10. Research and Development Contracts

NHLBI Research and Development Contract Obligations*: Fiscal Years 1994-2004

Dollars in Millions

Year	Major Contract-Supported Clinical Trials*	Other R&D Contracts
1994	42.2	76.1
1995	48.4	77.5
1996	52.9	68
1997	63.3	58.6
1998	65.8	50.9
1999	109.5	87.8
2000	115.4	85.9
2001	87.4	132.7
2002	91.8	166.5
2003	105.3	185.1
2004	107.5	177.9

* For detailed data on contract-supported clinical trials, see Chapter 11.

NHLBI Total Research and Development Contract Obligations: Fiscal Years 1994-2004

Dollars (Thousands)

	Fiscal Year										
	1994	**1995**	**1996**	**1997**	**1998**	**1999**	**2000**	**2001**	**2002**	**2003**	**2004**
Heart	$ 67,173	$ 70,178	$ 80,373	$ 84,820	$ 77,886	$ 93,270	$ 98,715	$125,291	$155,971	$195,425	$187,043
Lung	21,957	15,414	21,032	18,183	13,123	25,432	23,341	10,993	16,578	11,745	14,131
Blood	29,122	40,324	19,522	18,934	25,695	15,436	21,538	24,572	26,751	20,082	25,460
Women's Health Initiative						63,100	57,700	59,200	59,000	63,222	58,838
Total	**$118,252**	**$125,916**	**$120,927A**	**$121,937B**	**$116,704C**	**$197,238D**	**$201,294E**	**$220,056F**	**$258,300G**	**$290,474H**	**$285,472I**

A Includes Program Evaluation Assessment of $4,250,000.
B Includes Program Evaluation and IMPAC II Assessments of $8,986,000.
C Includes Program Evaluation and IMPAC II Assessments of $12,589,000.
D Includes Program Evaluation and IMPAC II Assessments of $14,904,000.
E Includes Program Evaluation and IMPAC II Assessments of $17,944,000.
F Includes Program Evaluation and IMPAC II Assessments of $24,579,000.
G Includes Program Evaluation and IMPAC II Assessments of $35,827,000.
H Includes Program Evaluation and IMPAC II Assessments of $54,550,000
I Includes Program Evaluation Assessment of $57,545,722.

Major NHLBI Research and Development Contracts by Program

	Total Obligations Prior to FY 2004	Total FY 2004 Obligations	Total Obligations to Date
Heart and Vascular Diseases			
Atherosclerosis Risk in Communities (ARIC)	$118,463,152	$162,979	$118,626,131
Cardiovascular Health Study (CHS)	72,602,830	1,557,410	74,160,240
Coronary Artery Risk Development in Young Adults (CARDIA)	60,197,437	10,373,960	70,571,397
Framingham Study	0	4,000,000	4,000,000
Jackson Heart Study (JHS)	56,148,221	6,018,417	62,166,638
Mammalian Genotyping Service (MGS)	14,291,000	378,854	14,669,854
Multi-Ethnic Study of Atherosclerosis (MESA)	21,519,750	3,600,000	25,119,750
Proteomics Initiative	48,741,999	5,528,000	54,269,999
Translational Behavioral Science Research Consortium	0	4,808,544	4,808,544
Lung Diseases			
Lung Tissue Research Consortium	0	3,999,995	3,999,995
Tuberculosis Curriculum Coordinating Center	2,700,000	300,000	300,000
Blood Diseases and Resources			
Hemochromatosis and Iron Overload Screening Study (HEIRS)	23,932,652	2,046,635	25,979,287
Maintenance of NHLBI Biological Specimen Repository	5,603,820	0	5,603,820
Refinement of New Assays for Direct Detection of Viral Nucleic Acids in Donated Organs	11,221,950	4,300,029	15,521,979
Retrovirus Epidemiology Donor Study (REDS)	68,774,125	5,000,000	73,774,125
Somatic Cell Therapy Processing Facilities	4,095,764	5,638,502	9,734,266

Heart and Vascular Diseases Program

Atherosclerosis Risk in Communities (ARIC), Initiated in Fiscal Year 1985

The ARIC program is a large-scale, long-term program that is measuring associations of CHD risk factors with atherosclerosis by race, gender, and geographic location. It focuses on early detection of CVD before symptoms, heart attacks, or strokes occur. The project consists of two groups: a community surveillance component and a cohort component from four communities. Three of the cohort components represent the racial mix of their community, whereas the fourth is exclusively black.

