

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

Office of AIDS Research

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**JUSTIFICATION  
OFFICE OF AIDS RESEARCH**

Budget Authority:

	FY 2001 Actual	FY 2002 Appropriation	FY 2002 Current Estimate	FY 2003 Estimate	Increase or Decrease
Current Law BA	\$2,242,994,000	\$2,511,676,000	\$2,510,672,000	\$2,765,438,000	\$254,766,000
Accrued Costs	4,021,000	4,282,000	4,282,000	4,559,000	277,000
Proposed Law BA	2,247,015,000	2,515,958,000	2,514,954,000	2,769,997,000	255,043,000

**INTRODUCTION**

**The Global HIV/AIDS Pandemic**

<b>Group</b>	<b>People Newly Infected in 2000</b>	<b>People Living with HIV/AIDS</b>	<b>AIDS Deaths in 2000</b>	<b>Total AIDS Deaths</b>
Adults <i>Women</i>	4.7 Million <i>2.2 Million</i>	34.7 Million <i>16.4 Million</i>	2.5 Million <i>1.3 Million</i>	17.5 Million <i>9.0 Million</i>
Children	600,000	1.4 Million	500,000	4.3 Million
Total <i>Source: UNAIDS</i>	5.3 Million	36.1 Million	3.0 Million	21.8 Million

AIDS is the greatest international health challenge of our generation. HIV has already infected more than 50 million people around the world, and AIDS has killed approximately 22 million people, surpassing tuberculosis and malaria as the leading infectious cause of death worldwide (1, 2). If the global spread of HIV/AIDS continues unchecked, South and Southeast Asia, and perhaps China will follow the disastrous course of sub-Saharan Africa. Rapid increases in HIV infection also are occurring in Eastern Europe and Central Asia, and AIDS represents a serious threat in Latin America and the Caribbean.

Recent data indicate that worldwide there are now almost equal numbers of men and women infected with HIV. In sub-Saharan Africa, UNAIDS/WHO estimated that more women than men were living with HIV/AIDS at the end of 1999: 12.2 million women and 10.1 million men between the ages of 15-49. Curbing the transmission of HIV from infected mother to infant is an especially compelling challenge in developing countries.

The coexistence of other endemic diseases widely prevalent in developing countries, such as respiratory and gastrointestinal infections, complicate treatment and pose additional problems for medical personnel caring for HIV-infected individuals. Of particular note is the parallel epidemic of tuberculosis in the developing world. Attitudes, beliefs, and taboos surrounding sex, the status of women and children, and the source and etiology of HIV can complicate attempts to control transmission and provide appropriate prevention and treatment.

### **The Epidemic in the United States**

The HIV/AIDS epidemic in the United States continues to evolve. The incidence of new AIDS cases has declined, due largely to expanded use of new antiretroviral therapies that prevent progression of HIV infection to AIDS. However, the decline in death rates observed in the late 1990s has now leveled off and, more disturbingly, the rate of new HIV infections has not changed since 1990 and remains constant at about 40,000 new infections each year, according to CDC estimates. This means that the overall epidemic is continuing to expand (3, 4, 5). In fact, HIV infection rates are continuing to climb among women, racial and ethnic minorities, young homosexual men, individuals with addictive disorders, and people over 50 years of age (3, 6). The appearance of multi-drug resistant strains of HIV presents an additional serious public health concern (7, 8, 9, 10, 11). These data forebode an epidemic of even greater magnitude in the coming years.

AIDS disproportionately affects African Americans and Hispanics. They account for 45 percent and 20 percent, respectively, of all persons newly diagnosed with AIDS during 1998. CDC's HIV/AIDS Surveillance Report of June 1999 states that among women with AIDS, minorities account for 80 percent of cases; among men, minorities account for 61 percent of cases. Addressing these racial disparities is a high priority for the NIH.

### **Setting the AIDS Research Priorities**

To respond to this pandemic, the NIH has developed a comprehensive biomedical and behavioral research program to better understand the basic biology of HIV, develop effective therapies to treat and control HIV disease, and design interventions to prevent new infections from occurring. The NIH supports AIDS research both in NIH intramural laboratories as well as at academic and medical institutions in the U.S. and internationally. The Office of AIDS Research (OAR) is mandated by public law to plan and coordinate the AIDS research programs sponsored by all of the NIH Institutes and Centers.

The OAR develops an annual comprehensive AIDS research plan called the *NIH Plan for HIV-Related Research* that is based on the most compelling scientific priorities that will lead to better therapies and prevention strategies for HIV infection and AIDS. The Plan serves as the framework for developing the annual NIH AIDS budget; for determining the use of NIH AIDS-designated dollars; for tracking and monitoring expenditures; and for informing the scientific community, the public, and the AIDS-affected community about NIH AIDS research priorities. OAR has established an effective model for developing a consensus on the scientific priorities of the plan. Planning Groups for each of the areas of the plan, composed of NIH scientists and experts from academia and industry, as well as representatives from the AIDS community meet together in workshops to develop each section of the plan. The plan also is reviewed by the OAR Advisory Council.

The plan is divided into Scientific Areas including: Natural History and Epidemiology; Etiology and

Pathogenesis; Therapeutics; Vaccines; and Behavioral and Social Science. The plan further addresses critical issues that cut across all of the scientific areas: Racial and Ethnic Minorities; International Research; Training, Infrastructure, and Capacity Building; and Information Dissemination. The FY 2003 plan includes three new important areas: Microbicides, Prevention Research, and Women and Girls.

In collaboration with the Director of NIH, the OAR Director determines the total annual AIDS research budget. Within that total, the OAR Director establishes the AIDS research budgets for each NIH institute and center, in accordance with the priorities and objectives of the plan. The institutes and centers use these funds to support their research portfolios in both intramural programs (on the NIH campus) and extramural grants and contracts awarded to research institutions in the United States and around the world.

### **FY 2003 Plan and Budget Request for HIV-Related Research: Research Priorities**

This budget request is framed on the scientific priorities and objectives of the FY 2003 NIH Plan for HIV-Related Research. The entire plan can be found on the OAR website:

<http://www.nih.gov/od/oar/public/public.htm#PLAN>. The FY 2003 research agenda continues the following over-arching themes: research to prevent and reduce HIV transmission, including vaccines, microbicides, and behavioral interventions; research to develop therapies to better treat those who are already infected; international research, particularly in developing countries; and biomedical and behavioral research targeting the disproportionate impact of the AIDS epidemic on minority populations in the United States. These efforts all require a strong foundation of basic science. The key priorities for each research area of the plan and directions for future research are summarized below.

