

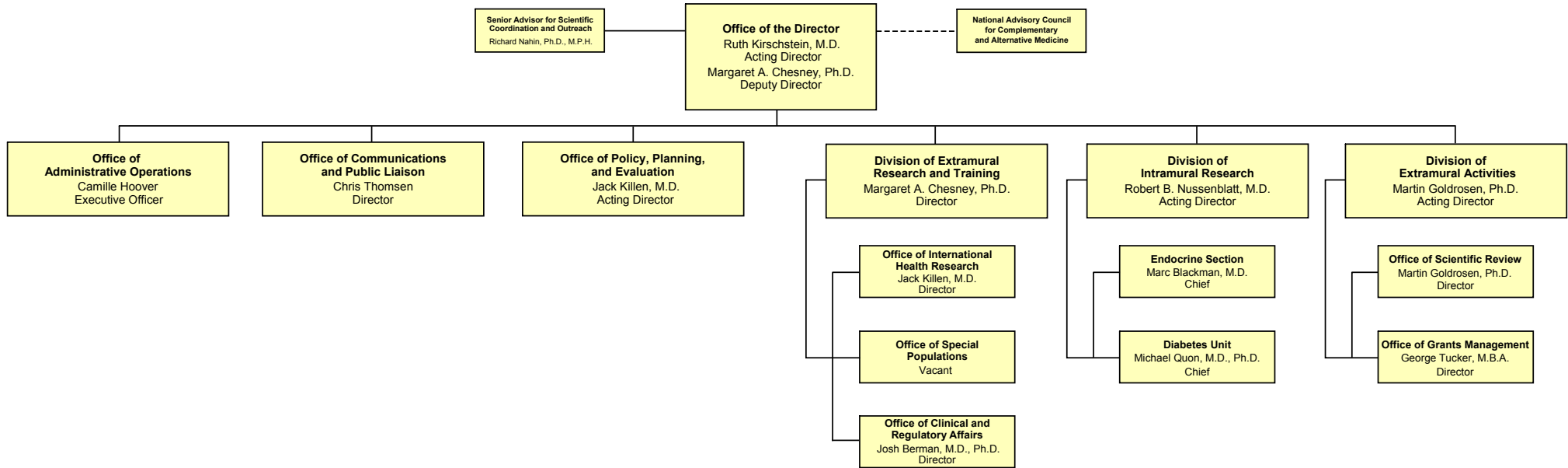
DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

National Center for Complementary and Alternative Medicine

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**National Institutes of Health**  
National Center for Complementary and Alternative Medicine



**FY 2008 Proposed Appropriation Language**

**NATIONAL INSTITUTES OF HEALTH**

National Center for Complementary and Alternative Medicine

*For carrying out section 301 and title IV of the Public Health Service Act with respect to complementary and alternative medicine \$121,699,000.*

**Supplementary Exhibit**

**Comparison of Proposed FY 2008 Appropriation Language to  
Most Recently Enacted Full-Year Appropriations**

**NATIONAL INSTITUTES OF HEALTH**

**NATIONAL CENTER FOR COMPLEMENTARY AND ALTERNATIVE MEDICINE**

For carrying out section 301 and title IV of the Public Health Services Act with respect to complementary and alternative medicine [~~\$121,268,000~~] \$121,699,000 (Department of Health and Human Services Appropriation Act, 2006)

**National Institutes of Health  
National Center for Complementary and Alternative Medicine**

**Amounts Available for Obligation 1/**

Source of Funding	FY 2006 Actual	FY 2007 Continuing Resolution	FY 2008 Estimate
Appropriation	\$122,692,000	\$121,465,000	\$121,699,000
Enacted Rescissions	-1,227,000	0	0
Subtotal, Adjusted Appropriation	121,465,000	121,465,000	121,699,000
Real Transfer under Roadmap Authority	-1,086,000	0	
Real Transfer under Secretary's One-percent transfer authority	-83,000		
Comparative transfer from OD for NIH Roadmap	1,086,000	0	
Comparative Transfer to NIBIB	-8,000	-8,000	
Comparative transfer to OD	-4,000	-4,000	
Comparative Transfer to NCRR	-236,000	-185,000	
Comparative Transfer to the Office of the Assistant Secretary for Admin. And Mgmt. and to the Office of the Assistant Secretary for Public Affairs.	0	0	
Comparative Transfer to the Office of Public Health Emergency Preparedness	0	0	
Comparative Transfer from the PHSSEF	0	0	
Comparative Transfer to DHHS for PHS Historian	0	0	
Subtotal, adjusted budget authority	121,134,000	121,268,000	121,699,000
Unobligated Balance, start of year	0	0	0
Revenue from Breast Cancer Stamp <u>2/</u>	0		
Unobligated Balance, end of year	0	0	0
Subtotal, adjusted budget authority	121,134,000	121,268,000	121,699,000
Unobligated balance lapsing	-2,000	0	0
Total obligations	121,132,000	121,268,000	121,699,000

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

FY 2006 - \$0 FY 2007 - \$5,000 FY 2008 - \$5,000

Excludes \$0 in FY 2007 and \$0 in FY 2008 for royalties.

**NATIONAL INSTITUTES OF HEALTH**  
**National Center for Complementary and Alternative Medicine**  
**Budget Authority by Program**  
(Dollars in thousands)

	FY 2004 Actual		FY 2005 Actual		FY 2006 Actual		FY 2006 Comparable		FY 2007 Continuing Resolution		FY 2008 Estimate		Change	
	FTEs	Amount	FTEs	Amount	FTEs	Amount	FTEs	Amount	FTEs	Amount	FTEs	Amount	FTEs	Amount
<b>Extramural Research</b>														
Detail:														
Clinical Research		49,546		49,444		54,003		54,003		53,803		53,915		\$112
Non-Clinical Research		33,736		33,858		31,215		31,215		31,085		31,160		75
Training		16,234		17,257		13,413		13,177		13,097		13,113		16
		99,516		100,559		98,631		98,395		97,985		98,188		203
<b>Intramural research</b>	15	4,240	18	7,198	15	7,448	15	7,440	15	7,402	16	7,350	1	-52
<b>Res. management &amp; support</b>	58	12,837	57		59	14,217	59	14,213	61	14,426	61	14,570	0	144
<b>Research</b>		385		772		1,086		1,086		1,455		1,591	0	136
<b>TOTAL</b>	73	116,978	75	108,529	74	121,382	74	121,134	76	121,268	77	121,699	1	431

