

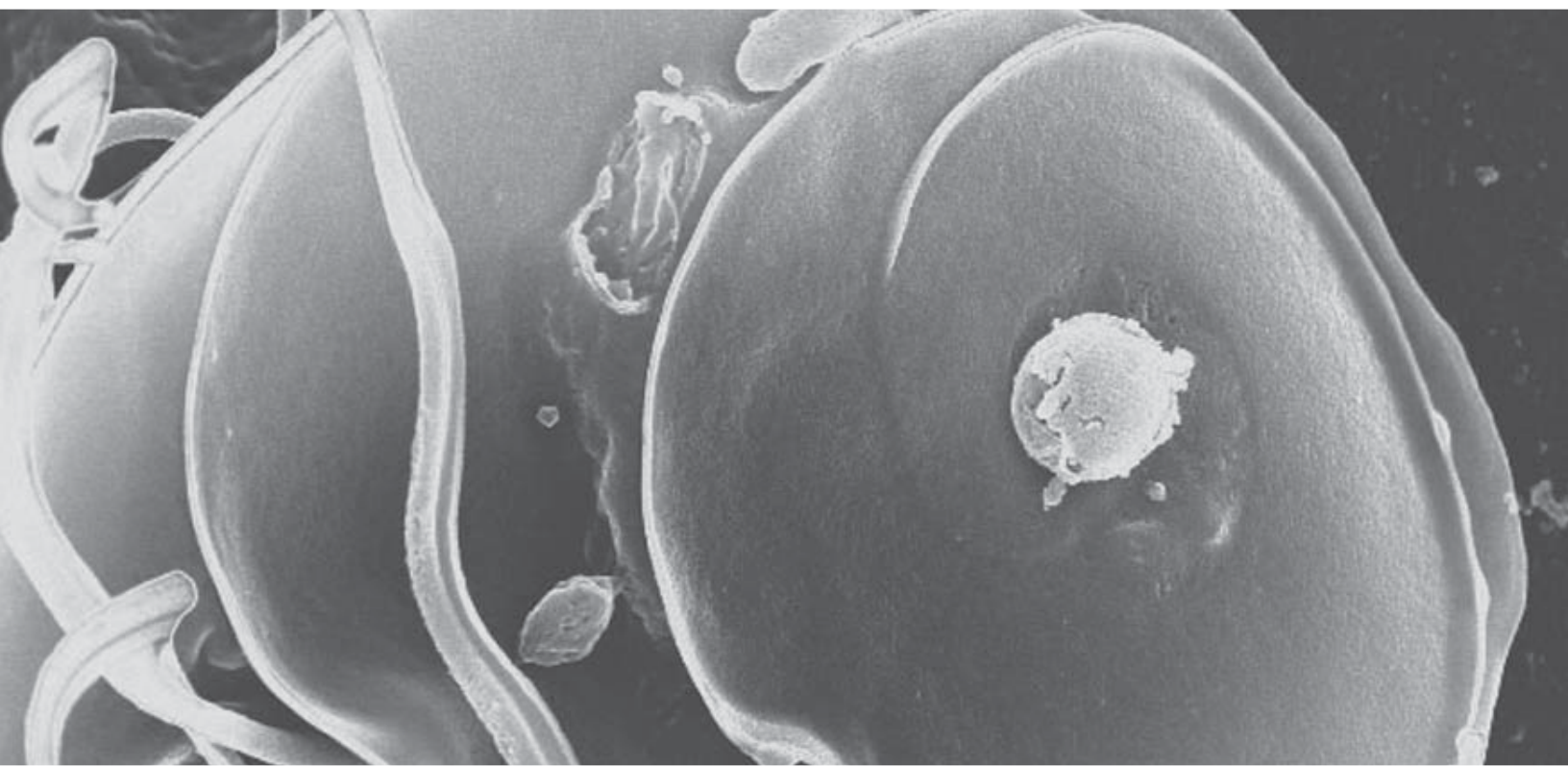
NIAID

NIAID: Planning for the 21st Century **2008 Update**

National Institute of Allergy and Infectious Diseases



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health



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A Letter From the Director

Dear Colleagues:

For nearly six decades, researchers supported by the National Institute of Allergy and Infectious Diseases (NIAID) have been responsible for many important accomplishments in microbiology, infectious diseases, immunology, and related disciplines. NIAID-supported scientists have developed vaccines, therapies, and diagnostic tools that have helped alleviate pain and suffering around the world.

To build on these advances, NIAID works to maintain a strong portfolio of basic, translational, and clinical research in the areas of infectious diseases and immunology. In addition, NIAID has an important mandate to respond rapidly to new infectious diseases and public health threats that appear periodically and unexpectedly. In this regard, since NIAID published its last Strategic Plan in 2000, we have witnessed the emergence of new diseases, such as Severe Acute Respiratory Syndrome (SARS), the re-emergence of old pathogens with new virulence, such as extensively drug-resistant tuberculosis, and the deliberate dissemination of *Bacillus anthracis* spores. We also have seen the rapid evolution of technological capabilities and research tools that offer an unprecedented range of new scientific opportunities. As a result, while the fundamental mission of the Institute has not changed, our research priorities have evolved. The purpose of this document is to update NIAID's Strategic Plan, *NIAID: Planning for the 21st Century (2000)*, and to articulate the Institute's current strategic priorities.

In recent years, hundreds of outside experts have helped us prepare numerous action plans, research agendas, and reports addressing a variety of specific areas that fall within the mission of NIAID. In preparing this update of our strategic priorities, we have attempted to distill a set of fundamental themes and priorities that can be found in these and other documents, and to incorporate them into a summary document that can be used to guide future decisionmaking.

With a strong research base, talented investigators in the United States and abroad, and the availability of powerful new research tools, we are confident that this Plan will help guide our basic and applied research programs in the fight against infectious and immune-mediated diseases toward the goal of improving global health.

This update of NIAID strategic priorities reflects the input of the broad scientific community in concert with the Institute's staff, including a group of external experts who provided helpful consultation regarding this update (see appendix). I wish to thank all who contributed their time and wisdom to the planning efforts.

Best regards.

Sincerely,

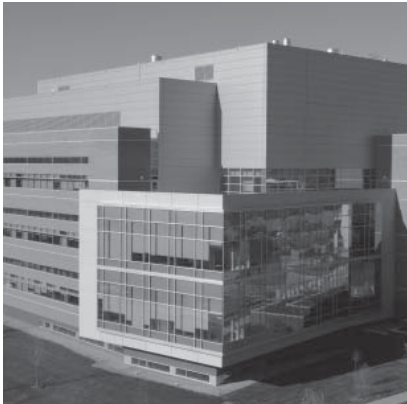


Anthony S. Fauci, M.D.
Director, NIAID



The NIAID Mission

The mission of the National Institute of Allergy and Infectious Diseases (NIAID) is to conduct and support basic and applied research to better understand, treat, and ultimately prevent infectious, immunologic, and allergic diseases. A unique component of this mission is the mandate to provide a rapid and effective biomedical research response to unforeseen microbial threats, such as Severe Acute Respiratory Syndrome (SARS), avian influenza, and drug-resistant microbes, while maintaining aggressive efforts focused on well-known killers such as HIV/AIDS and malaria as well as immune-mediated disorders. The strategic management of such a complex research mission has two core components: 1) maintaining a breadth and depth of knowledge in all areas of infectious and immune-related diseases, and 2) developing flexible domestic and international capacity to respond efficiently in the arena of biomedical research to newly emerging threats wherever they occur.



To accomplish its mission, NIAID conducts and supports a comprehensive portfolio of research on the biology of pathogenic organisms and the host response to microbes and on mechanisms of normal immune function and dysfunction resulting in autoimmunity, immunodeficiency, allergy, and transplant rejection. This basic research provides the scientific understanding and research platform for translational and clinical research to develop and test vaccines, therapeutics, and diagnostics to prevent and treat the many infectious, immune-mediated, and allergic diseases that afflict people throughout the world.

The events of September 11, 2001, and the subsequent release of anthrax spores brought new attention to the threat of bioterrorism and the need to develop medical countermeasures against weapons of mass destruction for the civilian population. This focus on biodefense became an important element of the NIAID mission, with the Institute assuming the principal responsibility within the U.S. Department of Health and Human Services (HHS) and the National Institutes of Health (NIH) for research and early development of medical countermeasures against terrorist threats from infectious diseases and radiation exposure. More recently, NIAID also assumed responsibility for coordinating the NIH-wide effort to develop medical countermeasures against chemical threats to the civilian population. In developing NIAID's biodefense portfolio, the Institute has followed the same two-pronged approach used in other areas: identifying specific gaps in knowledge regarding known pathogens, while at the same time developing a nimble research infrastructure capable of responding rapidly to previously unknown public health threats. Because new potentially deadly pathogens, such as avian influenza, may be naturally occurring as well as deliberately introduced by terrorists, NIAID's biodefense research is integrated into its larger emerging and re-emerging infectious diseases portfolio.