#### References:

1. "AIDS Epidemic Update: December 2000," (UNAIDS/WHO, Geneva, Switzerland, 2000).
2. "The World Health Report 2000," (WHO, Geneva, Switzerland, 2000).
3. *Morbidity and Mortality Weekly Report*. **50**, 434 (2001).
4. "Centers for Disease Control and Prevention HIV Prevention Strategic Plan Through 2005," (CDC, 2001).
5. "HIV/AIDS Update – A Glance at the HIV Epidemic," (CDC, 2001).
6. "U.S. HIV and AIDS Cases Reported through June 2000," *CDC HIV/AIDS Surveillance Report, Vol. 12* (2000).
7. N. Loder, *Nature* **407**, 120 (2000).
8. H. Salomon et al., *AIDS* **14**, 17 (2000).
9. Y.K. Chow et al., *Nature* **361**, 650 (1993).
10. M. Waldholz, "Drug Resistant HIV Becomes More Widespread," *Wall Street Journal*, 2/5/99, p. B-5.
11. "World Health Report on Infectious Diseases 2000: Overcoming Antimicrobial Resistance," (WHO, Geneva, 2000).

## SCIENCE ADVANCES AND NEW INITIATIVES

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### THERAPEUTICS

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#### Research Priorities of the FY 2003 Plan

- Advance the discovery and validation of new viral and cellular targets.
- Develop new therapeutic agents that: target drug-resistant virus; have activity in viral compartments and cellular reservoirs; and have improved pharmacologic properties.
- Develop *ex vivo* and/or animal models to evaluate the biological properties of drugs, including their pharmacology and toxicology.
- Develop safe, effective, feasible, and conveniently administered strategies to interrupt maternal-fetal transmission of HIV.
- Evaluate the safety and pharmacokinetics of antiviral agents in pregnant and breast-feeding women, including studies on the transplacental passage of the agents and safety for the fetus.
- Evaluate pharmacokinetics, metabolism, tissue absorption, and drug elimination in the newborn.
- Develop and evaluate therapeutic approaches that will improve and sustain immune function.
- Determine optimal therapeutic strategies including when to start, change, sequence, or “interrupt” therapies.
- Target populations, especially women, injecting drug users (IDUs), children, adolescents, older adults, and across racial/ethnic groups.
- Identify regimens with improved toxicity, efficacy, pharmacokinetics, activity in viral reservoirs, and adherence potential.
- Enhance capabilities for long-term follow-up and evaluate the long-term effects of therapy including delayed or late toxic effects.
- Evaluate the effect of co-infection especially with HBV, HCV, or TB on the management of HIV.
- Determine the bidirectional effects of co-infection and treatments on disease progression and drug interactions.
- Expand international clinical research programs in countries with limited resources.
- Evaluate the clinical and public health impact of prophylactic and therapeutic interventions for co-infections/OIs.
- Evaluate the clinical and public health impact of antiretroviral treatment.
- Design studies to improve and facilitate the delivery of therapeutic interventions for HIV disease.

The development of therapeutics for HIV/AIDS has long been a focus of NIH. Today, many HIV-infected people are living with the benefits resulting from NIH-supported research in this area. The development of combination regimens including protease inhibitors has extended the length and quality of life for many HIV-infected individuals in the United States and Western Europe. Unfortunately, however, highly active antiretroviral therapy (HAART) has failed to eradicate HIV, and a growing proportion of patients receiving therapy experience treatment failure. Some patients find it difficult or impossible to comply with arduous treatment regimens, develop toxicities and side-effects, or cannot afford their high cost of approximately \$15,000 per year. Others fail to obtain a satisfactory reduction in viral load even while adhering to treatment regimens. In addition, metabolic complications, including insulin resistance, and body composition changes such as deforming deposits of abdominal adipose tissue, have emerged in individuals who have been on long-term antiretroviral regimens. Finally, an increasing number of treatment failures are linked to the

increasing emergence of drug-resistant HIV.

The need for simpler, less toxic, and cheaper drugs and drug regimens to treat HIV infection and its associated opportunistic infections (OIs), malignancies, and other complications, continues to be a high priority. This includes the discovery and development of the next generations of antiviral drugs directed against new cellular and viral targets. Clinical trials will help to better define when to begin and/or switch drugs within a regimen as well as to identify regimens for treatment-experienced individuals who no longer respond to these anti-HIV drugs. Antiretroviral and OI prophylaxis regimens are becoming increasingly complex with respect to drug-drug interactions and adherence. Protease inhibitors, in particular, interact with each other and many other medications commonly used by HIV-infected individuals. Additional research is under way and planned with the goal of minimizing viral replication and delaying disease progression, drug resistance, and development of manifestations such as metabolic complications and body composition changes. Further studies also are needed to evaluate delayed and long-term effects of these antiretroviral drugs.

The scientific agenda for this area of research is answering the following questions: When should antiretroviral (HAART) therapies be initiated? When should they be changed? How long can successful therapies maintain decreased viral loads, increased CD4 counts, and improved clinical outcomes? What is the basis for the emergence of drug resistance, and how can it be prevented? What are the long-term clinical efficacy and tolerability associated with HAART? Can treatment strategies be developed for patients who no longer respond to current regimens? Can immune-restorative/immune-enhancing approaches rebuild the immune system, so that disease progression is delayed? Can treatment strategies be developed to eliminate HIV, so that it is not transmitted from an infected individual to others?

Recent advances in therapeutics research underscore the importance of continued and further collaboration of Government- and industry-sponsored drug development research and clinical trials with the common goal of developing therapeutic regimens that slow disease progression, extend life spans, and improve the quality of life for HIV-infected individuals.

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## ETIOLOGY AND PATHOGENESIS

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### Research Priorities of the FY 2003 Plan

- Facilitate the translation of new insights into HIV biology to develop novel interventions for the prevention and treatment of HIV infection.
- Elucidate the biologic determinants of HIV transmission between individuals and define the mechanisms by which host factors, viral factors, and co-factors may influence the process of virus transmission.
- Characterize the dynamics of virus-host interaction through the course of HIV infection.
- Investigate the mechanisms of persistence of HIV infection.
- Define the direct and indirect mechanisms that lead to T-cell depletion following HIV infection and the factors that determine numerical and functional reconstitution of T-cell populations in response to therapy.
- Enhance and expand innovative studies of human immunology to guide vaccine development and immune reconstitution efforts.
- Investigate the impact of gender, health status, race, and age on the biology of HIV infection and on the responses to therapies and vaccines.
- Advance the understanding of the mechanisms responsible for the toxicities and long-term complications of antiretroviral therapy and the factors that underlie changes in the causes of morbidity and mortality in an era of increasingly effective therapies.

Of paramount importance in our fight against HIV/AIDS is maintaining a strong commitment to basic research. Tremendous progress has been made in understanding the fundamental steps in the life-cycle of HIV, the host-virus relationship and the clinical manifestations attending HIV infection and AIDS. Groundbreaking research on basic HIV biology and AIDS pathogenesis has revolutionized the design of drugs, the methodologies for diagnosis, and the monitoring for efficacy of antiviral therapies. In spite of these achievements, we still do not have a clear understanding of major aspects of the virus interaction with the infected individual, the nature of the immune response to the virus, how the virus establishes infection and spreads throughout the body, and its mechanisms of pathogenesis. This basic knowledge is critical for our efforts to prevent and control HIV infection and disease progression. A substantial portion of NIH AIDS-related research will continue to be devoted to basic research. This area of investigation, driven by investigator-initiated research, has provided the constantly advancing knowledge base that permits the development of new applications for the prevention and treatment of disease.