Includes FTEs which are reimbursed from the NIH Roadmap for Medical Research

**NATIONAL INSTITUTES OF HEALTH**  
**National Center for Complementary and Alternative Medicine**  
(Dollars in Thousands)  
Budget Mechanism - Total

MECHANISM	FY 2006 Actual		FY 2007 Continuing Resolution		FY 2008 Estimate		Change	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
<b>Research Grants:</b>								
<b>Research Projects:</b>								
Noncompeting	160	\$53,650	155	\$52,015	145	\$44,699	(10)	-\$7,316
Administrative supplements	(15)	850	(10)	700	(10)	700	(0)	0
<b>Competing:</b>								
Renewal	0	0	2	516	2	516	0	0
New	80	16,717	86	17,814	121	25,152	35	7,338
Supplements	0	0	0	0	0	0	0	0
Subtotal, competing	80	16,717	88	18,330	123	25,668	35	7,338
Subtotal, RPGs	240	71,217	243	71,045	268	71,067	25	22
SBIR/STTR	13	2,709	12	2,679	12	2,621	0	-58
Subtotal, RPGs	253	73,926	255	73,724	280	73,688	25	-36
<b>Research Centers:</b>								
Specialized/comprehensive	5	1,895	5	2,250	5	2,250	0	0
Clinical research	0	0	0	0	0	0	0	0
Biotechnology	0	0	0	0	0	0	0	0
Comparative medicine	0	0	0	0	0	0	0	0
Research Centers in Minority Institutions	0	0	0	0	0	0	0	0
Subtotal, Centers	5	1,895	5	2,250	5	2,250	0	0
<b>Other Research:</b>								
Research careers	44	5,725	44	5,745	44	5,835	0	90
Cancer education	0	0	0	0	0	0	0	0
Cooperative clinical research	0	500	0	0	0	0	0	0
Biomedical research support	0	0	0	0	0	0	0	0
Minority biomedical research support	0	0	0	0	0	0	0	0
Other	22	3,785	22	3,765	22	3,765	0	0
Subtotal, Other Research	66	10,010	66	9,510	66	9,600	0	90
<b>Total Research Grants</b>	<b>324</b>	<b>85,831</b>	<b>326</b>	<b>85,484</b>	<b>351</b>	<b>85,538</b>	<b>25</b>	<b>54</b>
<b>Research Training:</b>								
Individual awards	20	761	20	757	20	757	0	0
Institutional awards	46	2,104	46	2,093	46	2,093	0	0
Total, Training	66	2,865	66	2,850	66	2,850	0	0
Research & development contracts (SBIR/STTR)	14	9,699	14	9,651	14	9,800	0	149
	(0)	(7)	(0)	(13)	(0)	(13)	(0)	(0)
Intramural research	15	7,440	15	7,402	16	7,350	1	(52)
Research management and support	59	14,213	61	14,426	61	14,570	0	144
Cancer prevention & control	0	0	0	0	0	0	0	0
Construction	0	0	0	0	0	0	0	0
Buildings and Facilities	0	0	0	0	0	0	0	0
NIH Roadmap for Medical Research	0	1,086	0	1,455	0	1,591		136
Total, NCCAM	74	121,134	76	121,268	77	121,699	1	431

Includes FTEs which are reimbursed from the NIH Roadmap for Medical Research

## **Major changes in the FY 2008 Budget Request**

Major changes by budget mechanism and/or budget activity are described below. Note that there may be overlap between budget mechanism and activity detail and these highlights will not sum to the total change for the FY 2008 budget request for NCCAM, which is +\$0.431 million more than the FY 2007 Continuing Resolution, for a total of \$121.699 million.

Research Project Grants (-\$0.036 million; total \$73.688 million). NCCAM will support a total of 280 Research Project Grant (RPG) awards in FY 2008. Noncompeting RPG's will decrease by 10 awards and decrease by \$7.316 million. Competing RPG's will increase by 35 awards and increase by \$7.338 million.

Research Careers (+\$0.09 million; total \$5.835 million). NCCAM will support the Pathway to Independence program, by funding 1 additional award in FY 2008. Total support for the Pathway program in FY 2008 is 3 awards and \$270,000. Other than the Pathway to Independence program, no additional new research career awards will be funded in FY 2008.

NIH Roadmap for Biomedical Research (+\$0.136 million; total \$1.591 million). NCCAM will continue its support of the NIH Roadmap, an incubator for new ideas and initiatives that will accelerate the pace of discovery, in FY 2008.

General Clinical Research Center (GCRC) Complementary and Alternative Medicine Research Program PAR-04-087. This program announcement was withdrawn on November 2, 2006 due to the transitioning of NIH GCRC program into the Clinical and Translational Science Awards program. No new NCCAM awards will be made under this initiative in FY 2007 or FY 2008.

Centers of Excellence for Research on Complementary and Alternative Medicine (CERCs) PAR-06-047. In FY 2006, with the concurrence of the National Advisory Council for Complementary and Alternative Medicine, no new CERCs were funded because applications were not found to be competitive through NIH review process. Applicants for FY 2006 CERC awards have been encouraged to revise and resubmit their applications for consideration. NCCAM expects that some of these resubmissions will be successful in FY 2007 and thus eligible for funding in FY 2008. (See Portrait of a Program: Centers of Excellence for Research on CAM below.) The savings realized from the reduction of Non-competing RPGs, along with the cost-containment measures implemented at NIH for non-competing RPG awards, will allow NCCAM to increase funding for these new Center awards along with the project goals and expected accomplishments as outlined in the Justification Narrative.

