



Duane Alexander, M.D., Director

DIRECTOR'S REPORT

***NATIONAL ADVISORY CHILD HEALTH
AND HUMAN DEVELOPMENT COUNCIL***

January 22, 2009

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LIST OF ACRONYMS**NIH INSTITUTES, CENTERS & OFFICES**

OD	Office of the Director
NCI	National Cancer Institute
NEI	National Eye Institute
NHLBI	National Heart, Lung, and Blood Institute
NHGRI	National Human Genome Research Institute
NIA	National Institute on Aging
NIAAA	National Institute on Alcohol Abuse and Alcoholism
NIAID	National Institute of Allergy and Infectious Diseases
NIAMS	National Institute of Arthritis and Musculoskeletal and Skin Diseases
NICHD	National Institute of Child Health and Human Development
NIDCD	National Institute on Deafness and Other Communication Disorders
NIDCR	National Institute of Dental and Craniofacial Research
NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases
NIDA	National Institute on Drug Abuse
NIEHS	National Institute of Environmental Health Sciences
NIGMS	National Institute of General Medical Sciences
NIMH	National Institute of Mental Health
NINDS	National Institute of Neurological Disorders and Stroke
NINR	National Institute of Nursing Research
NLM	National Library of Medicine
NIBIB	National Institute for Biomedical Imaging and Bioengineering
CC	Warren Grant Magnuson Clinical Center
CIT	Center for Information Technology
NCCAM	National Center for Complementary and Alternative Medicine
NCRR	National Center for Research Resources
NCMHD	National Center on Minority Health and Health Disparities
FIC	John E. Fogarty International Center
CSR	Center for Scientific Review
DPCPSI	Division of Program Coordination, Planning, and Strategic Initiatives
OAR	Office of AIDS Research
OBSSR	Office of Behavioral and Social Sciences Research
ODP	Office of Disease Prevention
ODS	Office of Dietary Supplements
ORD	Office of Rare Diseases
ORWH	Office of Research on Women's Health

FUTURE COUNCIL MEETING DATES

June 11, 2009 (Thursday)
September 21, 2009 (Monday)
January 28, 2010 (Thursday)
June 3, 2010 (Thursday)
September 20, 2010 (Monday)

PERSONNEL CHANGES - NICHD

Melissa Parisi, M.D., Ph.D., has been appointed Chief, Intellectual and Developmental Disabilities Branch (IDDB), Center for Developmental Biology and Perinatal Medicine (CDBPM). Prior to her IDDB appointment, Dr. Parisi was Assistant Professor in the Department of Pediatrics at the University of Washington and Seattle Children's Hospital, where she was active as a clinical geneticist and as a researcher in the field of congenital malformations of the human hindbrain. She earned her M.D. and Ph.D. degrees in Developmental Biology from Stanford University School of Medicine where her research focused on mitochondrial transcription and biogenesis. She completed a pediatric residency at the University of Washington in Seattle, followed by fellowship training in medical genetics. Dr. Parisi is board-certified in both general pediatrics and medical genetics. In her clinical practice in the states of Washington and Alaska, she has been involved in the evaluation, diagnosis, and management of children and adults with genetic syndromes, the majority of whom have major congenital defects and/or developmental disabilities including behavioral disorders such as autism. Dr. Parisi has served as the physician leader for the Gender Assessment Team, a multidisciplinary group of physicians who evaluate and manage infants, children, and adolescents with Disorders of Sex Development (DSD)/ambiguous genitalia. She was also a founding member of the Organizing Committee for Work-Life Balance Initiatives in the Department of Pediatrics at the University of Washington. She served as Chair of the Scientific Advisory Board of the Joubert Syndrome Foundation and Related Cerebellar Disorders.

Kathy Mann Koepke, Ph.D., has joined the Child Development and Behavior Branch (CDBB), Center for Research for Mothers and Children (CRMC). Dr. Mann Koepke received her Ph.D. degree in Applied Physiological Psychology (Cognitive Neuroscience) from the University of North Carolina at Chapel Hill and her NRSA post-doctoral fellowship at the University of Iowa College of Medicine in the Department of Pediatrics. Previous NIH positions include the Behavior and Social Research Branch, National Institute on Aging (NIA) and as the Director of the Neuroscience Program at the National Institute of Nursing Research (NINR). In her current

NICHD position, she will serve as the Director of the Math and Science Cognition and Learning Development and Disorders Program, CDBB. Prior to NIH, she held several faculty appointments, including more than a decade as faculty in Neurology at the Washington University School of Medicine in St. Louis.