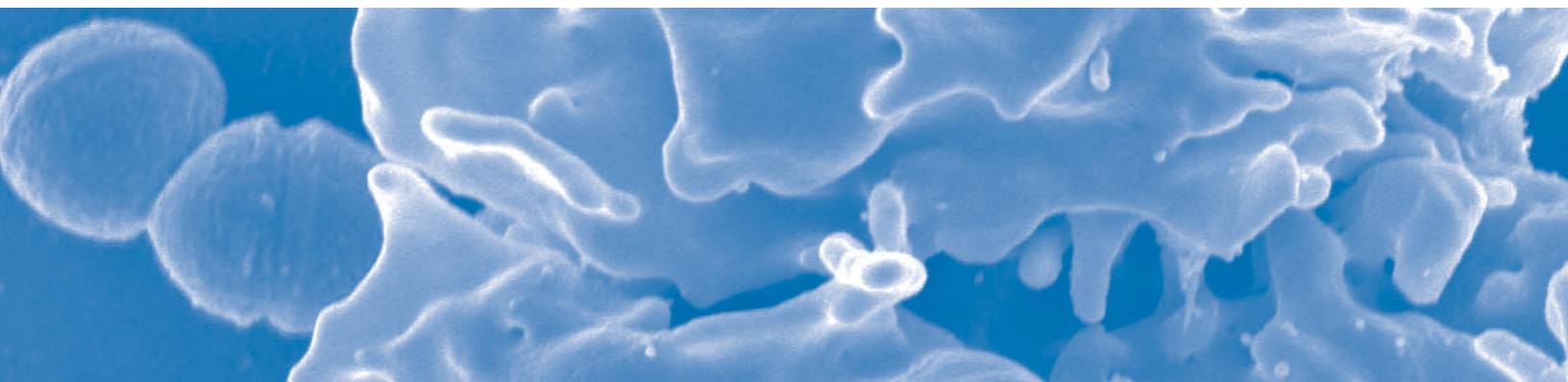
NIAID is dedicated to building and sustaining a comprehensive research infrastructure to support its mission. Such infrastructure includes adequate, well-placed facilities for conducting research on highly infectious

pathogens; expertise to facilitate product development leading to approval by the U.S. Food and Drug Administration (FDA) of vaccines, therapeutics, and diagnostics; and an extensive clinical trials infrastructure. The Institute also fosters the organization of consortia, repositories, and databases, thus providing critical resources to support its scientific research. Finally, NIAID supports the training and professional development of scientists in the fields of infectious diseases and immunology.

Given the global impact of infectious diseases, a key aspect of the Institute's mission is to foster and maintain a strong program of international research and research capacity building. Clinical research on HIV/AIDS, tuberculosis (TB), malaria, neglected tropical diseases, and other leading infectious causes of global mortality is best pursued through mutually beneficial partnerships that engage researchers and institutions in countries where these diseases are endemic. Thus, NIAID supports networks of U.S. and international scientists, trains American and foreign investigators to work internationally, and enhances research facilities around the world. NIAID recognizes that international research must involve shared leadership, a commitment to long-term sustainability, and the engagement of local communities if it is to contribute substantially to improvements in global public health.

An overarching priority in all NIAID research programs is to reduce health disparities and improve health for all people as we seek to translate research advances into clinical practice. Many NIAID advances have helped to address health disparities. Examples include the development of effective therapies for hepatitis B and interventions to reduce the burden of asthma on children residing in inner cities. In addition, NIAID actively seeks the participation of diverse populations in clinical studies to ensure the scientific validity and broad applicability of research findings.

For more than 50 years, NIAID research has led to new vaccines, therapeutics, diagnostics, and other technologies that have improved health and saved millions of lives in the United States and around the world. NIAID will continue to play a leading role in advancing knowledge of infectious and immune-mediated diseases and in accelerating the development of treatments and prevention strategies to respond to emerging public health threats.



Infectious Diseases (non-AIDS) Including Emerging and Re-emerging Diseases and Biodefense

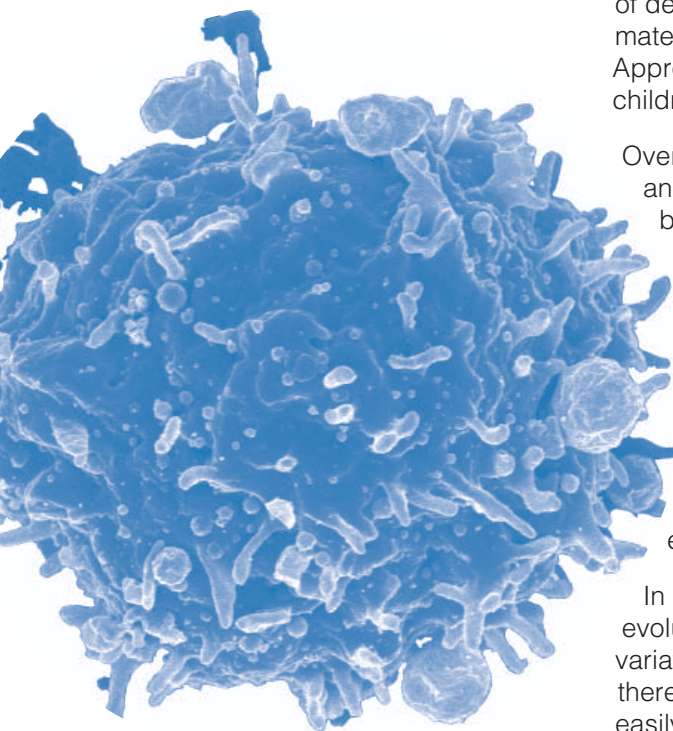
Throughout history, infectious diseases have posed a major threat to human health. Their impact continues to be an important human health concern today, both in the United States and around the world. Despite advances in medicine and public health—such as antibiotics, vaccines, and improved sanitation—that have helped control many endemic diseases, infectious diseases remain the second leading cause of death throughout the world. In 2002, more than one-quarter of approximately 57 million deaths worldwide¹ were caused by infectious diseases. Approximately two-thirds of all deaths in developing countries among children less than five years of age² are due to infectious diseases.

Over the past several decades there has been a global effort to identify and characterize more than 270 infectious agents, which include bacteria, viruses, fungi, parasites, and prions; to define the underlying pathways by which these agents infect humans and cause disease; and to develop preventive measures and treatments for many of the world's most dangerous pathogens. New challenges are constantly arising, however, including the emergence of new infectious diseases, such as SARS, the re-emergence of bacterial strains no longer responsive to our current treatments (such as methicillin-resistant *Staphylococcus aureus* and multi- and extensively-drug resistant TB), and the persistence of respiratory, sexually transmitted, and enteric pathogens that can cause serious epidemic and endemic global health problems.

In addition to the continual discovery of new human pathogens and the evolution and emergence of new infectious diseases, natural genetic variations allow novel strains of known pathogens to appear. For example, there is increasing concern that an avian influenza virus, if it became easily transmissible among people, would be unrecognized by the human immune system and lead to a pandemic.

Many important infectious diseases have never been adequately controlled. Some that have posed ongoing health problems in developing countries have emerged recently in the United States, including food- and waterborne (e.g., *Shigella*) and vector-borne (e.g., West Nile virus) infections. In addition, resurgence of some previously treatable diseases, such as TB and malaria, has occurred in part because improper use of pesticides and antimicrobial drugs has led to the evolution of highly resistant strains of the pathogens.

After the events of September 11, 2001, there were great concerns that potential agents of bioterror, especially Category A agents,³ could be deliberately released to cause widespread illness. Agents deliberately introduced into the population might be genetically engineered to resist current therapies and evade vaccine-induced immunity. To respond to



these ever-changing public health threats, our preparedness efforts have now evolved to include a broad-based approach to biodefense research. Furthermore, advances made through NIAID-sponsored research to better understand microbes that could be deliberately released and to develop biodefense countermeasures greatly increase our ability to respond rapidly to a wide range of emerging and re-emerging infectious diseases.

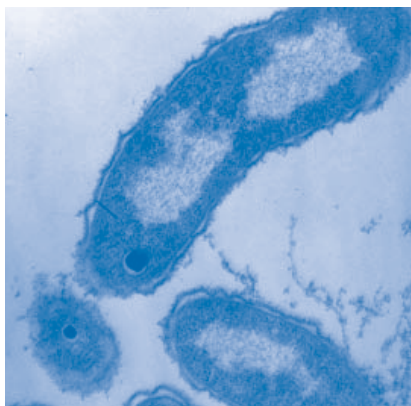
NIAID's work is part of a national and international effort to reduce morbidity and mortality from infectious diseases, support biodefense efforts, and improve public health around the world. Therefore, NIAID partners with many organizations, including other U.S. government agencies, foundations, nonprofit organizations, foreign governments, and pharmaceutical and biotechnology companies.

In addition to the broadly stated priorities presented in this document, other published reports identify more specific research needs and opportunities relevant to emerging and re-emerging infectious diseases and biodefense, including:

- *NIAID Strategic Plan for Biodefense Research (2002)*
- *NIAID Biodefense Research Agenda for CDC Category A Agents (2002)*
- *NIAID Biodefense Research Agenda for CDC Category A Agents Progress Report (2003)*
- *NIAID Biodefense Research Agenda for CDC Category A Agents Progress Report (2006)*
- *NIAID Biodefense Research Agenda for Category B and C Priority Agents (2003)*
- *NIAID Biodefense Research Agenda for Category B and C Priority Agents Progress Report (2004)*
- *NIAID Expert Panel on Botulinum Toxins (2002)*
- *NIAID Expert Panel on Immunity and Biodefense (2002)*
- *NIAID Expert Panel on Botulinum Diagnostics (2003)*
- *NIAID Expert Panel on Botulinum Neurotoxins Therapeutics (2004)*
- *Advanced Product Development for Multiplex Infectious Disease Diagnostics (2005)*
- *Emergence of New Epidemic Viruses Through Host Switching, Workshop Report (2005)*
- *NIAID Global Health Research Plan for HIV/AIDS, Malaria, and Tuberculosis (2001)*
- *NIAID Research Agenda: Multidrug-Resistant and Extensively Drug-Resistant Tuberculosis (2007)*



- *HHS Pandemic Influenza Plan (2005)*
- *NIAID Report on Development of a Clinical Trial Plan for Pandemic Influenza Vaccines (2003)*
- *NIAID Influenza Blue Ribbon Panel Report (2007)*



Biology of Pathogens and Host-Pathogen Interactions

Basic research lays the groundwork for understanding the biology of pathogens as well as interactions among pathogens, hosts, and the environment—critical elements in advancing our understanding of human health. By studying the cellular and molecular biology of pathogen and host, physiologic processes, and genome sequences and structures, scientists elucidate the varied and ingenious ways that microbes survive and multiply, including the set of microbes present on or within the human body (human microbiome). Significant progress has been made recently to: 1) determine the genetic sequences for multiple pathogens, including more than 2,000 human and avian influenza viruses, as well as the parasites that cause African sleeping sickness and trichomoniasis—a common sexually-transmitted infection (STI); 2) characterize specialized poxvirus genes and determine how these viruses evade the immune system; and 3) identify entry mechanisms for multiple pathogens. Enterprising research efforts continue to uncover the mysteries of infectious disease pathogens, providing an important knowledge base that enhances our ability to identify and characterize newly emerging or re-emerging threats.

