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 100-07), 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.

July 21, 2004

The Project Bioshield Act (Public Law 108-276) authorized the Director of NIH to employ expedited peer review procedures for grants, contracts, and cooperative agreements addressing qualified countermeasures research. In addition, the Act authorized the Director of NIAID to award grants or contracts to public and nonprofit private entities to expand, remodel, renovate, or alter existing research facilities or construct new facilities.

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), Collaboration Agreements (CAs), 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) 2004, TEAC reviewed 41 intramural EIRs and recommended that patent applications be filed on 26 of them.

NIAID currently has 386 active U.S. patent properties, including 209 issued patents and 177 pending patent applications.

NIAID had a total of 226 active license agreements in FY 2004 for both patented inventions and biological materials. These licenses generated about $11 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 2004, a total of 128 MTAs, 9 CTAs, 53 CDAs, 6 CRADAs, 12 M-CRADAs, 5 CAs, and 15 other agreements were executed and negotiated by OTD. NIAID extramural divisions referred technology transfer issues to OTD on 9 contracts, and OTD NIAID scientists performed research under 32 CRADAs and 38 M-CRADAs in FY 2004. 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
1992	77	48	65	21
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
2004	177	209	226	70

Technology Transfer Highlights

In FY 2004, OTD negotiated or facilitated the following public-private partnerships:

- **Development and selection of research-grade plasmid DNA vectors encoding West Nile virus proteins and formulations for potential use as prophylactic vaccines in human and veterinary applications (Vical)** Investigators at the Vaccine Research Center (VRC), NIAID, and Vical, Incorporated will collaborate in the development and evaluation of West Nile Virus (WNV) DNA vaccine candidates. Recently, WNV DNA vaccines have shown promising protection in animal studies. The VRC and Vical will evaluate materials that might enhance or improve the immune response to WNV and select the best constructs and formulations of WNV DNA vaccine candidates appropriate for clinical development.

- **Evaluation of herpes simplex virus vectors encoding HIV-1 proteins (BioVex).** Herpes simplex virus (HSV) vectors are being investigated as a gene delivery system for gene therapy and vaccination. Recombinant HSV vectors offer a promising strategy for development of a candidate HIV-1 vaccine that could be effective in humans. Investigators at the Vaccine Research Center (VRC), National Institute of Allergy and Infectious Diseases, National Institute of Health, and BioVex, Ltd. will collaborate to evaluate and develop HSV vectors expressing VRC's modified HIV-1 genes. The collaboration will evaluate such HSV vectors for potential application as an HIV preventive or therapeutic vaccine. The VRC will provide BioVex with several modified HIV-1 genes, and BioVex will construct and produce recombinant HSV vectors that express VRC's HIV-1 genes utilizing the BioVex HSV system. The overall goal is to provide the VRC with advanced vector technologies suitable for rapid advancement toward clinical trial.

- ***In vitro* and *in vivo* evaluation of novel compounds with antitubercular activity (Anacor Pharmaceuticals).** Anacor Pharmaceuticals and the Tuberculosis Research Section of the Laboratory of Host Defenses, NIAID, NIH, are entering into a collaborative research and development agreement to screen promising candidate molecules for activity against *Mycobacterium tuberculosis*. These molecules have been shown to have a unique mechanism of action that targets problematic Gram-positive pathogens and members of this series. By providing selectivity for the treatment of tuberculosis these molecules may have utility in the chemotherapy of this important disease.

- **Development of prophylactic and therapeutic monoclonal antibodies to vaccinia/smallpox, SARS, and anthrax (MacroGenics).** Under this Cooperative Research and Development Agreement, investigators in the Laboratory of Infectious Diseases, the Laboratory of Viral Diseases, and the Bacterial Toxins and Therapeutics Section Division of Intramural Research at NIAID and MacroGenics, Inc., will attempt to isolate and characterize human and human-like neutralizing monoclonal antibodies to vaccinia virus, the SARS virus, and anthrax.

- **Identification of novel antitubercular agents through high-throughput screening (Exelixis).** The Tuberculosis Research Section of NIAID and Exelixis, Inc., are collaborating under this CRADA to screen compound libraries for potential new compounds active against *M. tuberculosis*, which can then be put forward for the treatment of tuberculosis.

