	226	179,345	28	27,046
Supplements	0	0	0	0	0	0	0	0
Subtotal, Competing	198	$152,299	211	$165,806	226	$179,345	28	$27,046
Subtotal, RPGs	408	$285,379	491	$316,360	493	$345,849	85	$60,470
SBIR/STTR	0	$0	0	$0	0	$0	0	$0
Research Project Grants	408	$285,379	491	$316,360	493	$345,849	85	$60,470
Research Centers								
Specialized/ Comprehensive	36	$119,059	40	$113,767	40	$114,905	4	-$4,154
Clinical Research	9	7,003	9	6,606	9	6,672	0	-331
Biotechnology	20	7,231	13	4,749	13	4,796	-7	-2,435
Comparative Medicine	0	0	3	6,000	3	6,060	3	6,060
Research Centers in Minority Institutions	0	0	0	0	0	0	0	0
Research Centers	65	$133,293	65	$131,122	65	$132,433	0	-$860
Other Research								
Research Careers	32	$13,820	30	$14,929	0	$0	-32	-$13,820
Cancer Education	0	0	0	0	0	0	0	0
Cooperative Clinical Research	0	0	0	0	0	0	0	0
Biomedical	0	0	0	0	0	0	0	0

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

	FY2010 Actual		FY 2011 Estimate		FY 2012 Estimate		Change	
MECHANISM	**No.**	**Amount**	**No.**	**Amount**	**No.**	**Amount**	**No.**	**Amount**
Research Support								
Minority Biomedical Research Support	0	0	0	0	0	0	0	0
Other	23	23,758	22	19,827	28	25,000	5	1,242
Other Research	55	$37,578	52	$34,756	28	$25,000	-27	-$12,578
Total Research Grants	528	$456,250	608	$482,238	586	$503,282	58	$47,032
Research Training		FTTPs		FTTPs		FTTPs		FTTPs
Individual Awards	0	$0	0	$0	0	$0	0	$0
Institutional Awards	336	12,160	200	8,713	0	0	-336	-12,160
Total Research Training	336	$12,160	200	$8,713	0	$0	-336	-$12,160
Research & Development Contracts	0	$29,396	0	$11,525	0	$11,640	0	-$17,756
(SBIR/STTR)	*0*	*$0*	*0*	*$0*	*0*	*$0*	*0*	*$0*
		FTEs		FTEs		FTEs		FTEs
Intramural Research	0	$34,617	0	$27,879	0	$28,158	0	-$6,459
Research Management and Support	0	11,605	0	13,673	0	13,810	0	2,205
Construction		0		0		0		0
Buildings and Facilities		0		0		0		0
Total, Common Fund	0	$544,028	0	$544,028	0	$556,890	0	$12,862

Major Changes in the Fiscal Year 2012 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; these highlights will not sum to the total change for the FY 2012 budget request for the NIH Common Fund, which is $12.862 million more than the FY 2010 Enacted level, for a total of $556.890 million.

Research Project Grants (+$60.470 million, total $345.849 million): The NIH Common Fund expects to support a total of 493 Research Project Grant (RPG) awards in FY 2012. Noncompeting RPGs will increase by 57 awards and increase by $37.318 million. Competing RPGs will increase by 28 awards and increase by $27.046 million. Expansion of the High-Risk High-Reward program, including support for the new Early Independence Awards in FY 2012, accounts for most of this increase in funding. The NIH Budget policy for RPGs in FY 2012

includes a 1.0 percent inflationary increase in noncompeting awards and for the average costs in competing grants.

Research Centers (-$0.860 million, total $132.433 million): The NIH Common Fund plans to support a total of 65 Research Center Awards in FY 2011. The decrease in number and amount reflects a decrease in funding for the National Centers for Biomedical Computing (NCBCs), which are undergoing a planned transition from the Common Fund to the ICs as described in the original NCBC plan.

Research Careers (-$13.820 million, total $0 million): The Clinical and Translational Science Awards (CTSAs) transition from the NIH Common Fund to the NCRR in FY 2012. This transition eliminates Common Fund activity in Research Careers.

Other Research, Other (+$1.242 million, total $25.000 million): The increase in Common Fund support in FY 2012 reflects adjustments in the Nanomedicine Program following a program review in FY 2009. The requested level of funding allows the Common Fund to maintain use of $25.000 million in Flexibility Research Authority (FRA) and fund existing FY 2012 commitments. $16.000 million of the FRA will be used in FY2012 to fund ongoing projects within the Nanomedicine program. In addition, $9.000 million are requested to use as needed for New Programs to be developed. These funds provide a great deal of flexibility for application and review so will allow the NIH Director to respond rapidly to emerging needs and opportunities.

Institutional Training Awards (-$12.160 million, total $0 million): The decrease in funding reflects a planned transition of the Interdisciplinary Research program to the ICs in FY 2012.

Research and Development Contracts (-$17.756 million, total $11.640 million): The requested level of funding reflects a balance of adjustments involving expiration of the pilot phase of the Genotype-Tissue Expression (GTEx) initiative and funding of the Gulf Long-term Follow-up of Workers Study via contract in FY 2011 and FY 2012.

Intramural Research (-$6.459 million, total $28.158 million): The requested level of funding reflects a discontinuation of Common Fund support for the Molecular Libraries and Imaging Program's Core Synthesis Facility to Produce Imaging Probes in FY 2010 and a shift in support for the Gulf Long-term Follow-up of Workers Study from intramural research to research and development contract in FY 2011.