Priority 1: Through basic research, increase understanding of the molecular structure and function of viral, bacterial, fungal, prion, and parasitic pathogens, and identify new pathogens.

Priority 2: Use advanced technologies including genomics and proteomics to extend insight into mechanisms of infection, pathogenicity, virulence, host-pathogen interactions, and development of drug resistance.

Priority 3: Understand the role of the innate immune system in protecting the host from infectious pathogens. Identify differences in immunologic function between individuals and populations in order to improve interventions.

Priority 4: Determine the influence of co-infecting microbes on the pathogenesis of infectious diseases in order to better understand the impact of eliminating secondary infections on disease outcomes.

Medical Interventions

Insights from basic research often yield concepts for new vaccines, therapeutics, and diagnostics that are validated in model systems and then further developed and tested in applied research settings. Promising candidates advance through the research and development pipeline to human testing in clinical trials. NIAID supports studies throughout the development pipeline, from early discovery to clinical evaluations of candidate diagnostics, vaccines, and therapeutics.

Diagnostics

As infectious diseases continue to take their toll around the world, there is an urgent need for rapid, highly sensitive, and specific clinical diagnostics that are easy to use, cost-effective, and can diagnose individuals infected with pathogens or exposed to toxins. Many of the initial symptoms caused by bacterial and viral infections are nonspecific and do not suggest a definitive diagnosis. This situation makes it difficult for both the clinician and patient to identify appropriate treatment options. In addition, the ability to determine rapidly whether an individual is infected by an organism posing a biological threat or by a more innocuous microbe is a critical component of public health preparedness, as are diagnostic tools to determine a pathogen's drug sensitivities. Currently, researchers are using advanced technologies to develop improved molecular assays and methods that can detect simultaneously multiple pathogens in a single assay. Continuing efforts are necessary for clinical validation of these methods, as well as studies to improve sample processing and preparation, decrease time to diagnosis, and develop instrumentation and platforms for point-of-care testing.

Priority 1: Conduct basic research on pathogens and host responses to discover unique characteristics that have the potential to be used as specific and sensitive targets for preventing, diagnosing, monitoring, and treating infectious diseases.

Priority 2: Develop and expand diagnostic platforms and technologies that can identify multiple pathogens, distinguish pathogen strains, recognize early infection or exposure, and detect drug sensitivity and resistance. These platforms and technologies must be reliable and easy to use in point-of-care settings.

Vaccines

Vaccines have led to some of the greatest public health triumphs in history. An improved understanding of the immune system and how it fights harmful microbes has led to exciting developments in vaccine research methodology and has ultimately resulted in clinical trials to evaluate candidate vaccines against malaria, TB, and West Nile virus. Technological advances continue to improve existing vaccines and identify vaccine candidates to prevent diseases for which no vaccines are currently available. However, NIAID will continue to face the challenges inherent in emerging and re-emerging diseases, since new human pathogens and novel strains of known pathogens will require the development of new vaccines. Additional research is also needed to understand better innate and adaptive immune responses to specific pathogens and to advance the development of cross-protective vaccine strategies.

Priority 1: Conduct basic research to elucidate mechanisms of host-pathogen interaction, to better understand and enhance immune response, and to identify promising new vaccine targets.

Priority 2: Design new or improved vaccines that are safe and effective, with particular emphasis on multivalent and cross-protective vaccine strategies.



Priority 3: Use advanced technologies to rapidly determine safety and immunogenicity of candidate vaccine products and to streamline manufacturing.

Therapeutics

NIAID supports a variety of approaches to identify potential targets for intervention and to engineer new therapies. The ability of pathogens to develop drug resistance makes establishing an arsenal of safe and effective antimicrobials especially challenging. Exciting progress is being made by screening existing products for activity against different pathogens. Because the existing antimicrobial therapeutics may not provide an effective defense against future emerging and resistant organisms and bioterrorism agents, there is a need to develop a pipeline of new treatments that are effective against a range of pathogens.

Priority 1: Conduct basic research to understand how pathogens develop drug resistance; to identify new strategies for immunotherapies, including those based on host response; and to explore classes of compounds with potential for broad-spectrum activity.

Priority 2: Use advanced technologies to screen, test, and develop novel and improved chemotherapies, biopharmaceuticals, and immunotherapies that offer broad-spectrum coverage.

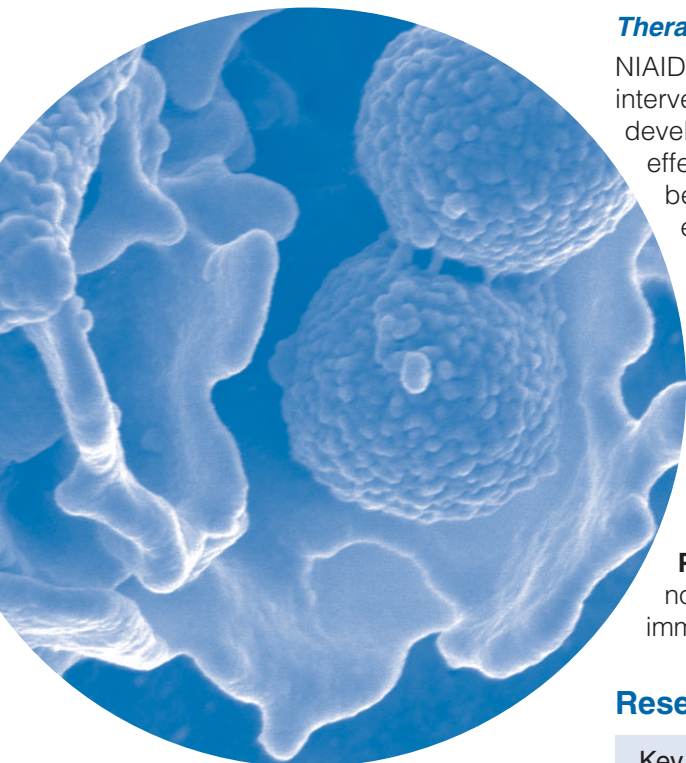
Research Resources

Key resources and infrastructure are necessary to facilitate basic research and to support the development of new vaccines, therapeutics, and diagnostics for infectious diseases. Over the last several years, significant progress in DNA sequencing technology has enabled expansion of large-scale DNA sequencing of the genomes of human pathogens and invertebrate vectors of disease, including microorganisms considered to be potential agents of bioterrorism. Critical companions to state-of-the-art DNA sequencing techniques are the bioinformatics, computational tools, and databases that provide the scientific community with the resources needed to analyze the sequencing data. Future scientific advances require continued development of such critical resources, including containment facilities for conducting research on highly infectious pathogens.

Priority 1: Create a system for making scientific resources readily available to authorized users, clearly delineating available resources and requirements for use. Support mechanisms for sharing data within the scientific community.

Priority 2: Build and maintain safe and secure containment research facilities for working with highly infectious pathogens, and ensure appropriate training for workers in these facilities.

Priority 3: Augment the capability for production and preclinical testing of pilot lots of infectious disease vaccines.



Global Health

For more than 50 years, NIAID has made research on global health a priority, leading to new vaccines, diagnostics, and therapeutics that have improved the health of millions of people in the United States and around the world. Through investigator-initiated grants and international research networks, NIAID is supporting projects to curtail infectious diseases that primarily affect specific regions of the world (e.g., malaria, leishmaniasis, schistosomiasis, and Ebola), as well as diseases that have the potential to cause global pandemics (e.g., influenza and SARS). NIAID recognizes that a solid foundation of global health research and collaborations enhances the U.S. capacity for infectious disease surveillance and the ability to respond to newly emerging disease threats. Moreover, improved global health is a key foundation for international stability and security.



Priority 1: Develop and maintain international multidisciplinary research capacity—including infrastructure, training, and networks—to support research on global and regional priorities that will improve public health in the United States and around the world.

Priority 2: Develop and participate in partnerships and collaborations with foreign governments and other organizations to address emerging and re-emerging infectious diseases at sites worldwide.



Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome

The *UNAIDS/WHO AIDS Epidemic Update* estimated that 33 million people were living with HIV in 2007; of these, approximately 2.7 million were newly infected persons, and 370,000 were children younger than 15 years of age.⁴ Global prevalence levels are expected to continue to rise, with major consequences to the public health, social, and economic stability of many countries, particularly in southern Africa and Asia. The ultimate priorities are to prevent new HIV infections and cure those individuals already living with HIV.



The progress made in HIV/AIDS research has been extraordinary during the 27 years since publication of the first scientific reports on AIDS. Scientists rapidly uncovered the structure and genetic organization of HIV and began to understand the mechanisms by which HIV causes disease. Along with the development of diagnostic tests for HIV infection, viral load, and immune function, these advances facilitated the rapid development of an array of potent anti-HIV drugs that have saved nearly three million years of life in the United States alone⁵ and prevented more than 100,000 cases of mother-to-child transmission worldwide. Nonetheless, while currently available treatments have greatly improved the outlook for persons who are infected with HIV, it is essential to continue research, both in the United States and internationally, to discover and develop new therapeutic agents and regimens that manifest increased efficacy, decreased toxicity, different resistance profiles, appropriateness for pediatric use, and ready accessibility, particularly in resource-limited settings.

Ending the AIDS epidemic will require multipronged biomedical and behavioral approaches. Vaccines or other highly effective means of preventing virus transmission must be developed. Until safe and effective vaccines are available, however, non-vaccine prevention strategies, such as the development of topical microbicides, the use of medically safe male circumcision, and integrated behavioral approaches will be critical to curbing the continued spread of the virus.