Obligations

Funding History:
Fiscal Year 2004—$162,979
Fiscal Years 1985-2003—$118,463,152
Total Funding to Date—$118,626,131

Current Active Organizations and Contract Numbers

1. University of North Carolina at Chapel Hill
Chapel Hill, North Carolina —HC-55015

2. Baylor College of Medicine
Houston, Texas —HC-55016

3. University of North Carolina at Chapel Hill
Chapel Hill, North Carolina —HC-55018

4. University of Minnesota, Twin Cities
Minneapolis, Minnesota —HC-55019

5. The Johns Hopkins University
Baltimore, Maryland —HC-55020

6. Mississippi Medical Center
Jackson, Mississippi —HC-55021

7. University of Texas Health Science Center
Houston, Texas —HC-55022

Cardiovascular Health Study (CHS), Initiated in Fiscal Year 1988

The CHS is a population-based, longitudinal study of risk factors for the development and progression of CHD and stroke in elderly adults. Specific objectives for this phase of the project include identifying risk association with clinical disease by accumulation of events; determining whether presence or progression of subclinical disease (abnormalities detected noninvasively without signs or symptoms) are better predictors of clinical disease than traditional risk factors; identifying determinants of change in subclinical disease; and identifying characteristics of subgroups at low risk for developing CVD (in whom preventive measures may be unnecessary). Minority representation is sufficient to assess black-white differences.

Obligations

Funding History:
Fiscal Year 2004—$1,557,410
Fiscal Years 1988-2003—$72,602,830
Total Funding to Date—$74,160,240

Current Active Organizations and Contract Numbers

1. The Johns Hopkins University
Baltimore, Maryland —HC-15103

2. University of Wisconsin
Madison, Wisconsin —HC-75150

3. University of Washington
Seattle, Washington —HC-85079

4. Wake Forest University
Winston-Salem, North Carolina —HC-85080

5. The Johns Hopkins University
Baltimore, Maryland —HC-85081

6. University of Pittsburgh
Pittsburgh, Pennsylvania —HC-85082

7. University of California, Davis
Davis, California —HC-85083

8. University of Vermont
Burlington, Vermont —HC-85086

Coronary Artery Risk Development in Young Adults (CARDIA), Initiated in Fiscal Year 1984

The purpose of this study is to increase understanding of contributors to changes in CVD risk factors that occur during the critical years of transition from adolescence through young adulthood to middle age in a cohort of black and white young adults, aged 18 to 30 years in 1985-1986. Currently, CARDIA is addressing questions about lifestyle/psychosocial/socioeconomic risk factors, race, genes, and inflammation in relation to subclinical CVD.

Obligations

Funding History:
Fiscal Year 2004—$10,373,960
Fiscal Years 1984-2003—$60,197,437
Total Funding to Date—$70,571,397

Current Active Organizations and Contract Numbers

1. Harbor-UCLA Research and Education Institute
Torrance, California —HC-05187

2. University of California at Irvine
Irvine, California —HC-45134

3. New England Medical Center Hospitals, Inc.
Boston, Massachusetts —HC-45204

4. Wake Forest University Health Sciences
Winston-Salem, North Carolina —HC-45205

5. University of Alabama at Birmingham
Birmingham, Alabama —HC-48047

6. University of Minnesota, Twin Cities
Minneapolis, Minnesota —HC-48048

7. Northwestern University
Chicago, Illinois —HC-48049

8. Kaiser Permanente Division of Research
Oakland, California —HC-48050

9. University of Alabama at Birmingham
Birmingham, Alabama —HC-95095

DNA Resequencing and Genotyping, Initiated in Fiscal Year 2004

The purpose of this program is to obtain rapid, reliable, and cost-efficient DNA sequencing and genotyping of candidate genomic regions potentially important in the disease pathways of heart, lung, and blood diseases and sleep disorders. This information will assist ongoing investigations of genetic components involved in the causes, variable outcome, and progression of the diseases and disorders.

Obligations

Funding History:
Fiscal Year 2004—$4,000,000
Total Funding to Date—$4,000,000

Current Active Organizations and Contract Numbers

1. Constella Group, Inc.
Bethesda, Maryland —HV-48193

2. University of Washington
Seattle, Washington —HV-48194

3. The Johns Hopkins University
Baltimore, Maryland —HV-48195

4. Center for the Advancement of Genetics, Inc.
Rockville, Maryland —HV-48196

Framingham Study

The orginal Framingham Study was designed as a longitudinal investigation of constitutional and environmental factors influencing the development of CVD in individuals free of these conditions at the outset. Of the original 5,209 subjects, about 500 members remain alive. In 1971, the Framingham Offspring Study was initiated to assess familial and genetic factors associated with CHD. More than 5,000 offspring (and their spouses) were included. A third-generation cohort consisting of 3,500 grandchildren has been added to permit examination of numerous hypotheses about the familial clustering of CVD and CVD risk factors. Additional goals include identifying new risk factors for cardiovascular, lung, and blood diseases and developing new imaging tests that can detect very early stages of coronary atherosclerosis in otherwise healthy adults.