NATIONAL INSTITUTES OF HEALTH
Common Fund by Initiative
(Dollars in Thousands)

Title of Initiative	FY 2010 Actuals	FY 2011 CR	FY 2012 President's Budget	Change[2]
Bioinformatics and Computational Biology				
National Centers for Biomedical Computing	$19,361	$13,411	$8,500	-$10,861
Building Blocks, Biological Pathways and Networks				
National Technology Centers & Metabolomics Development	10,121	10,141	10,399	278
Epigenomics				
Mapping Centers	10,428	10,411	10,000	-428
Human Health and Disease	4,060	4,016	4,000	-60
Data Management Center for the Mapping Centers	2,906	2,905	3,000	94
Technology Development in Epigenetics	6,067	6,668	3,500	-2,567
Discovery of Novel Epigenetic Marks in Mammalian Cells	2,349	0	0	-2,349
Subtotal, Epigenomics	25,810	24,000	20,500	-5,310
Genotype-Tissue Expression (GTEx) Resources				
Genotype-Tissue Expression (GTEx) Resources	22,329	2,878	3,000	-19,329
Global Health				
Medical Eduction Partnership Initiative (MEPI)	3,000	3,000	3,000	0
Human Heredity and Health in Africa (H3Africa)	750	0	5,000	4,250
Subtotal, Global Health	3,750	3,000	8,000	4,250
Gulf Long-term Follow-up of Workers Study				
Gulf Long-term Follow-up of Workers Study	5,000	2,500	2,500	-2,500
Health Economics				
Changing Incentives for Consumers, Insurers, and Providers	0	2,486	2,443	2,443
Science of Structure, Organization, and Practice Design in the Efficient Delivery of Healthcare	0	1,336	3,268	3,268
Economics of Prevention	0	1,338	2,868	2,868
Data Infrastructure to Enable Research on Health Reform	0	121	3,043	3,043

[2] Comparison of FY 2012 to FY 2010

Title of Initiative	FY 2010 Actuals	FY 2011 CR	FY 2012 President's Budget	Change[2]
Subtotal, Health Economics	0	5,281	11,622	11,622
High-Risk Research				
NIH Director's Pioneer Awards	37,430	40,400	40,600	3,170
NIH Director's New Innovator Awards	97,821	80,200	80,000	-17,821
Transformative R01's	39,644	75,000	100,000	60,356
NIH Director's Early Independence Award Program	0	4,000	8,400	8,400
Subtotal, High-Risk Research	174,895	199,600	229,000	54,105
HMO Research Network Collaboratory				
NIH-HMORN Coordinating Center	1,000	3,273	1,200	200
Expansion Activities	0	0	4,000	4,000
Subtotal, HMO Research Network Collaboratory	1,000	3,273	5,200	4,200
Human Microbiome				
Sequence a Reference Set of Genomes	9,952	3,239	1,980	-7,972
Demonstration Projects	16,088	13,259	11,517	-4,571
New Tools and Technologies for Metagenomic Analyses	9,467	5,621	7,000	-2,467
Data Coordination	2,187	2,562	2,606	419
Resource Repository for Materials & Reagents	0	0	400	400
ELSI Studies Unique to HMP	495	500	500	5
HMP Workshops	0	765	635	635
Subtotal, Human Microbiome	38,189	25,946	24,638	-13,551
Interdisciplinary Research				
Interdisciplinary Research Centers	42,179	42,199	0	-42,179
Interdisciplinary Research Training Initiative	0	0	0	0
Innovation in Interdisciplinary Technology and Methods	2,807	0	0	-2,807
Subtotal, Interdisciplinary Research	44,986	42,199	0	-44,986
Knockout Mouse Phenotyping Program				
Production, Characterization, and Cryopreservation	0	6,180	6,200	6,200
Phenotyping and Data Release	500	4,179	4,200	3,700
Data Coordination	0	641	600	600
Subtotal, Knockout Mouse Phenotyping Program	500	11,000	11,000	10,500
Library of Integrated Network-Based Cellular Signatures (LINCS)				
Large-Scale Production of Perturbation-Induced Gene Expression	3,000	5,349	5,350	2,350
New Laboratory-Based Technology Development	0	2,800	2,800	2,800

Title of Initiative	FY 2010 Actuals	FY 2011 CR	FY 2012 President's Budget	Change[2]
Computational Tool Development and Integrative Data Analysis	0	1,400	1,400	1,400
Integration of Existing Datasets	0	451	450	450
Subtotal, Library of Integrated Network-Based Cellular Signatures (LINCS)	3,000	10,000	10,000	7,000
Molecular Libraries and Imaging				
Creation of NIH Bioactive Small Molecule Library & Screening Centers	88,372	86,375	56,850	-31,522
Cheminformatics	4,100	3,900	3,700	-400
Technology Development	17,169	12,825	10,700	-6,469
Imaging Probe Database	600	0	500	-100
Core Synthesis Facility to Produce Imaging Probes	3,000	0	0	-3,000
Subtotal, Molecular Libraries and Imaging	113,241	103,100	71,750	-41,491
Nanomedicine				
Nanomedicine Development Centers	20,000	15,946	16,000	-4,000
NIH Center for Regenerative Medicine (NCRM)				
NIH Center for Regenerative Medicine (NCRM)	2,321	6,000	10,000	7,679
Protein Capture				
Antigen Production	980	870	900	-80
Production of anti-TF Antibodies	0	3,975	3,975	3,975
New Reagent Technology Development and Piloting	200	5,337	5,125	4,925
Subtotal, Protein Capture	1,180	10,182	10,000	8,820
Public-Private Partnerships				
Public-Private Partnerships	0	0	0	0
Re-engineering the Clinical Research Enterprise				
Clinical Research Policy Analysis and Coordination	0	0	0	0
Translational Research Core Services	5,848	5,000	5,000	-848
Dynamic Assessment of Patient-Reported Chronic Disease Outcomes	9,396	8,448	8,448	-948
Enhance Clinical Research Training via the National Multi-disciplinary CR Career Development Program and CRTP and MSTP Expansions	1,100	880	720	-380
Clinical and Translational Science Awards	25,245	22,703	0	-25,245
Subtotal, Re-engineering the Clinical Research Enterprise	41,589	37,031	14,168	-27,421
Regulatory Science				