In addition to the broadly stated priorities for HIV/AIDS research presented in this document, the following published plans contain goals or objectives that address HIV/AIDS research:

- *NIAID Global Health Research Plan for HIV/AIDS, Malaria, and Tuberculosis* (2001)
- *NIAID Vaccine Research Center Strategic Plan: Research Toward Development of an Effective AIDS Vaccine* (2001)
- *NIAID Topical Microbicide Strategic Plan* (2003)
- *Trans-NIH Plan for HIV-Related Research* (FY 2008)
- *President's Emergency Plan for AIDS Relief (PEPFAR/Emergency Plan)* (2004)

Biology and Transmission Dynamics

Despite enormous progress in understanding the biology of HIV, essential questions remain about the molecular interactions that regulate HIV expression and replication, and about how the virus evades the immune system. Additional basic research is needed to further understand the viral life cycle, the mechanisms of viral entry and infection, virus-host interactions, the structure and function of viral genes and proteins, and mechanisms of transmission and disease progression.

Priority 1: Understand the mechanisms by which HIV enters human tissues, the impact of HIV genetic variation on host immunity, factors that determine the virus' ability to replicate and cause disease, and the mechanisms by which the virus becomes drug-resistant.

Priority 2: Define the aspects of immune response and immune regulation that either control HIV or exacerbate disease progression in key anatomical sites, including the gut, genital tract, and lymph nodes.

Priority 3: Identify the cell and tissue reservoirs of HIV infection, and define the processes that govern their formation and persistence.

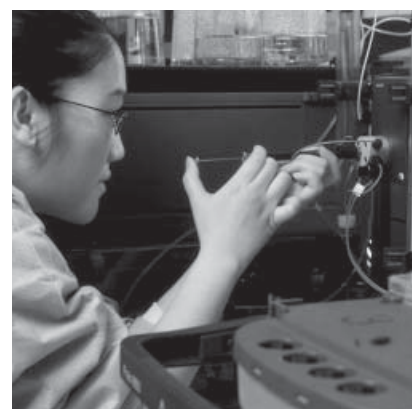
Priority 4: Identify and characterize infectious, genetic, and other cofactors that promote or prevent HIV transmission and disease progression and associated comorbidities, such as malignancies, metabolic complications, and neurological disorders.

Priority 5: Utilize information from pathogenesis research to identify new targets for HIV therapeutics, vaccines, and non-vaccine prevention approaches.

Epidemiology

Epidemiologic research provides population-based information that advances understanding of the biology, transmission, natural history, and optimal prevention as well as treatment and control of HIV infection. These studies examine the incidence, prevalence, and distribution of HIV/AIDS; the factors that cause or influence the incidence of HIV infection, including genetic and environmental factors; the attributes of HIV/AIDS in defined populations; and the effectiveness of control measures. Comprehensive data and collections of biological specimens have the potential to provide a broad picture of HIV infection, disease, and the impact of treatment, and serve as a unique resource for investigations of immunologic, virologic, genetic, and other factors that may modulate the various states of HIV disease and its treatment.

Priority 1: Understand the diversity and changing patterns of the HIV/AIDS epidemic throughout the world including natural history, clinical manifestations, nature and frequency of complications of HIV infection, and changes in the virus, including virulence and drug resistance.



Priority 2: Define differences in susceptibility to HIV infection, development of HIV disease, and response to therapy, including gender-, racial-, and ethnic-based differences.

Priority 3: Assess the effect of therapy, vaccines, and other interventions on short-, medium-, and long-term survival and clinical outcomes, including mother-to-child transmission.

Medical Interventions

Vaccines

HIV vaccines represent the best long-term hope for ending the HIV epidemic, but developing an effective HIV vaccine is one of the most daunting challenges facing the scientific community. A broad program encompassing basic, preclinical, and clinical research must be maintained to ensure progress toward identifying a safe and effective vaccine that prevents or reduces HIV infection and disease (for example, by inducing broadly neutralizing antibodies and strong mucosal immune responses) and that halts or slows transmission of all HIV subtypes. Priorities include the conduct of basic research to drive vaccine discovery, improve vaccine design, and broaden the immune response; research to translate scientific discoveries into clinical practice; and the development of domestic and international clinical trials capacity to enroll diverse populations at highest risk for HIV infection into efficacy trials to support licensure.

Priority 1: Support basic vaccine discovery research leading to novel vaccine concepts.

Priority 2: Design new or improved vaccine candidates and develop new vaccine vectors, adjuvants, and cytokines that can stimulate more potent and durable immune responses.

Priority 3: Develop and standardize assays (e.g., neutralizing antibody, T-cell, and mucosal immunity assays), and create animal models to understand better how HIV vaccines can prevent infection and to compare the efficacy of new vaccine products.

Priority 4: Evaluate the safety, immunogenicity, and efficacy of promising HIV vaccine candidates in systematic ways that permit comparison with other vaccine products.

Non-Vaccine Prevention Strategies

Non-vaccine prevention strategies are critical to curbing the continued spread of the HIV/AIDS epidemic. Evidence-based prevention strategies have already contributed to the maintenance of low infection rates in a number of settings and to declining HIV epidemics in specific populations around the world. Increased access to voluntary counseling and testing creates a new opportunity to integrate prevention in the context of health care delivery. As care and treatment initiatives expand in non-industrialized settings, it is essential to assure that prevention research is an integral part of these efforts.



Priority 1: Identify, develop, and evaluate topical microbicides for application to the surface of the vagina and/or rectum, as well as barrier methods, for prevention of HIV transmission.

Priority 2: Develop additional safe, effective, and feasible strategies for the prevention of mother-to-child transmission, especially in resource-limited settings, with particular focus on transmission via breastfeeding.

Priority 3: Assess pre- and postexposure antiretroviral and immune-based prophylactic interventions to reduce HIV transmission.

Priority 4: Encourage further development and evaluation of behavioral interventions and communication strategies to reduce high-risk behavior associated with HIV transmission.

Priority 5: Evaluate antiretroviral therapy of HIV-infected individuals as a means of preventing HIV transmission to others.

Priority 6: Evaluate the long-term impact of male circumcision on reducing HIV transmission. Determine the feasibility of examining the efficacy of male circumcision in preventing acquisition of HIV in predominantly men who have sex with men (MSM) epidemics. Partner with other agencies to evaluate male circumcision implementation.

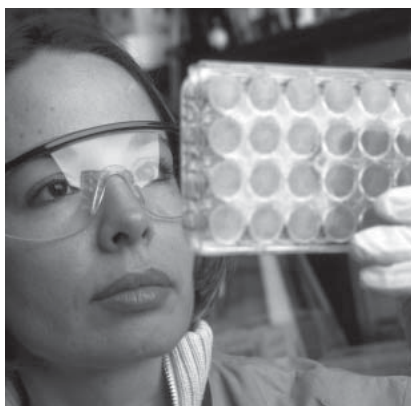
Therapeutics

NIAID-sponsored therapeutics research has had a dramatic impact on the clinical management of HIV infection throughout the world. NIAID clinical trials networks have contributed to the development of guidelines for: 1) the treatment of primary HIV infection and associated opportunistic infections; 2) prophylactic regimens for secondary infections; 3) the use of biological markers, such as CD4+ counts and HIV-1 viral load, for monitoring response to therapy and disease progression; and 4) the use of antiretroviral drugs for preventing mother-to-child transmission. Recent studies have shown that highly active antiretroviral therapy (HAART) regimens are now capable of suppressing HIV viral load in the vast majority of infected individuals and partially restoring immune function. Such regimens have had a dramatic role in reducing HIV morbidity and mortality. Nonetheless, treatment failures occur as a result of the development of resistance and/or nonadherence to regimens. Moreover, some of the damage to the immune system is not fully reversed. Thus, there is an ongoing, urgent need for new therapeutic agents to control HIV replication and to boost, rebuild, and/or replace immunity lost in HIV infection. As HIV-infected individuals live longer, new questions regarding the long-term clinical outcomes of HIV infection have emerged and must be addressed.

Priority 1: Develop new or improved treatments, based on novel targets or the utilization of new technologies, to minimize drug resistance, enhance tolerability, rebuild immunity, improve long-term clinical outcomes, and ultimately allow for the discontinuance of therapy.

Priority 2: Optimize the safety, adherence, resistance, and durability of response of available therapies in diverse settings by evaluating their effectiveness in different formulations, dosing regimens, and routes of administration, as well as in combination with new agents.





Priority 3: Promote the development of new delivery systems and formulations of antiretroviral and other drugs appropriate for use by infants, children, and adolescents, especially in resource-limited settings, and evaluate their long-term safety.

Priority 4: Define effective regimens and treatment strategies for individuals who have drug-resistant HIV.

Priority 5: Develop new interventions to prevent and treat the co-infections and comorbidities associated with HIV infection, especially the co-epidemics of HIV and TB, in domestic and international settings.

Priority 6: Develop and evaluate therapeutic approaches to enhance, restore, and/or maintain the immune systems of HIV-infected individuals; determine whether HIV-directed immune responses can be augmented and, if so, whether this benefits the patient.

Research Resources

In striving to develop interventions to prevent and treat HIV/AIDS, a significant investment in a broad expanse of research resources is necessary to enhance the basic, preclinical, and clinical research that will provide new vaccines, biomedical preventions, and therapeutics. To capitalize fully on the many recent discoveries in genomics, proteomics, and molecular and cell biology, the research community needs wide access to new technologies, well-characterized databases, repositories, and other scientific resources.

Priority 1: Provide state-of-the-art resources in bioinformatics, research and reference reagents, *in vitro* and *in vivo* model systems for discovery, improved laboratory standardization, pharmacokinetics and toxicology testing, analytical chemistry, and formulation and manufacturing services.

Priority 2: Make human biological specimens from well-characterized cohorts and corresponding databases widely available to the scientific community.

Priority 3: Improve the coordination and flexibility of HIV/AIDS clinical trials research networks to increase efficiency and maximize the potential to address new scientific opportunities domestically and internationally.

