Appendices

LEGISLATIVE CHRONOLOGY

NOV. 1, 1948

The National Microbiological Institute was established under authority of section 202 of the Public Health Service Act, as implemented by General Circular No. 55, Organization Order No. 20, dated October 8, 1948.

DEC. 29, 1955

NIAID was established (replacing the National Microbiological Institute) under authority of the Omnibus Medical Research Act (Public Law 81-692, 64 Stat. L. 443), as implemented by a Public Health Service Briefing Memorandum of November 4, 1955, from the Surgeon General to the Secretary of Health, Education, and Welfare.

NOV. 4, 1988

NIAID was provided with additional authorities for AIDS research under Title II of the Health Omnibus Programs Extension of 1988 (HOPE legislation) (Public Law 100-607), the first major law to address AIDS research, information, education, and prevention.

AUG. 14, 1991

The Public Health Service Act was amended by Public Law 102-96, the Terry Beirn Community-Based AIDS Research Initiative Act of 1991, which reauthorized NIAID's Community Programs for Clinical Research on AIDS (CPCRA). CPCRA was renamed in honor of Mr. Beirn (an AIDS activist and congressional staffer who died in 1991) and was reauthorized for an additional 5 years.

JUNE 10, 1993

The Public Health Service Act was amended by Public Law 103-43, the National Institutes of Health Revitalization Act of 1993. This comprehensive legislation required NIAID to include research on tropical diseases in its mission statement and directs the Secretary, U.S. Department of Health and Human Services, to ensure that individuals with expertise in chronic fatigue syndrome or neuromuscular diseases are appointed to appropriate NIH advisory committees.

DEC. 14, 1993

The Preventive Health Amendments of 1993 were passed, which included provisions requiring the Director, NIAID, to conduct or support research and research training regarding the cause, early detection, prevention, and treatment of tuberculosis. (The Institute already had authority to conduct such research under its authorities in Title IV, Public Health Service Act.)

NOV. 29, 1999

The fiscal year 2000 Appropriations Act (Public Law 106-113) established the NIH Challenge Grants program to promote joint ventures between the NIH and the biotechnology, pharmaceutical, and medical device industries. A one-time funding level of $20 million was provided within the Public Health and Social Services Emergency Fund.

OCT. 17, 2000

The Children's Health Act (Public Law 106-310) required the Directors of NIAID and the National Institute of Arthritis and Musculoskeletal and Skin Diseases to expand and intensify the activities of their Institutes with respect to research and related activities concerning juvenile arthritis and related conditions.

NOV. 13, 2000

The Public Health Improvement Act (Public Law 106-505) authorized the NIAID Director to establish a program of clinical research and training awards for sexually transmitted infections.

Previous Directors

Victor H. Haas, M.D., 1948–1957
Justin M. Andrews, Sc.D., 1957–1964
Dorland J. Davis, M.D., D.P.H., 1964–1975
Richard M. Krause, M.D., 1975–1984

TECHNOLOGY TRANSFER

Technology transfer in Federal laboratories facilitates the dissemination of new technologies and research materials developed by Government scientists. This technology transfer fuels further innovation and commercialization by the extramural research and development community, ultimately resulting in an improvement in the public health and an increase in the competitiveness of U.S. industry. Federal legislation mandates and defines the Government's technology transfer activities. The key pieces of legislation are the Federal Technology Transfer Act of 1986 and the National Technology Transfer and Advancement Act of 1995.

The NIAID Office of Technology Development (OTD) accomplishes technology transfer by facilitating the transfer of significant research advances and resources to the broader scientific community and the development of collaborative relationships between NIAID scientists, industry, and academia. NIAID uses various mechanisms to accomplish these ends, including Material Transfer Agreements (MTAs), Cooperative Research and Development Agreements (CRADAs), Materials-CRADAs (M-CRADAs), Confidential Disclosure Agreements (CDAs), Clinical Trial Agreements (CTAs), Drug Screening Agreements (DSAs), and, through the NIH Office of Technology Transfer (OTT), the patenting of inventions and the negotiation of various license agreements.

NIAID scientists report inventions to OTD by submitting Employee Invention Reports (EIRs). The EIRs are reviewed by OTD and, with the assistance of the NIAID Technology Evaluation Advisory Committee (TEAC), are evaluated for the purpose of filing domestic and foreign patent applications. In fiscal year (FY) 2003, TEAC reviewed 27 intramural EIRs and recommended that a patent application be filed on 22 of them. NIAID currently has 342 active U.S. patent properties, including 168 issued patents and 174 pending patent applications.

NIAID had a total of 245 active license agreements in FY 2003 for both patented inventions and biological materials. These licenses generated about $10.3 million in royalty income, which was first used to pay NIAID inventors their share according to Federal law and NIH policy. The Institute also distributed royalty income to intramural laboratories to support research projects and equipment acquisition that otherwise would not have been accomplished with appropriated funds. The remaining royalties were used to pay OTD's entire operating budget, including patent prosecution fees, OTD staff salaries, associated office expenses, and overhead charged by OTT.

