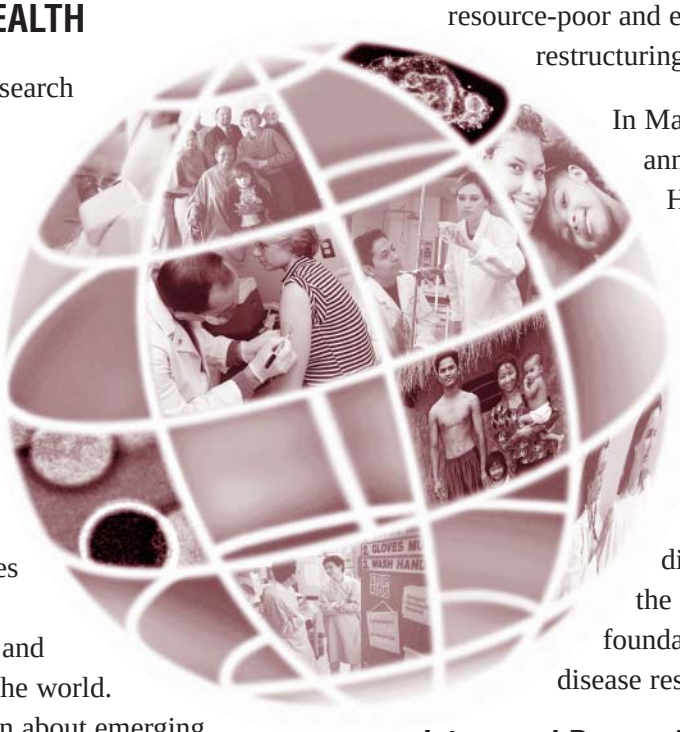
GLOBAL HEALTH



The NIAID research mission in infectious and allergic diseases is of global importance. When combined, these conditions are the most common causes of preventable human illness and death around the world. Recent concern about emerging and re-emerging infectious diseases and the anthrax biological weapon attacks of October 2001 further reinforced the importance of and added new dimensions to NIAID-supported research in improving early diagnosis, prevention, and control of these pathogens. Formal recognition of the importance of international research dates back to the International Health Act (1960), which gave the Secretary of Health and Human Services—formerly the Secretary of Health, Education, and Welfare—the authority to conduct research activities outside the United States, provided that the activities were beneficial to the health of U.S. citizens. This authority has been delegated to the NIH and to NIAID. The Public Health Service Act of 1988 (Public Law 100-607) created new HIV/AIDS authorities for the NIH. Subsequently, the NIH Revitalization Act (1993) gave NIAID specific authority to conduct research on tropical diseases that disproportionately affect populations in resource-poor and economically restructuring countries.

In May 2001, NIAID announced its Global Health Research Plan for HIV/AIDS, Malaria, and Tuberculosis. The Global Plan provides short-, medium-, and long-term objectives for treating, preventing, and controlling these diseases by building on the Institute's strong foundation in infectious disease research.

Intramural Research Training and Collaborative Research

NIAID laboratories located in the Bethesda/Washington metropolitan area and Hamilton, Montana, are a significant source of research training for postdoctoral non-U.S. scientists. The host NIAID laboratory usually provides the stipend for the visiting scientists. The research training experience often results in long-term intramural international collaborations once the scientists return to their home countries. In fiscal year (FY) 2003, the largest numbers of NIAID international scientists were from China, Italy, France, Japan, India, Russia, Australia, Germany, Canada, Korea, and Brazil.

NIAID laboratories become substantially involved in international research projects when these activities are essential to their research efforts. Funding ordinarily comes from the laboratory's regular budget and, for that reason, is not usually a major source of financial support. Exceptions may occur when

the intramural laboratory is part of a consortium and/or the laboratory is able to secure extra-budgetary funding.

In collaboration with the NIH National Center on Minority Health and Health Disparities, the Fogarty International Center (FIC), and the University of Maryland, NIAID's Laboratory of Parasitic Diseases developed a training program for young U.S. scientists and medical students to gain experience in an African setting. Since 1989, the NIAID Laboratory of Parasitic Diseases has been working with scientists and physicians at the National School of Medicine of Mali, located in Bamako, Mali, West Africa, to develop the Malaria Research and Training Center (MRTC). MRTC has developed into a well-equipped, highly productive facility in which the research is planned, directed, and executed by Malian staff. Funding comes from a number of U.S. and international agencies, including several NIAID-funded U.S. universities. MRTC recently dedicated a new laboratory research facility and dormitory.

Building on the experience in Mali, NIAID is developing the International Center for Excellence in Research (ICER) program, which has the objective of using longstanding intramural research to achieve long-term, sustainable collaboration and to attract extramural competitive funding. ICER projects are presently under development in India (tropical diseases), Mali (malaria), and Uganda (HIV/AIDS).

Domestic Research Awards With an International Component

NIAID funds the vast majority of its international research indirectly through competitive domestic extramural research awards that have an international component. Special emphasis programs have been developed in tropical medicine, emerging infectious diseases, HIV/AIDS, and tuberculosis to take advantage of research opportunities overseas in countries with a disproportionate burden of these diseases.

The NIAID International Centers for Tropical Disease Research (ICTDR) network is the earliest and most mature of these special programs. The ICTDR network consists of (1) Tropical Disease Research Units, which are U.S. institutions conducting multidisciplinary research relevant to the treatment, prevention, or control of tropical diseases; (2) the International Collaboration in Infectious Disease Research (ICIDR) program, which makes awards to U.S. institutions to engage in substantial international collaboration with overseas institutions in tropical medicine and emerging infectious diseases; (3) NIAID intramural laboratories active in tropical medicine and infectious disease research; (4) additional U.S. institutions with a critical mass of tropical and emerging infectious disease research; and (5) Tropical Medicine Research Centers, which provide direct funding to overseas centers of excellence. In FY 1999, NIAID formally linked the ICIDR program with the FIC Actions for Building Capacity institutional research training program.