Some of the outstanding questions within the area of etiology and pathogenesis research include: What role do the specific products of HIV (the viral genes and their protein products) play in the viral life cycle in individual cells and within the body of infected individuals? How is HIV transmitted between cells and between individuals? What contribution does the immune system make to controlling the infection and to the disease process? What mechanisms are involved in cell injury and death in the immune, nervous, and other systems that HIV afflicts? What host factors and cofactors influence the course and outcome of HIV infection? What is the relationship of HIV infection to the associated malignancies, OIs, neurological impairments, and metabolic disturbances that characterize AIDS?

The dramatic success of effective antiretroviral therapies in reducing plasma viremia to undetectable levels had raised the intriguing possibility that prolonged therapy might lead to virus eradication. However, recent data have indicated that the virus can persist in the body of HIV-infected patients for almost a lifetime. HIV can persist in a latent reservoir of resting memory CD4 T cells that is established very early after infection and by continuously replicating, albeit at very low levels, even in the presence of antiretroviral therapies able to drive viral load below the limits of detection. A better understanding of the different mechanisms of viral persistence is needed to understand the reasons for drug failure, to design rational approaches for virus eradication, and to better assess the impact of persistence on HIV transmission and its implications for HIV prevention.

Understanding the normal development and functioning of the human immune system is crucial to our ability to understand the effects of HIV on the immune system and the pathogenesis of AIDS. This understanding also holds the key to designing rational immune reconstitution approaches in persons undergoing antiretroviral treatment and identifying the characteristics of the immune response that are needed for a protective vaccine.

The basic science underlying HIV etiology and pathogenesis research is generally gender neutral. Basic mechanisms of viral replication and pathogenesis are not expected to differ in women and men. However, there are differences in the way HIV infection is transmitted and how the disease is manifested in women and men. Studies have been designed to elucidate the pathogenic mechanisms more commonly observed in women, children, and adolescents infected with HIV. Transmission of HIV from a mother to her infant may occur *in utero* through transplacental passage of virus, during delivery, or postnatally through breast-feeding. Many basic issues associated with maternal-fetal transmission remain unclear and are actively under investigation.

To ensure the continued growth of a powerful arsenal against HIV, it is imperative that scientists continue to study HIV pathogenesis and identify new targets for the design of drugs and vaccines. Design and development of new drugs are based on the study of the fundamental structural properties of the relevant viral targets. Efforts to develop effective therapies to treat HIV infection and its associated illnesses are providing a critical proving ground for the concept of rational drug design and for the refinement and advancement of its methods.

AIDS is associated with a broad spectrum of cancers and tumors. Because HIV causes immunosuppression and most AIDS-associated malignancies are strongly associated with viruses, HIV infection provides a unique model to study the interplay of viruses, a dysfunctional immune system, and the development of cancers. Elucidation of the interactive factors involved in the pathogenesis of AIDS-associated malignancies will possibly translate into the identification of new targets for prevention and treatment.

HIV infection results in progressive damage of the immune systems of infected individuals and makes them susceptible to a diverse collection of bacteria, viruses, fungi, and protozoa that represent the major causes of suffering and death for HIV-infected individuals. Opportunistic infections can affect virtually every tissue and organ system in the body, resulting in severe functional compromise. NIH currently supports a comprehensive portfolio of basic research on the pathogenesis of AIDS-associated OIs.

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## NATURAL HISTORY AND EPIDEMIOLOGY

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### Research Priorities of the FY 2003 Plan

- Target epidemiologic studies to achieve quantitative measurements of the success and failure of prevention interventions among HIV-infected populations and their uninfected contacts. This approach includes measuring the impact of treatment interventions (e.g., antiviral therapy, medication adherence programs, and injection drug use treatment programs) in modifying HIV spread within populations, and treatment regimens to prevent mother-to-child HIV transmission, particularly transmission by breast-feeding.
- Characterize how new HIV treatments lead to a changing spectrum of clinical outcomes (morbidity, adverse events, and mortality) and risk-taking behaviors.
- Develop, maintain and effectively utilize cohort studies among populations experiencing emerging epidemics (e.g., the underserved, heterosexual men and women, homosexual men with persistent risk-taking behaviors, and injection drug users). Use this approach domestically and internationally to study HIV/AIDS pathogenesis and natural history in the presence of interventions, including vaccine trials.
- Foster research by promoting innovative study design and analysis in observational studies and intervention trials and by developing and maintaining repositories of biological specimens.
- Develop and evaluate accurate, reproducible, and affordable virologic, immunologic, and genetic assays suitable for large-scale epidemiologic research in industrialized and developing nations. Such tools should enhance our understanding of viral resistance, diversity, and evolution.
- Enhance understanding of the interactions between HIV and concomitant infections (e.g., hepatitis C and B) and the natural history, prevention, treatment, and management of both. Investigate the implications of concomitant infections on immunogenicity and efficacy of HIV vaccine candidates.

Epidemiologic research is needed to monitor epidemic trends, develop and evaluate prevention modalities, follow the changing clinical manifestations of HIV disease in different populations, and measure the effects of treatment regimens. NIH will continue to support research to examine topics in HIV transmission, HIV/AIDS disease progression (including the occurrence of OIs), malignancies, metabolic complications, neurological and behavioral dysfunctions, and the development of other HIV/AIDS-related conditions. Domestically as well as internationally, the populations affected by HIV/AIDS are also those most severely affected by the spreading epidemics of sexually transmitted diseases (STDs) and tuberculosis (TB). Further studies are needed to investigate the effects of viral, host, and other factors on transmission and disease progression. Results from these studies will provide new directions and improvements in HIV/AIDS prevention and care.

The effects of the new antiretroviral therapies on HIV transmission are not completely understood. A few studies suggest that individuals on antiretroviral therapy may be less likely to transmit HIV infection because they have lower viral loads after treatment. The result of this phenomenon may be a decrease in the rates of transmission and HIV incidence. However, the net effect of the perception that individuals on antiretrovirals may be less likely to transmit HIV infection may be that more people are taking increased sexual risks. Thus, the paradoxical consequence of the lower viral loads that result from antiretroviral therapies may be higher rates of HIV transmission and infection.

Because biological, pharmacological, psychological, and behavioral factors all potentially influence the impact of antiretroviral therapies on HIV transmission, there is a need to evaluate the specific contributions of these factors and their net impact on HIV transmission.

Another area of primary prevention research focuses on developing new or improved means of reducing perinatal transmission in the United States and worldwide, with particular emphasis on methods appropriate to the developing world. NIH is supporting studies to better understand the timing, mechanisms, and risk factors of perinatal transmission; whether specific strains are more likely transmitted; the potential benefit of Caesarean section; and development of newer therapeutic regimens and immunotherapy. The elimination of perinatal transmission in our nation and the world is a goal that is being vigorously pursued.