In FY 2003, a total of 192 MTAs, 12 CTAs, 59 CDAs, 5 CRADAs, 14 M-CRADAs, and 21 other agreements, not including the screening agreement related to severe acute respiratory syndrome (SARS) discussed below, were executed and negotiated by OTD. NIAID extramural divisions referred technology transfer issues to OTD on 5 contracts, and OTD NIAID scientists performed research under 33 CRADAs and 40 M-CRADAs in FY 2003. The following table provides a history of NIAID's patent, license, and CRADA activities.

NIAID Technology Transfer Activities

Fiscal Year	Pending Patents	Issued Patents	Licenses in Effect	Active CRADAs
1994	85	65	84	29
1995	96	71	101	31
1996	95	84	120	42
1997	128	91	131	71
1998	154	83	155	95
1999	169	94	195	74
2000	229	100	196	86
2001	194	125	190	93
2002	147	139	197	85
2003	174	168	245	71

Technology Transfer Highlights

OTD supported NIAID's response to SARS by drafting an agreement for use in a collaboration between the NIAID Division of Microbiology and Infectious Diseases (DMID) and the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) to provide resources to screen possible anti-SARS proprietary compounds. This screening agreement has been provided to 190 companies, of which more than 40 requested that the screening agreement be renegotiated by OTD. In addition to this screening agreement, OTD negotiated and completed at least 13 other SARS-related agreements.

In FY 2003, OTD negotiated or facilitated the following public-private partnerships.

Evaluation of Adenoviral Encoding Proteins Associated With SARS (GenVec)

Recombinant adenoviral vectors have been widely investigated in recent years as a gene delivery system for gene therapy and vaccination. Recombinant adenoviral vectors offer a promising strategy for development of a candidate SARS vaccine that could be effective in humans. Investigators at the Vaccine Research Center (VRC), NIAID, the NIH, and GenVec, Inc. (GenVec) will collaborate to evaluate and develop adenoviral vectors expressing modified SARS genes. The collaboration will evaluate adenovectors for potential application, such as a SARS preventive vaccine. VRC will provide GenVec with several modified SARS genes, and GenVec will construct and produce recombinant adenovectors that express SARS genes, using the GenVec adenovector and cell line system. The overall goal is to provide VRC with advanced vector technologies suitable for rapid advancement toward clinical trial.

Analysis of the Immune Response to Hepatitis C Virus (Innogenetics)

Under this CRADA, investigators in the Hepatitis Viruses Section, Laboratory of Infectious Diseases, Division of Intramural Research at NIAID, and Innogenetics will perform basic and applied studies of the immune response to hepatitis C virus (HCV) in nonhuman primates in order to determine how to modify the host response to HCV for therapeutic and immunoprophylactic benefit.

Use of Quantum Dots for Improved Cellular Classification in Flow Cytometry (Quantum Dot Corporation)

Under this CRADA, investigators in the Immunology and Flow Cytometry Core of NIAID's VRC and Quantum Dot Corporation will aim to adapt quantum dots for use in detailed characterization of the function and types of immune cells that respond to pathogens and vaccines. The quantum dots are semiconductor nanocrystals with unique fluorescent properties that may significantly aid in the identification of specific properties of these cells using flow cytometry.

Oligonucleotide Control Sets for Microarray Applications (Invitrogen Corporation)

The purpose of this CRADA is to develop oligonucleotide sets of standards for use as a universal reference for interpreting and reporting microarray and other expression investigative research tools. The outcome of this project should result in two complementary standard sets that can be used for researchers: (1) oligonucleotide probe sets for use by facilities that produce custom or spotted DNA microarrays, and (2) premixed cocktails of target RNA standards and hybridization controls for researchers who perform the sample labeling and hybridization of microarrays. It is envisioned that these standards would benefit public health by facilitating the use of microarrays in biomedical research areas, including infectious diseases and genetic research as well as other research fields.

A Study of the Mechanism of Action of the Anti-HIV Compound, PA-457 (Panacos, Inc.)

NIAID and Panacos Pharmaceuticals, Inc., are collaborating under this CRADA to study the HIV inhibitory mechanism of action of Panacos Pharmaceuticals' proprietary compound PA-457. The parties will employ state-of-the-art biochemical and structural biology techniques to carry out their research program.

New CRADAs

During FY 2003, NIAID scientists entered into the following five new CRADAs:

Collaborator
GenVec, Inc.

Investigator
Phillip Gomez III, Ph.D., M.B.A.
Vaccine Research Center

Title
Evaluation of Adenoviral Encoding Proteins Associated With SARS

Collaborator
Innogenetics

Investigator
Robert H. Purcell, M.D.
Laboratory of Infectious Diseases

Title
Analysis of the Immune Response to Hepatitis C Virus

Collaborator
Invitrogen Corp.

Investigators
Thomas Kindt, Ph.D.
Michael Wilson, Ph.D.
Research Technologies Branch, Division of Intramural Research

Title
Oligonucleotide Control Sets for Microarray Applications

Collaborator
Panacos, Inc.