**Portrait of a Program: Centers of Excellence for Research on Complementary and Alternative Medicine (CERC)**

FY 2007 Level: \$12.4 million

FY 2008 Level: \$13.6 million

Change \$ 1.2 million

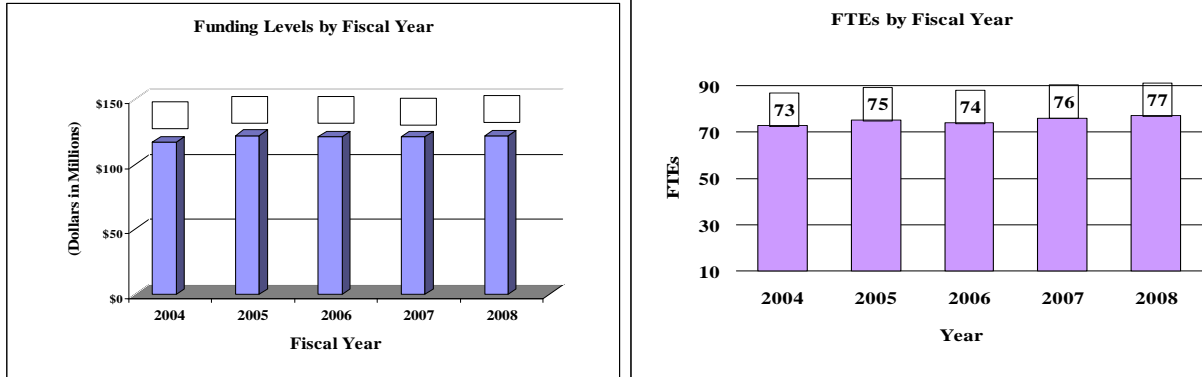
NCCAM's CERC program remains a critical part of its efforts to build and sustain complementary and alternative medicine (CAM) research capacity across the country. CERCs support synergistic studies of CAM approaches, such as mind-body medicine, acupuncture, dietary supplements, millimeter wave therapy, and traditional Chinese medicine, for major health conditions that affect Americans, including HIV/AIDS, cardiovascular disease, asthma, alcoholism, and arthritis.

NCCAM's CERCs provide 5 years of support for experienced researchers at some of the Nation's leading research institutions, including the Harvard Medical School; Temple University; the Mount Sinai School of Medicine; and the University of California, San Francisco. CERC awards promote the application of cutting-edge research techniques to identify the potential benefits, risks, and mechanisms of action of CAM modalities. To date, eight CERCs have been funded by NCCAM.

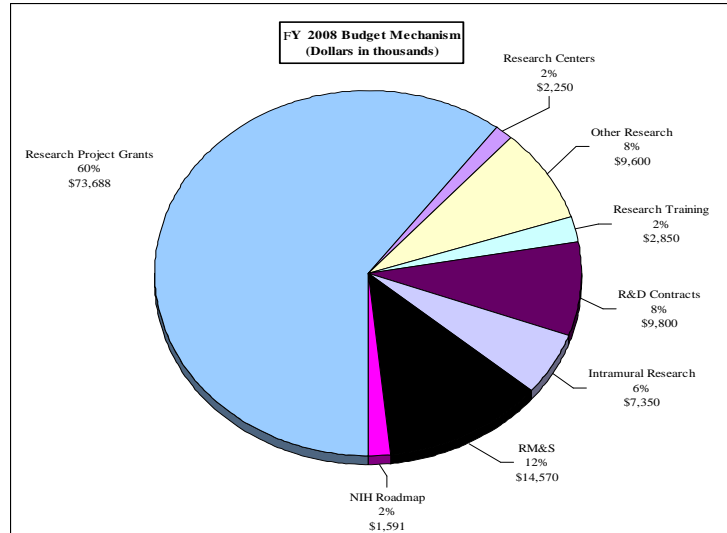


## Fiscal Year 2008 Budget Graphs

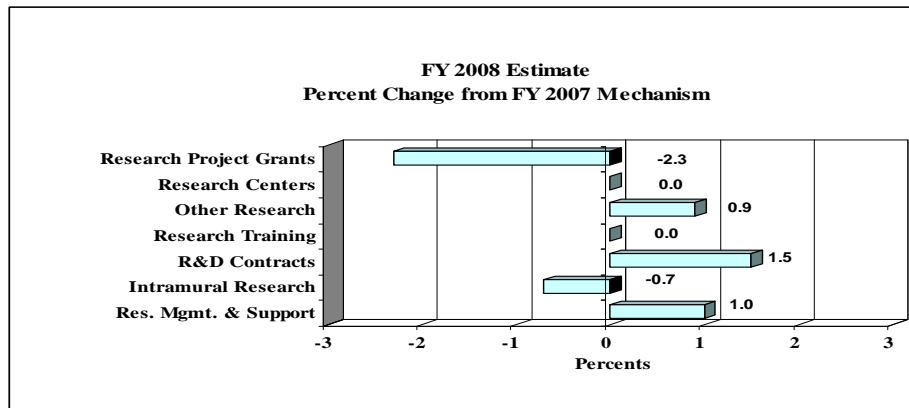
### History of Budget Authority and FTEs:



### Distribution by Mechanism



### Change by Selected Mechanisms:



## Justification of Budget Request

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

Budget Authority:

FY 2006 Actual		FY 2007 Continuing Resolution		FY 2008 Estimate		Increase or Decrease	
<u>FTE</u>	<u>BA</u>	<u>FTE</u>	<u>BA</u>	<u>FTE</u>	<u>BA</u>	<u>FTE</u>	<u>BA</u>
74	\$121,134,000	76	\$121,268,000	77	\$121,699,000	1	+\$431,000

This document provides justification for the Fiscal Year (FY) 2008 research activities of the National Center for Complementary and Alternative Medicine (NCCAM), including HIV/AIDS activities. Details of the FY 2008 HIV/AIDS activities are in “Office of AIDS Research” (OAR) section of the Overview. Details on the Roadmap/Common Fund are located in the Overview, Volume One.

### DIRECTOR’S OVERVIEW

In *Expanding Horizons of Health Care: Strategic Plan 2005-2009*, NCCAM presents its plans for exploring the potential of complementary and alternative medicine (CAM) in the context of the performance of rigorous science, the training of CAM researchers, and the dissemination of authoritative information to the public and to health care professionals. To organize its research portfolio, NCCAM categorizes the diverse field of CAM into five domains: mind-body medicine, biologically based practices, manipulative and body-based practices, energy medicine, and whole medical systems.

Since its formation in 1999, NCCAM has made significant progress in building a robust extramural and intramural research enterprise to evaluate CAM. This research includes therapies that have been used worldwide for thousands of years with limited proof of safety or efficacy. In supporting such research, NCCAM is generating the scientific evidence needed to guide clinicians’ and the public’s decisions about CAM use, including the recent publication on the effectiveness of yoga for lower back pain.