NIH will continue to emphasize the importance of epidemiologic cohort studies to investigate the mechanisms of disease progression, the causes of death, and the impact of therapy in changing the spectrum of HIV disease. The strengthening of existing cohorts in the United States will allow the identification of long-term effects of HIV therapy. The assembly of new, representative cohorts, specimen repositories, and databases in developing countries will be important to study key co-factors (e.g., infectious and nutritional) that modify HIV disease.

Like many other diseases in the United States, HIV/AIDS has become concentrated in urban, disenfranchised communities of low socioeconomic status, as well as in certain racial and ethnic minority groups (i.e., African Americans and Hispanics). A determination of the biological characteristics, sociocultural factors, and health services issues that contribute to the differential dynamics of HIV transmission and disease progression in men, women, and in different race/ethnicity groups is needed for developing appropriate prevention and treatment strategies across at-risk populations in domestic and international settings.

The availability of accurate and reproducible laboratory assays has become one of the most important means to rapidly acquire knowledge of the HIV epidemic in different populations and geographic areas. Molecular biology methods are invaluable to determine key viral and host features that can be used for screening, diagnosis, and prognosis. In developing countries, simple and affordable assays are necessary to define the epidemiologic features of emerging or evolving epidemics and for clinical use in hard-to-reach locales. NIH will foster basic and applied research that will develop inexpensive virologic, immunologic, and genetic assays for use in both domestic and developing country settings.

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## BEHAVIORAL AND SOCIAL SCIENCE

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### Research Priorities of the FY 2003 Plan

- Understand and address the disparate risks and consequences of HIV infection, as well as access, utilization, and quality of prevention and health care services among individuals and groups differing by socioeconomic status, geographic location, gender, sexual orientation, age, and ethnicity.
- Investigate changing patterns, contexts, and kinds of substance use (injection and other forms of drug use and routes of transmission, and alcohol use) and their implications for HIV transmission, with an emphasis on associated sexual risk-taking behaviors.
- Identify and address issues related to the initiation, sustainability, and renewal of HIV/AIDS risk reduction efforts at the individual, dyadic, group, and community levels over time, including changing perceptions and risk behaviors associated with the development of new HIV treatments, services, and prevention technologies.
- Better understand and address the psychological, social, economic, and cultural dynamics of gender and sexuality that play a role in promoting sexual health or conferring sexual risk related to HIV transmission.
- Conduct and support operational and health services research to better understand and address barriers to, and facilitators of, the implementation of science-based HIV/AIDS interventions at the public health level.
- Support research on the social and environmental factors and contexts that contribute to the co-occurrence of HIV/AIDS, other infectious diseases (e.g., tuberculosis, STDs, and hepatitis), substance use, mental illness, and homelessness; and support research on strategies for addressing such co-occurring conditions.

Studies have demonstrated that behavioral change can successfully prevent or reduce the spread of HIV infection in both domestic and international settings. Prevention programs resulting from such studies have altered sexual and drug-using behaviors and have reduced the risk of transmission in many communities and subgroups. NIH supports research to further our understanding of how to change the behaviors that lead to HIV transmission—including preventing their initiation—and how to maintain protective behaviors once they are adopted in all populations at risk. NIH also supports research on preventing and mitigating the psychosocial consequences of HIV/AIDS on individuals and communities. Three themes cross-cut, and are implicit in, priority areas in AIDS-related behavioral and social science: addressing ethical considerations in the conduct of research; further developing appropriate research methods; and investigating issues in both domestic and international settings, as appropriate.

NIH sponsors research related to the following: developing, implementing, and evaluating behavioral and social interventions to reduce HIV transmission in a range of populations and settings; strengthening our understanding of the determinants, trends, and processes of HIV-related risk behaviors and the consequences of HIV infection; developing and evaluating behavioral strategies for preventing or ameliorating the negative physical, psychological, and social consequences of HIV infection; and improving the research methodologies employed in behavioral and social science research.

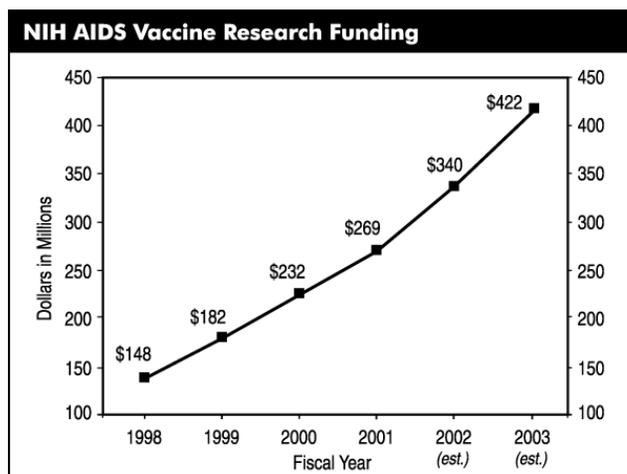
A more refined understanding of social and cultural factors that contribute to HIV risk or protection, particularly in minority communities, will have an enormous influence on the successful implementation of a broader range of preventive or therapeutic measures. Drug users and their sex partners are the fastest growing segment of AIDS cases in the United States and in many other countries. High priority is being given to research to understand the phenomenon of addiction itself, as well as the complex interaction of alcohol use, drug use, and poor impulse control, and to develop effective interventions from that knowledge base.

The development of new and more effective drug therapies—in particular combination therapies—for combating HIV infection has raised a host of behavioral questions that have significant implications for HIV prevention and treatment. With combination therapies, the number of drugs and frequency of dosing require strict adherence to regimens that may be difficult for many people to achieve. Lack of complete adherence may result in the development of drug-resistant strains of HIV, which could have devastating implications for our ability to stem transmission and treat HIV-infected individuals. In addition, as HIV-infected individuals experience improved health and a decline in detectable virus in their body as a result of taking the new combination therapies, they may believe that they are less infectious and may lapse into unsafe sexual and drug-using behaviors. This could have the effect of increasing HIV transmission, if the virus is still viable at undetectable levels. These issues highlight the importance of research on how best to ensure adherence to both pharmacological and behavioral HIV-related interventions.

### Research Priorities of the FY 2003 Plan

- Conduct clinical trials of promising vaccine candidates in both domestic and international settings, with sufficient laboratory support to define correlates of immunity.
- Continue to expand core programs in HIV/AIDS vaccine research and development to ensure that the research pipeline for vaccine research and development is robust.
- Continue to support innovative efforts to design and test vaccines that can induce antibody responses to HIV envelope capable of neutralizing a large array of HIV isolates.
- Develop a coordinated program of quality control and quality assurance for testing in both macaques and human studies for assays that now are being developed and evaluated so that assays essential for evaluation of clinical trial endpoints are in place when large efficacy trials are undertaken.
- Develop a strategy to ensure licensure of HIV vaccines for adolescents, including linking adolescent cohorts to networks that are anticipating vaccine and prevention efficacy trials as soon as possible.
- Expand immunological assessment of vaccines.
- Increase AIDS-dedicated non-human primate resources for breeding and holding.
- Invest in the development of critical vaccine research capabilities, information dissemination, and education to conduct vaccine trials in populations with a high incidence of HIV infection.
- Develop innovative ways to work with both not-for-profit and for-profit organizations to immediately build the capacity to breed macaques; develop and implement a long-term plan to ensure the future supply and housing of macaques.