- **Chlamydial antigen discovery (Chiron).** A cooperative approach will be used to

identify novel chlamydial antigens important to chlamydial vaccine development. The project involves the combination of *in vitro* models of cytokine mediated chlamydial persistent infection, isolation of HLA class I and II processed peptides from infected epithelial cells, elution of peptides from HLA molecules, and identification of peptides and native proteins by high-throughput mass spectrometry. The identified peptides might represent unique hereto-undiscovered antigens important to protective cellular immune responses and future anti-chlamydial therapeutic strategies.

New CRADAs

During FY 2004, NIAID scientists entered into the following six new CRADAs:

Collaborator	Investigator	Title
Anacor Pharmaceuticals, Inc.	Clifton E. Barry III, Ph.D. Laboratory of Immunogenetics	*In Vitro* and *In Vivo* screening of Novel Antitubercular Agents.
BioVex, Ltd.	Phillip Gomez III, Ph.D., M.B.A. Vaccine Research Center	Evaluation of HSV Vectors Encoding HIV-1 Proteins.
Chiron Corp.	Harlan D. Caldwell, Ph.D., Laboratory of Intracellular Parasites	Chlamydia Antigen Discovery.
Exelixis, Inc.	Clifton E. Barry III, Ph.D. Laboratory of Immunogenetics	New Lead Discovery for the Identification of Novel Antitubercular Agents.
MacroGenics, Inc.	Robert H. Purcell, M.D. Laboratory of Infectious Diseases	Development of Prophylactic and Therapeutic Monoclonal Antibodies to Vaccinia/Smallpox, SARS, and Anthrax.
Vical, Inc.	Phillip Gomez III, Ph.D., M.B.A. Vaccine Research Center	Development And Selection Of Research-Grade Plasmid DNA Vectors Encoding West Nile Virus (WNV) Proteins And Formulations For Potential Use As Prophylactic Vaccines In Human And Veterinary Applications.

Ongoing CRADAs

In addition to the new CRADAs, research was done under the following ongoing CRADAs:

Collaborator	Investigator	Title
Achillion Pharmaceuticals NCI	John Inman, Ph.D. Laboratory of Immunology	Development of Optimized Inhibitors of Protein Zinc Finger Domains
Chiron	H. Clifford Lane, M.D. Laboratory of Immunoregulation	Research and Development of IL-2 as a Treatment for HIV Infection
Crucell	Phillip Gomez III, Ph.D., M.B.A. Vaccine Research Center	Development of an Improved Recombinant Adenovirus Vector for Vaccination Against the Ebola Virus
Genetics Institute	Ethan Shevach, M.D. Laboratory of Immunology	Analysis Of Gene Expression In Immunoregulatory T Cells That Co-Express The CD4 And CD25 Surface Markers