Title of Initiative	FY 2010 Actuals	FY 2011 CR	FY 2012 President's Budget	Change[2]
Advancing Regulatory Science Through Novel Research and Science-Based Technologies	2,891	3,081	2,555	-336
Science of Behavior Change Mechanisms of Change	4,643	4,883	4,958	315
Structural Biology Membrane Protein Production	8,381	8,004	8,000	-381
Strategic Planning Funds	841	2,572	2,594	1,753
Subtotal Common Fund	544,028	544,028	484,384	-59,644
New Initiatives in Common Fund	**0**	**0**	**72,506**	**72,506**
Total Common Fund	**$544,028**	**$544,028**	**$556,890**	**$12,862**

Justification of Budget Request

Common Fund

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

Budget Authority:

	FY 2010 Appropriation	FY 2011 CR	FY 2012 Budget Request	FY 2012 + / - FY 2011
BA	$544,028,000	$544,028,000	$556,890,000	$12,862,000
FTE	0	0	0	0

Director's Overview

The 2006 NIH Reform Act called for the NIH Common Fund to support important areas of emerging scientific opportunities, rising public health challenges, or knowledge gaps that deserve special emphasis and would benefit from conducting or supporting additional research that involves collaboration between two or more national research institutes or national centers, or would otherwise benefit from strategic coordination and planning. To this end, the Common Fund programs encourage transformative research that tackles the most critical challenges in biomedical research and translation. These are short term (5-10 year) programs that are intended to solve problems or build resources that will then catalyze research throughout the entire biomedical research enterprise.

The catalytic nature of Common Fund programs often involves the generation, integration and an analysis of complex data sets using high-throughput tools and technologies for biological discovery related to health and disease. This category of program expanded in FY 2011. The Library of Integrated Network-Based Cellular Signatures (LINCS) program, launched in FY 2011, is using high-throughput approaches to develop a resource "library" for the biomedical community to determine how different types of cells respond to a variety of perturbing agents that may be related to disease. Also launched in FY 2011, the Knock-out Mouse Phenotyping ($KOMP^2$) program is providing resources to characterize an existing collection of mutant mice, in which most of the genes in the genome have been "knocked out," one gene at a time. This vast collection of mutant mouse strains will be much more useful to the community if the impact of each mutation is known. The Common Fund will therefore support fundamental characterization of each strain, to catalyze future investigator-initiated studies on how mammalian genes function.

The Common Fund also continues to support the Human Microbiome Program which is developing and applying high-throughput genomics and computational approaches to generate a reference set of genomes from the micro-organisms that inhabit various organs of the human body, the so-called human microbiome. These efforts will accelerate our understanding of the relationship between the human microbiome and health and disease. Researchers from the Human Microbiome Program have published the first reference set of 178 genomes from

microbes in or on the human body, revealing a vast amount of microbial diversity[3]. Similarly, the Epigenomics program is developing reference data pertaining to the human epigenome – the entire set of chemical and structural modifications to DNA that, although generally not inherited, determine which genes are active in a given cell type. These modifications can have profound effects on health and disease. Researchers in the Epigenomics program have discovered that a type of epigenetic modification differs between embryonic stem cells and adult, differentiated cells, which may help explain how stem cells maintain their ability to become any cell type in the body[4]. Finally, the Genotype-Tissue Expression (GTEx) project is using high-throughput genetic and genomic approaches to develop a set of reference gene expression profiles for specific human tissues that will greatly enhance our ability to characterize genetic variation as it relates to gene expression.

Common Fund programs also catalyze NIH-wide research through the provision of resources or development of novel technologies to advance the development of new and better drugs, biologics, and devices and bring new innovative treatments to patients. The Common Fund launched the NIH Center for Regenerative Medicine (NCRM) program in FY 2010 within the NIH Intramural Research Program (IRP). The program supports a collection of new intramural pilot projects that focus on induced pluripotent stem cells with the intent of building a cadre of investigators in the IRP focused on regenerative medicine. These pilot projects are intended to accelerate clinical applications of stem cells. The Common Fund also provides continued support for other programs that strengthen the therapeutics development pipeline. For example, the Molecular Libraries and Imaging program is identifying small molecules that may hold promise in the development of new disease therapies. Scientists in the Molecular Libraries and Imaging program have helped identify cellular pathways that contribute to insulin resistance, suggesting novel drug targets for the prevention or treatment of diabetes[5]. The NIH Rapid Access to Intervention Development (RAID) program is providing public sector researchers and small businesses with much needed resources to speed up the analysis, synthesis and formulation of potentially beneficial molecules through the valley of death phase of therapeutics development. RAID has supported the development of a drug currently in clinical trials as a potential treatment for Alzheimer's disease[6]. To hasten the development and testing of new designs, strategies and models for clinical trials of therapies, preventives, and diagnostics, the NIH is partnering with the Food and Drug Administration in the Common Fund's new Regulatory Science program.

Strategic planning in 2010 resulted in three new Common Fund programs in FY 2011 to to assist in reforming the health care system. The new Health Economics program supports a series of projects, some that build on the findings of comparative effectiveness research (CER), to identify and develop new approaches to improve health and increase the efficiency and quality of health care delivery. The HMO Research Network Collaboratory program was created in FY 2010 to leverage and expand existing information technology, electronic records

[3] The Human Microbiome Jumpstart Reference Strains Consortium (2010). A catalogue of reference genomes from the human microbiome. Science, 328, 994-999.
[4] Lister R, Pelizzola M, Dowen RH, et al. (2009). Human DNA methylomes at base resolution show widespread epigenomic differences. Nature, 462, 315-322.
[5] Choi JH, Banks AS, Estall JL, et al. (2010). Anti-diabetic drugs inhibit obesity-linked phosphoylation of PPARγ by Cdk5. Nature, 466, 451-456.
[6] Mithridion press release, http://mithridion.com/pr09.html.

systems, and scientific capacity within HMO health service networks to accelerate large epidemiology studies and clinical trials that address cross-cutting NIH priorities. Some of the projects funded through the High Risk/High Reward initiatives are enhancing the evidence base for clinical care by identifying and examining behavioral aspects of patient health, compliance and health costs. Specific projects are developing clinical markers for mood disorders as a way to design more effective treatments and monitor compliance and response to treatment, and assessing how the way health information is conveyed to patients affects their attitudes and prevention behavior related to cancer.

