11. Clinical Trials

A clinical trial is defined as a scientific research study undertaken with human subjects to evaluate prospectively the diagnostic, prophylactic, or therapeutic effect of a drug, device, regimen, or procedure used or intended ultimately for use in the practice of medicine or the prevention of disease. A clinical trial is planned and conducted prospectively and includes a concurrent control group or other appropriate comparison group.

NHLBI Investigator-Initiated Clinical Trials: Fiscal Years 1994–2004

Research Grants and Cooperative Agreements (Dollars in Thousands)

	Fiscal Year										
	1994	**1995**	**1996**	**1997**	**1998**	**1999**	**2000**	**2001**	**2002**	**2003**	**2004**
Heart and Vascular Diseases											
Program on Surgical Control of Hyperlipidemias (POSCH)	500	538	566	294							
Emory Angioplasty Versus Surgery Trial (EAST)	288	296	296								
Asymptomatic Carotid Artery Plaque Study (ACAPS)		66	70								
Infant Heart Surgery: Central Nervous System Sequelae of Circulatory Arrest	516	598	699	685	582	584	392	75			
Prevention of Early Readmission in Elderly Congestive Heart Failure Patients	77										
MRFIT Follow-up and Analysis	418										
Multicenter Unsustained Tachycardia Trial*	2,095	1,958	504								
Trial of Aspirin and Vitamin E in Nurses	1,488	1,426	1,434	1,473	1,536	1,530	1,594				
Diet and Exercise for Elevated Risk (DEER)	703										
Cardiovascular Risk Factors and the Menopause	601	451	478	494	528	186					
Sodium Sensitivity in African Americans	97	249									
Montreal Heart Attack Readjustment Trial (M-HART)	340										
Stress Reduction in Elderly Blacks With Hypertension	338	321									
Trial of Nonpharmacologic Intervention in the Elderly (TONE)	796	729									
CABG Patch Trial*	3,117	1,344	988	1,171							

	Fiscal Year										
	1994	**1995**	**1996**	**1997**	**1998**	**1999**	**2000**	**2001**	**2002**	**2003**	**2004**
Women's Antioxidant and Cardiovascular Study (WACS)	612	620	643	501	525	540	556	572	598	592	599
Oral Calcium in Pregnant Women With Hypertension	290	306	320	332							
Stress Reduction and Atherosclerotic CVD in Blacks	219	330	403	407	40	326	339	360	376	394	
Enalapril After Anthracycline Cardiotoxicity	587	647	707	724	789						
Stress and Anger Management for Blacks With Hypertension	221	232	241	250							
Estrogen Replacement and Atherosclerosis (ERA) Trial*	1,123	260	1,213	965	1,668	1,017					
Shock Trial: Should We Emergently Revascularize Occluded Coronaries for Cardiogenic Shock?	1,070	1,022	1,008	826	874		440	362	298	291	296
HDL-Atherosclerosis Treatment Study	484	480	427	445	340		326				
Influence of Cardiopulmonary Bypass (CPB) Temperature on CABG Morbidity	118	107	118								
Women's Estrogen/Progestin Lipid Lowering Hormone Atherosclerosis Regression Trial (WELL-HART)*		798	508	1,196	1,269	1,131		32			
Mode Selection Trial in Sinus Node Dysfunction (MOST)*		2,163	1,857	2,096	1,700	2,879	1,136	154			
Antioxidants and Prevention of Early Atherosclerosis*		793	240	603							
Postmenopausal Hormone Therapy In Unstable Angina		253	258	264	271	276					
Estrogen and Graft Atherosclerosis Research Trial (EAGER)*			476	488	305		361	371			
Soy Estrogen Alternative Study (SEA)			219	217	221						
REMATCH Trial*				1,258	1,798	1,333	825	750			
Dietary Patterns, Sodium Intake, and Blood Pressure (DASH Sodium)* **				2,233	3,693	3,646	1,247	151	387	376	395
Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT)*				1,571	1,667	1,709	1,698	1,798	1,412	1,930	
CVD Risk and Health in Post-Menopausal Phytoestrogen Users				631	662	574	244		304	152	

	Fiscal Year										
	1994	**1995**	**1996**	**1997**	**1998**	**1999**	**2000**	**2001**	**2002**	**2003**	**2004**
Treatment of Hypertension With Two Exercise Intensities				359	474	473	481	420			
Prevention of Recurrent Venous Thromboembolism (PREVENT)					1,242	894	521	543	1,272		
PREMIER: Lifestyle Interventions for Blood Pressure Control*					2,234	3,425	3,595	2,925	1,505	0	0
Azithromycin and Coronary Events Study (ACES)*					847	2,663	2,182	720	1,254	1,137	
Antiarrhythmic Effects of N-3 Fatty Acids						514	542	529	647		
Fatty Acid Antiarrhythmia Trial (FAAT)						519	605				
Occluded Artery Trial (OAT)*						4,892	5,079	2,604	1,724	1,963	
Bypass Angioplasty Revascularization Investigation in Type 2 Diabetics (BARI 2D)*							3,942	6,515	9,342	8,189	8,265
Hematocrit Strategy in Infant Heart Surgery*							473	557	596	590	492
Angiotensin-II Blockade in Mitral Regurgitation								553	610	629	500
Heart Failure Adherence and Retention Trial (HART)								795	1,617	1,453	1,174
Reduction of Triglycerides in Women on HRT								708	746	555	544
Women's Ischemia Syndrome Evaluation (WISE)* **								1,502	1,506	1,306	1,303
ACE Inhibition and Novel Cardiovascular Risk Factors									694	656	602
A CHF Trial Investigating Outcomes of Exercise (Action)*									7,471	9,582	7,973
Clinical Trial of Dietary Protein on Blood Pressure*									655	610	612
Home Automatic External Defibrillator Trial (HAT)*									3,567	5,433	4,264
Perioperative Interventional Neuroprotection Trial (POINT)									553	553	562
Stop Atherosclerosis in Native Diabetics Study (SANDS)*									2,410	2,165	2,107
Surgical Treatment for Ischemic Heart Failure (STICH)*									5,709	4,495	1,613

	Fiscal Year										
	1994	**1995**	**1996**	**1997**	**1998**	**1999**	**2000**	**2001**	**2002**	**2003**	**2004**
Girls Health Enrichment Multisite Studies (GEMS)										2,461	2,400
Treatment of Depression Following Bypass Surgery										964	1,132
Heart and Vascular Diseases (continued)											
Weight Loss Maintenance (WLM)*										3,687	4,368
Cardiovascular Outcomes in Renal Atherosclerotic Lesions (CORAL)*											4,343
FREEDOM Trial: Future Revascularization Evaluation in Patients with Diabetes Mellitus: Optional Management of Multivessel Disease											3,663
IMMEDIATE Trial: Immediate Myocardial Metabolic Enhancement During Initial Assessment and Treatment in Emergency Care*											5,170
Subtotal, Heart and Vascular Diseases	16,098	15,987	13,673	19,483	23,265	29,111	26,578	22,996	45,253	50,163	52,377
Lung Diseases											
Emphysema: Physiologic Effects of Nutritional Support	155										
Cardiopulmonary Effects of Ibuprofen in Human Sepsis*	683										
Inhaled Beclomethasone to Prevent Chronic Lung Disease*	690	738	551	436							
Lung Health Study II* **	3,307	4,434	3,183	3,508	980						
Lung Health Study III* **					1,997	1,986	1,616	1,672	927		
Asthma Clinical Research Network (ACRN)* **					4,934	5,399	5,686	5,705	5,863		8,424
Fetal Tracheal Occlusion for Severe Diaphragmatic Hernia*						419	429	181			
Scleroderma Lung Study*						1,040	1,501	1,761	1,501	1,055	
Inhaled Nitric Oxide for Prevention of Chronic Lung Disease*							1,959	1,803	1,764	1,442	1,245
Inhaled Nitric Oxide in Prevention of Chronic Lung Disease*							1,548	1,742	1,839	1,604	903
Prospective Investigation of Pulmonary Embolism Diagnosis II (PIOPED II)*							2,190	3,667	3,388	472	0