Zhen Chen, Ph.D., has joined the Epidemiology Branch, Division of Epidemiology, Statistics and Prevention Research (DESPR), in September 2008. Prior to his recruitment, Dr. Chen was an Assistant Professor in the Department of Biostatistics and Epidemiology at the School of Medicine, University of Pennsylvania, from 2003-2008. He earned a doctorate degree in statistics from the University of Connecticut in 2001 and later joined the Biostatistics Branch at the National Institute of Environmental Health Sciences (NIEHS) as a Research Fellow from 2001 to 2003. Dr. Chen's methodological research interests focus on the use of hierarchical models (e.g., Bayesian, mixed effects) for estimating conception probabilities and adverse reproductive and perinatal outcomes. In his DESPR position, Dr. Chen will collaborate with investigators involved in the ENDO and LIFE Studies while continuing to develop his statistical models.

PERSONNEL CHANGES - NIH

Raynard S. Kington, M.D., Ph.D., was named Acting Director of the National Institutes of Health (NIH) on October 31, 2008, following the departure of Elias A. Zerhouni, M.D. Since February 9, 2003, when Dr. Kington was appointed Deputy Director, NIH, he shared in the overall leadership, policy direction, and coordination of NIH biomedical research and research training programs of NIH's 27 Institutes and Centers with a budget of almost \$29 billion and 18,000 employees. In November 2008, Lawrence A. Tabak, D.D.S., Ph.D., Director, National Institute of Dental and Craniofacial Research (NIDCR), was appointed Acting Principal Deputy Director, NIH. While serving in this position Dr. Tabak will continue in his role as Director, NIDCR.

Linda S. Birnbaum, Ph.D., has been appointed as Director of the National Institute of Environmental Health Sciences (NIEHS) and the National Toxicology Program (NTP). Dr. Birnbaum, who is currently a senior advisor at the Environmental Protection Agency (EPA), where she served for 16 years as Director of the Experimental Toxicology Division, will begin her appointment in January 2009. As NIEHS Director, she will oversee a \$730 million budget that funds multidisciplinary biomedical research programs, prevention, and intervention efforts that encompass training, education, technology transfer, and community outreach. Dr. Birnbaum received her M.S. and Ph.D. degrees in microbiology from the University of Illinois, Urbana.

Dr. Birnbaum, a board certified toxicologist, has served as a federal scientist for nearly 29 years. The first ten of those were at NIEHS, first as a senior staff fellow at the NTP, then as a principal investigator and research microbiologist, and finally as a group leader for the Institute's Chemical Disposition Group.

Norka Ruiz Bravo, Ph.D., stepped down as NIH Deputy Director for Extramural Research and Director, Office of Extramural Research (OER) in November. Dr. Ruiz Bravo will transition to a new role as Special Advisor to the Acting Director, NIH. In her role as Deputy Director, OER, Dr. Ruiz Bravo made critical contributions to the development and implementation of the NIH Roadmap for Medical Research and many of its initiatives. In addition, she played a leadership role in developing and implementing transforming NIH policies, such as the Public Access and the Multiple Principal Investigator policies, and eSubmission, the NIH transition from paper to electronic submission of applications. She initiated the use of mathematical modeling to improve our understanding of the dynamics of the biomedical research workforce, and contributed greatly to the discussion and resulting programs to address the plight of new investigators. Sally J. Rockey, Ph.D., has been appointed Acting NIH Deputy Director for Extramural Research and Interim Director of OER. Dr. Rockey has served as the Deputy Director of OER since 2005 and has extensive experience and expertise in research administration.

Lana R. Skirboll, Ph.D., has been appointed as Acting Director of the newly established Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI). The new Division is composed of four program offices including Office of Behavioral and Social Sciences Research (OBSSR), Office of Research on Women's Health (ORWH), Office of AIDS Research (OAR), and Office of Disease Prevention (ODP), as well as the functions under the former Office of Portfolio Analysis and Strategic Initiatives (OPASI). The former Division of Strategic Coordination in OPASI will be reconstructed as the Office of Strategic Initiatives, while other OPASI functions will be moved into the Office of the DPCPSI Director. Former OPASI Director, Alan Krensky, M.D., has transitioned to his laboratory in the National Cancer Institute (NCI) and will also serve as Senior Advisor to the NIH Deputy Director.