Collaborator	Investigator	Title
Genetics Institute	Thomas Wynn, Ph.D. Laboratory of Parasitic Disease	Development Of IL-13 Antagonism As A Treatment For Fibrosis In Schistosomiasis
Genetics Institute	Warren Strober, M.D. Peter Mannon, M.D. Ivan Fuss, M.D. Laboratory of Clinical Investigation	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 Diseases
GenVec	Phillip Gomez III, Ph.D., M.B.A. Vaccine Research Center	Evaluation of Adenoviral Vectors Encoding HIV-1 Proteins
GenVec	Phillip Gomez III, Ph.D., M.B.A. Vaccine Research Center	Evaluation of Adenoviral Vectors Encoding Proteins Associated with SARS
Glaxo Research & Development	Clifton E. Barry III, Ph.D. Laboratory of Immunogenetics	Development of New Drugs for the Treatment of Tuberculosis
GlaxoSmithKline	Holli Hamilton, M.D., M.P.H. Barbara Savarese, R.N. Division of Microbiology and Infectious Diseases	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 (DMID#01-643)
IAVI	Richard T. Wyatt, Ph.D. Vaccine Research Center	Rational Design of HIV Envelope Glycoprotein Variants for Structural and Immunogical Analysis Using X-Ray Crystallography To Elicit Broadly Neutralizing HIV-1 Antibodies.
Ichor Medical Systems	Phillip Gomez III, Ph.D., M.B.A. Vaccine Research Center	Evaluation Of Electroporation-Mediated Delivery Of An HIV DNA Vaccine
Innogenetics	Robert H. Purcell, M.D. Laboratory of Infectious Diseases	Analysis of the Immune Response to Hepatitis C Virus
Invitrogen	Thomas Kindt, Ph.D. Michael Wilson, Ph.D. Research Technologies Branch, Division of Intramural Research	Oligonucleotide Control Sets for Microarray Applications
Maxygen	Louis Miller, M.D. Carole Long, Ph.D. Allan Saul, Ph.D. Laboratory of Parasitic Disease	Novel, Polyspecific Malaria Vaccine Development Based on PfEMP1 Using Molecular Breeding™ Directed Molecular Evolution Technologies
MedImmune Vaccines (formerly Aviron)	George Curlin, M.D. Division of Microbiology and Infectious Diseases	Development of a Live, Attenuated Cold-Adapted Influenza Vaccine
Merck	Gary Nabel, M.D., Ph.D. Vaccine Research Center	Development of an Adenoviral-Based HIV Vaccine
Merck	Stephen Straus, M.D. Laboratory of Clinical Investigation	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	Investigator	Title
Merial	José Ribeiro M.D., Ph.D. Laboratory of Parasitic Disease	Evaluation Of DNA Vaccines Encoding Sand Fly Salivary Proteins As Candidates To Control *Leishmania Infantum* Infection In Dog
Nexell Therapeutics	Harry L. Malech, M.D. Mitchell Horwitz, M.D. Laboratory of Host Defenses	Study of Low Intensity Preparative Regimen Followed By HLA-Matched Transplantation for Chronic Disease
Novartis	Marshall Plaut, M.D. Division of Allergy, Immunology, and Transplantation	A Double-Blind, Placebo Controlled Study Of The Efficiency of E25 Anti-Ige Reducing Asthma Symptoms In Inner City Children
Novavax	Louis Miller, M.D. Laboratory of Parasitic Disease	Merozoite Surface Protein 1 Expressed in Insect Cells: Process Development, Preclinical and Initial Clinical Evaluation
Osel	Edward Berger, Ph.D. Laboratory of Viral Diseases	SCD4-17b Expressed By/On *Lactobacillus* As An Anti-HIV Topical Microbicide
Panacos	Eric Freed, Ph.D. Laboratory of Molecular Microbiology	A Study of the Mechanism of Action of the Anti-HIV Compound, PA-457
Quantum Dot	Mario Roederer, Ph.D. Vaccine Research Center	Use of Quantum Dots for Improved Cellular Classification in Flow Cytometry
Wyeth-Lederle Vaccines	Pamela McInnes, Ph.D. Division of Microbiology and Infectious Diseases	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 supports the development of new didactic programs in clinical research at institutions that do not offer such programs or in institutions with existing programs in clinical research. In the latter, it supports the expansion of programs or improvement in the quality of instruction.

Research and Development-Related Contracts

N01 Research and Development (R&D) 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 Small Business Technology Transfer Research (STTR) Grant, Phase I—supports 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.

R42 STTR Grant, Phase II—supports 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 Small Business Innovation Research (SBIR) Grant, Phase I—enables small businesses to contribute to the R&D mission of the NIH. Phase I grants support projects, limited in time and amount, to establish the technical merit and feasibility of ideas that ultimately may lead to commercial products or services. The research must be conducted in the United States.