A safe and effective HIV preventive vaccine is essential for the global control of the AIDS pandemic. NIH funding for HIV vaccine research increased by more than 185 percent between FY 1998 and FY 2003, resulting in the award of new grants to foster innovative research on HIV vaccines, including vaccine design and development, and the invigoration and reorganization of the NIH vaccine clinical trials effort. The new intramural Dale and Betty Bumpers Vaccine Research Center recently initiated its first clinical trial. In February 1999, NIH-supported investigators initiated the first AIDS vaccine trial in Africa. The changes implemented in this area over the past few years have enormous significance, not only for AIDS research but for other diseases as well, as progress made in the development of an AIDS vaccine will have implications for vaccines against other life-threatening illnesses.



Recent progress in HIV/AIDS vaccine research in animal models has provided strong scientific motivation to further explore and develop several vaccine concepts, and to move additional candidate vaccines into clinical testing. As a result of increased funding from NIH in the area of HIV

vaccines, many new approaches to HIV vaccines are being pursued from basic research in vaccine design and studies of immune responses in small animals through vaccine product development. At least 10 new candidate vaccines will enter Phase I trials in the next 2 years.

To address the scientific obstacles and facilitate AIDS vaccine development, NIH continues to increase support for a broad program encompassing basic, preclinical, and clinical vaccine research on candidate vaccine products. As promising vaccines move further in the vaccine pipeline, expanded trials with populations at increased risk for HIV infection will become increasingly important. HIV/AIDS vaccine research requires trained health care, medical research, and prevention specialists as well as populations at risk who will be integrally involved in development of vaccine candidates and clinical vaccine and prevention trials. International and domestic trial sites are being developed, including a cadre of trained indigenous or minority personnel, to conduct vaccine trials with the direct involvement of the communities at risk.

The development of an AIDS vaccine is a complex research challenge because HIV is unusually well-equipped to elude immune defenses, as exemplified by its ability to persist in almost all instances and eventually overcome the immune system. Many different vaccine approaches are being pursued. Initial studies are leading to more advanced vaccine candidates that may provide protection. NIH has now conducted more than 50 Phase I and two Phase II clinical trials of nearly 30 vaccine products, individually or in combination, in human volunteers in collaboration with academic investigators and company co-sponsorship. Many of the early trials involved recombinant HIV envelope protein, the outer coating of the virus. However, complex vaccine products and products that contain other components of HIV have been included in a large number of these trials in the past few years.

To move forward in large-scale vaccine or prevention studies will require major efforts in communities that may be rarely involved in medical research. Development of infrastructure may need to be undertaken, as well as information dissemination and education of staff, potential participants, and community leaders of the groups that will participate in vaccine research.

Clearly, it will be more difficult to formulate an HIV/AIDS vaccine than was the case for prior vaccines directed against acute viral diseases. The scientific community must be mustered to make a broad and diverse attack upon this daunting challenge. Vaccine research is needed to attempt to unravel a wide variety of questions about the structure of the virus, its immunogenicity, the protective role of different components of the immune response, and the mechanism of viral escape from immune surveillance. In addition, fundamental work must be done to develop and refine a number of potentially effective methods for presentation of HIV antigens, including vectors engineered from a wide variety of viruses, and naked DNA itself. Building on this base, it will probably be important to utilize non-human primate models to elucidate the mechanisms of protective immunity and to screen a multitude of candidate immunogens for the most promising products for clinical trials in humans.

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## MICROBICIDES

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### **Research Priorities of the FY 2003 Plan**

- Elucidate basic mechanisms of HIV transmission (virus and host factors) at mucosal surfaces that are important for microbicide research and development in diverse populations.
- Support the discovery, development, and preclinical evaluation of topical microbicides alone and/or in combination.
- Develop and assess acceptable formulations and modes of delivery for microbicides, bridging knowledge and applications from the chemical, pharmaceutical, physical, bioengineering, and social sciences.
- Conduct clinical studies of candidate microbicides to assess safety, acceptance, and effectiveness in reducing sexual transmission of HIV in diverse populations in domestic and international settings.
- Conduct basic and applied behavioral and social science research to enhance microbicide development, testing, acceptability, and use domestically and internationally.
- Establish and maintain the appropriate infrastructure (including training) needed to conduct microbicide research domestically and internationally.

The vulnerability of women to acquiring HIV infection demands the development of effective and acceptable female-controlled chemical and physical barrier methods, such as topical microbicides, to reduce HIV transmission. To enhance and stimulate research in this area, the OAR co-sponsored the first international conference devoted to all aspects of microbicide research and development. The conference included more than 600 participants from 45 nations.

NIH is supporting Phase I, Phase II, and Phase III trials of various topical microbicides, as well as behavioral and social research on the acceptability and use of microbicides among different populations. The FY 2003 Plan includes a specific research agenda to accelerate microbicides research and to ensure a comprehensive program for screening, discovery, development, preclinical testing, and clinical evaluation of potential spermicidal and nonspermicidal topical agents and other barrier methods.

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## PREVENTION RESEARCH

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### Research Priorities of the FY 2003 Plan

- Elucidate the complex relationship among biological, behavioral, social, and environmental factors associated with risk of and protection from HIV transmission and acquisition, in order to prevent the spread of HIV infection.
- Develop and test innovative HIV preventive interventions—individually and in combination—for both HIV-infected and -uninfected populations.
- Identify and address issues in the initiation, sustainability, and adaptability of HIV prevention efforts among individuals and communities over time.
- Support research to better understand and mitigate the physical, psychological, and social consequences of HIV infection and disease progression on individuals, dyads, and groups (e.g., families, networks, and communities).
- Support research that addresses methodological and ethical issues in the conduct of HIV prevention studies, including those studies that are cross-cultural, multidisciplinary, and multimodal.
- Support research to better understand how to implement evidence-based HIV prevention interventions. Identify and evaluate strategies for translating proven/effective interventions into public health practice, including the integration of prevention into clinical care.
- Enhance capacity, training, and infrastructure for the conduct of HIV prevention research, especially in resource-poor settings.

NIH supports a comprehensive approach to HIV prevention science research that includes contributions from the biomedical, behavioral, and social sciences. The NIH prevention science research agenda targets interventions to both infected and uninfected at-risk individuals to reduce HIV transmission. Our biomedical prevention research priorities include the development of topical microbicides, strategies to prevent mother-to-child transmission (including a better understanding of risk associated with breast-feeding), and management of sexually transmitted diseases. NIH also supports behavioral research strategies, including prevention interventions related to drug and alcohol use and risky sexual behaviors. Efforts continue to identify the most appropriate intervention strategies for different populations and sub-epidemics in the United States and around the world.