Global Health

While the development of effective treatments has decreased the mortality from HIV/AIDS in the United States, the impact of the AIDS epidemic on developing nations is profound, especially in resource-constrained countries where access to health care in general, and antiretroviral drugs in particular, is often limited. Lost productivity and profitability, the costs of illness and death, and the decline in a skilled workforce in the developing world are having economic effects worldwide. In response to this global crisis, new international public and private partnerships have emerged. The U.S. government response includes the President's Emergency Plan for AIDS Relief (PEPFAR),

which supports integrated prevention, treatment, and care programs. NIAID also partners with the Global Fund to Fight AIDS, Tuberculosis, and Malaria (Global Fund); the World Bank; the Joint United Nations Programme on HIV/AIDS (UNAIDS); and private foundations such as the Global HIV Vaccine Enterprise and the Bill & Melinda Gates Foundation. Another international effort led by NIAID is the Partners in AIDS Vaccine Evaluation (PAVE) program that plans and coordinates clinical vaccine trials conducted by the federal government. Coordinated international and domestic programs offer the promise of “bi-directional” information flow, as findings from studies in other countries find applicability in the United States, and vice versa.

Priority 1: Establish, enhance, and build upon the in-country research capacity of low- and middle-income countries to develop sustainable capability to carry out research focused on the development of biomedical strategies to prevent transmission of HIV and treat HIV disease and its associated complications.

Priority 2: Assist in the development of vaccines, other prevention strategies, and therapeutic interventions that reflect local population/regional determinants, processes, cultural and contextual issues and that will be widely affordable, accessible, and practical in those settings.

Priority 3: Collaborate with other U.S. government agencies and programs, other health authorities, foreign governments, multinational collaborations, nongovernmental organizations, private industry, philanthropic organizations, and other partners.

Priority 4: Strengthen community input and involvement in clinical research planning, priority setting, ethical review, and study implementation to enhance investigator/community partnerships and ensure respect for community perspectives and priorities.

Priority 5: Develop, validate, and implement effective approaches for the enrollment and retention of women (including pregnant women), adolescents and young adults, minorities, and disenfranchised populations in clinical research to ensure that the results of research are applicable and acceptable to all populations affected by the disease.

Priority 6: Integrate the study of HIV/AIDS with that of other diseases with similar geographic distribution, such as malaria, TB, and neglected tropical diseases.

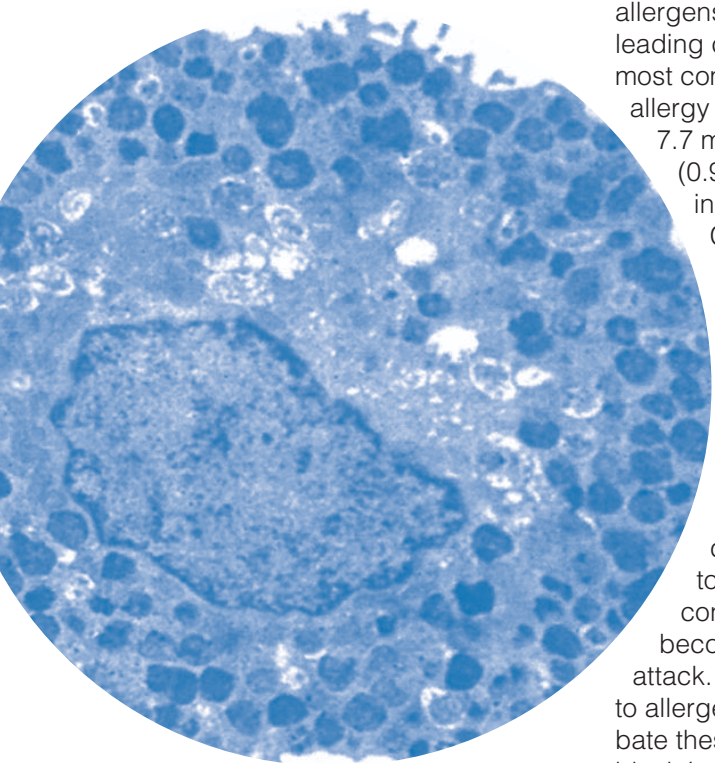


Allergy, Immunology, and Immune-Mediated Diseases

Allergic and immune-mediated diseases are major contributors to the burden of chronic illness throughout the industrialized world, including the United States. The Centers for Disease Control and Prevention (CDC) estimates that, in 2005, approximately 8 percent of Americans (22 million) had active asthma, with disproportionately higher prevalence amongst Puerto Ricans and African Americans; approximately 9 percent of children under 18 years of age (6.5 million) had asthma.⁶ According to a nationwide study, approximately 54 percent of Americans are estimated to have positive skin tests to at least 1 of 10 common allergens that contribute to allergic illness.⁷ Allergic disease is the fifth leading chronic disease in the United States among all ages, and the third most common chronic disease among children under 18 years old.⁸ Food allergy occurs in approximately 3.7 percent of adult Americans (about 7.7 million) and in 6 – 8 percent of children under four years of age (0.9 – 1.2 million). The prevalence of food allergy appears to be increasing, with allergies to peanuts increasing substantially.⁹ Collectively, autoimmune diseases are estimated to affect approximately 5 – 7 percent of people in the United States (15 – 24 million) and, because they are often chronic and disabling, account for high medical and other social costs.¹⁰ For example, type 1 diabetes afflicts between 300,000 and 500,000 (0.1 – 0.17 percent) Americans, of whom approximately 120,000 are younger than 20 years of age.¹¹

These disorders, as well as transplant rejection, are caused by immune responses that are ultimately detrimental. In autoimmune diseases, including rheumatoid arthritis, systemic lupus erythematosus, type 1 diabetes, and multiple sclerosis, a major goal of contemporary research is to “re-educate” the immune system to become tolerant to the antigens and tissues that are the targets of attack. In asthma and allergic diseases, the goal is to prevent responses to allergens, such as house dust mites or peanuts, that cause or exacerbate these diseases. For transplant rejection, the goal is to selectively block immune responses directed against the foreign antigens of the graft to allow long-term graft survival without the risks of broadly immunosuppressive therapies.

The NIAID mission encompasses basic and clinical research on the causes, treatment, and prevention of a wide range of immune-mediated disorders. NIAID-sponsored research is contributing to the fundamental discoveries that will lead to a comprehensive understanding of the mechanisms involved in immune regulation and immune protection, with wide application in vaccines and therapies for immune-mediated disorders. Emerging opportunities include new approaches to engage the innate immune system by using rationally designed adjuvants and immune-modulating agents for improved vaccine responses and control of allergic reactions. Further advances in understanding regulatory cells



and the normal processes of immune tolerance are opening up new avenues for potential therapies and prevention of allergic and autoimmune diseases.

Over the last decade, enormous growth has occurred in NIAID's research portfolio and changes in areas of emphasis related to allergy, immunology, and immune-mediated diseases. The NIAID's basic immunology research portfolio has been integrated across NIAID divisions, enhancing research in areas such as innate immunity, T- and B-cell epitope discovery, and establishment of long-term B- and T-cell memory, with a greater emphasis on human immunology. The clinical research portfolio has expanded substantially to include new and larger clinical networks with their own integrated support systems. The more than 80 clinical trials (a five-fold increase since 2000) currently in various stages of development are beginning to address major challenges in the clinical arena. These challenges include the increasing prevalence of certain immune-mediated diseases and the complexities that they present, both etiologically and in treatment approaches.

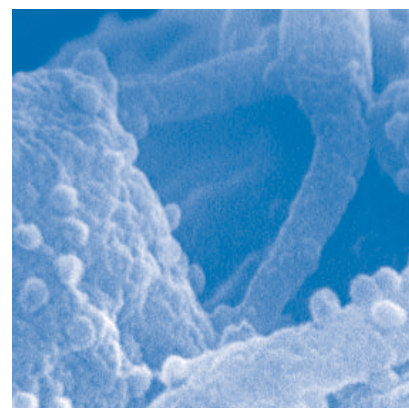
In addition to the broadly stated priorities presented in this section, several other recently published documents focus on more specific goals. These documents include:

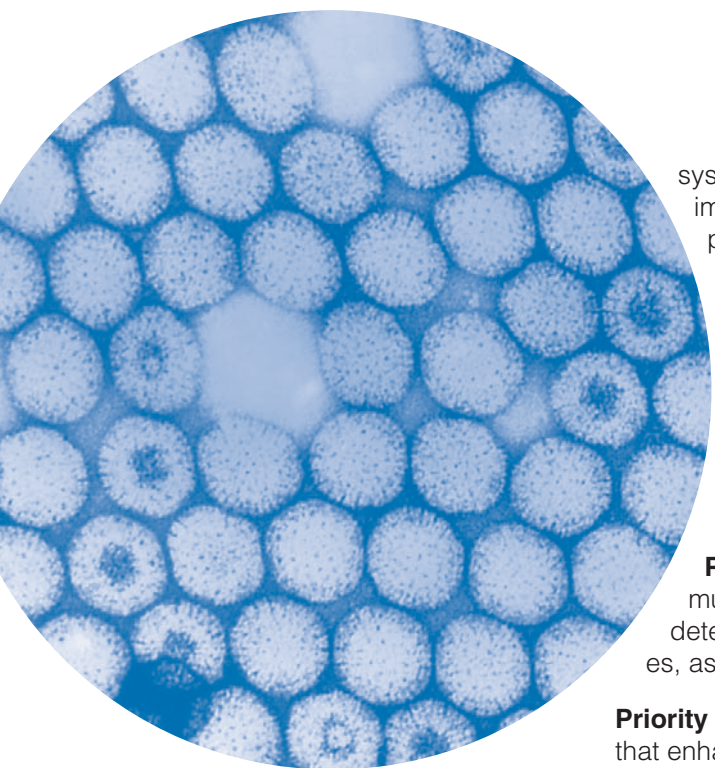
- *Action Against Asthma: A Strategic Plan for the Department of Health and Human Services* (2000)
- *NIH Autoimmune Diseases Research Plan* (2002)
- *NIH Strategic Plan and Research Agenda for Medical Countermeasures Against Radiological and Nuclear Threats* (2005)
- *Report of the Expert Panel on Food Allergy Research* (2003 and 2006)
- *NIH Action Plan for Transplantation Research* (2007)
- *NIAID Expert Panel Review of Medical Chemical Defense Research* (2003)
- *NIH Strategic Plan and Research Agenda for Medical Countermeasures Against Chemical Threats* (2007)

Basic Immunology

Over the past two decades, research in basic immunology has advanced substantially our knowledge of the immune system. Using a growing foundation of knowledge of the mechanisms involved in the host response to infection, and insights into the complexity of immune-mediated diseases and conditions, researchers are developing improved approaches to diagnose, prevent, and treat infectious diseases and immune-mediated disorders.