R44 SBIR Grant, Phase II—enables small businesses to contribute to the R&D mission of the NIH. Phase II grants support indepth development of 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 (National Center for Research Resources)—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 the Department of Health and Human Services (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 Centers
AAIB	Asthma, Allergy, and Inflammation Branch, DAIT
ACE	Autoimmunity Centers of Excellence
ACERRB	AIDS Clinical and Epidemiology Research Review Branch, DEA
ADAMHA	Alcohol, Drug Abuse, and Mental Health Administration
ADCC	Autoimmune Diseases Coordinating Committee
ADMO	Associate Director for Management and Operations
ADV	adenoviral
AfCS	Alliance for Cellular Signaling
AIDS	acquired immunodeficiency syndrome
AIEDRP	Acute Infection and Early Disease Research Program
AIT	allergen immunotherapy
AMOB	Acquisition Management and Operations Branch, NIAID
APRRB	AIDS Preclinical Research Review Branch, DEA
ARAC	AIDS Research Advisory Committee
AREA	Academic Research Enhancement Award
ART	antiretroviral therapy
ASIR	Richard M. Asofsky Scholars In Research
AVRWG	AIDS Vaccine Research Working Group
BAMBU	Bacteriology and Mycology Biostatistical and Operations Unit
BAMSG	Bacteriology and Mycology Study Group
BIB	Basic Immunology Branch, DAIT
BISC	Bioinformatics Integration Support Contract
BMB	Bacteriology and Mycology Branch, DMID
BRASS	Biomedical Research After School Scholars
BSC	Board of Scientific Counselors
BSE	bovine spongiform encephalopathy
BSL	biosafety level
BSP	Basic Sciences Program, DAIDS
CAB	community advisory board
CAP	community-acquired pneumonia
CASG	Collaborative Antiviral Study Group
CCRB	Complications and Co-Infections Research Branch, DAIDS

CCTPT	Cooperative Clinical Trials in Pediatric Transplantation program
CDA	Confidential Disclosure Agreements
CDC	Centers for Disease Control and Prevention
CEOPP	Community Education and Outreach Partnership Program
CFAR	Centers for AIDS Research
CHAVI	Center for HIV/AIDS Vaccine Immunology
CIB	Clinical Immunology Branch, DAIT
CIPRA	Comprehensive International Program of Research on AIDS
CJD	Creutzfeldt-Jakob disease
CMB	Comparative Medicine Branch, DIR
CMP	Contract Management Program
CMV	cytomegalovirus
CPCRA	Terry Beirn Community Programs for Clinical Research on AIDS
CRADA	Cooperative Research and Development Agreement
CRCA	Clinical Research Curriculum Award
CRMB	Clinical Research Management Branch, DAIDS
CRRB	Clinical Research Resources Branch, DAIDS
CTA	Clinical Trial Agreement
CWD	chronic wasting disease
DAIDS	Division of Acquired Immunodeficiency Syndrome
DAIT	Division of Allergy, Immunology, and Transplantation
DDCSB	Drug Development and Clinical Sciences Branch, DAIDS
DEA	Division of Extramural Activities
DHHS	Department of Health and Human Services
DIR	Division of Intramural Research
DIRB	DAIDS International Research Branch
DMID	Division of Microbiology and Infectious Diseases
DNA	deoxyribonucleic acid
DoD	Department of Defense
DSA	Drug Screening Agreements
EAMB	Extramural Administrative Management Branch, NIAID
EB	Epidemiology Branch, DAIDS
EHDB	Enteric and Hepatic Diseases Branch, DMID
EIR	Employee Invention Reports
ELISA	enzyme-linked immunosorbent assay
ELISPOT	enzyme-linked immunospot

ENSB	Extramural Network Systems Branch, NIAID
ESPRIT	Evaluation of Subcutaneous Proleukin in a Randomized International Trial
FCRDC	Frederick Cancer Research and Development Center
FDA	Food and Drug Administration
FOIA	Freedom of Information Act
FY	fiscal year
GBS	Group B streptococcus
GBV-B	GB virus type B
GBV-C	GB virus type C
GMB	Grants Management Branch, DEA
HAART	HIV highly active antiretroviral therapy
HBV	hepatitis B virus
HCV	hepatitis C virus
HHV	human herpesvirus
HIV	human immunodeficiency virus
HIVRAD	HIV Vaccine Research and Design Program
HIVRB	HIV Research Branch, DAIDS
HLA	human leukocyte antigen
HOPE	Health Omnibus Programs Extension of 1988
HPTN	HIV Prevention Trials Network
HSC	hematopoietic stem cell
HSV	herpes simplex virus
HUD	Department of Housing and Urban Development
HVAD	HIV Vaccine Awareness Day
HVCC	HIV Vaccine Communications Campaign
HVDDT	HIV Vaccine Design and Development Teams
HVTN	HIV Vaccine Trials Network
IAMB	Intramural Administrative Management Branch, NIAID
IAVI	International AIDS Vaccine Initiative
ICs	Institutes and Centers
ICAC	Inner-City Asthma Consortium
ICDs	Institutes, Centers, and Divisions
ICER	International Centers for Excellence in Research
ICIDR	International Collaboration in Infectious Disease Research
ICU	intensive care unit