Investigator
Eric Freed, Ph.D.
Laboratory of Molecular Microbiology

Title
A Study of the Mechanism of Action of the Anti-HIV Compound, PA-457

Collaborator
Quantum Dot Corp.

Investigator
Mario Roederer, Ph.D.
Vaccine Research Center

Title
Use of Quantum Dots for Improved Cellular Classification in Flow Cytometry

CRADAs in Effect, FY 2003

Collaborator
Achillion Pharmaceuticals

Investigator
John Inman, Ph.D.
Laboratory of Immunology

Title
Development of Optimized Inhibitors of Protein Zinc Finger Domains

Collaborator
American Cyanamid

Investigator
Brian Murphy, M.D.
Laboratory of Infectious Diseases

Title
Development of Safe and Effective Live Attenuated Vaccines for Respiratory Syncytial Virus Subgroups A and B and Parainfluenza Viruses Type 1, 2, and 3

Collaborator
Biospace.com

Investigator
Laurence Wolfe, Ph.D.
Office of Technology and Information Systems

Title
Development of an Electronic Procurement System for Commodity Identification, Product and Service Acquisition, and Budget Tracking

Collaborator
Chiron

Investigator
H. Clifford Lane, M.D.
Laboratory of Immunoregulation

Title
Research and Development of IL-2 as a Treatment for HIV Infection

Collaborator
Ciphergen Biosystems

Investigators
John Kehrl, M.D.
Tae-Wook Chun, Ph.D.
Laboratory of Immunoregulation

Title
Identification and Characterization of Novel Non-Cytolytic Antiviral Factors Derived From CD8+ T Cells of HIV-Infected Individuals Using the ProteinChip® System

Collaborator
Connaught Technology Corp.

Investigator
Warren Strober, M.D.
Laboratory of Clinical Investigation

Title
Development of Vectored Vaccines and Therapeutics for the Prevention and Treatment of AIDS

Collaborator
Crucell

Investigator
Phillip Gomez III, Ph.D., M.B.A.
Vaccine Research Center

Title
Development of an Improved Recombinant Adenovirus Vector for Vaccination Against the Ebola Virus

Collaborator
Genetics Institute

Investigator
Ethan Shevach, M.D.
Laboratory of Immunology

Title
Analysis of Gene Expression in Immunoregulatory T Cells that Co-Express the CD4 and CD25 Surface Markers

Collaborator
Genetics Institute

Investigators
Stephen Straus, M.D.
Warren Strober, M.D.
Peter Mannon, M.D.
Ivan Fuss, M.D.
Laboratory of Clinical Investigation

Title
A Randomized, Double-Blind, Placebo-Controlled, Dose-Finding, Safety Study of Two Parallel Dose Levels of Subcutaneously Administered Human Monoclonal Antibody to Interleukin-12 (J695) in Patients With Active Crohn's Disease

Collaborator
Genetics Institute

Investigator
Thomas Wynn, Ph.D.
Laboratory of Parasitic Disease

Title
Development of IL-13 Antagonism as a Treatment for Fibrosis in Schistosomiasis

Collaborator
GenVec

Investigator
Phillip Gomez III, Ph.D., M.B.A.
Vaccine Research Center

Title
Evaluation of Adenoviral Encoding Proteins Associated With SARS

Collaborator
GenVec

Investigator
Phillip Gomez III, Ph.D., M.B.A.
Vaccine Research Center

Title
Evaluation of Adenoviral Vectors Encoding HIV-1 Proteins

Collaborator
Glaxo Research & Development

Investigator
Clifton Barry III, Ph.D.
Laboratory of Host Defenses

Title
Development of New Drugs for the Treatment of Tuberculosis

Collaborator
GlaxoSmithKline

Investigator
David Klein, Ph.D.
Division of Microbiology and Infectious Diseases

Title
Adult Pertussis Vaccine

Collaborator
GlaxoSmithKline

Investigators
Holli Hamilton, M.D., M.P.H.
Barbara Savarese, R.N.
Division of Microbiology and Infectious Diseases

Title
A Double-Blind, Randomized, Controlled Phase III Study to Assess the Prophylactic Efficacy of rgD/Alum/MPL Vaccine in the Prevention of Genital Herpes Disease in Young Sexually Active Women

Collaborator
GlaxoSmithKline

Investigator
Robert H. Purcell, M.D.
Laboratory of Infectious Diseases

Title
Hepatitis C Vaccine

Collaborator
GlaxoSmithKline

Investigator
Robert H. Purcell, M.D.
Laboratory of Infectious Diseases

Title
Hepatitis E Vaccine

Collaborator
Ichor Medical Systems

Investigator
Phillip Gomez III, Ph.D., M.B.A.
Vaccine Research Center

Title
Evaluation of Electroporation-Mediated Delivery of an HIV DNA Vaccine

Collaborator
Innogenetics

Investigator
Robert H. Purcell, M.D.
Laboratory of Infectious Diseases

Title
Analysis of the Immune Response to Hepatitis C Virus

Collaborator
Invitrogen Corp.