	Fiscal Year										
	1994	**1995**	**1996**	**1997**	**1998**	**1999**	**2000**	**2001**	**2002**	**2003**	**2004**
Randomized Trial to Reduce ETS in Children With Asthma							555	545	468	277	0
Apnea Positive Pressure Long-Term Efficacy Study (APPLES)*									3,224	3,021	3,110
Childhood Asthma Management Program–Continuation Study (CAMP–CS)/Phase 2* **										1,489	2,043
Clinical Trial of Acid Reflux Therapy in Asthma*										736	783
Impact of CPAP on Functional Outcomes in Milder Obstructive Sleep Apnea (CATNAP)										682	612
Outcomes of Sleep Disorders in Older Men										4,163	4,262
Supplemental Selenium and Vitamin E and Pulmonary Function										698	610
Early Antipseudomonal Therapy in Cystic Fibrosis*											1,064
Improving Asthma Care in Minority Children in Head Start											721
Subtotal, Lung Diseases	4,835	5,172	3,734	3,944	7,911	8,844	15,484	17,076	18,974	15,639	23,777
Blood Diseases and Resources											
Multicenter Study of Hydroxyurea in Patients With Sickle Cell Anemia—Phase II*	3,271	1,238									
Trial to Reduce Alloimmunization to Platelets (TRAP)—Extension***	2,510	1,246	263								
Stroke Prevention in Sickle Cell Anemia (STOP)*	2,751	3,257	2,435	2,584	2,036		293				
Pediatric Hydroxyurea in Sickle Cell Anemia (PED HUG)	146	250	260	270							
Stroke Prevention in Sickle Cell Anemia (STOP 2)*							4,200	3,166	3,168	2,320	2,366
Induction of Stable Chimerism for Sickle Cell Anemia								489	525	527	551
Sibling Donor Cord Blood Banking and Transplantation								1,222	1,224	1,286	1,353
FOCUS										1,639	1,796

	Fiscal Year										
	1994	**1995**	**1996**	**1997**	**1998**	**1999**	**2000**	**2001**	**2002**	**2003**	**2004**
Subtotal, Blood Diseases and Resources	8,678	5,991	2,958	2,854	2,036	0	4,493	4,877	4,917	5,772	6,066
Total, NHLBI	**29,611**	**27,150**	**20,365**	**26,281**	**33,212**	**37,955**	**46,555**	**44,949**	**69,144**	**71,574**	**$82,220**

* Paid by U01/U10.
** Previously an Institute-Initiated Clinical Trial.Paid by U01/U10.

NHLBI Investigator-Initiated Clinical Trials, Fiscal Year 2004: Summary by Program

	Total Obligations Prior to FY 2004	**FY 2004 Obligations**	**Total Obligations to Date**
Heart and Vascular Diseases			
A CHF Trial Investigating Outcomes of Exercise (ACTION)*	$17,052,481	$7,973,471	$25,025,952
ACE Inhibition and Novel Cardiovascular Risk Factors	1,349,463	602,458	1,951,921
Angiotensin-II Blockade in Mitral Regurgitation	1,793,146	499,427	2,292,573
Bypass Angioplasty Revascularization Investigation in Type 2 Diabetics (BARI 2D)*	27,988,936	8,265,037	36,253,973
Cardiovascular Outcomes in Renal Atherosclerotic Lesions (CORAL)*	0	4,343,389	4,343,389
Clinical Trial of Dietary Protein on Blood Pressure	1,265,418	611,758	1,877,176
Dietary Patterns, Sodium Intake, and Blood Pressure (DASH Sodium)*	11,732,933	395,068	12,128,001
FREEDOM Trial:Future Revascularization Evaluation in Patients with Diabetes Mellitus:Optimal Management of Multivessel Disease	0	3,663,095	3,663,095
Girls Health Enrichment Multi-Site Studies*	2,461,487	2,399,948	4,861,435
Heart Failure Adherence and Retention Trial (HART)	3,864,646	1,173,937	5,038,583
Hematocrit Strategy in Infant Heart Surgery*	2,215,845	492,411	2,708,256
Home Automatic External Defibrillator Trial (HAT)*	8,999,887	4,263,755	13,263,642
IMMEDIATE Trial:Immediate Myocardial Metabolic Enhancement During Initial Assessment and Treatment in Emergency Care*	0	5,170,411	5,170,411
Perioperative Interventional Neuroprotection Trial (POINT)	1,105,701	562,346	1,688,047
Reduction of Triglycerides in Women on HRT	2,010,214	544,281	2,554,495
Shock Trial:Should We Emergently Revascularize Occluded Coronaries for Cardiogenic Shock?	6,189,213	295,949	6,485,162
Stop Atherosclerosis in Native Diabetics Study (SANDS)*	4,574,684	2,106,653	6,681,337
Surgical Treatment for Ischemic Heart Failure (STICH)*	10,204,028	1,613,058	11,817,086
Treatment of Depression Following Bypass Surgery	963,830	1,132,182	2,096,012
Weight Loss Maintenance (WLM)*	3,686,738	4,367,750	8,054,488
Women’s Antioxident and Cardiovasular Study (WACS)	6,344,116	598,635	6,942,751
Women’s Ischemia Syndrome Evaluation (WISE)* **	4,314,911	1,302,449	5,617,360

	Total Obligations Prior to FY 2004	FY 2004 Obligations	Total Obligations to Date
Heart and Vascular Diseases			
Subtotal, Heart and Vascular Diseases	129,488,841	52,377,468	181,866,309
Lung Diseases			
Apnea Positive Pressure Long-Term Efficacy Study (APPLES)*	6,244,439	3,109,570	9,354,009
Asthma Clinical Research Network (ACRN)*	27,584,539	8,424,129	36,008,668
Childhood Asthma Management Program II (CAMP II)*	1,489,491	2,043,311	3,532,802
Clinical Trial of Acid Reflux Therapy in Asthma*	736,466	783,078	1,519,544
Early Antipseudomonal Therapy in Cystic Fibrosis*	0	1,064,237	1,064,237
Impact of CPAP on Functional Outcomes in Milder Obstructive Sleep Apnea (CATNAP)	681,633	612,378	1,294,011
Improving Asthma Care for Minority Children in Head Start	0	721,025	721,025
Inhaled Nitric Oxide for Prevention of Chronic Lung Disease*	6,968,259	1,245,274	8,213,533
Inhaled Nitric Oxide in Prevention of Chronic Lung Disease*	6,732,859	903,335	7,636,194
Outcomes of Sleep Disorders in Older Men	4,162,661	4,261,833	8,424,494
Supplemental Selenium and Vitamin E and Pulmonary Function	698,489	609,585	1,308,074
Subtotal, Lung Diseases	**55,298,836**	**23,777,755**	**79,076,591**
Blood Diseases and Resources			
FOCUS*	1,639,478	1,795,724	3,435,202
Induction of Stable Chimerism for Sickle Cell Anemia*	1,541,037	550,666	2,091,703
Sibling Donor Cord Blood Banking and Transplantation*	3,731,256	1,352,571	5,083,827
Stroke Prevention in Sickle Cell Anemia (STOP 2)*	12,854,790	2,366,346	15,221,136
Subtotal, Blood Diseases and Resources	**19,766,561**	**6,065,307**	**25,831,868**
Total, NHLBI	**$204,554,238**	**$82,220,530**	**$286,774,768**

* Paid by U01/U10
** Previously an Institute-Initiated Clinical Trial.