IDPB	Infectious Disease Pathogenesis Branch, DIR
IHWG	International Histocompatibility Working Group
IL	interleukin
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
IPCP–HTM	Integrated Preclinical/Clinical Program for HIV Topical Microbicides
IRB	institutional review board
IRTA	Intramural Research and Training Awardees
ISAAC	International Studies of AIDS-Associated Co-Infections
ITN	Immune Tolerance Network
ITSB	Intramural Technical Systems Branch, NIAID
JDRF	Juvenile Diabetes Research Foundation International
LACD	Laboratory of Advanced Clinical Development, VRC
LAD	Laboratory of Allergic Diseases, DIR
LAM	Laboratory of Animal Medicine, VRC
LCID	Laboratory of Clinical Infectious Diseases, DIR
LCMI	Laboratory of Cellular and Molecular Immunology, DIR
LCT	Laboratory of Clinical Trials, VRC
LHBP	Laboratory of Human Bacterial Pathogenesis, DIR
LHD	Laboratory of Host Defenses, DIR
LI	Laboratory of Immunology
LICP	Laboratory of Intracellular Parasites, DIR
LID	Laboratory of Infectious Diseases, DIR
LIG	Laboratory of Immunogenetics, DIR
LIP	Laboratory of Immunopathology, DIR
LIR	Laboratory of Immunoregulation, DIR
LMI	Laboratory of Molecular Immunology, DIR
LMM	Laboratory of Molecular Microbiology, DIR
LMVR	Laboratory of Malaria and Vector Research, DIR
LPD	Laboratory of Parasitic Diseases, DIR
LPVD	Laboratory of Persistent Viral Diseases, DIR
LV	Laboratory of Virology, VRC
LVD	Laboratory of Viral Diseases, DIR

LVP	Laboratory of Vaccine Production, VRC
LVP	Laboratory of Viral Pathogenesis, VRC
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
MERIT	Method to Extend Research in Time Award
MHC	major histocompatibility complex
MIRB	Microbiology and Immunology Review Branch, DEA
MISB	Management Information Systems Branch, NIAID
MMF	mycophenolate mofetil
MR4	Malaria Research and Reference Reagent Repository
MRI	magnetic resonance imaging
MRSA	methicillin-resistant *Staphylococcus aureus*
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
MVDB	Malaria Vaccine Development Branch, DIR
NAAIDC	National Advisory Allergy and Infectious Diseases Council
NARAC	North American Rheumatoid Arthritis Consortium
NARSA	The Network on Antimicrobial Resistance in *Staphylococcus aureus*
NBL	national biocontainment laboratory
NCRR	National Center for Research Resources
NHLBI	National Heart, Lung, and Blood Institute
NHPCSG	Nonhuman Primate Cooperative Study Group
NIAID	National Institute of Allergy and Infectious Diseases
NIALS	NIAID Immune Assessment Laboratory Service
NICHD	National Institute of Child Health and Human Development
NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases
NIEHS	National Institute of Environmental and Health Sciences
NIGMS	National Institute of General Medical Sciences

NIH	National Institutes of Health
NK	natural killer [cells]
NNRTI	non-nucleoside reverse transcriptase inhibitor
NRSA	National Research Service Award
NRTI	nucleoside reverse transcriptase inhibitor
NVP	nevirapine
NVPO	National Vaccine Program Office
OAS	Office of Administrative Services, NIAID
OCA	Office of Clinical Applications, DAIT
OCPL	Office of Communications and Public Liaison, NIAID
OCR	Office of Clinical Research, NIAID
OCRA	Office of Clinical Research Affairs, DMID
OD	Office of the Director, NIAID
OE	Office of Ethics, NIAID
OECT	Office of Epidemiology and Clinical Trials, DAIT
OFM	Office of Financial Management, NIAID
OGA	Office of Global Affairs
OHRM	Office of Human Resources Management, NIAID
OI	opportunistic infections
OKR	Office of Knowledge Resources
OMNI	Office of Management for New Initiatives, NIAID
ONR	Office of Naval Research
OPA	Office of Policy Analysis, NIAID
OPCO	Office of Program Coordination and Operations, DEA
OPCRO	Office for Policy in Clinical Research Operations, DAIDS
OPOSI	Office of Program Operations and Scientific Information, DAIDS
OPOSI	Office of Program Planning, Operations, and Scientific Information, DAIT
ORA	Office of Regulatory Affairs, DMID
OSCPO	Office of Scientific Coordination and Program Operations, DMID
OSPRT	Office of Special Populations and Research Training, NIAID
OSRD	Office of Scientific Resource Development
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