Investigators
Thomas Kindt, Ph.D.
Michael Wilson, Ph.D.
Research Technologies Branch,
Division of Intramural Research

Title
Oligonucleotide Control Sets for Microarray Applications

Collaborator
Lederle-Praxis
Biologicals Division
American Cyanamid

Investigator
Peter Collins, Ph.D.
Laboratory of Infectious Diseases

Title
Production of Live Attenuated RSV and PIV Vaccine Viruses From cDNA

Collaborator
Maxygen

Investigator
Louis Miller, M.D.
Laboratory of Parasitic Disease

Title
Novel, Polyspecific Malaria Vaccine Development Based on PfEMP1 Using Molecular Breeding™ Directed Molecular Evolution Technologies

Collaborator
MedImmune Vaccines (formerly Aviron)

Investigator
Ann Ginsberg, M.D., Ph.D.
Division of Microbiology and Infectious Diseases

Title
Development of a Live Attenuated Cold-Adapted Influenza Vaccine

Collaborator
Merck

Investigator
Gary Nabel, M.D., Ph.D.
Vaccine Research Center

Title
Development of an Adenoviral-Based HIV Vaccine

Collaborator
Merck

Investigator
Stephen Straus, M.D.
Laboratory of Clinical Investigation

Title
A Double-Blind, Placebo-Controlled Study of the Efficacy of Live Attenuated Oka/Merck Varicella Zoster Vaccine in Reducing the Incidence and/or Severity of Shingles in Adults

Collaborator
Merial

Investigator
José Ribeiro, M.D., Ph.D.
Laboratory of Parasitic Disease

Title
Evaluation of DNA Vaccines Encoding Sand Fly Salivary Proteins as Candidates to Control Leishmania Infantum Infection in Dogs

Collaborator
Nexell Therapeutics

Investigators
Harry L. Malech, M.D.
Mitchell Horwitz, M.D.
Laboratory of Host Defenses

Title
Study of Low Intensity Preparative Regimen Followed by HLA-Matched Transplantation for Chronic Disease

Collaborator
Novartis

Investigator
Marshall Plaut, M.D.
Division of Allergy, Immunology, and Transplantation

Title
A Double-Blind, Placebo-Controlled Study of the Efficiency of E25 anti-IgE Reducing Asthma Symptoms in Inner-City Children

Collaborator
Novavax

Investigator
Louis Miller, M.D.
Laboratory of Parasitic Disease

Title
Merozoite Surface Protein 1 Expressed in Insect Cells: Process Development, Preclinical and Initial Clinical Evaluation

Collaborator
Osel

Investigator
Edward Berger, Ph.D.
Laboratory of Viral Diseases

Title
SCD4-17b Expressed by/on Lactobacillus as an Anti-HIV Topical Microbicide

Collaborator
Panacos

Investigator
Eric Freed, Ph.D.
Laboratory of Molecular Microbiology

Title
A Study of the Mechanism of Action of the Anti-HIV Compound, PA-457

Collaborator
Quantum Dot Corporation

Investigator
Mario Roederer, Ph.D.
Vaccine Research Center

Title
Use of Quantum Dots for Improved Cellular Classification in Flow Cytometry

Collaborator
Wyeth-Lederle Vaccines, American Home Products

Investigator
Pamela McInnes, Ph.D.
Division of Microbiology and Infectious Diseases

Title
Preventing Childhood Mortality—An Efficacy Trial of a Pneumococcal Conjugate Vaccine in Upper and Central River Divisions, The Gambia

NIH EXTRAMURAL FUNDING MECHANISMS USED BY NIAID

Fellowship Programs

F31 Predoctoral Individual National Research Service Award (NRSA)—provides predoctoral individuals with supervised research training in specified health and health-related areas leading toward the research degree (e.g., Ph.D.).

F32 Postdoctoral Individual NRSA—provides postdoctoral research training to individuals to broaden their scientific background and extend their potential for research in specified health-related areas.

F33 NRSA for Senior Fellows—provides opportunities for experienced scientists to make major changes in the direction of their research careers, to broaden their scientific background, or to acquire new research capabilities.

F35 Intramural NRSA Individual Postdoctoral Program—supports a postdoctoral trainee in the NIH intramural program.

Research Career Programs

K02 Independent Scientist Award—provides support for newly independent scientists who can demonstrate the need for a period of intensive research focus as a means of enhancing their research careers.

K08 Clinical Investigator Award—provides the opportunity for promising medical scientists (with demonstrated aptitude to develop into independent investigators) or faculty members who will pursue research aspects of categorical areas applicable to the awarding unit, and aids in filling the important academic faculty gap in these shortage areas within health professional institutions of the country.

K22 Career Transition Award—provides support to outstanding newly trained basic or clinical investigators to develop their independent research skills through a two-phase program: an initial period involving an intramural appointment of the NIH and a final period of support at an extramural institution. The award is intended to facilitate the establishment of a record of independent research by the investigator to sustain or promote a successful research career.