Recognizing the need for further stimulation of the biomedical workforce, specifically to support researchers at the beginning of their independent careers, the NIH Director expanded the High Risk/High Reward program in FY 2011 through the launch of the Early Independence Award (EIA) initiative. The EIA supports exceptionally creative individuals who are mature enough at the end of their graduate training to move directly into independent research careers and skip the traditional post-doctoral period. The Transformative Research Project (TR01) awards also expanded in FY 2011 to support the next cadre of highly innovative projects. Together with the Pioneer awards and the New Innovator awards, these initiatives allow creative investigators to define their own innovative, high-risk, original, and unconventional research projects without the need for extensive preliminary data required by traditional R01s.

Overall Budget Policy: The FY 2012 request for the Common Fund is $556.890 million, an increase of $12.862 million or 2.46 percent over the FY 2010 Actual level. The Common Fund plans to support a 1 percent inflationary increase for non-competing and competing grants. The Common Fund will continue to support research consistent with the NIH Director's Themes. As mature programs transition out of the Common Fund, new programs are being established through strategic planning activities that identify cross-cutting challenges and emerging scientific opportunities where short-term investment can have a catalytic impact. Programs that support regenerative medicine or that expand the clinical research networking capabilities of the HMO Research Network will expand. The Common Fund will also support the Director's Theme of Reinvigorating the Workforce through expanded funding of High Risk/High Reward research, emphasizing programs that foster the creativity and independence of exceptional early career investigators.

FY 2012 Justification by Program

Bioinformatics and Computational Biology: In an age where the ability to manage and organize large amounts of varied biomedical data is necessary for research, the need for informatics tools is critical. These tools must be adapted to handle data that are unique to studies of biological systems. The Bioinformatics and Computational Biology program, which supports the National Centers for Biomedical Computing (NCBCs), was funded beginning in 2003-2004 and has completed its first phase of funding through the Common Fund. The first phase established the utility of a network of integrated centers that collectively address a broad range of biological problems. In the second phase of the program, the network of centers will gradually transition to NIH's Institutes and Centers (ICs) support. The Centers will function as core resources for the development of novel software and computational tools that address IC-specific problems.

Budget Policy: The FY 2012 budget estimate of $8.500 million for this program represents a decrease of $10.861 million or 56.1 percent less than the FY 2010 Enacted level. This estimated decrease is consistent with the natural transition of NCBC support from the Common Fund to the ICs as described in the original NCBC plan.

Building Blocks, Pathways, and Networks: The basic building blocks of the human body, from individual genes to entire organs, work together to promote normal development and sustain health. This amazing feature of biological systems is accomplished mainly through ever-changing relationships between the proteins that make up biological pathways. Understanding how these pathways are interconnected and maintained, how they can become disturbed, and what might be done to restore disturbed pathways to their normal functions is key to understanding health and disease. Although scientists can currently study interactions between proteins within cells, their ability to do this is equivalent to taking a snapshot – looking at a single, isolated moment in time. The National Technology Centers for Networks and Pathways (TCNP) program supports the development of new technologies to help researchers view dynamic events, such as protein-protein interactions, in cells to better understand how these processes work under normal conditions and in disease. The centers serve as an important overall resource for NIH-supported investigators by promoting collaboration among biomedical researchers and speeding the transfer of new technologies to other laboratories.

Budget Policy: The FY 2012 budget estimate of $10.399 million for this program represents an increase of $0.278 million or 2.7 percent more than the FY 2010 Enacted level. FY 2012 funds will be used for continued development of new technology and dissemination of these research tools at the TCNPs.

Epigenomics: Epigenetics focuses on processes that regulate how and when certain genes are turned on and turned off, while epigenomics pertains to analysis of epigenetic changes across all of the genes in a cell. Some human diseases, such as cancer, are known to involve epigenetic changes; however, the role of epigenetics in other diseases is largely unknown and is difficult to study because researchers lack the tools to efficiently detect and correlate changes in the epigenome to specific diseases or health conditions. The Common Fund Epigenomics program includes a series of complementary initiatives to generate the research tools, technologies, and

infrastructure needed to accelerate our understanding of the role of epigenomics in human health and disease. The Reference Epigenome Mapping Centers are developing maps of epigenetic changes in a specific cell type that can be used to identify epigenomic changes that underlie biology and disease, and may be targeted in new therapeutics. An Epigenomics Data Analysis and Coordination Center is developing standardized datasets from the Mapping Center studies that will be made available to the public. Two other initiatives support projects on Technology Development in Epigenetics and Discovery of Novel Epigenetic Marks in Mammalian Cells. A fourth initiative, the Epigenomics of Human Health and Disease, provides funds for investigators to determine how or whether epigenomic changes correlate with disease.

Budget Policy: The FY 2012 budget estimate of $20.500 million for this program represents a decrease of $5.310 million or 20.6 percent less than the FY 2010 Enacted level. The FY 2010 completion of several 2-year projects funded under the Discovery of Novel Epigenetic Marks in Mammalian Cells initiative and a reduction in funding of the Technology Development in Epigenetics initiative in FY 2011, due to the completion of four-year grants awarded in FY 2008, accounts for this estimated decrease in funding.

Genotype-Tissue Expression (GTEx): Although genome-wide studies are an effective way to identify specific genes that may be associated with a disease, many diseases involve changes in DNA that lie outside of a specific gene region, making it difficult to study them using this approach. The Genotype-Tissue Expression (GTEx) project provides the scientific community with a much-needed resource with which to study how gene activity is controlled and how DNA variation correlates with variation in gene activity levels. The GTEx project was initiated in FY 2010 as a two-year pilot to test the feasibility of collecting high-quality RNA and DNA from multiple tissues from approximately 160 donors identified through autopsy or organ transplant. If the pilot phase proves successful, the project will be scaled up to involve approximately 1000 donors. The project involves consultation and research into the ethical, legal, and social issues raised by the research, support for new statistical methods, and creation of a database of genetic and clinical data generated by the program and obtained from other sources. The database allows users to view and download data about possible genomic regions that correlate with changes in gene activity while providing a controlled system to ensure privacy about genetic and clinical data. The tissue repository serves as a resource for conducting many kinds of follow-up analyses.