PAB	Pharmaceutical Affairs Branch, DAIDS
PACTG	Pediatric AIDS Clinical Trial Group
PATH	Program for Appropriate Technology in Health
PAVE	Partnership for HIV/AIDS Vaccine Evaluation
PBRB	Pathogenesis and Basic Research Branch, DAIDS
PEG-IFN	pegylated-interferon
PEPFAR	President's Emergency Plan for HIV/AIDS Relief
PFGRC	Pathogen Functional Genomics Resource Center
PGL	phenolic glycolipid
PID	primary immunodeficiency diseases
PIDR	Primary Immunodeficiency Diseases Registry
PIPB	Parasitology and International Programs Branch, DMID
PMB	Pediatric Medicine Branch, DAIDS
PR	protease
PRDB	Preclinical Research and Development Branch, DAIDS
PRP	polyribosylribose phosphate
PrP	prion protein
PSB	Prevention Sciences Branch, DAIDS
RAB	Regulatory Affairs Branch, DAIDS
RBL	Regional Biocontainment Laboratories
RCE	Research Centers of Excellence
RCMI	Research Centers in Minority Institutions
R&D	research and development
RDB	Respiratory Diseases Branch, DMID
RFA	request for applications
RFP	request for proposals
RML	Rocky Mountain Laboratories
RMVB	Rocky Mountain Veterinary Branch, DIR
RNA	ribonucleic acid
RPAB	Referral and Program Analysis Branch, DEA
RSUM	Research Supplements for Underrepresented Minorities
RSV	respiratory syncytial virus
RT	reverse transcriptase
RTB	Research Technologies Branch, DIR
SARS	severe acute respiratory syndrome
SARS-CoV	SARS-associated coronavirus

SBIR	Small Business Innovation Research
SLE	systemic lupus erythematosus
SMART	Strategies for Management of Anti-Retroviral Therapy
SNP	single nucleotide polymorphism
SPR	Summer Policy Retreat
SRB	Special Review Branch, DEA
SRP	Scientific Review Program, DEA
STD	sexually transmitted diseases
STI	sexually transmitted infections
STIB	Sexually Transmitted Infections Branch, DMID
STI CTG	Sexually Transmitted Infections Clinical Trials Group
STTR	Small Business Technology Transfer
TAACF	Tuberculosis Antimicrobial Acquisition and Coordinating Facility
TB	tuberculosis
TBRU	Tuberculosis Research Unit
TDRU	Tropical Diseases Research Unit
TEAC	Technology Evaluation Advisory Committee
TIB	Targeted Interventions Branch, DAIDS
TIB	Transplantation Immunobiology Branch, DAIT
TIGR	The Institute for Genomic Research
TMP-SMX	trimethoprim-sulfamethoxazole
TMRC	Tropical Medicine Research Centers
TRP	Therapeutics Research Program, DAIDS
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
USIDNET	U.S. Immunodeficiency Network
USJCMSP	U.S.–Japan Cooperative Medical Science Program
VA	Veterans Administration
VB	Virology Branch, DMID
VCRB	Vaccine Clinical Research Branch, DAIDS
VDRG	Vaccine Developmental Resources Group
Vif	Virion Infectivity Factor
VPP	Vaccine Pilot Plant

VPRP	Vaccine and Prevention Research Program, DAIDS
VRC	Vaccine Research Center
VRE	vancomycin-resistant enterococci
VZV	varicella-zoster virus
WG	Wegener's granulomatosis
WHO	World Health Organization
WIHS	Women's Interagency HIV Study
WITS	Women and Infants Transmission Study
WNV	West Nile virus
WPR	Winter Program Review

INDEX

A

B

C

D

E

F

G

H

I

J

K

L

M

N

O

P

R

S

T

U

V

W

X

Y