K23 Mentored Patient-Oriented Research Career Development Award—provides support for the career development of investigators who have made a commitment to focus their research endeavors on patient-oriented research. This mechanism provides support for a 3-year minimum up to a 5-year period of supervised study and research for clinically trained professionals who have the potential to develop into productive clinical investigators.

K24 Midcareer Investigator Award in Patient-Oriented Research—provides support for experienced clinicians to allow them protected time to devote to patient-oriented research and to act as mentors for beginning clinical investigators.

K25 Mentored Quantitative Research Career Development Award—supports junior-faculty-level investigators with quantitative scientific and engineering backgrounds outside of biology or medicine who have the potential to integrate their expertise with biomedicine

and to develop into productive investigators with a period of mentored study and research.

K30 Clinical Research Curriculum Award (CRCA)—awarded to institutions to stimulate the inclusion of high-quality, multidisciplinary didactic training as part of the career development of clinical investigators. This award is intended to support the development of new didactic programs in clinical research at institutions that do not currently offer such programs or in institutions with existing didactic programs in clinical research to support or expand their programs or to improve the quality of instruction.

Research and Development-Related Contracts

N01 Research and Development Contract—develops or applies new knowledge or tests, screens, or evaluates a product, material, device, or component for use by the scientific community.

Research Program Projects and Centers

P01 Research Program Project—provides a qualified institution, on behalf of a principal investigator, with the support of a broad-based, multidisciplinary, often long-term research program with a particular major objective or theme. A program project involves the organized efforts of groups of investigators who conduct research projects related to the overall program objective. The grant can provide support for the projects and for certain shared resources necessary for the total research effort. Each project supported under a program project grant is expected to contribute to the overall program objective.

P30 Center Core Grant—supports shared resources and facilities for categorical research by a number of investigators from different disciplines who provide a multidisciplinary approach to a joint research effort or from the same discipline who focus on a common research problem. Although funded independently of the center's component projects or program projects, the core grant relates integratively to them. By providing more accessible resources, this support is expected to ensure greater productivity than that obtained from the separate projects and program projects.

P50 Specialized Center—supports any part of the full range of R&D, from basic to clinical, and may involve ancillary supportive activities, such as protracted patient care necessary to the primary research or R&D effort. The spectrum of activities comprises a multidisciplinary attack on a specific disease entity or biomedical problem area. These grants differ from program project grants in that they are usually developed in response to an announcement of the programmatic needs of an Institute or Division and subsequently receive continuous attention from its staff. Centers also may serve as regional or national resources for special research purposes.

Research Project Grants and Grants Related to Research Projects

R01 Research Project Grant (traditional)—provides support to an institution (domestic or foreign) on behalf of a principal investigator for a discrete

project related to the investigator's interests and competence. Most of the research that the NIH supports is maintained through this funding mechanism. Although rare, such a grant may be awarded directly to an individual.

R03 Small Grant—provides research support specifically limited in time and amount for studies in categorical program areas. Small grants provide flexibility for initiating studies, which are generally for preliminary short-term projects and are nonrenewable.

R09 Scientific Evaluation—provides the chairman of an initial review group funds for operation of the initial review group.

R13 Conference Grant—provides funding for conferences to coordinate, exchange, and disseminate information related to program interests. In general, such awards are modest and limited to participation with other organizations in the support of conferences rather than as a provision of sole support. Among the costs eligible for support are salaries, equipment rental, travel, consultant services, and supplies. Prospective applicants should inquire in advance concerning possible interest on the part of an Institute.

R15 Academic Research Enhancement Award (AREA)—provides support to scientists at eligible domestic institutions for small-scale, new, or expanded health-related research projects, such as pilot research projects and feasibility studies; development, testing, and refinement of research techniques; secondary analysis of available data sets; and similar discrete research projects that demonstrate research capability. This award is directed toward smaller, less-prominent 4-year public and private colleges and universities that provide undergraduate training for a significant number of U.S. research scientists but have not had an adequate share in the growth of the NIH extramural program.

R18 Research Demonstration and Dissemination Project—provides support to develop, test, and evaluate health-service activities and to foster the application of existing knowledge for the control of categorical diseases.

R21 Exploratory/Developmental Grant—used by NIAID for bridge awards. The bridge award provides support for a limited time and amount to investigators to enable them to continue meritorious research and improve the competitiveness of future grant applications.

R24 Resource-Related Research Project—supports research projects that will enhance the capability of resources to serve biomedical research.

R25 Education Project—provides support to develop or implement a program in education, information, training, technical assistance, coordination, or evaluation.

R33 Exploratory and Developmental Grants, Phase II—provide a second phase of support for innovative, exploratory, and developmental research begun as an R21 award. Only R21 awardees are eligible to apply for R33 support. Applications are accepted only in response to RFAs and PAs that specify the R33 mechanism.