Obligations

Funding History:
Fiscal Year 2004—$6,018,417
Fiscal Years 1983-2003—$56,148,221
Total Funding to Date—$62,166,638

Current Active Organizations and Contract Numbers

1. Boston University Medical Center
Boston, Massachusetts —HC-25195

2. Boston University Medical Center
Boston, Massachusetts —HC-38038

Jackson Heart Study (JHS), Initiated in Fiscal Year 1998

The JHS is a single-site epidemiologic study of CVD in blacks, similar to established studies in Framingham, Massachusetts, and Honolulu, Hawaii, with primary goals of identifying risk factors for development and progression of CVD; enhancing recruitment, cohort retention, and scientific productivity of the existing Jackson site of the ARIC study; building research capabilities at minority institutions; developing partnerships between minority and majority institutions; and expanding minority investigator participation in large-scale epidemiologic studies.

* Additional funding is provided by the National Center on Minority Health and Health Disparities (NCMHD).

Obligations

Funding History:
Fiscal Year 2004—$378,854*
Fiscal Years 1998-2003—$14,291,000
Total Funding to Date—$14,669,854

Current Active Organizations and Contract Numbers

1. Jackson State University
Jackson, Mississippi —HC-95170

2. Mississippi Medical Center
Jackson, Mississippi —HC-95171

3. Tougaloo College
Tougaloo, Mississippi —HC-95172

Mammalian Genotyping Service (MGS), Initiated in Fiscal Year 1994

The MGS provides genotyping to meritorious projects involving humans, mice, rats, zebrafish, and dogs in all disease areas. It provides genome-wide screens, using short tandem repeat polymorphisms, to assist in finding genes associated with health and disease. Currently, the capacity of the MGS is 7.7 million genotypes per year.

Obligations

Funding History:
Fiscal Year 2004—$3,600,000
Fiscal Years 1994-2003—$21,519,750
Total Funding to Date—$25,119,750

Current Active Organization and Contract Number

1. Marshfield Medical Research and Educational Foundation
Marshfield, Wisconsin —HV-48141

Multi-Ethnic Study of Atherosclerosis (MESA), Initiated in Fiscal Year 1999

The purpose of this study is to investigate the prevalence, correlates, and progression of subclinical CVD, i.e., disease detected noninvasively before it has produced clinical signs and symptoms, in a population that is 38 percent white, 28 percent black, 22 percent Hispanic, and 12 percent Asian.

Obligations

Funding History:
Fiscal Year 2004—$5,528,000
Fiscal Years 1999-2003—$48,741,999
Total Funding to Date—$54,269,999

Current Active Organizations and Contract Numbers

1. University of Washington
Seattle, Washington —HC-95159

2. University of California, Los Angeles
Los Angeles, California —HC-95160

3. Columbia University
New York, New York —HC-95161

4. The Johns Hopkins University
Baltimore, Maryland —HC-95162

5. University of Minnesota, Twin Cities
Minneapolis, Minnesota —HC-95163

6. Northwestern University
Chicago, Illinois —HC-95164

7. Wake Forest University
Winston-Salem, North Carolina —HC-95165

8. University of Vermont
Colchester, Vermont —HC-95166

9. New England Medical Center
Boston, Massachusetts —HC-95167

10. The Johns Hopkins University
Baltimore, Maryland —HC-95168

11. Harbor-UCLA Research and Education Institute
Los Angeles, California —HC-95169

Pediatric Circulatory Support, Initiated in Fiscal Year 2004

The purpose of this program is to establish multidisciplinary teams to develop innovative circulatory assist devices or other bioengineered systems for infants and children with congenital and acquired CVD who experience cardiopulmonary failure and circulatory collapse.