Institute-Initiated Clinical Trials: Fiscal Years 1994–2004 Contracts Dollars (Thousands)

Dollars (Thousands)

	Fiscal Year										
	1994	**1995**	**1996**	**1997**	**1998**	**1999**	**2000**	**2001**	**2002**	**2003**	**2004**
Heart and Vascular Diseases											
Lipid Research Clinics	622	583	660	650	685						
Cardiac Arrythmia Suppression Trial (CAST)	29										
Effects of Digitalis on Survival in Patients With Congestive Heart Failure	270	2,235									

	Fiscal Year										
	1994	**1995**	**1996**	**1997**	**1998**	**1999**	**2000**	**2001**	**2002**	**2003**	**2004**
Asymptomatic Cardiac Ischemia Pilot Study (ACIP)	210	7									
Psychophysiological Investigations of Myocardial Ischemia (PIMI)	433	165									
Arterial Disease Multifactorial Intervention Trial (ADMIT)	2,341	395									
Raynaud's Treatment Study	2,532	1,664	221	19							
Antiarrhythmic vs. Implantable Defibrillator (AVID)	1,068	5,348	2,475		871	548					
Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial (ALLHAT)	10,914	3,412	9,676	5,943	7,119		6,259	7,000	3,980	2,761	3,346
Activity Counseling Trial (ACT)	1,260	5,000		2,167	2,439						
Postmenopausal Estrogen/Progestin Interventions (PEPI)	600	1,305		3	170						
Enhancing Recovery in Coronary Heart Disease Patients (ENRICHD)		1,871	6,993	6,837	5,904	3,303	3,487	596	425	70	
Atrial Fibrillation Follow-up: Investigation in Rhythm Management (AFFIRM)		883	2,510	6,330		3,785	1,239	2,401	802		
Beta-Blocker Evaluation Survival Trial (BEST)		2,500	1,435	2,300	2,448						
Women's Angiographic Vitamin and Estrogen Trial (WAVE)			731	2,891	1,917	3,878	886	756		32	
Women's Ischemia Syndrome Evaluation (WISE)			1,577	133	2,932	856	1,424	10	50		
Prevention of Events With Angiotensin Converting Enzyme Inhibitor Therapy (PEACE)			3,632	2,838	2,836	2,850	5,988		2,849	558	
Magnesium in Coronaries (MAGIC)					1,169	2,009	1,243		238		
Evaluation Study of Congestive Heart Failure and Pulmonary Artery Catheterization Effectiveness (ESCAPE)					0	1,750	1,820		1,129		
Action to Control Cardiovascular Risk in Diabetes (ACCORD)						4,130	6,590		1,750	18,521	33,779
Public Access Defibrillation (PAD) Community Trial						2,923	2,414	3,058	1,101		
Aldosterone Antagonist for Treatment of Heart Failure											837
Subtotal, Heart and Vascular Diseases	20,279	25,368	29,910	40,111	38,490	26,032	31,350	13,821	12,324	21,942	37,962

	Fiscal Year										
	1994	**1995**	**1996**	**1997**	**1998**	**1999**	**2000**	**2001**	**2002**	**2003**	**2004**
Lung Diseases											
Lung Health Study I	3,398	650	350								
Pediatric Pulmonary and Cardiac Complications of HIV Infection (P2C2)	10,550	2,627	4,033	668	1,979		315		113		
Institute-Initiated Clinical Trials: Fiscal Years 1994–2004											
Childhood Asthma Management Program (CAMP)	9,745	5,096	7,977	5,695		6,551	729	1,330	2,786	2,287	1,475
Acute Respiratory Distress Syndrome Clinical Network (ARDSNET)	1,800	4,170	4,337	4,510	4,880	6,837	5,587	2,667	1,502	4,402	5,517
National Emphysema Treatment Trial (NETT)				2,710	3,367	7,545	4,047	6,989	7,910	1,630	1,648
Feasibility of Retinoid Treatment in Emphysema (FORTE)						884	7,711		2,429	725	507
Subtotal, Lung Diseases	25,493	12,543	16,697	13,583	10,226	21,817	18,389	10,986	14,740	9,044	9,147
Blood Diseases and Resources											
Clinical Course of Sickle Cell Disease	2,390	4,375	376	205	2,144	350	106				
Penicillin Prophylaxis in Sickle Cell Disease (PROPS II)	226										
Anti-HIV Immunoglobulin (HIVIG) in Prevention of Maternal-Fetal HIV Transmission	3,016	1,819	706								
T-Cell Depletion in Unrelated Donor Marrow Transplantation	1,310	1,917	1,461	639	2,228	690	1,085	1,144	557	774	164
Viral Activation Transfusion Study (VATS)		5,000	5,647	2,353	1,668		339				
Cord Blood Stem Cell Transplantation Study (COBLT)			1,419	6,573	2,530	1,456	5,122	1,846	2,166	588	707
Multicenter Study of Hydroxyurea (MSH) in Sickle Cell Anemia Adult Follow-up			703	472	475	469			588	994	1,136
Pediatric Hydroxyurea Phase III Clinical Trial (BABY HUG)							1,606	405	3,100	1,112	1,964
Subtotal, Blood Diseases and Resources	6,942	3,111	10,312	10,242	9,045	2,965	8,258	3,395	6,411	3,468	3,971
Women's Health Initiative											
Subtotal, Women's Health Initiative						59,100	57,700	59,200	59,010	63,222	57,483
Total, NHLBI Clinical Trials Contracts	**52,714**	**51,022**	**56,919**	**63,936**	**67,761**	**109,914**	**115,697**	**87,402**	**92,485**	**97,676**	**108,563**

	Fiscal Year										
	1994	**1995**	**1996**	**1997**	**1998**	**1999**	**2000**	**2001**	**2002**	**2003**	**2004**
Cooperative Agreements											
Heart and Vascular Diseases											
Trials of Hypertension Prevention (TOHP)	4,385	1,240	649								
Dietary Intervention Study in Children (DISC)	1,615	1,625	1,625	746							
Bypass Angioplasty Revascularization Investigation (BARI)	3,965	3,882	2,757	2,894	1,360	1,609	1,634	1,549	1,456		
Postmenopausal Estrogen/Progestin Interventions (PEPI)	1,109	584	331								
Child and Adolescent Trial for Cardiovascular Health (CATCH)	2,586	2,342	2,682	3,956	572	210					
Dietary Effects on Lipoproteins and Thrombogenic Activity (DELTA)	3,121	2,485	132	290							
Obesity Prevention in Young American Indians (PATHWAYS)	1,814	2,150	3,432	4,119	3,945	4,196	2,459				
Dietary Approaches to Stop Hypertension (DASH)	2,350	2,513	899								
Rapid Early Action for Coronary Treatment (REACT)	2,609	5,091	4,992	2,866	496						
Girls Health Enrichment Multisite Studies (GEMS)						2,282	2,365	2,877	2,713	2,461	
Trial of Activity for Adolescent Girls (TAAG)							5,274	4,831	5,919	5,828	6,350
Pediatric Cardiovascular Clinical Research Network								3,447	4,822	5,381	4,948
Clinical Research Consortium to Improve Resuscitation Outcome											6,886
Dynamic Assessment of Patient-Reported Chronic Disease Outcomes											1,010
Subtotal, Heart and Vascular Diseases	23,554	21,912	17,499	14,871	6,373	8,297	11,732	12,704	14,910	13,670	19,194
Lung Diseases											
Asthma Clinical Research Network (ACRN)*	3,694	3,640	4,526	4,479						8,181	8,424
Asthma and Pregnancy Studies	1,000	991	1,000	913							
Childhood Asthma Research and Education (CARE) Network						4,175	5,002	5,314	6,005	5,610	5,292
COPD Clinical Research Network										6,843	6,848