Use of CAM among Americans is substantial for a range of common conditions. The 2002 National Health Interview Survey (NHIS) conducted by the Centers for Disease Control and Prevention (CDC) with support from NCCAM for a CAM supplement, found that more than one-third of Americans are using some form of CAM to prevent or treat a variety of conditions. In FY 2007, NCCAM again is collaborating with CDC to learn about CAM use among children in the first nationwide Government survey of its kind. The results from this new pediatric CAM component of the NHIS will inform NCCAM regarding new areas of research on CAM safety and efficacy in children.

In its early years, NCCAM made a relatively higher investment in clinical research than other NIH Institutes and Centers (ICs). This decision was driven by the fact that Americans were

already using CAM therapies without evidence of safety or efficacy. However, as NCCAM has matured and learned the challenges of conducting CAM research, it has found an increasing need for basic research to understand how these therapies work, using state-of-the-art laboratory assays to look at cellular and molecular mechanisms and animal models to look at mechanism of action in complex systems. Examples of basic research include animal models to study the effects of the herb, “turmeric,” on rheumatoid arthritis and green tea on insulin resistance. Similarly, NCCAM has expanded its investment in preclinical research, working to improve the characterization and standardization of interventions and to ascertain optimal doses and formulations for biologically active products. This work is needed to ensure the safety of research subjects, the ability to replicate findings, and the likelihood of detecting efficacy. NCCAM has also learned that better tools to measure protocol adherence and clinical outcomes must be developed to facilitate clinical trials of CAM interventions. Furthermore, a fair, yet rigorous evaluation of whole medical systems may not be possible without first developing novel design and statistical methods to evaluate complex treatment regimens that involve a number of components. NCCAM will continue to monitor the balance of its basic and clinical research portfolio, making adjustments as scientific opportunity warrants.

NCCAM’s strategic plan establishes the framework for a CAM research agenda. The Center’s extramural and intramural research programs support basic and clinical research across a range of CAM modalities, such as herbal products, acupuncture, meditation, magnetic energy, spinal manipulation, and Ayurvedic medicine, an ancient Indian system of medicine. This research addresses a broad range of health conditions such as diabetes, osteoarthritis, Alzheimer’s disease, and Huntington’s disease. The body of research funded by NCCAM seeks to unlock the therapeutic potential and determine the safety of CAM therapies, including dietary supplement contamination and herb-drug interactions.

NCCAM uses an array of NIH funding mechanisms to support its extramural research program, including research centers and individual research project grants. Through programs such as the Centers of Excellence for Research on CAM (CERCs), NCCAM research centers are bringing together multidisciplinary teams of experienced and new investigators to conduct CAM research. Understanding that a CAM research enterprise cannot be sustained without training and attracting scientists to conduct CAM research, NCCAM has developed a targeted program to train conventional and CAM practitioners in CAM research. In FY 2005, in accordance with recommendations of an expert working group that evaluated NCCAM’s research training and career development programs, a CAM career transition initiative was developed. (See Extramural Research Training section.)

To fulfill its mission, NCCAM collaborates with multiple NIH ICs as well as other Federal agencies, such as the CDC and the Agency for Healthcare Research and Quality (AHRQ). AHRQ partners with NCCAM on evidence-based reviews of CAM therapies including dietary supplements, such as soy, melatonin, and berries for neuroprotection as well as meditation for health purposes. Other examples of collaborative work include the FY 2005 initiative by NCCAM and National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) for Phase I/II clinical studies of silymarin (milk thistle) to determine efficacy and optimal doses for use against chronic hepatitis C and nonalcoholic steatohepatitis (liver disease). In addition, in FY 2006, NCCAM signed a letter of intent to collaborate with Chinese government agencies to

foster scientific exchange and collaboration between China and the U.S. regarding the advancement of the scientific discipline of traditional Chinese medicine research.

## **FY 2008 Justification by Activity Detail**

### **Overall Budget Policy**

Investigator-initiated research projects and new investigator research and career development awards are the center's highest priorities. The NCCAM carefully evaluates investigator-initiated requests to all its programs, conducts scientific review, and presents results to the NCCAM Advisory Council for recommended levels of support. This process applies to Institute-initiated projects (e.g. RFAs) as well. The Center recognizes the need for a balance between solicitations issued to the extramural community in areas that need stimulation and funding to support investigator-initiated projects.

### **Extramural Research: Clinical Research**

NCCAM's extramural clinical research program includes domestic and international studies in the five domains of CAM, including the largest clinical trials to date on *Ginkgo biloba* to prevent age-related dementia in the elderly, chelation therapy for heart attack patients, and echinacea for the prevention of colds in children. Based on findings from animal studies, NCCAM recently funded a translational research center that includes a study of the effectiveness of gamma tocopherol, a form of vitamin E, on allergen-induced nasal and bronchial airway inflammation in adults with severe dust mite allergies. NCCAM's clinical research targets a range of populations across the lifespan, men and women as well as members of specific racial or ethnic groups. NCCAM uses a variety of mechanisms to support clinical research. The developmental research grant mechanism, which does not require preliminary data, is useful in emerging areas of CAM research where little or no previous research has been conducted. While NCCAM's clinical research portfolio cuts across all five CAM domains, the preponderance of research studies are in biologically based practices, such as dietary supplements and botanicals. For example, NCCAM has funded a Phase III trial of S-adenosyl-L-methionine (SAME) for major depression. A growing area of research investment is in mind-body medicine. For example, NCCAM is funding studies to test the efficacy of meditation for chronic pain and side effects associated with HIV treatment; yoga for cancer-related fatigue; and tai chi for heart failure. NCCAM's clinical research portfolio also includes studies in other CAM domains, such as massage and spinal manipulation for back pain and acupuncture for irritable bowel syndrome. NCCAM collaborates with other NIH ICs in supporting complex clinical trials, such as the glucosamine and chondroitin sulfate trial for osteoarthritis of the knee with the National Institute of Arthritis and Musculoskeletal and Skin Diseases, (NIAMS) (see portrait), and a trial of St. John's wort for minor depression with the National Institute of Mental Health (NIMH) and the NIH Office of Dietary Supplements (ODS). NCCAM and ODS also collaborate on the NIH Botanical Research Center Program.