Obligations

Funding History:
Fiscal Year 2004—$4,808,544
Total Funding to Date—$4,808,544

Current Active Organizations and Contract Numbers

1. Cleveland Clinic Lerner College of Medicine
Cleveland, Ohio —HV-48188

2. Ension, Inc.
Pittsburgh, Pennsylvania —HV-48189

3. Jarvik Heart, Inc.
New York, New York —HV-48190

4. Pennsylvania State University
Hershey, Pennsylvania —HV-48191

5. University of Pittsburgh
Pittsburgh, Pennsylvania —HV-48192

Proteomics Initiative, Initiated in Fiscal Year 2002

The purpose of this program is to establish highly interactive, multidisciplinary centers to enhance and develop innovative proteomic technologies directed to relevant biologic questions associated with heart, lung, blood, and sleep health and disease. Scientists will focus on the cells' protein machinery directed toward understanding the molecular basis of the causes and progression of heart, lung, blood, and sleep disorders and identifying targets for therapeutic interventions.

Obligations

Funding History:
Fiscal Year 2004—$0

Fiscal Year 2002-2003—$72,997,890
Total Funding to Date—$72,997,890

Current Active Organizations and Contract Numbers

1. Boston University
Boston, Massachusetts —HV-28178

2. Institute for Systems Biology
Seattle, Washington —HV-28179

3. The Johns Hopkins University
Baltimore, Maryland —HV-28180

4. Medical University of South Carolina
Charleston, South Carolina —HV-28181

5. Medical College of Wisconsin
Milwaukee, Wisconsin —HV-28182

6. Stanford University
Stanford, California —HV-28183

7. University of Texas
Galveston, Texas —HV-28184

8. University of Texas Southwestern Medical Center
Dallas, Texas —HV-28185

9. Yale University
New Haven, Connecticut —HV-28186

10. Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc.
Rockville, Maryland —HV-28187

Translational Behavioral Science Research Consortium, Initiated in Fiscal Year 2002

The purpose of this program is to establish a consortium of interdisciplinary basic and applied social scientists to conduct research related to developing and testing theories from the behavioral or social sciences concerning cognitive, affective, motivational, developmental, and other factors and processes underlying human behavior. Acquired knowledge will be used to develop and test methods to encourage individuals to adopt and maintain a healthy lifestyle and manage behavioral risk factors for heart, lung, and blood diseases and sleep disorders.

Obligations

Funding History:
Fiscal Year 2004—$4,312,876
Fiscal Year 2002-2003—$10,000,000
Total Funding to Date—$14,312,876

Current Active Organizations and Contract Numbers

1. Weill Medical College of Cornell University
New York, New York —HC-25196

2. Mount Sinai School of Medicine
New York, New York —HC-25197

Lung Diseases Program

Lung Tissue Resource Consortium, Initiated in Fiscal Year 2004

The purpose of this program is to establish a resource consortium for collecting lung tissues and preparing and distributing them for research. Scientists seek to improve management of lung diseases by increasing understanding of the pathogenetic mechanisms of lung diseases through molecular histopathological studies on tissues with and without disease. Primary emphases will be on COPD and idiopathic pulmonary fibrosis.

Obligations

Funding History:
Fiscal Year 2004—$3,999,995
Total Funding to Date—$3,999,995

Current Active Organizations and Contract Numbers

1. Mayo Clinic College of Medicine
Rochester, New York —HR-46158

2. University of Colorado Health Science Center
Denver, Colorado —HR-46159

3. University of Colorado Health Science Center
Denver, Colorado —HR-46160

4. Mayo Clinic College of Medicine
Rochester, New York —HR-46161

5. University of Michigan
Ann Arbor, Michigan —HR-46162

6. University of Pittsburgh
Pittsburgh, Pennsylvania —HR-46163

7. Clinical Trials and Survey Corporation
Baltimore, Maryland —HR-46164

Tuberculosis Curriculum Coordinating Center, Initiated in Fiscal Year 2003

The purpose of this program is to establish a consortium of five Tuberculosis Curriculum Centers to strengthen and increase access to the best ongoing educational and training opportunities in TB for medical, nursing, and allied health schools, especially those that provide primary care to communities where TB is endemic and the population is at high risk.

Obligations

Funding History:
Fiscal Year 2004—$300,000
Fiscal Year 2003—$2,700,000
Total Funding to Date—$3,000,000

Current Active Organization and Contract Number

1. University of California, San Diego
La Jolla, California —HR-36157

Blood Diseases and Resources Program

Hemochromatosis and Iron Overload Screening Study (HEIRS), Initiated in Fiscal Year 2000

The purpose of this project is to determine the prevalence of iron overload and hereditary hemochromatosis and to study genetic and environmental determinants and potential clinical, personal, and societal impact of the disorder.