	Fiscal Year										
	1994	**1995**	**1996**	**1997**	**1998**	**1999**	**2000**	**2001**	**2002**	**2003**	**2004**
Subtotal, Lung Diseases	4,694	4,631	5,526	5,392	0	4,175	5,002	5,314	6,005	20,634	20,564
Blood Diseases and Resources											
Thalassemia (Cooley's Anemia) Clinical Research Network							2,192	2,219	2,269	2,320	2,375
Blood and Marrow Transplant Clinical Research Network								5,360	5,899	5,950	5,292
Transfusion Medicine/Hemostasis Clinical Research Network									6,053	6,241	6,093
Subtotal, Blood Diseases and Resources							2,192	7,579	14,221	14,511	14,440
Total, NHLBI-Initiated Clinical Trials, Cooperative Agreements	**28,248**	**26,543**	**23,025**	**20,263**	**6,373**	**12,472**	**18,926**	**25,597**	**35,136**	**48,815**	**54,198**
Total, NHLBI-Initiated Clinical Trials	**80,962**	**77,565**	**79,944**	**84,199**	**74,134**	**122,386**	**134,623**	**112,999**	**127,621**	**146,491**	**162,761**

Institute-Initiated Clinical Trials, Fiscal Year 2004: Summary by Program

	Total Obligations Prior to FY 2004	**Total FY 2004 Obligations**	**Total Obligations to Date**
Contracts			
Heart and Vascular Diseases			
Action to Control Cardiovascular Risk in Diabetes (ACCORD)	30,990,133	33,779,345	64,769,478
Aldosterone Antagonists for Treatment of Heart Failure		837,227	837,227
Antihypertensive and Lipid-Lowering Treatment To Prevent Heart Attack Trial (ALLHAT)	79,824,059	3,346,000	83,170,059
Enhancing Recovery in Coronary Heart Disease Patients (ENRICHD)	29,486,924		29,486,924
Evaluation Study of Congestive Heart Failure and Pulmonary Artery Catheterization Effectiveness (ESCAPE)	4,699,537		4,699,537
Prevention of Events With Angiotensin Converting Enzyme Inhibitor Therapy (PEACE)	21,550,000		21,550,000
Subtotal, Heart and Vascular Diseases	166,550,653	37,962,572	204,513,225
Lung Diseases			
Acute Respiratory Distress Syndrome Clinical Network (ARDSNET)	40,692,155	5,516,811	46,208,966
Childhood Asthma Management Program (CAMP)	54,845,605	1,475,006	56,320,611
Feasibility of Retinoid Treatment in Emphysema (FORTE)	11,749,283	506,758	12,256,041
National Emphysema Treatment Trial (NETT)	34,198,310	1,648,000	35,846,310
Subtotal, Lung Diseases	**141,485,353**	**9,146,575**	**150,631,928**

	Total Obligations Prior to FY 2004	Total FY 2004 Obligations	Total Obligations to Date
Blood Diseases and Resources			
Cord Blood Stem Cell Transplantation Study (COBLT)	31,699,365	707,000	32,406,365
Multicenter Study of Hydroxyurea (MSH) in Sickle Cell Anemia Adult Follow-up	3,700,743	1,136,093	4,836,836
Pediatric Hydroxyurea Phase III Clinical Trial (BABY HUG)	6,223,568	1,963,630	8,187,198
T-Cell Depletion in Unrelated Donor Marrow Transplantation	11,804,918	163,598	11,968,516
Subtotal, Blood Diseases and Resources	53,428,594	3,970,321	57,398,915
Women's Health Initiative			
Subtotal, Women's Health Initiative	615,132,161	57,483,316	672,615,477
Total, NHLBI-Initiated Clinical Trials, Contracts	**976,596,761**	**108,562,784**	**1,085,159,545**
Cooperative Agreements			
Heart and Vascular Diseases			
Clinical Research Consortium to Improve Resuscitation Outcome		6,886,109	6,886,109
Dynamic Assessment of Patient-Reported Chronic Disease Outcomes		1,009,694	1,009,694
Pediatric Cardiovascular Clinical Research Network	13,650,229	4,947,982	18,598,211
Trial of Activity for Adolescent Girls (TAAG)	21,853,035	6,349,902	28,202,937
Subtotal, Heart and Vascular Diseases	35,503,264	19,193,687	54,696,951
Lung Diseases			
Asthma Clinical Research Network	8,181,429	8,424,129	16,605,558
Childhood Asthma Research and Education (CARE) Network	26,106,032	5,292,305	31,398,337
COPD Clinical Research Network	6,843,405	6,848,345	13,691,750
Subtotal, Lung Diseases	41,130,866	20,564,779	61,695,645
Blood Diseases and Resources			
Blood and Marrow Transplant Clinical Research Network	17,209,287	5,972,521	23,181,808
Thalassemia (Cooley's Anemia) Clinical Research Network	8,999,883	2,374,805	11,374,688
Transfusion Medicine/Hemostasis Clinical Research Network	12,293,630	6,092,846	18,386,476
Subtotal, Blood Diseases and Resources	38,502,800	14,440,172	52,942,972
Total, NHLBI-Initiated Clinical Trials, Cooperative Agreements	**115,136,930**	**54,198,638**	**169,335,568**
Total, NHLBI-Initiated Clinical Trials	**1,091,733,691**	**162,761,422**	**1,254,495,113**

Heart and Vascular Diseases Program

Action to Control Cardiovascular Risk in Diabetes (ACCORD), Initiated in Fiscal Year 1999

The purpose of this study is to evaluate three diabetic treatment strategies (intensive glycemic control, blood pressure control, and fibrate treatment to raise HDL-cholesterol and lower triglycerides) to prevent major cardiovascular events in patients with Type 2 diabetes mellitus. The primary outcome measure is CVD mortality or major morbidity (MI and stroke). A vanguard phase of about 1,000 participants was completed in FY 2002, and the main trial proceeded in FY 2003.

Obligations

Funding History:
Fiscal Year 2004—$33,779,345
Fiscal Years 1999–2003—$30,990,133
Total Funding to Date—$64,769,478

Current Active Organizations and Contract Numbers

1. Veteran Affairs Medical Center, Albuquerque
Albuquerque, New Mexico —HC-10100

2. Veteran Affairs Medical Center, Memphis
Memphis, Tennessee —HC-90350

3. Wake Forest University
Winston-Salem, North Carolina —HC-95178

4. McMaster University
Hamilton, Ontario —HC-95179

5. University of Washington
Seattle, Washington —HC-95180

6. Case Western Reserve University
Cleveland, Ohio —HC-95181

7. Wake Forest University
Winston-Salem, North Carolina —HC-95182

8. Minneapolis Medical Research Foundation
Minneapolis, Minnesota —HC-95183

9. Trustees of Columbia University of New York
New York, New York —HC-95184

Aldosterone Antagonists for Treatment of Heart Failure, Initiated in Fiscal Year 2004

The purpose of this study is to evaluate the effectiveness of aldosterone antagonist therapy to reduce mortality in patients who have heart failure with preserved systolic function.