Marie A. Bernard, M.D., has been appointed Deputy Director, National Institute on Aging (NIA). Dr. Bernard previously held the position of the Donald W. Reynolds Chair in Geriatric Medicine and Professor and Chairman of the Donald W. Reynolds Department of Geriatric Medicine at the University of Oklahoma College of Medicine. She received her M.D. degree from the University of Pennsylvania and trained in internal medicine at Temple University Hospital where she also served as Chief Resident. Dr. Bernard's research interests have included nutrition and function in aging populations, with a particular emphasis on ethnic minorities. She has written numerous journal and chapter articles on geriatric care, nutrition, medication issues and health problems among minorities.

STATUS OF FY 2008, 2009 AND 2010 BUDGETSFY 2008

In FY 2008, the NICHD obligated \$1.259 billion in appropriated funds, including \$138.4 million for AIDS research. In addition to NICHD appropriated funds, the Institute obligated more than \$29 million from reimbursements and \$60 million from co-funding received from other federal agencies and NIH components, including the NIH Office of the Director, for a total of over \$89 million.

The NICHD awarded 1,799 research project grants (RPGs), including 455 competing awards for \$139 million. Preliminary estimates for the RPG success rate is 16.9 percent, compared to the FY 2007 success rate of 20.6 percent.

Other key funding mechanisms supported includes 47 research centers at \$65.4 million; 838 full time training positions at \$36.4 million; and research and development contracts at a total of \$140.2 million.

FY 2009

The NIH is currently operating under a Continuing Resolution (CR), at the FY 2008 level, which is in effect until March 6, 2009. In keeping with NIH policy, the NICHD is awarding non competing grants at 90 percent of the committed level.

The FY 2009 President's budget request was released to the public on February 4, 2008. The President's request for NIH was \$29.2 billion. The FY 2009 President's budget request for the NICHD provides a funding level of \$1.255 billion. This is approximately \$3.5 million less than the FY 2008 appropriation level, which included the addition of supplemental funds in the amount of \$6.7 million received in the fourth quarter of FY 2008. An appropriation bill has not passed the House or Senate.

FY 2010

Preliminary work on the budget for the FY 2010 has begun, using the FY 2009 President's budget request as the base. After intermediate stages of review, the President's budget request for FY 2010 will be presented to Congress in February 2009, at which time it will become available to the public.

Attached is an NICHD budget mechanism table that identifies FY 2008 actual obligations and the FY 2009 President's budget request.

PROGRAM AND PUBLIC LIAISON REPORT

This report on legislative and public liaison activities of interest to Council is current as of December 24, 2008. If warranted, an update will be provided to Council at its meeting on January 22, 2009.

Unusually, the 110th Congress has not yet adjourned "sine die," and technically, could reconvene at any time before the scheduled adjournment date of January 3. All legislative measures introduced during the two-year Congress will no longer be pending, and would have to be reintroduced in the 111th Congress, scheduled to convene January 6 for the swearing in of new members, and begin other business. Topping the legislative agenda is a massive economic stimulus bill that may include additional funding for NIH, and an omnibus 2009 appropriations measure, including funding for the Fiscal Year 2009 Labor-Health and Human Services-Education appropriations bill. If passed and signed by the new president, that bill would supersede the Continuing Resolution, which is currently keeping NIH and the other health agencies operating at FY 2008 funding levels until March 2009.

Legislation

In the waning days of this Congress, two bills potentially affecting NICHD's research activities were passed and signed by the President:

On October 8, 2008, the Paul D. Wellstone Muscular Dystrophy Community Assistance, Research and Education (MD-CARE) Amendments of 2008 became Public Law 110-361. The Act names the muscular dystrophy centers of excellence (several of which are partially funded by NICHD) as the Paul D. Wellstone Muscular Dystrophy Cooperative Research Centers. In addition, the Muscular Dystrophy Interagency Coordinating Committee, on which the Director, NICHD, sits, is authorized to give special consideration to enhance the clinical research infrastructure to test emerging therapies for the various forms of muscular dystrophy.