NIH's HIV prevention research activities include both basic and intervention studies. Research that elucidates the fundamental mechanisms of human behavior and disease transmission and progression provides the essential basic knowledge needed for the development of testable interventions. Such studies include those that examine the range and interaction of biological, neurological, psychological, familial, social network, and other environmental factors that have an impact on HIV transmission, acquisition, or protection.

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## RACIAL AND ETHNIC MINORITIES

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### Research Priorities of the FY 2003 Plan

- Invest and expand funding in research infrastructure at minority institutions to increase capacity to support HIV/AIDS research.
- Increase the number of funded minority investigators for greater efficacy in HIV research.
- Decrease the health disparities among racial and ethnic minorities to increase their health status to that of the majority population with respect to HIV infection.
- Include racial and ethnic minorities in prevention, therapeutic, vaccine, and clinical trials in numbers that reflect the current incidence data.
- Develop, pilot, evaluate, and sustain effective interventions to prevent HIV transmission and its co-morbidities.
- Promote and increase adherence to treatment regimens among racial and ethnic minorities.

Research to address the disproportionate impact of the HIV/AIDS epidemic on United States racial and ethnic minority communities continues to be a high priority. OAR has established the Ad Hoc Working Group on Minority Research to provide advice on the scientific priorities in this critical research area, which are reflected in this plan. OAR is directing increased resources toward new interventions that will have the greatest impact on these groups. These include interventions that address the co-occurrence of other STDs, hepatitis, drug abuse, and mental illness; and interventions that consider the role of culture, family, and other social factors in the transmission and prevention of these disorders in minority communities. NIH is making significant investments to improve research infrastructure and training opportunities for minorities, and will continue to assure the participation of minority subjects in AIDS clinical trials as well as in natural history, epidemiologic, and prevention studies. The OAR has provided additional funds to projects aimed at: increasing the number of minority investigators conducting behavioral and clinical research; targeting the links between substance abuse, sexual behaviors and HIV infection; increasing outreach education programs targeting minority physicians and at-risk populations; and expanding our portfolio of population-based research. One of these projects is a series of Training and Career Development Workshops for racial and ethnic minority investigators. These workshops provide minority investigators with an opportunity to learn about available NIH funding mechanisms and to meet and network with senior minority investigators who receive significant levels of NIH funding.

NIH supports a broad array of behavioral intervention studies with specific focus on African American populations. These studies are characterizing the disease process in drug users, factors influencing disease progression, consequences of multiple co-infections, effectiveness of therapeutic regimens, and impact of health care access and adherence to therapeutic regimens on disease outcomes. The increasing number of minority AIDS cases provide a powerful reminder that behavioral research must continue to define and utilize cultural, social, and contextual factors that affect HIV risk behaviors. The role of alcohol and drug use in facilitating HIV transmission through social networks in all communities also must be explored within these social frameworks.

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## INTERNATIONAL AIDS RESEARCH

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### Research Priorities of the FY 2003 Plan

- Develop in-country infrastructure for the conduct of clinical trials of therapeutic and prevention interventions, including the use of antiretroviral therapy (ART), therapies for opportunistic infections (OIs), vaccines, microbicides, other biomedical and behavioral strategies to prevent sexual transmission, and interventions to prevent mother-to-child transmission.
- Facilitate the rapid initiation of studies of the use of ART in resource-limited settings through: (1) training developing country clinicians and scientists; (2) strengthening in-country laboratory capacity; (3) developing low cost alternatives to viral load and CD4 cell counts for monitoring treatment efficacy and toxicity; (4) creating innovative funding approaches; and (5) establishing early dialogue with industry.
- Define the spectrum of HIV-related illness relative to diverse geographic settings, including OIs and those conditions that emerge as a consequence of ART and longer term survival.
- Support studies addressing drug and alcohol use and risk of transmitting and acquiring HIV infection, including transition between non-injection and injection drug use, drug addiction treatment strategies, and the relationship between alcohol use and sexual risk behaviors.
- Address ethical challenges in research in resource-poor settings, including developing in-country human subjects review committees; ensure a leadership role for in-country investigators in the countries where studies take place.

To address the increasing urgency of the global AIDS pandemic, the OAR has established a new initiative and strategic plan for global research on HIV/AIDS aimed at slowing the disaster and reversing its destruction of communities, economies, and nations worldwide. The Global AIDS Research Initiative and Strategic Plan reaffirms NIH's long-standing commitment to international AIDS research and will significantly increase research efforts in the coming year to benefit resource- and infrastructure-poor nations. NIH supports a growing portfolio of research conducted in collaboration with investigators in developing countries. Results of this research benefit the people in the country where the research is conducted as well as people affected by HIV/AIDS worldwide. NIH collaborates with UNAIDS, host country governments, and in-country scientists for vaccine development and in preparations for efficacy trials. NIH-sponsored programs target studies on factors related to HIV transmission and the pathogenic mechanisms associated with HIV disease progression through studies in Africa, Asia, and Latin America. It is critical to the success of international studies that foreign scientists be full and equal partners in the design and conduct of collaborative studies and that they have full responsibility for the conduct of studies in-country. To that end, NIH supports international training programs and initiatives that help to build infrastructure and laboratory capacity in developing countries where the research is conducted.

To enhance NIH international research efforts, the OAR established the Global AIDS Research Strategy Group, co-chaired by the Director of OAR and the Director of NIAID. The Group provides a forum for discussion of current and planned international HIV research efforts; key scientific policy and bioethics issues in international research; and exchange of scientific information. The Group includes representatives of the NIH institutes with major international AIDS research portfolios as well as other federal agencies, departments, and international organizations.

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## TRAINING, INFRASTRUCTURE, AND CAPACITY BUILDING

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### Research Priorities of the FY 2002 Plan

- Continue to support training of domestic and international biomedical and behavioral AIDS researchers, including programs designed to recruit individuals from minority communities into research careers and to build research infrastructure in minority institutions.
- Continue to support improvement of facilities and equipment for the conduct of domestic and international AIDS research, including support of animal facilities for animal model research.

The NIH will continue to support training of domestic and international biomedical and behavioral AIDS researchers as well as the improvement of facilities and equipment for the conduct of AIDS research, including support of facilities for animal model research. Numerous NIH-funded programs have increased the number of training positions for AIDS-related research, including programs specifically designed to recruit individuals from minority communities into research careers and to build research infrastructure in minority institutions. The NIH Loan Repayment Program (LRP) was mandated by Congress under Public Law 100-607 in 1988 and authorized under 42 USC 288-1 to encourage health professionals to engage in AIDS-related research at the NIH. The Fogarty International Center sponsors the AIDS International Training and Research Program (AITRP), a program established in 1988 at the request of Congress to train scientists in developing countries to undertake AIDS research. The goal of the program is to expand scientific capabilities in the epidemiology, prevention, diagnosis, and treatment of HIV/AIDS throughout the world and to facilitate the evaluation internationally of AIDS interventions, such as vaccines and other strategies. The Regional Primate Research Centers (RPRC) Program, supported by the National Center for Research Resources, provides specialized facilities, scientific and technical personnel, animal models research and breeding, and a wide variety of non-human primate species to support diverse requirements for AIDS-related research.