Priority 1: Expand our knowledge of innate and adaptive immune mechanisms to develop improved strategies to prevent and treat infectious and immune-mediated diseases. Research in this area includes the identification of new adjuvants that exploit the natural capacity of the innate immune





system to initiate and sustain protective immune responses and the improvement of vaccination approaches to enhance long-term protective immunity in humans.

Priority 2: Identify the underlying genes and determine the mechanisms of immune activation and regulation to develop novel therapeutics that selectively modify immune and inflammatory responses in humans.

Priority 3: Integrate basic immunology research with other research disciplines, such as cellular, molecular, and computational biology; genomics; proteomics; and bioinformatics.

Priority 4: Analyze the influence of the human microbiome on mucosal and systemic immune responsiveness and its role in determining the outcome of infectious diseases, autoimmune diseases, asthma, allergic disease, and obesity.

Priority 5: Develop specialized biological tools, such as humanized mice, that enhance and expand knowledge discovery in basic human immunology. Expand applied research in immunology, in areas such as imaging technology, nanotechnology, and miniaturization, to enable development of new assays and diagnostic capabilities for use at point of care.

Priority 6: Understand the mechanisms of radiation injury, especially as it affects the human immune system.

Clinical Immunology

NIAID-sponsored clinical immunology research encompasses studies of a broad range of immune-mediated disorders, including asthma, allergic and autoimmune diseases, primary immunodeficiency disorders, and transplantation immunobiology. These efforts are characterized by cross-disciplinary activities involving multiple scientific and medical disciplines, with a shared focus on the mechanistic processes responsible for the onset and progression of disease and response to therapy.

Priority 1: Conduct clinical trials to evaluate approaches that include tolerogenic, anti-inflammatory, and immunomodulatory strategies to treat and prevent immune-mediated diseases and to explore the mechanisms of action of such approaches.

Priority 2: Identify the underlying cellular and molecular mechanisms that cause immune-mediated diseases and graft rejection in order to improve therapeutic and prevention strategies. Research in this area includes studies of genetic susceptibility, identification of molecular defects, characterization of signaling pathways, identification of specific autoantigens, and analysis of inflammatory responses that cause tissue and organ injury.

Priority 3: Determine the molecular and functional characteristics of airborne, food, and other allergens and the immune responses triggered in susceptible persons.

Priority 4: Ensure that NIAID-supported research is responsive to health-disparity issues, such as the treatment and prevention of asthma in inner-city children.

Priority 5: Establish and maintain clinical research partnerships with other NIH Institutes to study immune-mediated diseases such as diabetes, asthma, and lupus.

Priority 6: Leverage the capabilities of basic immunology to improve clinical practice (bench to bedside), and use lessons learned in the clinic to stimulate new questions in basic research (bedside to bench). For example, train clinicians to understand the underlying genetic components that affect the efficacy of treatment or the risk of adverse events in subsets of the population.

Priority 7: Develop medical countermeasures capable of preventing and treating radiation injury, including research on immune homeostasis and therapies to reconstitute the immune system.

Immune Tolerance

The development of immune tolerance strategies to treat and prevent immune-mediated diseases is one of the major goals of clinical immunology. Immune tolerance strategies aim to selectively block or prevent deleterious immune responses, while leaving protective immunity intact. The prospects for developing such strategies are increasingly promising because research in basic immunology is delineating the fundamental processes responsible for self-tolerance and immune regulation. Various agents and approaches to induce and restore immune tolerance are now entering clinical trials and, if successful, may find a range of clinical applications, from asthma to allergy to autoimmunity to transplantation rejection.

Priority 1: Conduct clinical trials to evaluate immune tolerance-based strategies for adult and pediatric transplantation, autoimmune diseases, and asthma and allergic diseases.

Priority 2: Identify and validate biomarkers of induction, maintenance, and loss of immune tolerance, as well as of disease stage, activity, and therapeutic response as a means of improving management of immune-mediated diseases.

Priority 3: Elucidate the molecular mechanisms responsible for tolerance induction and maintenance, and suppression of disease by integrating mechanistic studies, clinical research studies, and studies of animal models of disease.

Priority 4: Understand mechanisms by which certain microorganisms and viruses induce tolerance to evade immune defenses, and apply this knowledge to restore protective immunity and maintain effective vaccine responses.



Research Resources

NIAID supports research databases and facilities for the production, characterization, storage, curation, and distribution of specialized reagents and animal models for biomedical research.

Priority 1: Facilitate the development of new collaborations, sharing of valuable resources, and accelerated testing of immunomodulatory and tolerance-induction strategies through workshops, formal and informal cross-disciplinary teams, and partnerships with industry.

Priority 2: Support the discovery, validation, development, and standardization of specialized reagents, repositories, assays, technologies, and bioinformatics and database resources needed to facilitate basic and clinical research programs in immunology and immune-mediated diseases, such as the NIH Tetramer Facility and the Immune Epitope Database and Analysis Resource.

Priority 3: Support: 1) development of animal models for research on immunology and immune-mediated diseases; 2) housing and distribution of widely used rodents and large animals to the research community; and 3) breeding and genetic characterization of specialized animal resources, including nonhuman primates.



Essential Foundations for the Future

In the research and development pathway, concepts discovered through basic research may generate candidate products—vaccines, diagnostics, and therapeutics—that need to be tested in preclinical models and ultimately in clinical trials. Research resources and physical infrastructure provide the foundation for this full spectrum of exploration and discovery. Intellectual infrastructure propels the research enterprise and must be sustained through training and career development. Partnerships among academia, industry, private foundations, constituency groups, and other government agencies facilitate research, product development, and information dissemination and outreach. Domestic and international infrastructure and research resources with the breadth and flexibility to meet changing research needs and to incorporate new technologies are critical to pursuing successful strategies designed to address NIAID's strategic priorities and support the Institute's research portfolio.

Research Resources and Infrastructure

NIAID is dedicated to building and sustaining comprehensive domestic and international resources that provide expertise and services throughout the research and product development lifecycle. These resources support scientists worldwide in conducting the highest quality research by leveraging state-of-the-art technology, accessing critical data and materials through registries and repositories, and establishing and supporting networks of collaborating institutions, Centers of Excellence, and clinical trials networks.

The Institute supports: 1) common vocabularies and interoperability standards in research computing applications that facilitate needed collaboration; 2) accessible, common resources for biostatistical and mathematical collaboration, including the design and analysis of experiments and clinical trials; and 3) training in Good Clinical Practices (GCP) for investigators conducting clinical research.

NIAID fosters the development of partnerships between and among NIAID and other NIH Institutes, other federal agencies, national and international research agencies, academia, private foundations, regulatory agencies, patient advocacy and community organizations, and the pharmaceutical and biotechnology industries. These partnerships have the potential to facilitate the development of research resources globally, enrich the research enterprise through community involvement, and address issues affecting product development, such as technology transfer and intellectual property.

NIAID constructs and upgrades biosafety laboratory (BSL) facilities to safely manage pathogens used in infectious disease research as well as chemical and radiological agent research. National and regional BSL facilities now completed or under construction or renovation provide improved and novel resources to conduct research safely and efficiently on infectious agents requiring BSL 2/3/4 containment.



Priority 1: Establish and maintain comprehensive, state-of-the-art genomics, proteomics, and bioinformatics centers and tools.

Priority 2: Establish resources to acquire, authenticate, produce, and appropriately distribute the needed biological reagents (such as viruses, bacteria, antigens, antibodies, peptides, and nucleic acids) to support basic research and to develop new and improved diagnostics, vaccines, and therapeutics.

Priority 3: Support the development of screening systems to identify promising agents for further testing and *in vitro*, small animal, and large animal models to assess the toxicology, immunogenicity, safety, and efficacy of vaccine candidates and potential therapeutics.

Priority 4: Establish and maintain national and international collaborative research networks, Centers of Excellence, and clinical trials networks with the capacity to conduct efficiently clinical trials on candidate vaccines and therapeutic products.

Priority 5: Enhance the clinical research infrastructure by establishing standards-based, interoperable, and broadly accessible patient registries; clinical data management systems; specimen repositories and databases; systems to identify appropriate participant cohorts; a standardized program of GCP training; and initiatives for protocol format standardization, identification of clinical endpoints, and innovative trial design.

Priority 6: Foster the development of partnerships with public and private sector organizations to leverage resources; facilitate the identification of biomarkers of infection and disease; expedite the design and conduct of clinical trials; and speed the translation of research findings into novel or improved diagnostics, vaccines, and therapeutics.

Priority 7: Enhance the existing infrastructure to provide guidance, policies, procedures, and services that enable investigators to conduct clinical research of the highest quality in accordance with applicable U.S. and international regulations, ethical standards, and appropriate guidelines.



Research Training and Career Development

Sustaining a broad research program requires support for investigators to help them develop the knowledge and skills required by changing public health needs and new scientific opportunities. The complexity of contemporary research and the emergence of new fields of study, such as bioinformatics, and of new technologies (e.g., high-throughput screening) increasingly demand that investigators take an integrated, multidisciplinary approach to solving scientific problems. In addition, NIAID is committed to encouraging a diverse research workforce equipped to conduct research in the fields of infectious disease, allergy, and immunology, including those diseases within the Institute's research portfolio that disproportionately affect underserved populations.