Obligations

Funding History:
Fiscal Year 2004—$2,046,635
Fiscal Years 2000-2003—$23,932,652
Total Funding to Date—$25,979,287

Current Active Organizations and Contract Numbers

1. University of Minnesota, Twin Cities
Minneapolis, Minnesota —HC-05185

2. Howard University
Washington, DC —HC-05186

3. University of Alabama at Birmingham
Birmingham, Alabama —HC-05188

4. Kaiser Foundation Research Institute
Oakland, California —HC-05189

5. University of California at Irvine
Irvine, California —HC-05190

6. London Health Science Centre
Ontario, Canada —HC-05191

7. Wake Forest University
Winston-Salem, North Carolina —HC-05192

Maintenance of NHLBI Biological Specimen Repository, Initiated in Fiscal Year 1998

The purpose of this project is to establish an NHLBI Biological Specimen Repository for blood specimens from Institute-supported research. The Repository monitors storage, labeling, and testing of the specimens, as well as administers safe shipment of precise sample aliquots to approved investigators for future studies.

Obligations

Funding History:
Fiscal Year 2004—$0
Fiscal Years 1998-2003—$5,603,820
Total Funding to Date—$5,603,820

Current Active Organization and Contract Number

1. BBI-Biotech Research Laboratories, Inc.
Gaithersburg, Maryland —HB-87144

Refinement of New Assays for Direct Detection of Viral Nucleic Acids in Donated Organs, Initiated in Fiscal Year 2000

The objective of this program is to refine for clinical and blood bank use, one or more nucleic acid-based techniques to detect blood-borne viruses (HIV-1, hepatitis B virus, and hepatitis C virus) in donors of organs for transplantation. The goal is to reduce the antibody-negative window between infectivity and detection to the shortest possible time.

Obligations

Funding History:
Fiscal Year 2004—$4,300,029
Fiscal Years 2000-2003—$11,221,950
Total Funding to Date—$15,521,979

Current Active Organization and Contract Number

1. Gen-Probe, Inc.
San Diego, California —HB-07148

Retrovirus Epidemiology Donor Study (REDS), Initiated in Fiscal Year 1989

This program was established to determine the prevalence of retrovirus positivity in blood donors, a majority of whom are minority. Researchers are evaluating the demographic, risk

factor, and behavioral characteristics of blood donors with high risks who continue to donate. A blood specimen repository also is being established as a mechanism for evaluating new tests for known viruses and as a sentinel for as-yet-unrecognized viruses.

Obligations

Funding History:
Fiscal Year 2004—$5,000,000
Fiscal Years 1989-2003—$68,774,125
Total Funding to Date—$73,774,125

Current Active Organizations and Contract Numbers

1. University of California, San Francisco
San Francisco, California —HB-47114

2. Oklahoma Blood Institute
Oklahoma City, Oklahoma —HB-97078

3. Blood Center of Southeastern Wisconsin
Milwaukee, Wisconsin —HB-47168

4. American Red Cross Blood Services
Dedham, Massachusetts —HB-47169

5. Emory University
Atlanta, Georgia —HB-47170

6. University of Cincinnati
Cincinnati, Ohio —HB-47171

7. Institute for Transfusion Medicine
Pittsburgh, Pennsylvania —HB-47172

8. University of California, San Francisco
San Francisco, California —HB-47174

9. Westat, Inc.
Rockville, Maryland —HB-47175

10. American Red Cross Greater Chesapeake and Potomac Region
Baltimore, Maryland —HB-97079

11. American Red Cross Southern California
Los Angeles, California —HB-97080

12. American Red Cross Southeastern Michigan
Region Detroit, Michigan —HB-97081

13. Westat, Inc.
Rockville, Maryland —HB-97082

Somatic Cell Therapy Processing Facilities, Initiated in Fiscal Year 2003

This program is designed to develop novel somatic cellular therapies in areas ranging from basic science through animal studies to proof-of-principle and eventually human trials for heart, lung, and blood diseases and sleep disorders. The goal is to provide rapid, safe translation of basic research ideas into clinical practice.

Obligations

Funding History:
Fiscal Year 2004—$5,638,502
Fiscal Year 2003—$4,095,764
Total Funding to Date—$9,734,266

Current Active Organizations and Contract Numbers

1. Baylor College of Medicine
Houston, Texas —HB-37163

2. University of Minnesota, Twin Cities
Minneapolis, Minnesota —HB-37164

3. University of Pittsburgh
Pittsburgh, Pennsylvania —HB-37165