Initiated in 1994, the NIAID Tuberculosis Prevention Research Center has operated through a research contract with Case Western Reserve University to coordinate a consortium of U.S. and international (Brazil and Uganda) institutions to conduct high-priority research projects that range from basic research to the development and evaluation of new or improved diagnostic tests, drugs, and vaccine candidates.

Each of NIAID's HIV/AIDS clinical research networks has international components. The HIV Vaccine Trials Network (HVTN) was created in May 2000 to advance worldwide efforts to develop an HIV vaccine. The network's U.S.-based units are integrated with sites around the globe to ensure appropriate vaccine approaches for these regions and to help HVTN expand rapidly when it is ready to carry out large-scale studies of suitable vaccines. HVTN international sites are located in Botswana, Brazil, China, Dominican Republic, Haiti, Honduras, India, Malawi, Peru, South Africa, Thailand, and Trinidad and Tobago.

The HIV Prevention Trials Network (HPTN) is a second worldwide collaborative effort established by NIAID to evaluate the safety and efficacy of nonvaccine prevention interventions. To carefully evaluate the safety and efficacy of approaches such as topical microbicides and behavioral interventions, HPTN consists of operational, data, and laboratory centers to support international research sites in Brazil, China, India, Malawi, Peru, Russia, South Africa, Tanzania, Thailand, Uganda, Zambia, and Zimbabwe.

NIAID's Acute HIV Infection and Early Disease Research Program is collaborating with the University of Alabama at Birmingham and the University Teaching Hospital in Lusaka, Zambia, to study the effects of a short course of antiretroviral therapy on the viral load in newly infected persons when it is initiated early after acute HIV infection.

The NIAID Centers for AIDS Research (CFARs) support a multidisciplinary environment that promotes basic, clinical, behavioral, and translational research in the prevention, detection, and treatment of HIV infection and AIDS. Current CFAR collaborations are taking place in Belize, Kenya, Mexico, Peru, Thailand, Uganda, and Zambia.

International Awards

NIAID and the NIH accept investigator-initiated research proposals from international scientists and permit international scientists to respond to most program announcements and requests for applications. To be funded, international applications must receive a competitive peer review score and be approved by the National Advisory Allergy and Infectious Diseases Council on the basis of their uniqueness and/or program relevance. International scientists also may be eligible to compete for NIAID research contracts when U.S. institutions cannot carry out the project (e.g., pertussis vaccine trials in Italy and Sweden) or when the domestic applications are not responsive to the solicitation.

Historically, international awards have accounted for about 1 percent of the NIAID budget. As basic research results in new or improved products that require evaluation in populations with heavy burdens of disease, this amount is expected to increase. Furthermore, long-term NIAID investment in collaborative research has resulted in the development of overseas sites capable of independent research. The establishment of the Tropical Medicine Research Center program a decade ago was a reflection of this phenomenon.

In FY 2001, NIAID launched the Comprehensive International Program of Research on AIDS (CIPRA). CIPRA provides long-term support directly to developing countries to plan and implement a

comprehensive HIV/AIDS prevention and research agenda relevant to their populations and to strengthen the infrastructure required to carry out this research. As national research capacity grows, countries can seek renewable CIPRA funding for multidisciplinary research projects and/or clinical trials for HIV prevention and/or treatment.

In FY 2003, CIPRA awarded seven planning and organizational grants to Argentina, Brazil, Egypt, the Republic of Georgia, Kenya, Malaysia, and Mozambique and one large multiproject grant to Senegal.

Official Bilateral Programs

In addition to regular scientific channels, the United States often develops formal, bilateral scientific agreements with foreign governments or organizations at the level of the President, Department of Health and Human Services (DHHS), the NIH, or NIAID. NIAID carries out these programs with budgeted funds unless special or supplementary funds are made available. During FY 2001, NIAID actively participated in bilateral programs involving Brazil, China, France, the Republic of Georgia, Germany, India, Italy, Japan, Russia, South Africa, and Taiwan. Of particular interest is the U.S.-Japan Cooperative Medical Science Program (USJCMSP), which consists of committees of senior scientists and panels of experts in high-priority diseases of the Pacific Basin. Both the Joint USJCMSP Committee and Joint Panels meet annually, alternating countries in conjunction with scientific conferences. The USJCMSP has organized annual workshops on emerging and re-emerging infectious diseases in the Pacific Basin at different sites in the region. Active priority areas are AIDS, acute respiratory infections, cholera and other bacterial enteric diseases, environmental mutagenesis and carcinogenesis, infectious hepatitis, immunology, leprosy/tuberculosis, nutrition, parasitic diseases, and viral diseases.

International Agencies and Organizations

NIAID has joined with other organizations to enhance scientific collaborations in combating infectious diseases. Examples include the Presidential Millennium Vaccine Initiative; the Global Alliance for Vaccines and Immunization; the Multilateral Initiative on Malaria in Africa; the International Cooperative Biodiversity Groups Program; and the DHHS-State Department BioTechnology Engagement Program and the Civilian Research and Development Foundation, both of which provide support to scientists in the Newly Independent States to conduct collaborative research on problems of public health importance.

NIAID staff members also participate on the scientific boards of and as consultants to the World Health Organization (WHO), the Pan American Health Organization, and the U.S. Agency for International Development. During FY 2003, NIAID provided consultation to WHO in the development and implementation of a global research response to severe acute respiratory syndrome (SARS).