Priority 1: Utilize the full variety of available extramural and intramural award mechanisms to attract and develop the next generation of talented, domestic and international research investigators, including transition to the first independent academic research appointment and grant. Equip them to engage in interdisciplinary research in immunology and infectious diseases that incorporates state-of-the-art and emerging technologies.

Priority 2: Support extramural and intramural training and career development programs to expand the pool of well-trained U.S. and foreign investigators capable of designing and conducting patient-oriented research. This research includes international clinical trials that ensure the ethical treatment of human subjects and consider social, cultural, and local community concerns.

Priority 3: Provide a broad spectrum of research training and career development opportunities at various educational and career stages to help ensure that diverse pools of highly trained scientists will be available to conduct infectious disease and allergy/immunology research, with an emphasis on the elimination of health disparities.



Communications and Outreach

The full benefit of research through translation into medical practice can be realized only when new knowledge is disseminated, not only to other scientists, but also to voluntary and scientific organizations, health care providers, and the general public in the United States and internationally. An important part of the NIAID mission is to disseminate research results to the media, health professionals, and the general public and to facilitate recruitment of volunteers into clinical trials of candidate vaccines, diagnostics and therapeutics, and other clinical research studies.

Priority 1: Promote and sustain interaction with researchers, health care professionals, and the general public: 1) by communicating research results using print, audiovisual, and electronic materials; and 2) by targeting outreach activities via professional and community meetings, workshops, seminars, and conferences.

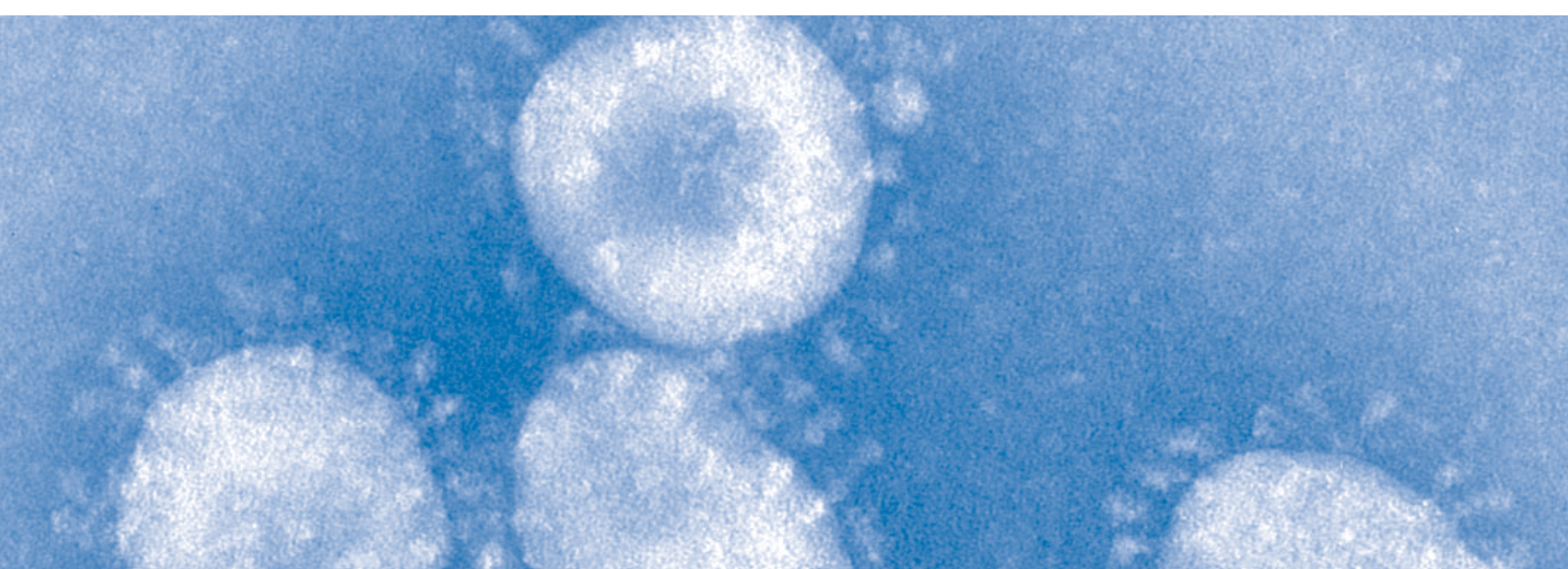
Priority 2: Maintain effective communication with Congress and other branches of the U.S. government to delineate clearly the role of NIAID in improving public health, both domestically and internationally.

Priority 3: Enhance the recruitment and retention of volunteers into clinical research studies through the production and dissemination of culturally appropriate educational materials and outreach to relevant communities, with special attention to those communities, including international settings, most affected by the disease being addressed.



End Notes

- ¹ World Health Organization (WHO). *The world health report 2004—Changing history*; <http://www.who.int/whr/2004/en>.
- ² WHO. *The world health report: 2005—Make every mother and child count*; <http://www.who.int/whr/2005/en/index.html>.
- ³ NIAID Category A, B, and C Priority Pathogens (updated February 2008); <http://www3.niaid.nih.gov/topics/BiodefenseRelated/Biodefense/research/CatA.htm>.
- ⁴ Joint United Nations Programme on HIV/AIDS (UNAIDS) and WHO. *Report on the global AIDS epidemic*, July 2008.
- ⁵ RP Walensky et al. The survival benefits of AIDS treatment in the US, *J Infect Dis*. 2006;194:1.
- ⁶ National Center for Health Statistics, CDC. *Asthma prevalence, health care use and mortality: United States, 2003-05*; <http://www.cdc.gov/nchs/products/pubs/pubd/hestats/ashtma03-05/asthma03-05.htm>.
- ⁷ SJ Arbes et al. Prevalences of positive skin test responses to 10 common allergens in the US population: Results from the Third National Health and Nutrition Examination Survey. *J Allergy Clin Immunol*. 2005;116:377-383.
- ⁸ National Academy on an Aging Society. *Chronic conditions: A challenge for the 21st century*. 2000.
- ⁹ *Report of the NIH Expert Panel on Food Allergy Research*, 2006. <http://www3.niaid.nih.gov/topics/foodAllergy/PDF/FoodAllergyExpertReport.pdf>.
- ¹⁰ The Autoimmune Diseases Coordinating Committee, NIH. *Progress in autoimmune diseases research*. (NIH Pub. No. 05-5140), 2005. http://www3.niaid.nih.gov/about/organization/dait/PDF/ADCC_Final.pdf.
- ¹¹ NIH, NIDDK, *Diabetes in America*, 2nd ed. (NIH Pub. No. 95-1468), p. 1, 1995.



Appendix: NIAID Research Plans, Agendas, and Reports and Relevant NIH and HHS Plans and Agendas

NIAID Strategic Plan

NIAID: Planning for the 21st Century – 2008 Update

<http://www3.niaid.nih.gov/about/overview/planningPriorities/>

Expert Panel

Barbara A. Baird, Ph.D.
Raphael Dolin, M.D.
Wafaa El-Sadr, M.D., M.P.H.

Richard A. Insel, M.D.
Martin Rosenberg, Ph.D.
Gary K. Schoolnik, M.D.

Laurence A. Turka, M.D.
Gail W. Wertz, Ph.D.

NIAID: Planning for the 21st Century (2000)

<http://www3.niaid.nih.gov/about/overview/planningpriorities/strategicplan/strategicplan2000.htm>

Expert Panel

Michael Apicella, M.D.
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Hugh Auchincloss, M.D.
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Steven Burakoff, M.D.
Arturo Casadevall, M.D., Ph.D.
Gail Cassell, Ph.D.
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Lawrence Corey, M.D.
George Curlin, M.D.
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Raphael Dolin, M.D.
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John E. Edwards, Jr., M.D.
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Raif Geha, M.D.

Ann Gershon, M.D.
Janis Giorgi, Ph.D.
David M. Gold, J.D.
Harry B. Greenberg, M.D.
Stephen C. Harrison, Ph.D.
Carole Heilman, Ph.D.
Marty Hirsch, M.D.
Margaret K. Hostetter, Ph.D.
Peter M. Howley, M.D.
Stephanie James, Ph.D.
Charles Janeway, M.D.
Jonathan Kagan, Ph.D.
Dennis Kasper, M.D.
Elliott Kieff, M.D., Ph.D.
Scott Koenig, M.D., Ph.D.
Richard Koup, M.D.
Joshua Lederberg, Ph.D.
Myron Levine, M.D.
Peter E. Lipsky, M.D.

Hugh McDevitt, M.D.
Pamela McInnes, D.D.S., M.Sc.
John Mekalanos, Ph.D.
Lee Nadler, M.D.
Regina Rabinovich, M.D., M.P.H.
Lee W. Riley, M.D.
Paul Rogers, Hon.
Bernard Roizman, Sc.D.
Stephen Rose, Ph.D.
Daniel Rotrosen, M.D.
Nancy Sander
Gary K. Schoolnik, M.D.
Rona Siskind
Cox Terhorst, Ph.D.
Emil Unanue, M.D.
Bruce D. Walker, M.D.
Robert Webster, Ph.D.
Gail Wertz, Ph.D.
Richard Young, Ph.D.

Special Populations

The NIAID Strategic Plan for Addressing Health Disparities Fiscal Years 2002 – 2006

http://www.niaid.nih.gov/healthdisparities/NIAID_HD_Plan_Final.pdf

Women's Health in the U.S.: Research on Health Issues Affecting Women (2004)

<http://www.niaid.nih.gov/publications/womenshealth/womenshealth.pdf>

Emerging/Re-emerging/Deliberately Emerging (Biodefense) Infectious Diseases

NIAID Strategic Plan for Biodefense Research (2002)

http://www3.niaid.nih.gov/topics/BiodefenseRelated/Biodefense/PDF/strategic_plan.pdf

NIAID Biodefense Research Agenda for CDC Category A Agents (2002)

<http://www3.niaid.nih.gov/topics/BiodefenseRelated/Biodefense/PDF/biotresearchagenda.pdf>

Expert Panel

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James Meegan, Ph.D.