Budget Policy: The FY 2012 budget estimate of $3.000 million for this program represents a decrease of $19.329 million or 86.6 percent less than the FY 2010 Enacted level. Beginning in FY 2010, the pilot phase of the GTEx included a contract that incurred no costs in FY 2011. Support of a small grant program to analyze gene sequence and expression data as part of the pilot phase of GTEx continues in FY 2012.

Global Health: The NIH Common Fund Global Health Program is partnering with other NIH Institutes, Centers, and Offices as well as other Federal agencies and the UK Wellcome Trust to support two initiatives that will expand research capacity in Africa. The Medical Education Partnership Initiative (MEPI) is developing and strengthening models of medical education and building research and clinical capacity in countries of Sub-Saharan Africa that are part of the U.S. President's Emergency Plan for AIDS Relief (PEPFAR). The Human Heredity and Health in Africa (H3Africa) initiative involves collaboration with the Wellcome Trust to build research

capacity in Africa for the study of the genetic and environmental contributions to health and disease. Both communicable and non-communicable diseases and conditions are being addressed through this initiative.

Budget Policy: The FY 2012 budget estimate of $8.000 million for this program represents an increase of $4.250 million or 113.3 percent more than the FY 2010 Enacted level. This estimated increase is due to the launch in FY 2012 of the Human Heredity and Health and Africa (H3Africa) initiative as a partnership between the NIH and the UK Wellcome Trust.

Gulf Long Term Follow-Up (GuLF) of Workers Study: The oil from the April 20, 2010 explosion on the Deepwater Horizon oil rig in the Gulf of Mexico contaminated the Gulf and has settled along the coastline and marshes of Alabama, Louisiana and Florida. In his testimony before the Senate Subcommittee on Health, Committee on Energy and Commerce on June 15, 2010, the NIH Director pledged support from the Office of the Director and the NIH Common Fund for research into the environmental health hazards posed by the Gulf oil spill. The Gulf program, initiated with FY 2010 funds, includes a prospective study of clean-up workers, called the Gulf Long-term Follow-up (GuLF) study, and toxicological studies. Longer term requirements for funds from the Common Fund will be determined when information concerning the availability of additional funds from BP becomes available. The NIH efforts for Gulf program complement and are coordinated with response efforts of other federal, state, and local agencies and institutions working in the Gulf region.

Budget Policy: The FY 2012 budget estimate of $2.500 million for this program represents a decrease of $2.500 million or 50.0 percent less than the FY 2010 Enacted level. The decrease reflects additional sources of funding, in addition to the Common Fund, for the prospective study of clean-up workers.

Health Economics: This program, launched in the wave of national health care reform, addresses research needs identified through strategic planning conducted in FY 2010. In FY 2012, the program includes a series of developmental research projects intended to identify and develop approaches to improve health and increase efficiency in delivery of health care.

Budget Policy: The FY 2012 budget estimate of $11.622 million for this program represents an increase of $11.622 million or 100 percent more than the FY 2011 Enacted level. This new FY 2011 program supports initiatives investigating economics of prevention strategies, costs and outcomes of health care delivery, and improvement of data infrastructure resources.

Portrait of a Program: Health Economics

FY 2010 Level: $ 0 million
FY 2012 Level: $11.622 million

The Affordable Care Act of 2010 set in motion a major expansion of insurance coverage, testing of several approaches to controlling costs, and creation of a new long-term care insurance fund. With other recent legislation, it provides funding for an expansion of health information technology (IT) in primary care. These reforms constitute the largest

Portrait of a Program: Health Economics

changes to the health care system in the US since the enactment of Medicare and Medicaid in 1965. But reform is a work in progress. A major challenge is to slow the rate of cost growth without jeopardizing access to high-value care or slowing technological innovation. The Health Economics program was initiated in FY 2011. FY 2012 funds support a series of small developmental projects to examine:

-- Effects of changing incentives for consumers, providers and insurers
-- Scientific questions underlying supply-side changes in organization of health care
-- Economics of prevention
-- Data infrastructure needed for research to inform health care reform.

Expansion of the program in FY 2012 represents new initiatives to develop and analyze the economics of prevention strategies, evaluate costs and outcomes of health care delivery, and improve existing data resources to promote data sharing and linkage across data sets and researchers.

High-Risk High-Reward Investigator-Initiated Research: Research that aims to transform science is inherently difficult; if it was either obvious or easy, the need for transformation would not exist. A primary goal of the Common Fund is to provide opportunities for investigators to take risks when the potential impact is high, to think outside the box, and to try things that may not fare well in standard peer review, which relies on solid preliminary data to support proposed hypotheses. Although all of the Common Fund programs encourage risk-taking to overcome significant challenges in research, most of them involve designated funds for particular high risk objectives (such as clinical applications of nanobiology) or approaches (such as screening for new drugs or probes in the Molecular Libraries Program.) However, four initiatives within the Common Fund foster innovation, risk-taking, and transformative research in any area of health research chosen by the investigators: the NIH Director's Pioneer Award Program, the NIH Director's New Innovator Award Program, the Transformative Research Projects (TR01) program, and the NIH Director's Early Independence Award program. These initiatives represent complementary approaches to foster innovation and promote transformation. In FY 2011, the Early Independence Awards program was launched with a goal of invigorating the workforce by fostering independence of exceptional young scientists immediately after completion of their doctoral degrees.