R37 Method to Extend Research in Time (MERIT) Award—provides long-term, stable support to investigators who are likely to continue to perform in an outstanding manner and spares them the administrative burdens associated with preparing and submitting research grant applications. An initial 5-year award is accompanied by an opportunity for a 3- to 5-year extension, based on an expedited review of the accomplishments during the initial award period. Investigators may not apply for a MERIT award. NIH staff and advisors base their selection of MERIT award recipients on competing R01 applications, prepared and submitted in accordance with NIH procedures. MERIT awards are awarded to a limited number of selected investigators who have demonstrated superior competence and outstanding productivity during previous research endeavors.

Small Business Funding Opportunities

R41 **R42** Small Business Technology Transfer (STTR) Grants—support cooperative R&D projects between small business concerns and research institutions, limited in time and amount, to establish the technical merit and feasibility of ideas that have potential for commercialization. Awards are made to small business concerns only.

R43 **R44** Small Business Innovation Research (SBIR) Grants—enable small businesses possessing technological expertise to contribute to the R&D mission of the NIH. Phase I (R43) grants support projects, limited in time and amount, to establish the technical merit and feasibility of R&D ideas that ultimately may lead to commercial products or services. Phase II (R44) grants support indepth development of R&D ideas whose feasibility has been established in phase I and that are likely to result in commercial products or services. The research must be conducted in the United States.

Research Training Programs

T32 Institutional NRSA—enables institutions to grant NRSAs for predoctoral and postdoctoral research training in specified shortage areas to individuals selected by the institutions.

T35 NRSA Short-Term Research Training—provides individuals with research training during off-quarters or summer periods to encourage research careers or research in areas of national need.

Cooperative Agreements

U01 Research Project (Cooperative Agreement)—provides an assistance relationship between the NIH and a recipient, but with substantial programmatic involvement by the NIH. The NIH assists, supports, or stimulates the recipients and is involved substantially with recipients in conducting projects similar in program content to those for grants, with the NIH playing a “partner” role in the effort.

U19 Research Program (Cooperative Agreement)—supports a research program of multiple projects directed toward a specific major objective, basic theme, or program goal that requires a broad-based, multidisciplinary, and often long-term approach.

U24 Resource-Related Research Projects/Cooperative Agreements—support research projects contributing to improvement of the capability of resources to serve biomedical research.

U42 Animal (Mammalian and Nonmammalian) Model and Animal and Biomedical Materials Resource Cooperative Agreements (NCRR)—develop and support an animal (mammalian and nonmammalian) model or animal or biological materials resources available to all qualified investigators without regard to the scientific disciplines or disease orientations of their research activities or specifically directed to a categorical program. Nonmammalian resources include nonmammalian vertebrates, invertebrates, cell systems, and nonbiological systems.

U54 Specialized Centers Cooperative Agreements—support research and development from basic to clinical, including ancillary supportive activities that create a multidisciplinary focus on a disease or a biomedical problem. Centers also may serve as regional or national resources for special research purposes.

U56 Exploratory Grants Cooperative Agreements—support planning for new programs, expansion or modification of existing resources, and feasibility studies for interdisciplinary programs that may lead to specialized or comprehensive centers.

UC1 NIH Challenge Grants and Partnerships Program, Phase II, Cooperative Agreements (NIAID)—promote joint ventures between the NIH and both domestic and global entities to facilitate rapid biomedical or biotechnology R&D for infectious diseases to benefit public health; projects should have a commercial potential that could not have been attained without matching funds.

Interagency and Intra-Agency Agreements

Y01 NIH Interagency Agreement—provides a written reimbursable agreement by which a component of the NIH provides a source of funds to another Federal organization outside DHHS to acquire specific products, services, or studies.

Y02 NIH Intra-agency Agreement—provides a written reimbursable agreement by which a component of the NIH provides funds to another NIH component or to another organization within DHHS to acquire specific products, services, or studies.

ACRONYMS

AACTG	Adult AIDS Clinical Trials Group
AADRC	Asthma and Allergic Diseases Research Center
ABC	Actions for Building Capacity
ACE	Autoimmunity Centers of Excellence
ADAMHA	Alcohol, Drug Abuse, and Mental Health Administration
ADCC	Autoimmune Diseases Coordinating Committee
ADMO	Associate Director for Management and Operations
ADV	adenoviral vector-based
AfCS	Alliance for Cellular Signaling
AIDS	acquired immunodeficiency syndrome
AIEDRP	Acute HIV Infection and Early Disease Research Program
AIT	allergen immunotherapy
ALT	alanine aminotransferase
AREA	Academic Research Enhancement Award
ART	antiretroviral therapy
ASIR	Richard M. Asofsky Scholars In Research
ATCC	American Type Culture Collection
AVRWG	AIDS Vaccine Research Working Group
AZT	zidovudine
BAMBU	Bacteriology and Mycology Biostatistical Unit
BAMSG	Bacteriology and Mycology Study Group
BISC	Bioinformatics Integration Support Contract
BSC	Board of Scientific Counselors
BSE	bovine spongiform encephalopathy or “mad cow” disease
BSL	biosafety level
BTEP	BioTechnology Engagement Program
CASG	Collaborative Antiviral Study Group
CCTAT	Cooperative Clinical Trials in Adult Kidney Transplantation