The same day, the Prenatally and Postnatally Diagnosed Conditions Act was signed (Public Law 110-374). The goal of the Act is to increase the provision of information, referrals and support services to families of patients receiving a diagnosis of Down syndrome or other prenatally or

postnatally (up to one year after birth) diagnosed conditions. The Secretary of HHS, acting through the Directors of NIH or CDC, or the Administrator of HRSA, is directed to award grants or contracts to coordinate the provision of “up-to-date and evidence-based” information regarding such services to families.

Briefings

On October 3, 2008, Drs. Alexander and Peter Scheidt, Program Director, National Children’s Study (NCS), announced the locations of the second “wave” of study centers that had just been awarded contracts to carry out the NCS at a briefing on Capitol Hill. Attendance at the briefing, which was organized and hosted by the co-chairs of the Congressional Children’s Study Working Group, Reps. Doris Matsui (D-CA) and Christopher Smith (R-NJ), was excellent, despite it being the same day as the bailout vote.

Drs. Duane Alexander and Estella Parrott, Medical Officer, Reproductive Sciences Branch (RSB), Center for Population Research (CPR), provided another briefing on the Institute’s research activities related to vulvodynia for staff from Rep. Lois Capps’ (D-CA) office and other Women’s Caucus staff on October 23, 2008. Representatives from the National Vulvodynia Association were also present.

Public Liaison

On November 13, 2008, Dr. Yvonne Maddox, Deputy Director, NICHD, presented an overview of NICHD’s research efforts to improve global health to the Friends of NICHD at their semi-annual meeting, covering a wide range of topics, including nutrition, HIV/AIDS, and maternal and child health.

Dr. R. Rodney Howell, IDDB, CDBPM, presented the Institute’s research activities to enhance and improve newborn screening, including the new translational research network, to a coalition of organizations interested in maternal and child health on December 1, 2008. The meeting was sponsored by the March of Dimes.

Prior to the holidays, Dr. Lynne Mofenson, Chief of the Pediatric, Adolescent and Maternal AIDS Branch (PAMAB), CRMC, provided a briefing by “webinar” to members of the Friends of NICHD and other interested organizations on the far-ranging research activities of the branch.

CONFERENCES AND WORKSHOPS

- Title:** **Safe and Effective Instruments and Devices for Use in the NICU**
- Date:** February 12-13, 2009
- Sponsor/Co-Sponsor(s):** Pregnancy and Perinatology Branch (PPB), Center for Developmental Biology and Perinatal Medicine (CDBPM), NICHD; Office of Rare Diseases (ORD); and the National Heart, Lung and Blood Institute (NHLBI)
- Location:** Fifth Floor Conference Room, 6100 Executive Boulevard, Rockville, Maryland
- Purpose:** To discuss the challenges and opportunities for developing safe and effective devices and instruments for use in the neonatal period. The topic areas for discussion by the invited experts in biomedical and bioengineering communities include: cardiopulmonary; cerebral oxygenation and imaging; metabolic monitoring; and sepsis.
- Organizer(s):** Dr. Tonse Raju, Medical Officer, PPB, CDBPM, NICHD
- For Information:** Dr. Tonse Raju
Tel: (301) 402-1872
Fax: (301) 496-3790
Email: rajut@mail.nih.gov
-
- Title:** **Early Detection and Screening for Neuromuscular Diseases**
- Date:** March 16-17, 2009
- Sponsor/Co-Sponsor(s):** Intellectual and Developmental Disabilities Branch (IDDB), CDBPM, NICHD; ORD; Centers for Disease Control and Prevention (CDC); Muscular Dystrophy Association (MDA/pending); American College of Medical Genetics (ACMG/pending); National Institute of Arthritis and Musculoskeletal Diseases (NIAMS)/pending)
- Location:** Bethesda, Maryland
- Purpose:** Early detection and treatment of neuromuscular diseases in newborns and infants is critical in order to reduce long-term morbidity and mortality. This workshop will provide an opportunity for both the neuromuscular disease research and service communities, along with their supporters, to learn about the specific state of readiness for early detection and screening for

these disorders. The workshop participants will also discuss steps to be taken to assist these communities with their research and infrastructure needs in order to help them progress towards the screening of various neuromuscular conditions.