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Robert B. Tesh, M.D.

Ed Tramont, M.D.

Emil R. Unanue, M.D.

Richard J. Whitley, M.D.

John A.T. Young, Ph.D.

NIAID Biodefense Research Agenda for CDC Category A Agents Progress Report (2003)

http://www3.niaid.nih.gov/topics/BiodefenseRelated/Biodefense/PDF/category_A_Progress_Report.pdf

NIAID Biodefense Research Agenda for CDC Category A Agents: 2006 Progress Report

http://www3.niaid.nih.gov/topics/BiodefenseRelated/Biodefense/PDF/CatA_2006.pdf

NIAID Biodefense Research Agenda for Category B and C Priority Agents (2003)

<http://www3.niaid.nih.gov/topics/BiodefenseRelated/Biodefense/PDF/categorybandc.pdf>

Expert Panel

L. Garry Adams, D.V.M., Ph.D., DACVP	Samuel Katz, M.D.	R. Martin Roop II, Ph.D.
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NIAID Biodefense Research Agenda for Category B and C Priority Agents Progress Report (2004)

http://www3.niaid.nih.gov/topics/BiodefenseRelated/Biodefense/PDF/category_bc_progress_report.pdf

NIAID Expert Panel on Botulinum Toxins (2002)

http://www3.niaid.nih.gov/Biodefense/PDF/bot_toxins.pdf

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Basil Golding, M.D.	Jim Marks, M.D., Ph.D.	Willie F. Vann, Ph.D.
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NIAID Expert Panel on Immunity and Biodefense (2002)

<http://www.niaid.nih.gov/publications/pdf/biodimmunpan.pdf>

Expert Panel

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NIAID Expert Panel on Botulinum Diagnostics (2003)

http://www3.niaid.nih.gov/topics/BiodefenseRelated/Biodefense/PDF/bot_toxins_mtg.pdf

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HIV/AIDS

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<http://aspe.hhs.gov/sp/asthma>

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http://www3.niaid.nih.gov/about/organization/dait/PDF/dec2002_ADCC.pdf

Expert Panel

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http://www3.niaid.nih.gov/about/organization/dait/PDF/june30_2003.pdf

Report of the NIH Expert Panel on Food Allergy Research (2006)

<http://www3.niaid.nih.gov/topics/foodAllergy/PDF/FoodAllergyExpertReport.pdf>

Expert Panel

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NIH Action Plan for Transplantation Research (2007)

<http://www3.niaid.nih.gov/about/overview/planningPriorities/trap2007.pdf>

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http://www3.niaid.nih.gov/about/overview/planningpriorities/RadNuc_StrategicPlan.pdf

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<http://www3.niaid.nih.gov/topics/BiodefenseRelated/ChemicalCountermeasures/PDF/NIHStrategicPlanChem.pdf>

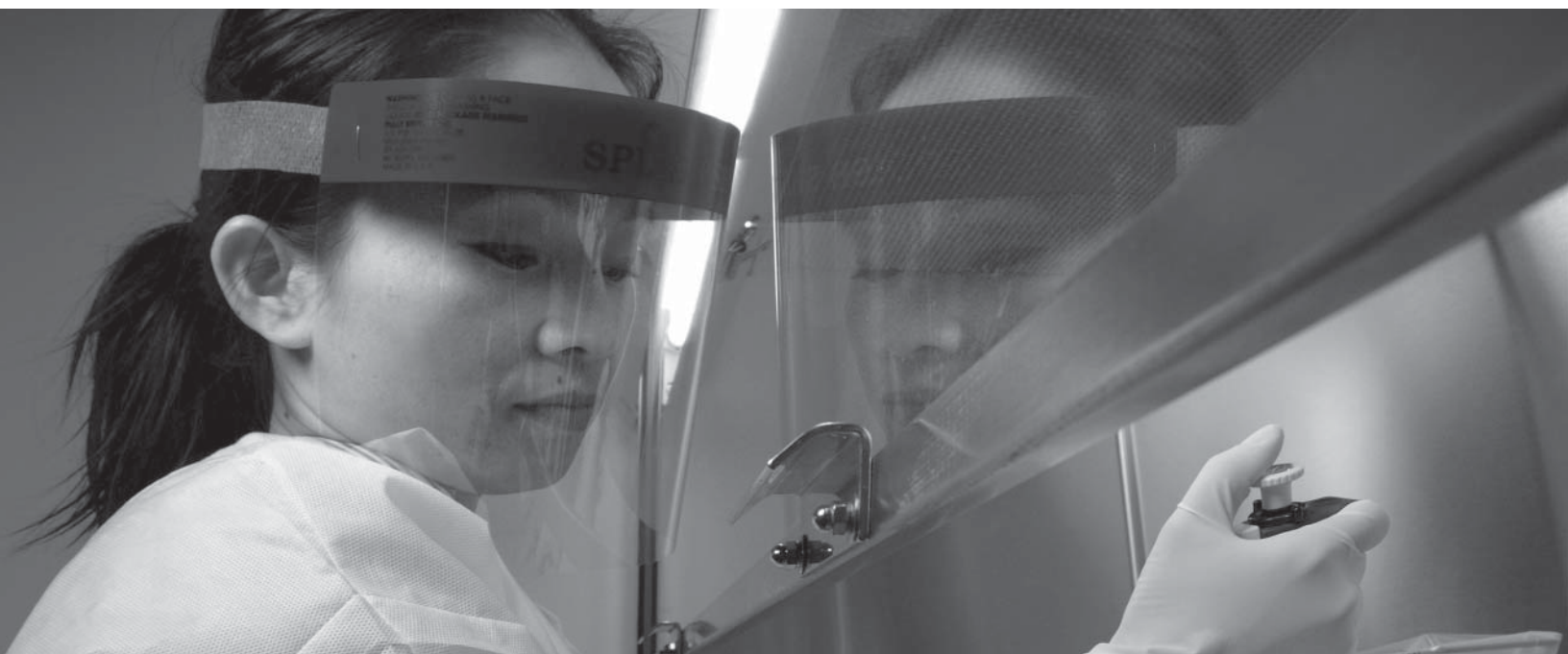
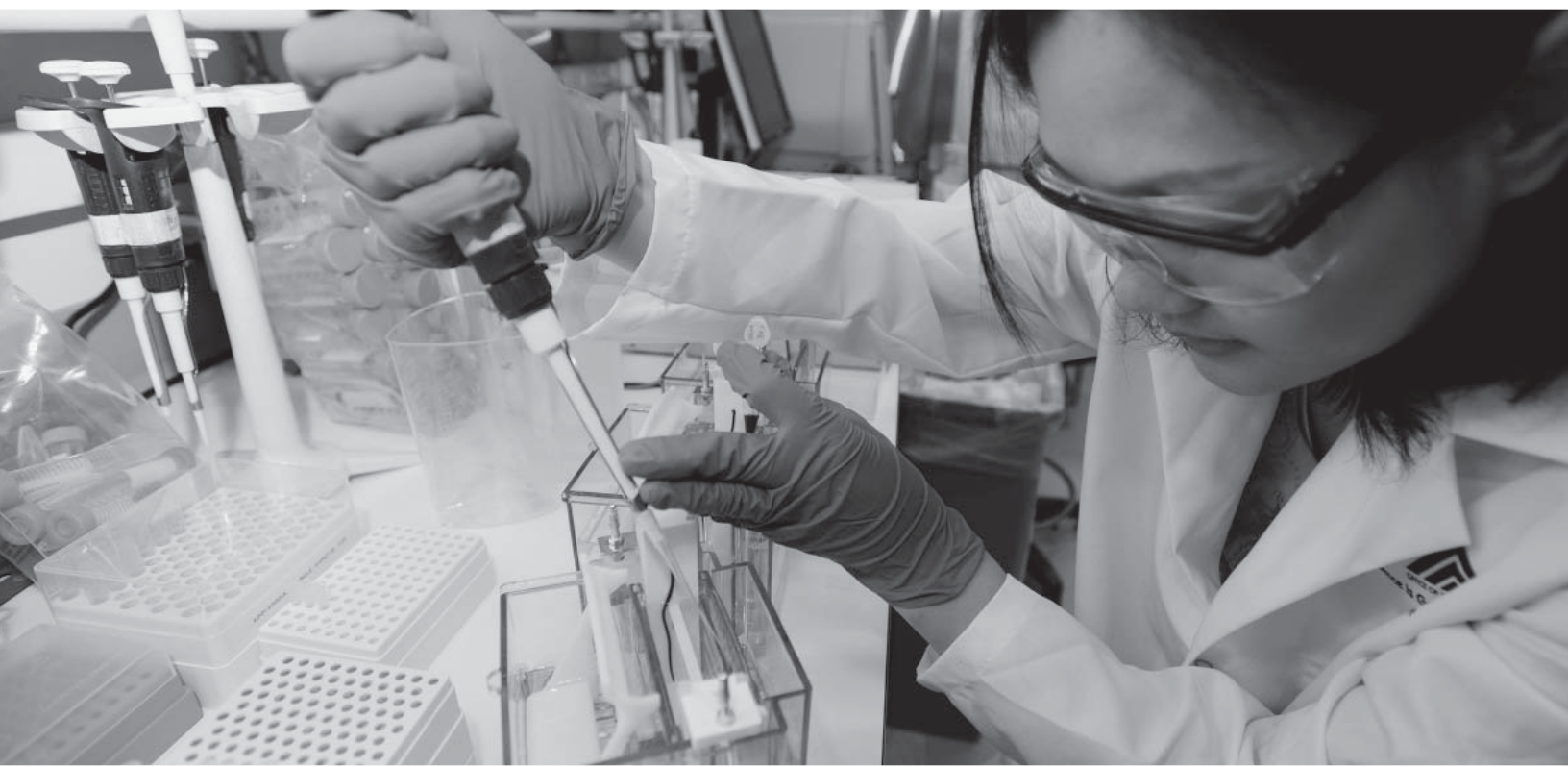


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