Obligations

Funding History:
Fiscal Year 2004—$837,227
Total Funding to Date—$837,227

Current Active Organization and Contract Number

1. New England Research Institutes, Inc.
Watertown, Massachusetts —HC-45207

Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial (ALLHAT), Initiated in Fiscal Year 1993

The ALLHAT is a practice-based, randomized clinical trial to determine whether combined incidence of fatal CHD and nonfatal MI differs between diuretic-based and newer antihypertensive treatments (ACE inhibitor, calcium channel blocker, alpha blocker) in high-risk hypertensive patients. The objective of the lipid-lowering component of the study is to determine whether lowering serum cholesterol with an HMG CoA reductase inhibitor reduces the total mortality in a subset of hypertensive patients with moderately elevated LDL cholesterol. Because blacks and Hispanics are at high risk for hypertension and CHD, investigators recruited a high percentage of minorities into the study.

In February 2000, the alpha blocker arm of the study was discontinued at the recommendation of the Data Safety Monitoring Committee and an independant expert review committee because the CVD event rate was significantly greater among those patients compared to the control group.

Obligations

Funding History:
Fiscal Year 2004—$3,346,000
Fiscal Years 1993–2003—$79,824,059
Total Funding to Date—$83,170,059

Current Active Organization and Contract Number

1. University of Texas Health Science Center
Houston, Texas —HC-35130

Clinical Research Consortium To Improve Resuscitation Outcomes, Initiated in Fiscal Year 2004

The purpose of this study is to establish a resuscitation research consortium to conduct research in cardiopulmonary arrest and traumatic injury leading to arrest. The consortium will facilitate the rapid translation of promising scientific and clinical advances to improve resuscitation outcomes.

Obligations

Funding History:
Fiscal Year 2004—$6,886,109
Total Funding to Date—$6,886,109

Current Active Organizations and Grant Numbers:

1. University of Washington
Seattle, Washington —HL-077863

2. University of Iowa
Iowa, City, Iowa —HL-077865

3. Medical College of Wisconsin
Milwaukee, Wisconsin —HL-077866

4. University of Washington
Seattle, Washington —HL-077867

5. University of Pittsburgh
Pittsburgh, Pennsylvania —HL-077871

6. St. Michael's Hospital
Toronto, Ontario —HL-077872

7. Oregon Health and Science University
Portland, Oregon —HL-077873

8. University of Alabama at Birmingham
Birmingham, Alabama —HL-077881

9. Ottawa Health Research Institute
Ottawa, Ontario —HL-077885

10. University of Texas Southwestern Medical Center
Dallas, Texas —HL-077887

11. University of California, San Diego
La Jolla, California —HL-077908

Dynamic Assessment of Patient-Reported Chronic Disease Outcomes, Initiated in Fiscal Year 2004

The purpose of this study, which emanates from a NIH Roadmap Initiative, is to develop a computerized system of patient-reported outcomes that will meet the needs of clinical researchers across a wide variety of chronic disorders and diseases. Investigators will develop and test a large bank of items measuring patient-reported outcomes; create a computerized adaptive testing system that will allow for efficient assessment of patient-reported outcomes in clinical research; and create a publicly available system that can be added to and modified periodically for clinical researchers.

Obligations

Funding History:
Fiscal Year 2004—$1,009,694
Total Funding to Date—$1,009,694

Current Active Organizations and Grant Numbers

1. University of Pittsburgh
Pittsburgh, Pennsylvania —AR-52155

2. Stanford University
Stanford, California —AR-52158

3. State University New York, Stony Brook
Stony Brook, New York —AR-52170

4. University of Washington
Seattle, Washington —AR-52171

5. Evanston Northwestern Healthcare
Evanston, Illinois —AR-52177

6. University of North Carolina at Chapel Hill
Chapel Hill, North Carolina —AR-52181

7. Duke University
Durham, North Carolina —AR-52186

Enhancing Recovery in Coronary Heart Disease Patients (ENRICHD), Initiated in Fiscal Year 1995

The objective of this multicenter, randomized clinical trial was to test whether treating symptoms of depression and low social support with cognitive behavior therapy and selective serotonin re-uptake inhibitors immediately after MI reduces morbidity and mortality. The primary endpoint was a combination of reinfarction and death. Secondary outcomes included changes in cardiovascular mortality, depression, social support, and quality of life. The cohort included 34 percent minorities. Results showed that the treatment did not lower mortality or the risk of a

second heart attack. However, the intervention reduced patients' depression and increased their level of social support.

Obligations

Funding History:
Fiscal Year 2004—$0
Fiscal Years 1995–2003—$29,486,924
Total Funding to Date—$29,486,924

Current Active Organizations and Contract Numbers

1. University of North Carolina at Chapel Hill
Chapel Hill, North Carolina —HC-55140

2. Duke University
Durham, North Carolina —HC-55142

3. Washington University
St. Louis, Missouri —HC-55146

Evaluation Study of Congestive Heart Failure and Pulmonary Artery Catheterization Effectiveness (ESCAPE), Initiated in Fiscal Year 1999

The purpose of this study was to compare the efficacy of pulmonary artery catheterization (PAC)-directed treatment strategy to a noninvasive treatment strategy on morbidity and mortality in patients with severe CHF. The results of the study showed that PAC did not significantly increase or decrease deaths or the number of days patients were hospitalized with severe heart failure.

Obligations

Funding History:
Fiscal Year 2004—$0
Fiscal Years 1999–2003—$4,699,537
Total Funding to Date—$4,699,537

Current Active Organization and Contract Number

1. Duke University
Durham, North Carolina —HV-98177

Pediatric Cardiovascular Clinical Research Network, Initiated in Fiscal Year 2001

The objective of this study is to establish a clinical network to evaluate novel treatment methods and management strategies for children with structural congenital heart disease, inflammatory heart disease, heart muscle disease, or arrhythmias.

Obligations

Funding History:
Fiscal Year 2004—$4,947,982
Fiscal Years 2001–2003—$13,650,229
Total Funding to Date—$18,598,211

Current Active Organizations and Grant Numbers

1. Duke University
Durham, North Carolina —HL-068269

2. New England Research Institute, Inc.
Watertown, Massachusetts —HL-068270

3. Children's Hospital of Philadelphia
Philadelphia, Pennsylvania —HL-068279

4. Medical University of South Carolina
Charleston, South Carolina —HL-068281

5. Children's Hospital
Boston, Massachusetts —HL-068285

6. Hospital for Sick Children
Toronto, Ontario —HL-068288

7. Columbia University Health Sciences
New York, New York —HL-068290

8. University of Utah
Salt Lake City, Utah —HL-068292

Prevention of Events With Angiotensin Converting Enzyme Inhibitor Therapy (PEACE), Initiated in Fiscal Year 1996

The purpose of this multicenter, randomized trial was to determine whether addition of an ACE inhibitor to standard therapy in patients with known coronary artery disease and preserved left ventricular function would prevent CVD mortality and reduce risk of MI and the need for revascularization. The results of the study showed that patients with coronary diseases and normal or mildly reduced heart function do not benefit from ACE inhibitors unless the drug is being used to treat another condition.

Obligations

Funding History:
Fiscal Year 2004—$0
Fiscal Years 1996–2003—$21,550,000
Total Funding to Date—$21,550,000

Current Active Organization and Contract Number

1. The George Washington University Biostatistics Center
Rockville, Maryland —HC-65149

Trial of Activity for Adolescent Girls (TAAG), Initiated in Fiscal Year 2000

This community-based study is testing the effects of a school–community-linked intervention to prevent decline in physical activity and cardiorespiratory fitness seen during adolescence in girls. The study is being conducted in 36 schools; 43 percent of the population are minorities.