Budget Policy: The FY 2008 budget estimate for extramural clinical research is \$53.9 million, an increase of \$112,000 or 0.2 percent above the FY 2007 Continuing Resolution. The program plans for FY 2008, along with expected accomplishments, follow. In FY 2008, NCCAM, guided by its

strategic plan and the Institute of Medicine's report, *Complementary and Alternative Medicine in the United States*, will expand its extramural clinical research program to address important questions related to health services research through existing primary care research networks, including those supported by the NIH and Agency for Healthcare Research and Quality, (AHRQ). NCCAM anticipates making awards in this area in FY 2008. Research supported under this initiative will cover large patient populations treated in diverse settings. This research should provide important information on the cost effectiveness of CAM and the impact of integrating CAM with conventional health services. The Center will continue to fund studies under its ongoing initiatives, "Exploratory/Developmental Grant for Clinical Studies of Complementary and Alternative Medicine" and "CAM at Minority or Health Disparities Research Centers," to support small pilot studies to build a sound empirical base for future clinical trials. In accordance with GPRA goals, NCCAM anticipates initiating, in FY 2008, at least one clinical study of menopausal hot flashes using outcome measurement tools developed in FY 2006 and FY 2007. Also, Small Business Innovation Research (SBIR) awards will be made in FY 2008 to develop tools to assess adherence to CAM modalities in the study of biologically active CAM products and mind-body interventions. In FY 2008, NCCAM anticipates supporting additional CERCs (see portrait) and Developmental Centers for Research on CAM (DCRCs). The DCRCs are centers that partner CAM institutions and practitioners with experienced researchers to conduct research on a variety of CAM modalities, such as osteopathic manipulation of the skeletal system, tumor-fighting properties of mushroom extracts, and the placebo effect. As noted above, NCCAM partnered with AHRQ to conduct systematic reviews of the literature on meditation and the neuroprotective effects of berries. In FY 2008, NCCAM plans to convene workshops to review the findings of these reports and any implications for its research agenda.

**Portrait of a Program: Challenges and Lessons in CAM Clinical Trials: the GAIT Trial**

Fiscal year 2005 was the last year of funding for the Glucosamine/chondroitin Arthritis Intervention Trial (GAIT).

Dietary supplements, most notably herbal products, are among the most popular CAM therapies in the U.S. There are many challenging issues to be addressed in conducting research to determine the safety and efficacy of these products, not the least of which is that there is rarely consensus among CAM experts on the optimal product or dose, the targeted condition and patient population, or what constitutes a fair test of the CAM therapy in question. The literature is rife with studies of less-than-rigorous research design. Moreover, dietary supplements are subject to less stringent controls over purity and manufacturing processes than are drugs. In certain instance, there have been problems with dietary supplements in regard to their characterization, standardization, and stability, and they can be contaminated with unwanted ingredients. When this happens, it raises serious questions about reproducibility of results, an essential ingredient of rigorous scientific research.

NCCAM has taken significant steps to ensure the quality of products used in the research it funds, such as establishing a Product Quality Working Group and a policy on product quality. The Working Group includes a representative from the dietary supplement industry as well as individuals with expertise specific to the products under review; its function is to review the quality of products for biologically active substances to be used in NCCAM-funded research. In addition, NCCAM's Phase I Resource Center provides critical information currently missing from the literature about the safety and pharmacokinetic profile of biologically active products.

In conjunction with NIAMS, NCCAM supported the Glucosamine/chondroitin Arthritis Intervention Trial (GAIT) that enrolled 1,600 subjects at 16 U.S. sites to test the short-term effectiveness of glucosamine hydrochloride (GH) and chondroitin sulfate (CS) -- alone and in combination -- in reducing pain in knee osteoarthritis (OA). This study was funded at a total level of \$ 16.2 million, with NCCAM providing \$14.4 million. Previous studies reported conflicting results on the effectiveness of the popular dietary supplement combination as treatments for OA. To address some of the problems encountered in earlier trials, GAIT used a rigorous research design to evaluate the efficacy of GH and CS. NCCAM and NIAMS took steps to ensure the quality and stability of the products used in this trial. This study was conducted under an FDA investigational new drug application; all of the products were subject to FDA's pharmaceutical regulations and evaluated and manufactured by an FDA-licensed clinical research pharmacy center. The GH and CS used were tested for purity, potency, quality, and consistency among batches and retested for stability throughout the study.

The study results, which were published in *The New England Journal of Medicine* in 2006, showed that the combination of GH plus CS did not provide significant relief from OA pain among all participants, which was the study's primary outcome measure. A smaller subgroup of study participants with moderate-to-severe pain had significant relief with the combination of supplements.

**Extramural Research: Basic or Non-Clinical Research**

Based on lessons learned from previous investments in clinical research, NCCAM is now emphasizing basic, non-clinical research. It has issued an ongoing initiative on "Basic and Preclinical Research on Complementary and Alternative Medicine" to elucidate mechanisms of action for a range of CAM therapies. Examples of recently funded basic research include animal studies to examine the mechanism of action of electroacupuncture on irritable bowel syndrome and imaging studies of the brain's response to meditation, acupuncture, and placebo analgesia. NCCAM has issued initiatives for mechanistic studies of CAM modalities purported to enhance immune function and for basic science and mechanistic studies on the biomechanical, immunological, endocrinological, and/or neurophysiological consequences of manual therapies, such as spinal manipulation and massage. The knowledge gained from these initiatives will provide a stronger foundation for future clinical studies and will inform CAM clinical practitioners. Research on the mechanism of action of CAM modalities, including the use of

animal models, also can be supported through CERCs and CAM at Minority or Health Disparities Research Centers initiative.

Budget Policy: The FY 2008 budget estimate for CAM non-clinical research is \$31.16 million, an increase of \$75,000 or 0.2 percent above the FY 2007 Continuing Resolution. The program plans for FY 2008, along with expected accomplishments, follow; in FY 2008, NCCAM expects to fund new studies in response to the initiatives mentioned above. In addition, in FY 2008 NCCAM will fund Phase I SBIR applications to develop diagnostics, protocols, assays, imaging technologies, and methods to determine the potential mechanism of action or biological effects of manual therapies as well as novel approaches to the diagnosis, monitoring, prevention, and treatment of neuro-musculoskeletal conditions that are treated by manual therapies. NCCAM will also convene an expert workshop on whole medical systems to identify methodologies and analytic tools from other research fields that could be adapted for use by CAM researchers in assessing the effectiveness of more complex treatment systems that use combinations of CAM modalities, such as traditional Chinese medicine.