Organizer(s): Gilian Engelson, IDDB, CDBPM, NICHD (contractor); Dr. Tiina K. Urv, Health Scientist Administrator, IDDB, CDBPM, NICHD

For Information: Gilian Engelson
Email: engelsong@mail.nih.gov

Title: **Clinical and Translational Workshop on Niemann-Pick Disease, Type C**

Date: April 3-4, 2009

Sponsor/Co-Sponsor(s): Division of Intramural Research (DIR), NICHD

Location: Bethesda, Maryland

Purpose: To facilitate coordination of translational and clinical aspects of NPC on an international basis. Sessions include Translational Research, Clinical Research and Coordination of Clinical Trials.

Organizer(s): Dr. Forbes D. Porter, Heritable Disorders Branch, Section on Molecular Dismorphology, DIR, NICHD

For Information: Dr. Forbes D. Porter
Tel: (301) 435-4432
Fax: (301) 480-4791
Email: fp15m@nih.gov

Title: **Sleepiness and Health Related Quality of Life**

Date: April 14-15, 2009

Sponsor/Co-Sponsor(s): National Center for Sleep Disorders Research; NHLBI; Center for Research for Mothers and Children (CRMC) and Center for Population Research (CPR), NICHD

Location: Natcher Auditorium, NIH Campus

Purpose: This conference will assess new findings emerging from national health surveillance studies, genetic epidemiological studies, and mechanistic pathophysiological analyses to identify specific research opportunities that would lead to the development of improved strategies for the prevention, therapy, and management of sleep-related impaired quality of life, morbidity, and mortality.

Organizer(s): Drs. Michael Twery, NHLBI; Lynne Haverkos, Child Development and Behavior Branch (CDBB), CRMC, NICHD and Rosalind King, Demographic and Behavioral Sciences Branch (DBSB), CPR, NICHD

- For Information:** Dr. Lynne Haverkos
Tel: (301) 435-6881
Fax: (301) 480-0230
Email: lh179r@nih.gov
- Title:** **2009 Research Meeting of the Specialized Cooperative Centers Program in Reproduction and Infertility Research (SCCPIR)**
- Date:** May 11-12, 2009
- Sponsor/Co-Sponsor(s):** Reproductive Sciences Branch (RSB), CPR, NICHD
- Location:** The Inn of Chicago, Chicago, Illinois
- Purpose:** The purpose of this meeting is to highlight significant advances in research, technology and resource development and bioinformatic efforts supported by the SCCPIR. The agenda will include both oral and poster presentations, the Sadler Lectureship given by Dr. Jerome Strauss and a Keynote Address given by Dr. Rudolph Jaenisch. The meeting also presents an opportunity for investigators supported through the Reproductive Medicine Network, Contraceptive Development Centers and RSB-administered Program Project grants to interact with SCCPIR-supported investigators and their trainees. Meetings of SCCPIR Research Focus Groups will take place prior to this meeting and leaders from these groups will report on the progress of collaborative research activities amongst investigators at the Research Meeting.
- Organizer(s):** Drs. Louis DePaolo, RSB, CPR, NICHD and Asgerally Fazleabas, University of Illinois at Chicago
- For Information:** Dr. Louis DePaolo
Tel: (301) 435-6970
Fax: (301) 496-0962
Email: ld38p@nih.gov
- Title:** **Reproductive Problems in Women of Color**
- Date:** May 12-14, 2009
- Sponsor/Co-Sponsor(s):** DIR, NICHD
- Location:** Bethesda, Maryland
- Purpose:** The purpose of the NIH Expert panel is to bring investigators together to examine epidemiologic data related to access to reproductive health care, and ethnic disparities in pregnancy rates and obstetrical outcomes.