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## INFORMATION DISSEMINATION

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### Research Priorities of the FY 2002 Plan

- Continue to support effective information dissemination approaches among researchers, health care providers, and affected communities to rapidly translate research into practice.

Effective information dissemination approaches will continue to be integral to HIV prevention and treatment efforts. Such programs are critical in light of the continuing advent of new and complex antiretroviral treatment regimens, the adherence issues related to HIV/AIDS treatment, the need for research communities to work and communicate globally, and the need to translate behavioral and social prevention approaches into practice. The changing pandemic and the increasing number of HIV infections in specific population groups, such as minorities and women, also underscore the need to disseminate HIV research findings and other related information to communities at risk. The flow of information among researchers, health care providers, and the affected communities represents new opportunities to rapidly translate research into practice and to shape future research directions.

### AIDS Research Benefits Other Diseases

AIDS research is unraveling the mysteries surrounding many other infectious, malignant, neurologic, autoimmune, and metabolic diseases. AIDS research has provided an entirely new paradigm for drug design, development, and clinical trials to treat viral infections. For example, the drug known as 3TC, developed to treat AIDS, is now the most effective therapy for chronic hepatitis B infection. Drugs developed to prevent and treat AIDS-associated opportunistic infections also provide benefit to patients undergoing cancer chemotherapy or receiving anti-transplant rejection therapy. AIDS also is providing a new understanding of the relationship between viruses and cancer.

NATIONAL INSTITUTES OF HEALTH

Office of AIDS Research

Total - Proposed Law

SUMMARY BY BUDGET MECHANISM

MECHANISM	FY 2001 Actual		FY 2002 Appropriation		FY 2002 Current Estimate		FY 2003 Estimate	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Grants:								
<u>Research Projects</u>								
Noncompeting	2,112	\$977,468,000	2,235	\$1,058,572,000	2,235	\$1,058,572,000	2,379	\$1,156,706,000
Administrative supplements	(152)	60,858,000	(106)	19,378,000	(106)	19,378,000	(105)	19,749,000
Competing:								
Renewal	205	77,115,000	231	115,672,000	231	115,672,000	227	121,720,000
New	522	190,034,000	579	218,888,000	579	218,888,000	635	251,864,000
Supplements	18	5,962,000	27	9,320,000	27	9,320,000	27	9,759,000
Subtotal, competing	745	273,111,000	837	343,880,000	837	343,880,000	889	383,343,000
Subtotal, RPGs	2,857	1,311,437,000	3,072	1,421,830,000	3,072	1,421,830,000	3,268	1,559,798,000
SBIR/STTR	77	22,919,000	88	26,827,000	88	26,827,000	100	30,386,000
Subtotal, RPGs	2,934	1,334,356,000	3,160	1,448,657,000	3,160	1,448,657,000	3,368	1,590,184,000
<u>Research Centers</u>								
Specialized/comprehensive	48	77,038,000	55	93,925,000	55	93,925,000	57	102,841,000
Clinical research	0	41,599,000	0	41,581,000	0	41,581,000	0	41,581,000
Biotechnology	0	8,058,000	0	7,756,000	0	7,756,000	0	7,805,000
Comparative medicine	13	40,657,000	13	50,674,000	13	50,674,000	13	50,674,000
Research Centers in Minority Institu	0	5,490,000	0	8,578,000	0	8,578,000	0	10,256,000
Subtotal, Centers	61	172,842,000	68	202,514,000	68	202,514,000	70	213,157,000
<u>Other Research</u>								
Research careers	194	23,712,000	218	27,451,000	218	27,451,000	218	28,237,000
Cancer education	0	10,000	0	40,000	0	40,000	0	40,000
Cooperative clinical research	21	33,571,000	24	35,164,000	24	35,164,000	24	39,888,000
Biomedical research support	1	1,472,000	1	1,892,000	1	1,892,000	1	1,892,000
Minority biomedical research support	1	787,000	2	1,137,000	2	1,137,000	2	1,186,000
Other	64	38,676,000	69	42,739,000	69	42,739,000	99	58,572,000
Subtotal, Other Research	281	98,228,000	314	108,423,000	314	108,423,000	344	129,815,000
Total Research Grants	3,276	1,605,426,000	3,542	1,759,594,000	3,542	1,759,594,000	3,782	1,933,156,000
<u>Training</u>								
Individual awards	62	2,089,000	66	2,410,000	66	2,410,000	65	2,442,000
Institutional awards	797	29,284,000	798	32,055,000	798	32,055,000	796	33,190,000
Total, Training	859	31,373,000	864	34,465,000	864	34,465,000	861	35,632,000
Research & development contracts (SBIR/STTR)	181 (3)	227,007,000 (1,079,000)	195 (1)	292,036,000 (750,000)	195 (1)	291,225,000 (750,000)	218 (1)	321,585,000 (750,000)
Intramural research		251,973,000		279,735,000		279,590,000		318,279,000
Research management and support		75,703,000		85,568,000		85,552,000		91,775,000
Cancer prevention & control		0		0		0		0
Construction		1,450,000		4,000,000		4,000,000		4,000,000
Library of Medicine		5,589,000		6,742,000		6,742,000		7,248,000
Office of the Director		48,494,000		53,818,000		53,786,000		58,322,000
Subtotal		2,247,015,000		2,515,958,000		2,514,954,000		2,769,997,000
Buildings and Facilities		0		0		0		0
Total, NIH		2,247,015,000		2,515,958,000		2,514,954,000		2,769,997,000
(Clinical Trials)		(452,826,000)		(498,331,000)		(498,331,000)		(547,093,000)

NATIONAL INSTITUTES OF HEALTH

**Office of AIDS Research**

Spending by the NIH Plan for HIV-Related Research  
(dollars in thousands)

Research Area	FY 2001 Actual	FY 2002 Estimate	FY 2003 Estimate	Change
Natural History and Epidemiology	\$253,717	\$270,947	\$293,853	\$22,906
Etiology and Pathogenesis	662,769	718,775	771,317	52,542
Therapeutics	633,972	701,888	750,688	48,800
Vaccines	269,169	339,547	422,253	82,706
Behavioral and Social Science	302,599	344,663	376,076	31,413
Training and Infrastructure	92,585	104,234	118,304	14,070
Information Dissemination	32,204	34,900	37,506	2,606
<b>Total, Budget Authority</b>	<b>2,247,015</b>	<b>2,514,954</b>	<b>2,769,997</b>	<b>255,043</b>