CCTPT	Cooperative Clinical Trials in Pediatric Kidney Transplantation
CDA	Confidential Disclosure Agreement
CDC	Centers for Disease Control and Prevention
CFAR	Center for AIDS Research
CIPRA	Comprehensive International Program of Research on AIDS
CJD	Creutzfeldt-Jakob disease
CMB	Contract Management Branch
CMS	Centers for Medicare & Medicaid Services
CMV	cytomegalovirus
CPCRA	Terry Beirn Community Programs for Clinical Research on AIDS
CRADA	Cooperative Research and Development Agreement
CRC	Cooperative Research Center
CRCA	Clinical Research Curriculum Award
CRDF	Civilian Research and Development Foundation
CTA	Clinical Trial Agreement
CTL	cytotoxic T lymphocyte
CWD	chronic wasting disease
DAIDS	Division of Acquired Immunodeficiency Syndrome, NIAID
DAIT	Division of Allergy, Immunology, and Transplantation, NIAID
DARPA	Defense Advanced Research Projects Agency
DEA	Division of Extramural Activities, NIAID
DEN4	dengue virus type 4
DHHS	Department of Health and Human Services
DIR	Division of Intramural Research, NIAID
DMID	Division of Microbiology and Infectious Diseases, NIAID
DNA	deoxyribonucleic acid
DoD	Department of Defense
DOE	Department of Energy
DSA	Drug Screening Agreement

ED	emergency department
EF	edema factor
EIR	Employee Invention Report
ELISA	enzyme-linked immunosorbent assay
EPA	Environmental Protection Agency
ESPRIT	Evaluation of Subcutaneous Proleukin in a Randomized International Trial
ESRD	end-stage renal disease
FDA	Food and Drug Administration
FIC	Fogarty International Center
FOIA	Freedom of Information Act
FY	fiscal year
GAVI	Global Alliance for Vaccines and Immunization
GM-CSF	granulocyte-macrophage colony-stimulating factor
GP	glycoprotein
GSK	GlaxoSmithKline
HAART	highly active antiretroviral therapy
HAV	hepatitis A virus
HBV	hepatitis B virus
HC CRCs	Hepatitis C Cooperative Research Centers
HCV	hepatitis C virus
HEV	hepatitis E virus
HIV	human immunodeficiency virus
HIV+	HIV positive
HIVRAD	HIV Vaccine Research and Design Program
HLA	human leukocyte antigen
HOPE	Health Omnibus Programs Extension
HPIV3	human parainfluenza type 3
HPTN	HIV Prevention Trials Network

HPV	human papillomavirus
HSC	hematopoietic stem cell
HSV	herpes simplex virus
HVDDT	HIV Vaccine Design and Development Teams
HVTN	HIV Vaccine Trials Network
ICAC	Inner-City Asthma Consortium
ICBG	International Cooperative Biodiversity Groups Program
ICDs	Institutes, Centers, and Divisions
ICER	International Center for Excellence in Research
ICIDR	International Collaboration in Infectious Disease Research
ICs	Institutes and Centers
ICTDR	International Centers for Tropical Disease Research
ICU	intensive care unit
IDF	Immune Deficiency Foundation
IGIV	intravenous immunoglobulin
IHWG	International Histocompatibility Working Group
IL-2	interleukin-2
IL-4	interleukin-4
IND	investigational new drug
INRO	Intramural NIAID Research Opportunities
IOM	Institute of Medicine
IPCAVD	Integrated Preclinical/Clinical AIDS Vaccine Development Program
IPCP	Integrated Preclinical/Clinical Program
IRTA	Intramural Research and Training Awardees
ISAAC	International Studies of AIDS-Associated Co-infections
IT	immunotherapy
ITN	Immune Tolerance Network
JDRF	Juvenile Diabetes Research Foundation International
JEV	Japanese encephalitis virus

KNCV	Royal Netherlands TB Association
LF	lethal factor
M.tb	*Mycobacterium tuberculosis*
MACS	Multicenter AIDS Cohort Study
MADGC	Multiple Autoimmune Disease Genetics Consortium
M-CRADA	Materials Cooperative Research and Development Agreement
MDR-TB	multidrug-resistant tuberculosis
MEP	multi-epitope peptide
MERIT	Method to Extend Research in Time
MGC	Mammalian Gene Collection
MHC	major histocompatibility complex
MIM	Multilateral Initiative on Malaria
MR4	Malaria Research and Reference Reagent Resource
MRI	magnetic resonance imaging
MRSA	methicillin-resistant *Staphylococcus aureus*
MRTC	Malaria Research and Training Center
MRU	Microbiology Research Unit
MS	multiple sclerosis
MSG	Mycoses Study Group
MSM	men who have sex with men
MTA	Material Transfer Agreement
MTCT	mother-to-child transmission
MVA	modified vaccinia Ankara virus
MVDB	Malaria Vaccine Development Branch
NAAIDC	National Advisory Allergy and Infectious Diseases Council
NARAC	North American Rheumatoid Arthritis Consortium
NARSA	Network on Antimicrobial Resistance in *Staphylococcus aureus*
NBL	National Biocontainment Laboratory
NCDDG-TB	National Cooperative Drug Discovery Groups for Tuberculosis