Budget Policy: The FY 2012 budget estimate of $229.000 million for this program represents an increase of $54.105 million or 30.9 percent more than the FY 2010 Enacted level. This estimated increase in funding is due to an expansion of the FY 2011 NIH Director's Early Independence Award program to support exceptional young scientists in independent research positions, as well as expansion of the TR01 program in FY 2011 and FY 2012 to support two new cohorts of investigators exploring bold, innovative, and high-risk research.

Portrait of a Program: NIH Director's Early Independence Award (EIA)

FY 2010 Level: $0 million
FY 2012 Level: $8.400 million

The Early Independence Award (EIA), launched by the NIH Director through the Common Fund, addresses a fundamental need to bolster the biomedical workforce in the United States by supporting a cadre of highly creative and mature scientists who are prepared to tackle biomedical research problems earlier in their career than is typically allowed. Recent trends show an increase in the length of the traditional scientific training period with a concomitant increase in the age at which scientists establish independent research careers. Although traditional post-doctoral training is likely most appropriate for the majority of new Ph.D.s and M.D.s, there is a pool of talented young scientists who have the intellect, scientific creativity, drive, and maturity to flourish independently without the need for traditional post-doctoral training. Reducing the amount of time these scientists spend in training would provide them the opportunity to start highly innovative research programs as early in their careers as possible. To facilitate this, the NIH Common Fund established the NIH Director's EIA to provide a mechanism for exceptional, early career scientists who are U.S. residents or permanent citizens to omit traditional post-doctoral training, and move into temporary, independent academic positions at U.S. institutions directly upon completion of their graduate degrees (Ph.D, M.D. or equivalent). This highly competitive program is being expanded in FY 2012 to support a second cadre of exceptional research scientists.

HMO Research Network Collaboratory (HMORC): In the context of health care reform activities, the Common Fund is leveraging prior investments from ICs in a network of 15 U.S. member health plans of the national HMO Research Network (HMORN), started in 2007. The research infrastructure and capacity of the HMORC are being expanded to extend utility of the network to all NIH ICs. The increased collaborative potential of the network is reflected in the Common Fund name of this effort as a Research Collaboratory. The HMORN research organizations, because of their history of public sector research and their affiliation with leading-edge integrated healthcare delivery systems, are ideally positioned to lead new research efforts in a number of cross-cutting NIH interest areas, including Mega-Epidemiology Studies, Clinical Trial Enterprise, and Health Care Delivery.

Budget Policy: The FY 2012 budget estimate of $5.200 million for this program represents an increase of $4.200 million or 420.0 percent more than the FY 2010 Enacted level. This estimated increase in funding is a result of expansion of the HMORC program to explore current capabilities of the HMORN research organizations and define collaborative opportunities with these organizations.

Human Microbiome Project: Microbes such as bacteria, viruses, and fungi found naturally in the human body outnumber human cells 100 to 1. Most of the microbes living in our bodies are

beneficial whereas others cause disease. Bacteria have been implicated in conditions as diverse as asthma, cancer and obesity; yet the great majority of bacteria and viruses that reside on and in people are unidentified and uncharacterized. The Common Fund Human Microbiome Project was launched in FY 2008 to leverage advances in high throughput genomic technologies to identify and characterize approximately 600 new human microbes and to establish causal links between specific bacteria and disease. The program is focusing on sampling microbes from several different body sites from many different individuals to determine whether there is a common set of microbes, or so-called microbiome, that is shared by all people or whether each person has a unique microbiome. In FY 2012, the program investigators will focus on sequencing and cataloging of the microbiome samples, establishing links between the microbiome and disease, developing technologies to identify unknown microbes.

Budget Policy: The FY 2012 budget estimate of $24.638 million for this program represents a decrease of $13.551 million or 35.5 percent less than the FY 2010 Enacted level. The estimated decrease in funding levels reflects the balance of adjustments to several individual initiatives, including a reduction in Sequence a Reference Set of Genomes and an increase in Data Coordination.

Interdisciplinary Research Consortia: A major focus of the NIH Common Fund has been to foster new modes of conducting research, with emphasis on the need for interdisciplinary approaches to address complex health problems. In FY 2007, the NIH awarded funds to nine Interdisciplinary Research Consortia to explore new ways to integrate different scientific disciplines to address critical health challenges. This program piloted new award mechanisms for Interdisciplinary Research and Training as well as new methods of review for Interdisciplinary Research. It also resulted in a change of policy within the NIH to recognize multiple Principal Investigators on NIH grants and developed new methods of inter-IC award management. Common Fund support of this program ends in FY 2011, with the expectation that ICs will continue to use the award mechanisms as needed to support interdisciplinary approaches, working together to foster research that cuts across IC mission boundaries.

Budget Policy: The Interdisciplinary Research Consortia will receive no funding in FY 2012 from the Common Fund. This reflects the planned transition of support from the Common Fund to individual ICs, as appropriate.

Knock-out Mouse Phenotyping Program: Recognizing the value and utility of a readily accessible, genome-wide collection of knockouts as the lynchpin to determine how mammalian genes function, several international programs were launched in 2006 to develop mutant mouse strains. Collectively, these programs have created almost 8,000 prototype knockout mice, and they are on track to complete the resource by the end of 2011. The new Common Fund program builds upon this resource by expanding the efforts to characterize the mutant strains. The data will be made rapidly available to the entire research community through an internationally-coordinated data coordinating center.

Budget Policy: The FY 2012 budget estimate of $11.000 million for this program represents an increase of $10.500 million or 2100 percent more than the FY 2010 Enacted level. New FY

2011 initiatives to characterize mutant strains of mice and disseminate data to the research community continue in FY 2012 and account for the increase in funding.

Library of Integrated Networks of Cellular Signatures (LINCS): The LINCS program aims to develop a "library" of molecular signatures based on gene expression and other cellular changes that describe the response that different types of cells elicit when exposed to various perturbing agents, including small interfering RNAs (siRNAs), which are short RNA molecules that can inhibit expression of specific genes, and small bioactive molecules. High-throughput screening approaches are used to interrogate the cells and mathematical approaches will be used to describe the molecular changes and patterns of response. The data are being collected in a standardized, integrated, and coordinated manner to promote consistency and comparison across different cell types.