### **Extramural Research Training**

Following its strategic plan, NCCAM's training and career development programs provide research training for CAM professionals and for investigators with conventional research backgrounds. These programs target individuals at different career stages -- from pre-doctoral students to mid- and senior-level investigators. The cadre of NCCAM investigators is growing and productive, contributing to the scientific literature through peer reviewed journals, such as *The Annals of Internal Medicine*, *New England Journal of Medicine*, and *Journal of the American Medical Association*. NCCAM also provides administrative supplements for CAM Practitioner Research Trainees and technical assistance on applying for NIH support for all newly independent investigators receiving NCCAM career development awards. NCCAM supports two types of curriculum development awards to incorporate CAM information into the curriculum of conventional medical, nursing, and allied health schools and to develop research curricula at schools that train CAM practitioners. NCCAM convenes an annual meeting of development award investigators and their key staff. Plans are under way for a publication on CAM curriculum development in FY 2007. In FY 2007, NCCAM expects to make its first awards under NCCAM program announcement, the "Complementary and Alternative Medicine Career Transition Award." In addition to these efforts, NCCAM's DCRCs provide research training for CAM institutions and practitioners.

Budget Policy: The FY 2008 budget estimate for CAM research training and career development is \$13.1 million, an increase of \$16,000 or 0.1 percent above the FY 2007 Continuing Resolution. The program plans for FY 2008, along with expected accomplishments, follow. In FY 2008, awards will be made under the initiative, "Collaborative CAM Research Development Capability Enhancement Grant at Minority-Serving Institutions" designed to advance research development capability at minority-serving institutions for CAM-related research projects conducted in association with investigators at research-experienced institutions. NCCAM is also participating in the FY 2006 trans-NIH "Pathway to Independence" career transition award initiative; the first awards will be made in FY 2008. In FY 2007, a program announcement was

issued for the “CAM Practitioner Research Career Development Award” in collaboration with the Bernard Osher Foundation. The first awards will be made in FY 2008.

### **Intramural Research**

NCCAM’s Division of Intramural Research (DIR) focuses on basic, translational, and clinical research regarding the efficacy, safety, and mechanisms of action of a range of CAM modalities. DIR includes a Laboratory of Clinical Investigation (LCI) comprised of a Diabetes Unit, an Endocrine Section, and an oncology program. In the Diabetes Unit, molecular, cellular, and animal studies are being conducted to elucidate mechanisms of action of dietary supplements and functional foods, including cocoa, green tea, vitamin C, DHEA, and glucosamine. The findings of this research are translated into clinical research studies on the safety and efficacy of these treatments for diabetes, obesity, hypertension, and the metabolic syndrome. In the Endocrine Section, investigators are pursuing laboratory studies on DHEA and prostate cancer as well as a Phase II clinical trial examining the effects of placebo treatment on the endocrine response to osteoarthritis pain in middle-aged men. Oncology studies include a multi-center randomized trial of electroacupuncture for delayed chemotherapy-induced nausea and vomiting in pediatric patients with solid tumors, and a Phase I /II dose-escalation trial of mistletoe extract and gemcitabine (a cancer drug) in patients with advanced solid tumors. In addition, the oncology group is conducting a study on the effectiveness of tai chi to aid in the well-being of long-term cancer survivors. DIR is also committed to investigator training programs that integrate into established clinical and pre-clinical NIH training programs, as well as privately funded programs such as the Howard Hughes Medical Student Program. Other programs unique to DIR include the NCCAM Director's Fellowship funded in part by the Prince of Wales Foundation, and a combined NCCAM-National Cancer Institute (NCI) fellowship, which offers training in oncology.

Budget Policy: The FY 2008 budget estimate for NCCAM intramural research is \$7.35 million, a decrease of \$52,000 or 0.7 percent below the FY 2007 Continuing Resolution. The program plans for FY 2008, along with expected accomplishments, follow. The program plans for FY 2008 are to investigate selected CAM interventions for age-associated diseases such as cancer, musculoskeletal pain, arthritis, diabetes, obesity, and cardiovascular disease. In addition, NCCAM is working with NIH to establish an Integrative Medicine Consult Service at the NIH Clinical Center. The service will consult on and, as appropriate, treat inpatients and outpatients using integrative medicine therapies such as acupuncture, meditation, and massage.

### **Research Management and Support (RMS)**

Budget Policy: The FY 2008 budget estimate for RMS is \$14.57 million, an increase of \$144,000 or 1.0 percent above the FY 2007 Continuing Resolution. NCCAM RMS activities provide administrative, budgetary, logistical, and scientific support in the review, award, and monitoring of research grants, training awards and research and development contracts. RMS functions also encompass strategic planning, coordination, and evaluation of the Institute’s programs, regulatory compliance, international coordination, and liaison with other Federal agencies, Congress, and the public. The Institute currently oversees more than 342 research project grants and centers, as well as more than 14 research and support contracts.



A critical component of NCCAM's mission, which is also supported through RMS, is outreach -- public health education, information dissemination, workshops, conferences, and meetings. NCCAM's communications activities reach the public and professional audiences through a variety of channels: fact sheets, alerts and advisories, quarterly newsletters, NCCAM website <sup>1</sup>, and NCCAM Clearinghouse. NCCAM reaches the public with authoritative information on CAM in a number of ways. The NCCAM website offers "CAM Online" continuing education series for health professionals (CME) and the public. Each year, NCCAM invites leading scientists to participate in the "Distinguished Lecture Series in the Science of CAM" at NIH. These lectures are open to the public and videocast on the NIH website. NCCAM and the National Library of Medicine (NLM) have partnered to create CAM on PubMed, a searchable database of CAM articles from the MEDLINE database and other compendia of scientific journals. In addition, it has an exhibit program to conduct outreach at scientific, medical, and consumer meetings throughout the country. The presence and presentations of NCCAM staff at professional and other stakeholder meetings offer opportunities for dialogue with the many communities interested in CAM research. NCCAM is also planning a publication on CAM curriculum development in FY 2007 based on lessons learned from the curriculum development awards (R25s).

