

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

# **Ongoing CRADAs**

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

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

| Collaborator                            | Investigator   | Title  |
|---|--|--|
| Genetics Institute                      | Thomas Wynn, Ph.D.<br>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,<br>Safety Study Of Two Parallel Dose Levels Of Subcutaneously<br>Administered Human Monoclonal Antibody To Interleukin-12 (J695)<br>In Patients With Active Crohn's Diseases |
| GenVec                                  | Phillip Gomez III, Ph.D., M.B.A.<br>Vaccine Research Center  | Evaluation of Adenoviral Vectors Encoding HIV-1 Proteins   |
| GenVec                                  | Phillip Gomez III, Ph.D., M.B.A.<br>Vaccine Research Center  | Evaluation of Adenoviral Vectors Encoding Proteins Associated with SARS  |
| Glaxo Research &<br>Development         | Clifton E. Barry III, Ph.D.<br>Laboratory of Immunogenetics  | Development of New Drugs for the Treatment of Tuberculosis   |
| GlaxoSmithKline                         | Holli Hamilton, M.D., M.P.H.<br>Barbara Savarese, R.N.<br>Division of Microbiology and<br>Infectious Diseases    | A Double-Blind, Randomized, Controlled Phase III Study To<br>Assess The Prophylactic Efficacy Of Rgd/Alum/MPL Vaccine In The<br>Prevention Of Genital Herpes Disease In Young Sexually Active<br>Women (DMID#01-643)                       |
| IAVI                                    | Richard T. Wyatt, Ph.D.<br>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.<br>Vaccine Research Center  | Evaluation Of Electroporation-Mediated Delivery Of An HIV DNA Vaccine  |
| Innogenetics                            | Robert H. Purcell, M.D.<br>Laboratory of Infectious<br>Diseases  | Analysis of the Immune Response to Hepatitis C Virus   |
| Invitrogen                              | Thomas Kindt, Ph.D.<br>Michael Wilson, Ph.D.<br>Research Technologies Branch,<br>Division of Intramural Research | Oligonucleotide Control Sets for Microarray Applications   |
| Maxygen                                 | Louis Miller, M.D.<br>Carole Long, Ph.D.<br>Allan Saul, Ph.D.<br>Laboratory of Parasitic Disease                 | Novel, Polyspecific Malaria Vaccine Development Based on PfEMP1 Using Molecular Breeding™ Directed Molecular Evolution Technologies  |
| MedImmune Vaccines<br>(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.<br>Vaccine Research Center   | Development of an Adenoviral-Based HIV Vaccine   |
| Merck                                   | Stephen Straus, M.D.<br>Laboratory of Clinical<br>Investigation  | A Double-Blind, Placebo-Controlled Study Of The Efficacy Of Live,<br>Attenuated Oka/Merck Varicella Zoster Vaccine In Reducing The<br>Incidence And/Or Severity Of Shingles In Adults  |

| Collaborator           | Investigator  | Title   |
|------------------------|---|---|
| Merial                 | José Ribeiro M.D., Ph.D.<br>Laboratory of Parasitic Disease                     | Evaluation Of DNA Vaccines Encoding Sand Fly Salivary Proteins As Candidates To Control <i>Leishmania Infantum</i> Infection In Dog   |
| Nexell Therapeutics    | Harry L. Malech, M.D.<br>Mitchell Horwitz, M.D.<br>Laboratory of Host Defenses  | Study of Low Intensity Preparative Regimen Followed By HLA-<br>Matched Transplantation for Chronic Disease                            |
| Novartis               | Marshall Plaut, M.D.<br>Division of Allergy, Immunology,<br>and Transplantation | A Double-Blind, Placebo Controlled Study Of The Efficiency of E25<br>Anti-Ige Reducing Asthma Symptoms In Inner City Children         |
| Novavax                | Louis Miller, M.D.<br>Laboratory of Parasitic Disease                           | Merozoite Surface Protein 1 Expressed in Insect Cells: Process<br>Development, Preclinical and Initial Clinical Evaluation            |
| Osel                   | Edward Berger, Ph.D.<br>Laboratory of Viral Diseases                            | SCD4-17b Expressed By/On <i>Lactobacillus</i> As An Anti-HIV Topical Microbicide  |
| Panacos                | Eric Freed, Ph.D.<br>Laboratory of Molecular<br>Microbiology                    | A Study of the Mechanism of Action of the Anti-HIV Compound, PA-457   |
| Quantum Dot            | Mario Roederer, Ph.D.<br>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.
- KO8 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 healthrelated 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.

(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**

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.

W19 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.

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.

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.

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 CampaignHVDDT 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, DIRIHWG 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

**USICMSP** 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, DAI | VPRP | Vaccine and | Prevention | Research | Program, | DAID |
|---|------|-------------|------------|----------|----------|------|
|---|------|-------------|------------|----------|----------|------|

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

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