Budget Policy: The FY 2012 budget estimate of $10.000 million for this program represents an increase of $7.00 million or 233.3 percent more than the FY 2010 Enacted level. New FY 2011 initiatives to support technology development and investigate molecular signatures of perturbation and provide insights about cellular changes in disease will continue in FY 2012 and account for the increase in funding.

Molecular Libraries and Imaging: The pharmaceutical industry has for years used a process known as high-throughput screening (HTS) to identify new small molecule probes that can be used for drug development and to study biological processes involved in disease. Prior to the launch of the Molecular Libraries and Imaging Program, HTS capabilities were not available to academic researchers. This program provides public sector, biomedical researchers much needed access to HTS approaches to develop small molecule probes. Data about the structure and function of the probes are deposited in a free, online public database called PubChem (http://pubchem.ncbi.nlm.nih.gov/), which was designed and implemented by the Molecular Libraries and Imaging program. The program has developed 87 compounds that are in pre-clinical tests as new leads for drug development. In FY 2012, the program begins its transition out of the Common Fund. Having been successfully launched, elements of the program will continue through IC funding and/or funding through the Therapies for Rare and Neglected Diseases (TRND) Program and the Cures Acceleration Network (CAN).

Budget Policy: The FY 2012 budget estimate of $71.750 million for this program represents a decrease of $41.491 million or 36.6 percent less than the FY 2010 Enacted level. This estimated reduction is due to the transition of the Molecular Libraries and Imaging program from Common Fund support to IC support as planned.

Nanomedicine: Nanotechnology, the study and manipulation of molecules less than 100 nanometers in size, holds great promise for use in diagnosing and treating disease. Nanotechnology is currently being used to: deliver drugs to specific locations in the body, diagnose disease, and view inside the body through the use of imaging. The goal of this Common Fund program is to use nanotechnology to understand and manipulate biological processes in a cell for specific medical purposes. For example, nanoscale protein folding machines are being developed for the treatment of diseases such as Alzheimer's and Huntington's, where misfolded proteins are thought to play a role. In FY 2005, a network of eight Nanomedicine Centers at

academic institutions across the country was established. The program underwent an extensive review in FY 2009 to inform the next phase, which is focusing on making the nanobiological structures developed in the first phase more clinically useful. The second phase of the program constitutes a more focused effort involving a smaller number of centers. This program uses the Flexible Research Authority, or Other Transaction Mechanism, which will continue in FY 2012.

Budget Policy: The FY 2012 budget estimate of $16.000 million for this program represents a decrease of $4.000 million or 20.0 percent less than the FY 2010 Enacted level. The estimated funding reflects an overall reduction in the number of funded centers and ongoing support of the selected centers following the FY 2009 review.

NIH Center for Regenerative Medicine (NCRM): This new program, housed in the NIH Intramural Research Program (IRP), will provide a national resource for stem cell science that is specifically focused on facilitating the development of medical applications and cell therapies.

Budget Policy: The FY 2012 budget estimate of $10.000 million for this program represents an increase of $7.679 million or 330.8 percent more than the FY 2010 Enacted level. This estimated increase reflects a planned scale-up to support increased cell production and research capacity in the intramural center.

Portrait of a Program: NIH National Center for Regenerative Medicine (NCRM)

FY 2010 Level: $2.321 million
FY 2012 Level: $10.000 million

The NIH Center for Regenerative Medicine (NCRM), initiated in FY 2010, is intended to accelerate the development of cell based therapies for regenerative medicine. Housed within the NIH Intramural program, this Center will provide research resources to intramural and extramural investigators. The program will:

-- Establish a stem cell core facility that will be a resource for the scientific community, providing reagents and technologies and establishing collaborative projects with both intramural and extramural partners
-- Establish a lab for the Director of the Center within the NIH IRP, with the expectation that the Center Director will be a leader in clinical application of stem cell technologies
-- Provide pilot funds to intramural investigators to launch clinically-driven regenerative medicine projects which will then feed into the collaborative projects funded through the core activities of the Center.

FY 2012 funds provide support for a new Center Director, a series of intramural pilot projects on clinical applications of induced pluripotent stem cells (iPSCs), and continued development of the NCRM as a national resource.

Protein Capture: This program is intended to develop a renewable resource of protein capture reagents specifically designed to meet research and clinical demands ranging from protein isolation and high-throughput assays to diagnostics and biomarker development. To have the

maximum benefit, such reagents would need to include high quality, affordable, reliable monoclonal antibodies as well as other reagents that can collectively target the range of possible proteins within cells and tissues. This program provides support for the development of new technologies and for the provision of monoclonal antibodies.

Budget Policy: The FY 2012 budget estimate of $10.000 million for this program represents an increase of $8.820 million or 747.5 percent more than the FY 2010 Enacted level. The increase in funding reflects the new FY 2011 initiative to develop reagents for a specific class of human proteins called transcription factors, and increased funding for the Antigen Production and New Reagent Technology Development and Piloting initiatives as the Protein Capture program advances.

Re-engineering the Clinical Research Enterprise: This program seeks to enhance the efficiency and effectiveness of clinical research. The initiatives within Re-engineering the Clinical Research Enterprise strive to transform the entire system of clinical research in order to fulfill the potential of modern medicine. These initiatives will foster the creation of new partnerships and a higher level of institutional integration in order to improve the working relationships among the numerous entities that are part of the clinical research process.