NCCAM will continue to develop informational products, such as the fact sheet series "Herbs at a Glance" in FY 2008, expand CME program with new lectures, develop an educational initiative about talking with your health care provider about CAM, and continue to present its Distinguished Lecture Series.

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<sup>1</sup> <http://nccam.nih.gov/>

**NATIONAL INSTITUTES OF HEALTH**  
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**Summary of Changes**

FY 2007 Continuing Resolution		121,268,000	
FY 2008 Estimated Budget Authority		121,699,000	
Net change		431,000	
CHANGES	FY 2007		Change from Base
	FTEs	Budget Authority	FTEs Budget Authority
A. Built-in:			
1. Intramural research:			
a. Annualization of January 2007 pay increase			
		\$1,944,000	13,000
		1,944,000	45,000
		1,944,000	12,000
		1,312,000	13,000
		4,018,000	42,000
Subtotal		125,000	
2. Research Management and Support:			
a. Annualization of January 2007 pay increase			
		\$7,667,000	51,000
		7,667,000	177,000
		7,667,000	57,000
		2,137,000	21,000
		4,622,000	65,000
Subtotal		371,000	
Subtotal, Built-in		496,000	

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**Summary of Changes--continued**

CHANGES	FY 2007			
	Continuing Resolution		Change from Base	
	No.	Amount	No.	Amount
<b>B. Program:</b>				
1. Research project grants:				
a. Noncompeting	155	\$52,715,000	-10	-7,316,000
b. Competing	88	18,330,000	35	7,338,000
c. SBIR/STTR	12	2,679,000	0	-58,000
<b>Total</b>	<b>255</b>	<b>73,724,000</b>	<b>25</b>	<b>-36,000</b>
2. Research centers	5	2,250,000	0	0
3. Other research	66	9,510,000	0	90,000
4. Research training	66	2,850,000	0	0
5. Research and development contracts	14	9,651,000	0	149,000
Subtotal, extramural				203,000
6. Intramural research	<u>FTEs</u> 15	7,402,000	<u>FTEs</u> 1	-137,000
7. Research management and support	61	14,426,000	0	-267,000
8. Cancer control and prevention	0	0	0	0
9. Construction		0		0
10. Buildings and Facilities		0		0
11. NIH Roadmap for Medical Research	0	1,455,000	0	136,000
Subtotal, program		121,268,000		-65,000
<b>Total changes</b>	<b>76</b>		<b>1</b>	<b>431,000</b>

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**Budget Authority by Object**

	FY 2007 Continuing Resolution	FY 2008 Estimate	Increase or Decrease
Total compensable workyears:			
Full-time employment	76	77	1
Full-time equivalent of overtime & holiday hours	0	0	0
Average ES salary	\$0	\$0	0
Average GM/GS grade	12.2	12.2	0
Average GM/GS salary	\$74,225	\$76,451	\$2,226
Average salary, grade established by act of July 1, 1944 (42 U.S.C. 207)	\$89,381	\$92,062	\$2,681
Average salary of ungraded positions	\$147,976	\$152,415	\$4,439
<b>OBJECT CLASSES</b>	<b>FY 2007 Estimate</b>	<b>FY 2008 Estimate</b>	<b>Increase or Decrease</b>
Personnel Compensation:			
11.1 Full-Time Permanent	\$5,102,000	\$5,380,000	\$278,000
11.3 Other than Full-Time Permanent	1,848,000	1,943,000	95,000
11.5 Other Personnel Compensation	154,000	160,000	6,000
11.7 Military Personnel	200,000	210,000	10,000
11.8 Special Personnel Services Payments	200,000	205,000	5,000
<b>Total, Personnel Compensation</b>	<b>7,504,000</b>	<b>7,898,000</b>	<b>394,000</b>
12.0 Personnel Benefits	1,922,000	2,025,000	103,000
12.2 Military Personnel Benefits	185,000	195,000	10,000
13.0 Benefits for Former Personnel	0	0	0
<b>Subtotal, Pay Costs</b>	<b>9,611,000</b>	<b>10,118,000</b>	<b>507,000</b>
21.0 Travel & Transportation of Persons	180,000	177,000	-3,000
22.0 Transportation of Things	25,000	25,000	0
23.1 Rental Payments to GSA	2,000	2,000	0
23.2 Rental Payments to Others	3,000	3,000	0
23.3 Communications, Utilities & Miscellaneous Charges	180,000	177,000	-3,000
24.0 Printing & Reproduction	86,000	86,000	0
25.1 Consulting Services	160,000	158,000	-2,000
25.2 Other Services	5,098,000	4,667,000	-431,000
25.3 Purchase of Goods & Services from Government Accounts	11,020,000	11,153,000	133,000
25.4 Operation & Maintenance of Facilities	2,150,000	2,150,000	0
25.5 Research & Development Contracts	2,095,000	2,130,000	35,000
25.6 Medical Care	5,000	5,000	0
25.7 Operation & Maintenance of Equipment	180,000	182,000	2,000
25.8 Subsistence & Support of Persons	0	0	0
<b>25.0 Subtotal, Other Contractual Services</b>	<b>20,708,000</b>	<b>20,445,000</b>	<b>-263,000</b>
26.0 Supplies & Materials	545,000	547,000	2,000
31.0 Equipment	140,000	140,000	0
32.0 Land and Structures	0	0	0
33.0 Investments & Loans	0	0	0
41.0 Grants, Subsidies & Contributions	88,333,000	88,388,000	55,000
42.0 Insurance Claims & Indemnities	0	0	0
43.0 Interest & Dividends	0	0	0
44.0 Refunds	0	0	0
<b>Subtotal, Non-Pay Costs</b>	<b>110,202,000</b>	<b>109,990,000</b>	<b>-212,000</b>
<b>NIH Roadmap for Medical Research</b>	<b>1,455,000</b>	<b>1,591,000</b>	<b>136,000</b>
<b>Total Budget Authority by Object</b>	<b>121,268,000</b>	<b>121,699,000</b>	<b>431,000</b>