Obligations

Funding History:
Fiscal Year 2004—$6,349,902
Fiscal Years 2000–2003—$21,853,035
Total Funding to Date—$28,202,937

Current Active Organizations and Grant Numbers

1. University of Minnesota, Twin Cities,
Minneapolis, Minnesota —HL-066845

2. University of South Carolina
Columbia, South Carolina —HL-066852

3. University of North Carolina at Chapel Hill
Chapel Hill, North Carolina —HL-066853

4. Tulane University
New Orleans, Louisiana —HL-066855

5. San Diego State University
San Diego, California —HL-066856

6. The Johns Hopkins University
Baltimore, Maryland —HL-066857

7. University of Arizona
Tucson, Arizona —HL-066858

Lung Diseases Program

Acute Respiratory Distress Syndrome Clinical Network (ARDSNET), Initiated in Fiscal Year 1994

The objective of this network is to test new therapeutic agents with a potential for improving the outcome of patients with ARDS and those at risk of developing ARDS.

Obligations

Funding History:
Fiscal Year 2004—$5,516,811
Fiscal Years 1994–2003—$40,692,155
Total Funding to Date—$46,208,966

Current Active Organizations and Contract Numbers

1. Vanderbilt University
Nashville, Tennessee —HR-46054

2. University of Washington
Seattle, Washington —HR-46055

3. Duke University Medical Center
Durham, North Carolina —HR-46056

4. University of Michigan at Ann Arbor
Ann Arbor, Michigan —HR-46057

5. University of Pennsylvania Hospital
Philadelphia, Pennsylvania —HR-46058

6. University of California, San Francisco
San Francisco, California —HR-46059

7. Cleveland Clinic Foundation
Cleveland, Ohio —HR-46060

8. University of Colorado
Denver, Colorado —HR-46061

9. Latter Day Saints Hospital
Salt Lake City, Utah —HR-46062

10. University of Maryland
Baltimore, Maryland —HR-46063

11. Coordinating Center Massachusetts General Hospital
Boston, Massachusetts —HR-46064

12. Baylor College of Medicine
Houston, Texas —HR-16146

13. Baystate Medical Center
Springfield, Massachusetts —HR-16147

14. University of British Columbia
Vancouver, Canada —HR-16148

15. University of Chicago
Chicago, Illinois —HR-16149

16. Louisiana State University
New Orleans, Louisiana —HR-16150

17. University of Pittsburgh
Pittsburgh, Pennsylvania —HR-16152

18. University of Texas
San Antonio, Texas —HR-16153

19. University of Virginia
Charlottesville, Virginia —HR-16154

20. Wake Forest University
Winston-Salem, North Carolina —HR-16155

Asthma Clinical Research Network (ACRN), Initiated in Fiscal Year 2003

The purpose of this network is to evaluate current and novel therapies and management strategies for adult asthma and to ensure that findings are rapidly disseminated to the medical community. Approximately 33 percent of the participants will be minorities.

Obligations

Funding History:
Fiscal Year 2004—$8,424,129
Fiscal Year 2003—$8,181,429
Total Funding to Date—$16,605,558

Current Active Organizations and Grant Numbers

1. National Jewish Medical and Research Center
Denver, Colorado —HL-074073

2. University of California, San Francisco
San Francisco, California —HL-074204

3. University of Pittsburgh
Pittsburgh, Pennsylvania —HL-074206

4. Washington University
St. Louis, Missouri —HL-074208

5. University of Wisconsin
Madison, Wisconsin —HL-074212

6. University of California, San Diego
La Jolla, California —HL-074218

7. Wake Forest University Health Sciences
Winston-Salem, North Carolina —HL-074225

8. Brigham and Women's Hospital
Boston, Massachusetts —HL-074227

9. Pennsylvania State University Hershey Medical Center
Hershey, Pennsylvania —HL-074231

Childhood Asthma Management Program (CAMP), Initiated in Fiscal Year 1991

The purpose of this study is to evaluate the long-term effects of anti-inflammatory therapy compared to bronchodilator therapy on the course of asthma, particularly on lung function and bronchial hyperresponsiveness, and on physical and psychosocial growth and development. Results showed that 4 ½ to 6 years of daily treatment with inhaled corticosteroids was safe and provided superior control of asthma compared to a different antiinflammatory medication or treatment only when symptoms occurred. The CAMP study will continue to observe the children for 5 years to determine the effect of early treatment on maximum lung growth and on height.

Obligations

Funding History:
Fiscal Year 2004—$1,475,006
Fiscal Years 1991–2003—$54,845,605
Total Funding to Date—$56,320,611

Current Active Organizations and Contract Numbers

1. The Johns Hopkins University
Baltimore, Maryland —HR-16044

2. University of California, San Diego
La Jolla, California —HR-16045

3. University of New Mexico
Albuquerque, New Mexico —HR-16046

4. Hospital for Sick Children
Toronto, Ontario —HR-16047

5. National Jewish Medical and Research Center
Denver, Colorado —HR-16048

6. Brigham and Women's Hospital
Boston, Massachusetts —HR-16049

7. Asthma, Inc.
Seattle, Washington —HR-16050

8. Washington University
St. Louis, Missouri —HR-16051

9. The Johns Hopkins University
Baltimore, Maryland —HR-16052

Childhood Asthma Research and Education (CARE) Network, Initiated in Fiscal Year 1999

The purpose of this clinical network is to evaluate current and novel therapies and management strategies for children with asthma. Emphasis is on clinical trials that help identify optimal therapy for children with different asthma phenotypes, genotypes, and ethnic backgrounds and children at different developmental stages.

Obligations

Funding History:
Fiscal Year 2004—$5,292,305
Fiscal Years 1999–2003—$26,106,032
Total Funding to Date—$31,398,337

Current Active Organizations and Grant Numbers

1. Washington University
St. Louis, Missouri —HL-064287

2. National Jewish Medical and Research Center
Denver, Colorado —HL-064288

3. University of California, San Diego
La Jolla, California —HL-064295

4. University of Wisconsin
Madison, Wisconsin —HL-064305

5. University of Arizona
Tucson, Arizona —HL-064307

6. Pennsylvania State University
Hershey, Pennsylvania —HL-064313

COPD Clinical Research Network, Initiated in Fiscal Year 2003

The purpose of this network is to investigate disease management approaches in patients with moderate-to-severe COPD and to ensure that the findings are rapidly disseminated to the medical community.

Obligations

Funding History:
Fiscal Year 2004—$6,848,345

Fiscal Year 2003—$6,843,405
Total Funding to Date—$13,691,750

Current Active Organizations and Grant Numbers

1. Harbor-UCLA Research and Education Institute
Torrance, California —HL-074407

2. Denver Health and Hospital Authority
Denver, Colorado —HL-074409

3. Minnesota Veterans Research Institute
Minneapolis, Minnesota —HL-074416

4. University of Alabama at Birmingham
Birmingham, Alabama —HL-074418

5. University of Minnesota, Twin Cities
Minneapolis, Minnesota —HL-074424

6. Brigham and Women's Hospital
Boston, Massachusetts —HL-074428

7. University of California, San Francisco
San Francisco, California —HL-074431

8. University of Maryland Baltimore Professional School
Baltimore, Maryland —HL-074441

Feasibility of Retinoid Treatment in Emphysema (FORTE), Initiated in Fiscal Year 1999

The purpose of this program is to conduct preliminary studies to identify optimal patient populations, drugs and dosing schedules, and outcome measures before conducting a larger clinical trial on retinoid treatment for emphysema.