Translational Research Core Services: NIH Rapid Access to Intervention Development (RAID): Many promising new therapeutics encounter roadblocks during clinical development. Especially vulnerable are therapeutic approaches that involve high risk ideas or therapies for uncommon disorders that cannot attract private sector investment. Where private sector support for drug development is limited or not available, the NIH Rapid Access to Intervention Development Pilot program (NIH-RAID) can help fill the gap and reduce some of the common barriers that block progress of therapeutic discoveries from the bench to the bedside. The NIH-RAID program is not a grant program. Instead, it makes available critical resources that are needed to develop new therapeutic agents, including ones that can generate bulk amounts of the drug candidate or test its stability or toxic effects. It also provides researchers with access to expertise at the Food and Drug Administration on document preparation and submission. This program forms a critical component of the therapeutics pipeline and will be closely coordinated with the Therapeutics for Rare and Neglected Diseases (TRND) and Cures Acceleration Network (CAN) programs.

Budget Policy: The FY 2012 budget estimate of $5.000 million for this program reflects a decrease of $0.848 million or 14.5 percent less than the FY 2010 Enacted level. The funds provide support for ongoing programs and outreach efforts enhance the use of resources developed through the program.

Dynamic Assessment of Patient-Reported Chronic Disease Outcomes: Patient-Reported Outcomes Measurements Information System (PROMIS): PROMIS is a revolutionary effort to enhance the precision of measures of patient-reported symptoms and function or outcomes. Patient-reported outcomes are essential for proper medical care but are often difficult to collect reliably. The PROMIS program has developed an interactive, computerized testing system that accurately reports patient-reported outcomes by

adapting questions to the responses of each individual patient. This standardized measurement tool will increase the comparability of studies while reducing the reporting burden on patients. The initial PROMIS network of seven research sites and one coordinating center developed questionnaires tailored to a number of symptoms of chronic diseases and conditions including anxiety, pain, and fatigue. In FY 2009, the second phase of the PROMIS program began with an expansion of the network to 14 research sites and three supporting centers to extend the PROMIS system to several new areas with an emphasis on questionnaires tailored to children, minorities, women and the underserved.

Budget Policy: The FY 2012 budget estimate of $8.448 million for this program represents a decrease of $0.948 million or 10.1 percent less than the FY 2010 Enacted level. This estimated funding reflects the continued support of PROMIS as this program continues to develop questionnaires tailored to underserved and minority populations.

Clinical and Translational Science Awards (CTSAs): The CTSA program was established through Common Fund support as an effort to is a unique and bold venture to restructure and improve the clinical research enterprise. The CTSA program is enabling researchers to provide and deliver new treatments more efficiently and quickly to patients. Common Fund support for this program has ended, with the final year of support being FY 2011. Funding and management have transitioned to NCRR.

Budget Policy: The CTSA program will receive no funds from the Common Fund in FY2012, as support for this program transition to NCRR in FY 2011.

Regulatory Science: The NIH and the U. S. Food and Drug Administration (FDA) have formed an interagency partnership to foster regulatory science, a specialized and interdisciplinary area of biomedical research that serves to generate new knowledge and tools for assessing experimental therapies, preventives, and diagnostics. A key goal of this new Regulatory Science program is to accelerate the development and use of new tools, standards, and approaches to develop products efficiently and to evaluate product safety, efficacy, and quality more effectively.

Budget Policy: The FY 2012 budget estimate of $2.555 million for this program represents a decrease of $0.336 million or 11.6 percent less than the FY 2010 Enacted level. This estimated funding reflects a planned decrease in funding for this program due to the completion of one of its four grant projects during FY 2011.

Science of Behavior Change: The Common Fund launched the Science of Behavior Change program to improve our understanding of human behavior change across a broad range of health-related behaviors. This is being accomplished by supporting basic research to improve our understanding of human motivation and the maintenance of behavior change across multiple diseases and conditions, and then using this knowledge to develop more effective and economical behavioral interventions.

Budget Policy: The FY 2012 budget estimate of $4.958 million for this program represents an increase of $0.315 million or 6.8 percent more than the FY 2010 Enacted level. This estimated

funding reflects continued support of grants investigating behavior change at the social, contextual, behavioral, psychological, neurobiological, or genetic level of analysis.

Structural Biology: The overall health of a cell is maintained by an important class of proteins called membrane-bound proteins that are strategically located at the boundary between the cell and the external environment. The Structural Biology initiatives aim to create new methods and approaches for producing membrane-bound proteins in sufficient quantity and quality for use in research studies. The ability to produce membrane-bound proteins to meet this need has led to major breakthroughs in biological sciences and disease research. In FY 2009, the Structural Biology Centers began a second five-year phase of support through the Common Fund. While the first five years of the program led to major breakthroughs in the ability to produce and analyze membrane proteins, it revealed that this class of proteins is highly variable – methods that work for one protein seem unlikely to work for many. Therefore, the second five years of this program are intended to discover unifying principles so that membrane proteins may be more broadly studied.

Budget Policy: The FY 2012 budget estimate of $8.000 million for this program represents a decrease of $0.381 million or 4.5 percent less than the FY 2010 Enacted level. This estimated funding reflects continued support of research about methods to produce and analyze a broad range of membrane proteins.

NIH Strategic Planning Funds: The core mission of the NIH Common Fund is to foster collaboration, coordination, and strategic planning activities across the NIH. New research opportunities that would benefit from Common Fund support are being envisioned for FY 2012. To facilitate these planning efforts, the NIH Director is convening a series of trans-NIH workshops and brainstorming sessions, beginning in FY2011, involving external and internal experts, public and private sector partners, and stakeholders. These planning efforts are being supported through the Common Fund Strategic Planning Funds. In keeping with the mission of the Common Fund, new programs initiated in FY 2012 will address emerging opportunities and public health challenges through the development of new tools, technologies, approaches, and research data needed to tackle pressing biological problems and accelerate the translation of research findings into new and better therapies.

Budget Policy: The FY 2012 budget estimate of $2.594 million for this program represents an increase of $1.753 million or 208.4 percent more than the FY 2010 Enacted level. Strategic planning led to the development of several new programs launched in FY 2011. This level of funding reflects the Common Fund's commitment to design and implement a strategic planning process for gathering bold and innovative ideas to address cross-cutting challenges and promote emerging scientific opportunities.