NCICAS	National Cooperative Inner-City Asthma Study
NCRR	National Center for Research Resources
NHIS	National Health Interview Survey
NHLBI	National Heart, Lung, and Blood Institute
NIAID	National Institute of Allergy and Infectious Diseases
NICHD	National Institute of Child Health and Human Development
NIDA	National Institute on Drug Abuse
NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases
NIEHS	National Institute of Environmental Health Sciences
NIGMS	National Institute of General Medical Sciences
NIH	National Institutes of Health
NK	natural killer [cells]
NMR	nuclear magnetic resonance
NNIS	National Nosocomial Infections Surveillance
NRSA	National Research Service Award
NVP	nevirapine
NVPO	National Vaccine Program Office
OAS	Office of Administrative Services, NIAID
OCPL	Office of Communications and Public Liaison, NIAID
OCR	Office of Clinical Research, NIAID
OD	Office of the Director, NIAID
OE	Office of Ethics, NIAID
OFM	Office of Financial Management, NIAID
OHRM	Office of Human Resources Management, NIAID
OI	opportunistic infection
OMNI	Office of Management for New Initiatives, NIAID
ONR	Office of Naval Research
OPA	Office of Policy Analysis, NIAID
OSPRT	Office of Special Populations and Research Training, NIAID
OTD	Office of Technology Development, NIAID

OTIS	Office of Technology Information Systems, NIAID
OTSEP	Office of Training and Special Emphasis Programs
OTT	Office of Technology Transfer, NIH
PA	program announcement
PACTG	Pediatric AIDS Clinical Trials Group
PAVE	Partnership for HIV/AIDS Vaccine Evaluation
PCR	polymerase chain reaction
PFGRC	Pathogen Functional Genomics Resource Center
PID	pelvic inflammatory disease
PIDR	Primary Immunodeficiency Diseases Registry
PIV	parainfluenza virus
PMN	polymorphonuclear neutrophil
PMPA	9-(2-phosphonylmethoxypropyl)-adenine
PR	protease
PRP	polyribosylribose phosphate
PrP	prion protein
PrP-res	abnormal form of prion protein
R&D	research and development
RBL	Regional Biocontainment Laboratory
RCE	Regional Centers of Excellence for Biodefense and Emerging Infectious Diseases
RCMI	Research Centers in Minority Institutions
RFA	request for application
RIT	rush immunotherapy
RML	Rocky Mountain Laboratories
RNA	ribonucleic acid
rPA	recombinant protective antigen vaccine
RPAB	Referral and Program Analysis Branch
RPG	Research Project Grant
RSUM	Research Supplements for Underrepresented Minorities

RSV	respiratory syncytial virus
RT	reverse transcriptase
SAIC	Science Applications International Corporation
SARS	severe acute respiratory syndrome
SARS-CoV	SARS-associated coronavirus
SBIR	Small Business Innovation Research
SCID	severe combined immunodeficiency disease
SIV	simian immunodeficiency virus
SLE	systemic lupus erythematosus
SLEV	St. Louis encephalitis virus
SMART	Strategies for Management of Anti-Retroviral Therapies
SNP	single nucleotide polymorphisms
SPR	Summer Policy Retreat
SRP	Scientific Review Program
STD	sexually transmitted disease
STI	sexually transmitted infection
STTR	Small Business Technology Transfer
SVEU	Simian Vaccine Evaluation Unit
TAACF	Tuberculosis Antimicrobial Acquisition and Coordinating Facility
TB	tuberculosis
TBRU	Tuberculosis Research Unit
TEAC	Technology Evaluation Advisory Committee
TIGR	The Institute for Genomic Research
TMP-SMX	trimethoprim-sulfamethoxazole
TMRC	Tropical Medicine Research Center
TSE	transmissible spongiform encephalopathy
USAID	U.S. Agency for International Development
USAMRIID	U.S. Army Medical Research Institute of Infectious Diseases
USAMRMC	U.S. Army Medical Research and Materiel Command
USJCMSP	U.S.-Japan Cooperative Medical Science Program

VAP	Vaccine Action Program
VDF	Vaccine Development Facility
VPP	Vaccine Pilot Plant
VRC	Dale and Betty Bumpers Vaccine Research Center
VRE	vancomycin-resistant enterococci
VTEU	Vaccine and Treatment Evaluation Unit
WHO	World Health Organization
WIHS	Women's Interagency HIV Study
WITS	Women and Infants Transmission Study
WNV	West Nile virus
WPR	Winter Program Review
YFV	yellow fever virus

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