Obligations

Funding History:
Fiscal Year 2004—$506,758
Fiscal Years 1999–2003—$11,749,283
Total Funding to Date—$12,256,041

Current Active Organizations and Contract Numbers

1. University of Minnesota, Twin Cities,
Minneapolis, Minnesota —HR-96140

2. Boston University
Boston, Massachusetts —HR-96141

3. University of Pittsburgh
Pittsburgh, Pennsylvania —HR-96142

4. University of California, Los Angeles
Los Angeles, California —HR-96143

5. University of California, San Diego
La Jolla, California —HR-96144

6. Columbia University
New York, New York —HR-96145

National Emphysema Treatment Trial (NETT), Initiated in Fiscal Year 1997

The NETT is a multicenter trial designed to evaluate the efficacy and role of lung volume reduction surgery (a procedure in which part of the lung is removed in an attempt to improve breathing) in the treatment of severe emphysema. If surgery proves to be effective, a major secondary objective is to determine which patients are most likely to benefit.

Obligations

Funding History:
Fiscal Year 2004—$1,648,000
Fiscal Years 1997–2003—$34,198,310
Total Funding to Date—$35,846,310

Current Active Organizations and Contract Numbers

1. Baylor College of Medicine
Houston, Texas —HR-76101

2. Brigham and Women's Hospital
Boston, Massachusetts —HR-76102

3. University of California, San Diego
La Jolla, California —HR-76103

4. Cedars-Sinai Medical Center
Los Angeles, California —HR-76104

5. Cleveland Clinic Foundation
Cleveland, Ohio —HR-76105

6. Columbia University
New York, New York —HR-76106

7. Duke University Medical Center
Durham, North Carolina —HR-76107

8. University of Maryland
Baltimore, Maryland —HR-76108

9. Mayo Foundation
Rochester, Minnesota —HR-76109

10. University of Michigan at Ann Arbor
Ann Arbor, Michigan —HR-76110

11. National Jewish Medical and Research Center
Denver, Colorado —HR-76111

12. The Ohio State University
Columbus, Ohio —HR-76112

13. University of Pennsylvania
Philadelphia, Pennsylvania —HR-76113

14. University of Pittsburgh
Pittsburgh, Pennsylvania —HR-76114

15. Saint Louis University
St. Louis, Missouri —HR-76115

16. Temple University
Philadelphia, Pennsylvania —HR-76116

17. University of Washington
Seattle, Washington —HR-76118

18. The Johns Hopkins University
Baltimore, Maryland —HR-76119

Blood Diseases and Resources Program

Blood and Marrow Transplant Clinical Research Network, Initiated in Fiscal Year 2001

The purpose of this network is to promote the efficient comparison of novel treatment methods and management strategies of potential benefit for children and adults undergoing blood or marrow transplantation.

Obligations

Funding History:
Fiscal Year 2004—$5,972,521
Fiscal Years 2001–2003—$17,209,287
Total Funding to Date—$23,181,808

Current Active Organizations and Grant Numbers

1. University of Nebraska Medical Center
Omaha, Nebraska —HL-069233

2. Fred Hutchinson Cancer Research Center
Seattle, Washington —HL-069246

3. Dana Farber Cancer Institute
Boston, Massachusetts —HL-069249

4. Children's Mercy Hospital
Kansas City, Missouri —HL-069254

5. University of California, San Diego
La Jolla, California —HL-069273

6. Duke University
Durham, North Carolina —HL-069274

7. City of Hope Medical Center
Duarte, California —HL-069278

8. University of Pennsylvania
Philadelphia, Pennsylvania —HL-069286

9. University of Minnesota, Twin Cities,
Minneapolis, Minnesota —HL-069290

10. Stanford University
Stanford, California —HL-069291

11. Medical College of Wisconsin
Milwaukee, Wisconsin —HL-069294

12. University of Florida
Gainesville, Florida —HL-069301

13. The Johns Hopkins University
Baltimore, Maryland —HL-069310

14. Sloan Kettering Institute for Cancer Research
New York, New York —HL-069315

15. University of Michigan
Ann Arbor, Michigan —HL-069330

16. Case Western Reserve University
Cleveland, Ohio —HL-069348

Cord Blood Stem Cell Transplantation Study (COBLT), Initiated in Fiscal Year 1996

This multicenter study is designed to show whether umbilical cord blood stem cell transplants from unrelated, newborn donors are a safe and efficient alternative to bone marrow transplantation for children and adults with a variety of cancers, blood diseases, and genetic disorders.

Obligations

Funding History:
Fiscal Year 2004—$707,000
Fiscal Years 1996–2003—$31,699,365
Total Funding to Date—$32,406,365

Current Active Organizations and Contract Numbers

1. The EMMES Corporation
Potomac, Maryland —HB-67132

2. Dana Farber Cancer Institute
Boston, Massachusetts —HB-67133

3. Fred Hutchinson Cancer Research Center
Seattle, Washington —HB-67134

4. University of California, Los Angeles
Los Angeles, California —HB-67135

5. Indiana University
Indianapolis, Indiana —HB-67137

6. Duke University Medical Center
Durham, North Carolina —HB-67138

7. University of Minnesota, Twin Cities
Minneapolis, Minnesota —HB-67139

8. Duke University Medical Center
Durham, North Carolina —HB-67141

9. University of California, Los Angeles
Los Angeles, California —HB-67142

Multicenter Study of Hydroxyurea (MSH) in Sickle Cell Anemia Adult Follow-up, Initiated in Fiscal Year 1996

The purpose of this trial is to determine the long-term effects of hydroxurea. Patients were examined annually to determine their health status, quality of life, incidence of malignancies, and birth defects in their offspring(s). Mortality rates from this cohort were compared to mortality

data from the CSSCD cohort and the normal black population mortality. Results showed that patients who took hydroxyurea over a 9-year period experienced a 40 percent reduction in deaths. Improved survival was related to benefits of drug therapy—an increase in fetal hemoglobin level and reduced episodes of severe pain "crises" and acute chest syndrome.

Obligations

Funding History:
Fiscal Year 2004—$1,136,093
Fiscal Years 1996–2003—$3,700,743
Total Funding to Date—$4,836,836

Current Active Organization and Contract Number

1. Maryland Medical Research Institute
Baltimore, Maryland —HB-67129

Pediatric Hydroxyurea Phase III Clinical Trial (BABY HUG), Initiated in Fiscal Year 2000

The objective of this clinical trial is to determine if hydroxyurea therapy is effective in prevention of chronic end organ damage in pediatric patients with sickle cell anemia.

Obligations

Funding History:
Fiscal Year 2004—$1,963,630
Fiscal Years 2000–2003—$6,223,568
Total Funding to Date—$8,187,198

Current Active Organizations and Contract Numbers

1. Children's Research Institute
Washington, DC —HB-07150

2. Duke University Medical Center
Durham, North Carolina —HB-07151

3. Howard University
Washington, DC —HB-07152

4. The Johns Hopkins University
Baltimore, Maryland —HB-07153

5. Medical University of South Carolina
Charleston, South Carolina —HB-07154

6. St. Jude Children's Research Hospital
Memphis, Tennessee —HB-07155

7. The Research Foundation of SUNY
New York, New York —HB-07156

8. University of Miami
Miami, Florida —HB-07157

9. University of Mississippi Medical Center
Jackson, Mississippi —HB-07158

10. University of Texas Southwestern Medical Center
Dallas, Texas —HB-07159

11. Clinical Trials and Surveys Corporation
Baltimore, Maryland —HB-07160

T-Cell Depletion in Unrelated Donor Marrow Transplantation, Initiated in Fiscal Year 1994

The purpose of this randomized multicenter clinical trial is to determine whether a reduction in morbidity and mortality from acute and chronic graft-versus-host disease can be achieved without a counterbalancing increase in relapse of leukemia in patients receiving an unrelated donor marrow transplant.