National Institutes of Health

Office of AIDS Research

AIDS Funding by Institute and Center

Institute/Center	FY 2001 Actual	FY 2002 Appropriation	FY 2002 Current Estimate	FY 2003 Estimate
NCI	\$239,066,000	\$256,443,000	\$256,319,000	\$266,539,000
NHLBI	67,437,000	72,146,000	72,146,000	75,380,000
NIDCR	21,942,000	23,473,000	23,473,000	25,338,000
NIDDK	24,685,000	27,642,000	27,642,000	29,847,000
NINDS	37,774,000	42,380,000	42,366,000	45,682,000
NIAID	1,063,074,000	1,192,554,000	1,191,919,000	1,350,452,000
NIGMS	43,298,000	48,391,000	48,391,000	52,385,000
NICHD	101,851,000	116,101,000	116,101,000	126,249,000
NEI	11,555,000	12,730,000	12,730,000	12,777,000
NIEHS	7,855,000	8,344,000	8,336,000	8,682,000
NIA	4,386,000	4,985,000	4,985,000	5,379,000
NIAMS	5,692,000	6,469,000	6,467,000	6,687,000
NIDCD	1,592,000	1,737,000	1,737,000	1,738,000
NIMH	145,112,000	164,008,000	163,938,000	176,207,000
NIDA	245,397,000	279,776,000	279,676,000	304,187,000
NIAAA	21,222,000	23,979,000	23,979,000	25,913,000
NINR	9,678,000	10,990,000	10,990,000	11,891,000
NHGRI	5,809,000	6,313,000	6,310,000	6,812,000
NIBIB	843,000	843,000	843,000	843,000
NCRR	117,485,000	135,207,000	135,195,000	147,198,000
NCCAM	1,030,000	2,555,000	2,555,000	2,718,000
NCMHD	---	---	---	---
FIC	16,149,000	18,332,000	18,328,000	21,523,000
NLM	5,589,000	6,742,000	6,742,000	7,248,000
OD	48,494,000	53,818,000	53,786,000	58,322,000
B&F	---	---	---	---
TOTAL, Bud. Auth., Proposed Law	2,247,015,000	2,515,958,000	2,514,954,000	2,769,997,000

**NATIONAL INSTITUTES OF HEALTH**  
**Office of AIDS Research**

SIGNIFICANT ITEMS IN HOUSE APPROPRIATIONS COMMITTEE REPORTS

FY 2002 House Appropriations Committee Report Language (H. Rpt. 107-229)

Item

***[Office of AIDS Research]*** - ...This language permits the Director of OAR, jointly with the Director of NIH, to transfer between ICDs up to three percent of the funding determined by NIH to be related to AIDS research. This authority could be exercised throughout the fiscal year subject to normal reprogramming procedures, and is intended to give NIH flexibility to adjust the AIDS allocations among Institutes if research opportunities and needs should change. The Committee also repeats language from last year's bill making the research funds identified by NIH as being AIDS related available to the OAR account for transfer to the Institutes. This provision permits the flow of funds through the OAR in the spirit of the authorization legislation without requiring the Congress to earmark a specific dollar amount for AIDS research. (p. 94)

Action taken or to be taken

The Director of OAR in consultation with the Director of NIH will allocate all monies for AIDS-related research to the Institutes and Centers in accordance with the scientific priorities and objectives of the NIH FY 2002 Plan for HIV-Related Research. The Plan serves as the framework for developing the NIH AIDS budget as well as for determining the use of NIH AIDS-designated dollars. In addition, all AIDS-designated expenditures are coded and tracked in accordance with the objectives of the plan.

The OAR appreciates the critical flexibility that the 3 percent transfer authority provides to move funds to meet the scientific priorities. We will reserve the use of this critical authority for only the most pressing need that could not be addressed by use of other funding mechanisms, for example, if a scientific breakthrough required expanded clinical trials.

Item

***[Office of AIDS Research]***- The Office is encouraged to expand and strengthen science-based HIV prevention research for African Americans, Latinos, Native Americans, Asian Americans, Native Hawaiians, and Pacific Islanders. The Office is also encouraged to expand existing and develop new areas of culturally appropriate behavior and social research that seeks to reduce the risk of contracting HIV through high risk behaviors and the transmission of HIV infection in the targeted minority populations. OAR, and a number of NIH Institutes and Centers, have a

longstanding commitment to AIDS research and training efforts to benefit minority populations and increase minority investigators. The Committee strongly supports the continued efforts in this area. (p. 94-95)

#### Action taken or to be taken

##### *NIH AIDS Research Priorities*

Research to address the disproportionate impact of the HIV/AIDS epidemic on racial and ethnic minority communities in the United States continues to be a high priority of the Office of AIDS Research (OAR). OAR established the Ad Hoc Working Group on Minority Research, comprised of leading scientific and community experts, to advise us on the scientific priorities in this critical research area. OAR is directing increased resources toward new interventions that will have the greatest impact on these populations. The key priorities are prevention of transmission; prevention of disease progression; and prevention of mortality. These include interventions that address the co-occurrence of other STDs, hepatitis, drug abuse, and mental illness as well as interventions that consider the role of culture, family, and other social factors in the transmission and prevention of these diseases in minority communities. Specific prevention research priorities also include the development of an AIDS vaccine, microbicides and other female-controlled interventions, behavioral interventions, mechanisms to interrupt perinatal transmission; approaches to enhance immune reconstitution, and simpler and less expensive antiretroviral treatment regimens. These strategies focus on the salient problems confronting African Americans and other minority populations, as well as the medically indigent, homeless, and drug-using groups.

OAR has provided additional funds to projects aimed at: increasing the number of minority investigators conducting behavioral and clinical research; targeting the links between substance abuse and sexual behaviors with HIV infection; increasing outreach education programs targeting minority physicians, researchers and at-risk populations; and expanding our portfolio of population-based research.

##### *Training and Career Development Workshops*

One of these projects is the Training and Career Development Workshop series for racial and ethnic minority investigators. These workshops are designed to: 1) increase awareness of the types of NIH funding available for HIV/AIDS research, especially in the areas of prevention and treatment; 2) provide protected time to meet and discuss with senior minority scientists research projects that will be conducted in racial and ethnic minority communities, with the goal of seeking technical advice and assistance; 3) review submission of research applications to the NIH; and 4) interact with NIH program staff from several Institutes and Centers with specific research initiatives and/or interests that target racial and ethnic minority communities.

##### *Research Infrastructure Development*

The OAR recently collaborated with the National Institute of Neurological Diseases and Stroke (NINDS) in funding another Specialized Neurosciences Research Program (SNRPs) site. These

sites represent a unique partnership between majority and minority institutions, in which collaboration is essential to address some of the major complications of HIV infection in the human central nervous system. Several of these centers have developed into Centers of Excellence which have attracted other minority investigators at various stages of their career.

#### *Computer Access Initiative*

The OAR launched a program to provide computer hardware and software to scientists at minority predominant and minority serving institutions to assist in the development of research infrastructure, provide access to national databases for further investigation of time trends in racial and ethnic minorities, and to facilitate the development of research networks at these institutions.

#### *Regional Technology Transfer Programs*

OAR established this program in 1990 to support workshops for individuals and groups that provide health care services to HIV-infected people in underserved and disadvantaged communities. These workshops bring the latest information from ongoing HIV/AIDS research programs to health care providers to assist them in treating their patients.