Includes FTEs which are reimbursed from the NIH Roadmap for Medical Research

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**Salaries and Expenses**

OBJECT CLASSES	FY 2007 Continuing Resolution	FY 2008 Estimate	Increase or Decrease
<b>Personnel Compensation:</b>			
Full-Time Permanent (11.1)	\$5,102,000	\$5,380,000	\$278,000
Other Than Full-Time Permanent (11.3)	1,848,000	1,943,000	95,000
Other Personnel Compensation (11.5)	154,000	160,000	6,000
Military Personnel (11.7)	200,000	210,000	10,000
Special Personnel Services Payments (11.8)	200,000	205,000	5,000
<b>Total Personnel Compensation (11.9)</b>	<b>7,504,000</b>	<b>7,898,000</b>	<b>394,000</b>
Civilian Personnel Benefits (12.1)	1,922,000	2,025,000	103,000
Military Personnel Benefits (12.2)	185,000	195,000	
Benefits to Former Personnel (13.0)	0	0	0
<b>Subtotal, Pay Costs</b>	<b>9,611,000</b>	<b>10,118,000</b>	<b>507,000</b>
Travel (21.0)	180,000	177,000	-3,000
Transportation of Things (22.0)	25,000	25,000	0
Rental Payments to Others (23.2)	3,000	3,000	0
Communications, Utilities and Miscellaneous Charges (23.3)	180,000	177,000	-3,000
Printing and Reproduction (24.0)	86,000	86,000	0
<b>Other Contractual Services:</b>			
Advisory and Assistance Services (25.1)	160,000	158,000	-2,000
Other Services (25.2)	5,098,000	4,667,000	-431,000
Purchases from Govt. Accounts (25.3)	6,166,000	6,182,250	16,250
Operation & Maintenance of Facilities (25.4)	2,150,000	2,150,000	0
Operation & Maintenance of Equipment (25.7)	180,000	182,000	2,000
Subsistence & Support of Persons (25.8)	0	0	0
<b>Subtotal Other Contractual Services</b>	<b>13,754,000</b>	<b>13,339,250</b>	<b>-414,750</b>
Supplies and Materials (26.0)	545,000	547,000	2,000
<b>Subtotal, Non-Pay Costs</b>	<b>14,773,000</b>	<b>14,354,250</b>	<b>-418,750</b>
<b>Total, Administrative Costs</b>	<b>24,384,000</b>	<b>24,472,250</b>	<b>88,250</b>

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**Authorizing Legislation**

	PHS Act/ Other Citation	U.S. Code Citation	2007 Amount Authorized	FY 2007 Continuing Resolution	2008 Amount Authorized	FY 2008 Budget Estimate
Research and Investigation	Section 301	42§241	Indefinite	\$118,418	Indefinite	\$118,849
Complementary and Alternative	Section 402(a)	42§285b	Indefinite		Indefinite	
National Research Service Awards	Section 485D(j)	42§288		2,850		2,850
<b>Total, Budget Authority</b>				<b>121,268</b>		<b>121,699</b>

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**Appropriations History**

Fiscal Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation <u>1/</u>
2000	50,168,000 <u>2/</u>	68,000,000	56,214,000	68,753,000
Rescission				-363,000
2001	71,362,000 <u>2/</u>	78,880,000	100,089,000	89,211,000
Rescission				-54,000
2002	100,063,000	99,288,000	110,000,000	104,644,000
Rescission				-52,000
2003	112,547,000	112,547,000	114,149,000	114,149,000
Rescission				-742,000
2004	116,202,000	116,202,000	117,092,000	117,752,000
Rescission				-774,000
2005	121,116,000	121,116,000	121,900,000	123,116,000
Rescission				-1,011,000
2006	122,692,000	122,692,000	126,978,000	122,692,000
Rescission				-1,227,000
2007	120,554,000	120,554,000	121,982,000	121,465,000 <u>3/</u>
2008	121,699,000			

1/ Reflects enacted supplementals, rescissions, and reappropriations.

2/ Excludes funds for HIV/AIDS research activities consolidated in the NIH Office of AIDS Research

3/ Annualized current rate

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

OFFICE/DIVISION	FY 2006 Actual	FY 2007 Continuing Resolution	FY 2008 Estimate
Office of the Director	8	8	8
Office of Administrative Operations	15	15	15
Office of Communication and Public Liaison	8	8	8
Office of Science Policy and Operations	6	6	6
Division of Extramural Research and Training	11	13	13
Office of Scientific Review	5	5	5
Office of International Health Research and Office of Special Populations	3	3	3
Office of Clinical and Regulatory Affairs	3	3	3
Division of Intramural Research	15	15	16
Total	74	76	77
Includes FTEs which are reimbursed from the NIH Roadmap for Medical Research			
FTEs supported by funds from Cooperative Research and Development Agreements			
	(0)	(0)	(0)
FISCAL YEAR	Average GM/GS Grade		
2004	11.6		
2005	11.8		
2006	12.2		
2007	12.2		
2008	12.2		



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**Detail of Positions**

GRADE	FY 2006 Actual	FY 2007 Continuing Resolution	FY 2008 Estimate
Total, ES Positions	0	0	0
Total, ES Salary	0	0	0
GM/GS-15	8	8	8
GM/GS-14	17	17	17
GM/GS-13	11	13	13
GS-12	12	12	12
GS-11	2	2	3
GS-10	0	0	0
GS-9	3	3	3
GS-8	2	2	2
GS-7	3	3	3
GS-6	0	0	0
GS-5	1	1	1
GS-4	1	1	1
GS-3	1	1	1
GS-2	0	0	0
GS-1	0	0	0
Subtotal	61	63	64
Grades established by Act of July 1, 1944 (42 U.S.C. 207):			
Assistant Surgeon General	0	0	0
Director Grade	2	2	2
Senior Grade	0	0	0
Full Grade	0	0	0
Senior Assistant Grade	0	0	0
Assistant Grade	0	0	0
Subtotal	2	2	2
Ungraded	4	4	4
Total permanent positions	62	0	0
Total positions, end of year	83	85	86
Total full-time equivalent (FTE) employment, end of year	74	76	77
Average ES salary	0	0	0
Average GM/GS grade	12.2	12.2	12.2
Average GM/GS salary	72,316	74,225	76,451

Includes FTEs which are reimbursed from the NIH Roadmap for Medical Research.

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**New Positions Requested**

	FY 2008		
	Grade	Number	Annual Salary
Chemist	11	1	\$55,706
<b>Total Requested</b>		1	