Obligations

Funding History:
Fiscal Year 2004—$163,598
Fiscal Years 1994–2003—$11,804,918
Total Funding to Date—$11,968,516

Current Active Organizations and Contract Numbers

1. The EMMES Corporation
Potomac, Maryland —HB-47094

2. University of Minnesota, Twin Cities
Minneapolis, Minnesota —HB-47095

3. University of Kentucky
Lexington, Kentucky —HB-47097

4. Sloan-Kettering Institute for Cancer Research
New York, New York —HB-47098

Thalassemia (Cooley's Anemia) Clinical Research Network, Initiated Fiscal Year 2000

The purpose of this network is to accelerate research in the management of thalassemia, standardize existing treatments, and evaluate new ones in a network of clinical centers.

Obligations

Funding History:
Fiscal Year 2004—$2,374,805
Fiscal Years 2000–2003—$8,999,883
Total Funding to Date—$11,374,688

Current Active Organizations and Grant Numbers

1. Children's Hospital of Philadelphia
Philadelphia, Pennsylvania —HL-065232

2. Hospital for Sick Children
Toronto, Ontario —HL-065233

3. New England Research Institute, Inc.
Watertown, Massachusetts —HL-065238

4. Children's Hospital Oakland
Oakland, California —HL-065239

5. Weill Medical College of Cornell University
New York, New York —HL-065244

6. Children's Hospital
Boston, Massachusetts —HL-065260

Transfusion Medicine/Hemostasis Clinical Research Network, Initiated in Fiscal Year 2002

The purpose of this network is to promote the efficient comparison of new management strategies for individuals with hemostatic disorders, such as idiopathic thrombocytopenia and thrombotic thrombocytopenic purpura, and to evaluate new and existing blood products and cytokines for treatment of hematologic disorders.

Obligations

Funding History:
Fiscal Year 2004—$6,092,846
Fiscal Years 2002–2003—$12,293,630
Total Funding to Date—$18,386,476

Current Active Organizations and Grant Numbers

1. University of Iowa
Iowa City, Iowa —HL-072028

2. Case Western Reserve University
Cleveland, Ohio —HL-072033

3. University of Minnesota, Twin Cities
Minneapolis, Minnesota —HL-072072

4. The Johns Hopkins University
Baltimore, Maryland —HL-072191

5. Weill Medical College of Cornell University
New York, New York —HL-072196

6. Emory University
Atlanta, Georgia —HL-072248

7. New England Research Institutes, Inc.
Watertown, Massachusetts —HL-072268

8. Tulane University of Louisiana
New Orleans, Louisiana —HL-072274

9. University of Oklahoma Health Sciences Center
Oklahoma City, Oklahoma —HL-072283

10. Duke University
Durham, North Carolina —HL-072289

11. Blood Center of Southeastern Wisconsin
Milwaukee, Wisconsin —HL-072290

12. Children's Hospital Boston
Boston, Massachusetts —HL-072291

13. Massachusetts General Hospital
Boston, Massachusetts —HL-072299

14. Puget Sound Blood Center
Seattle, Washington —HL-072305

15. University of Pittsburgh
Pittsburgh, Pennsylvania —HL-072331

16. University of Pennsylvania
Philadelphia, Pennsylvania —HL-072346

17. University of North Carolina at Chapel Hill
Chapel Hill, North Carolina —HL-072355

18. University of Maryland Baltimore Professional School
Baltimore, Maryland —HL-072359

Women's Health Initiative, Initiated in Fiscal Year 1992

The purpose of the WHI is to study cardiovascular disease, cancer, and osteoporosis in postmenopausal women. The program consists of three major components: a randomized controlled clinical trial of HRT, dietary modification, and calcium/vitamin D supplementation;

an observational study to identify predictors of disease; and a study of community approaches to developing healthful behaviors.

Obligations

Funding History:
Fiscal Year 2004—$57,483,316
Fiscal Years 2000–2003—$615,132,161 (This figure reflects funding for the clinical trials and observational studies only. From 1992–98, major support was provided through the Office of the Director, NIH. The Community Prevention Study receives funding through an interagency agreement with the CDC: $4,000,000 in FY 1999 and $12,000,000 from FY 1996–98.)
Total Funding to Date—$672,615,477

Current Active Organizations and Contract Numbers

1. Fred Hutchinson Cancer Research Center
Seattle, Washington —WH-22110

2. University of Medicine and Dentistry of New Jersey
Newark, New Jersey —WH-24152

3. Fred Hutchinson Cancer Research Center
Seattle, Washington —WH-32100

4. University of Minnesota, Twin Cities
Minneapolis, Minnesota —WH-32101

5. University of Iowa College of Medicine
Iowa City, Iowa —WH-32102

6. University of Alabama at Birmingham
Birmingham, Alabama —WH-32105

7. Wake Forest University
Winston-Salem, North Carolina —WH-32106

8. Northwestern University
Chicago, Illinois —WH-32108

9. Brigham and Women's Hospital
Boston, Massachusetts —WH-32109

10. University of Medicine and Dentistry of New Jersey
Newark, New Jersey —WH-32110

11. Emory University
Atlanta, Georgia —WH-32111

12. University of Pittsburgh
Pittsburgh, Pennsylvania —WH-32112

13. University of California, Davis
Davis, California —WH-32113

14. University of Arizona
Tucson, Arizona —WH-32115

15. University of Tennessee
Memphis, Tennessee —WH-32118

16. Memorial Hospital of Rhode Island
Pawtucket, Rhode Island —WH-32119

17. University of California, San Diego,
La Jolla, California —WH-32120

18. State University of New York at Buffalo,
Buffalo, New York —WH-32122

19. American College of Obstetricians and Gynecologists
Washington, DC —WH-34205

20. University of California, Irvine,
Irvine, California —WH-42107

21. The George Washington University,
Washington, DC —WH-42108

22. Stanford University
Stanford, California —WH-42109

23. Baylor College of Medicine,
Houston, Texas —WH-42110

24. University of Texas Health Science Center
San Antonio, Texas —WH-42111

25. The Ohio State University,
Columbus, Ohio —WH-42112

26. University of Nevada School of Medicine
Reno, Nevada —WH-42113

27. Kaiser Foundation Research Institute
Oakland, California —WH-42114

28. State University of New York at Stony Brook
Stony Brook, New York —WH-42115

29. University of Massachusetts Medical School,
Worcester, Massachusetts —WH-42116

30. University of North Carolina at Chapel Hill
Chapel Hill, North Carolina —WH-42117

31. Wayne State University
Detroit, Michigan —WH-42118

32. Albert Einstein College of Medicine,
New York, New York —WH-42119

33. Harbor-UCLA Research and Education Institute
Torrance, California —WH-42120

34. Kaiser Foundation Research Institute
Oakland, California —WH-42121

35. Medical College of Wisconsin,
Milwaukee, Wisconsin —WH-42122

36. Medlantic Research Institute,
Washington, DC —WH-42123

37. Rush-Presbyterian-St. Luke's Medical Center
Chicago, Illinois —WH-42124

38. University of California, Los Angeles School of Medicine,
Los Angeles, California —WH-42125

39. University of Cincinnati Medical Center
Cincinnati, Ohio —WH-42126

40. University of Florida College of Medicine
Gainesville, Florida —WH-42129

41. University of Hawaii at Manoa,
Honolulu, Hawaii —WH-42130

42. University of Miami
Miami, Florida —WH-42131

43. University of Wisconsin
Madison, Wisconsin —WH-42132