- Organizer(s):** Dr. Alicia Armstrong, Reproductive Biology and Medicine Branch, Unit on Reproductive Endocrinology and Infertility, DIR, NICHD
- For Information:** Dr. Alicia Armstrong
Tel: (301) 402-6080
Fax: (301) 402-0884
Email: armstroa@mail.nih.gov
- Title:** **Writing Development and Instruction Workshop**
- Date:** May 18-19, 2009
- Sponsor/Co-Sponsor(s):** National Institute for Literacy
- Location:** Washington, DC area
- Purpose:** This meeting will serve as a venue to discuss the state of the science, including behavioral, neurobiological and genetic research, related to the development and acquisition of writing skills, development of writing interventions and instruction, and the relationship to meta-cognition and reading.
- Organizer(s):** Dr. Brett Miller, Health Scientist Administrator, Reading, Writing, and Related Learning Disabilities Research Program, CDBB, CRMC, NICHD
- For Information:** Dr. Brett Miller
Tel: (301) 496-9849
Fax: (301) 480-7773
Email: millerbre@mail.nih.gov
- Title:** **New Research Directions in Chronic Disease Prevention in the Workplace**
- Date:** May 21-22, 2009
- Sponsor/Co-Sponsor(s):** Division of Population and Prevention Sciences, NHLBI; Office of the Director, National Institute for Occupational Safety and Health (NIOSH); DBSB, NICHD; NIDDK; NCI
- Purpose:** To develop a comprehensive, coordinated research plan for prevention of chronic disease in working adults through worksite interventions.
- Organizer(s):** Drs. Lawrence Fine and Charlotte Pratt, Division of Population and Prevention Sciences, NHLBI and Dr. Gregory Wagner, Office of the Director, NIOSH
- For Information:** Dr. Rosalind King, DBSB, CPR, NICHD
Tel: (301) 435-6986
Fax: (301) 496-0962
Email: rozking@mail.nih.gov

- Title:** **DNA Repair and Mutagenesis**
Date: May 30-June 5, 2009
Sponsor/Co-Sponsor(s): DIR, NICHD and the American Society for Microbiology
Location: Whistler, Canada
Purpose: To continue the tradition of the informal series of community-wide DNA repair meetings that have been held approximately every four years since 1974 and have played a key role in the development of this field of study.
- Organizer(s):** Dr. Roger Woodgate, Laboratory of Genomic Integrity, DIR, NICHD
- For Information:** Dr. Roger Woodgate
 Tel: (301) 217-4040
 Fax: (301) 217-5815
 Email: woodgatr@mail.nih.gov
- Title:** **Families and Health**
Date: June 1-2, 2009
Sponsor/Co-Sponsor(s): Bowling Green State University; Office of the Assistant Secretary of Planning and Evaluation (ASPE), Department of Health and Human Services (DHHS); and DBSB, CPR, NICHD
Location: Natcher Conference Center, NIH Campus
Purpose: This conference will feature cutting edge papers examining how families condition the development and treatment of disease, care giving and the cost of illness. Also, the conference will examine how illness affects family structure, process and functioning.
- Organizer(s):** Dr. V. Jeffery Evans, Health Scientist Administrator, DBSB, CPR, NICHD
- For Information:** Dr. V. Jeffery Evans
 Tel: (301) 496-1176
 Fax: (301) 496-0962
 Email: Jeff_evans@nih.gov
 Email: stratak@mail.nih.gov
- Title:** **International Workshop on Phosphodiesterases: Their Genetics, Function and Human Disease (PDE2009)**
Date: June 7-9, 2009
Sponsor/Co-Sponsor(s): DIR, NICHD and the University of Milan
Location: Bethesda, Maryland

- Purpose:** To bring together experts from a variety of disciplines (endocrinology, pharmacology and biochemistry, dietary medicine, reproduction science, cancer and others) with the scope of refocusing research on PDEs to a more translational, bench-to-bedside manner.
- Organizer(s):** Dr. Constantine Stratakis, Developmental Endocrinology Branch, DIR, NICHD
- For Information:** Dr. Constantine Stratakis
Tel: (301) 402-1998
Fax: (301) 402-0574
- Title:** **Conference on Research Designs for Evaluating Scale-Up Strategies in Reproductive Health**
- Date:** June 10-12, 2009
- Sponsor/Co-Sponsor(s):** World Health Organization Program for Research for Reproductive Health: Division of Maternal and Perinatal Mortality (WHO/RHR/MPH), Canadian Institute of Health Research (CIHR) through The Cochrane Effective Practice and Organization of Care Group (EPOC) and the NICHD Global Network for Women's and Children's Health Research
- Location:** Ottawa, Canada
- Purpose:** The purpose of this conference is to design guidelines that are scientifically sound and acceptable to policy makers for evaluating the cost- effectiveness of scale-up programs and methods used for scale-up implementation. Two interventions aimed at improving maternal and neonatal mortality will be used as case examples.
- Organizer(s):** Dr. Mario Merialdi, Coordinator for Maternal and Child Health at the Department of Reproductive Health and Research and WHO; Dr. Linda Wright, Global Network, NICHD
- For Information:** Dr. Jeremy Grimshaw, Director, Clinical Epidemiology Program, Ottawa Health Research Institute, EPOC Editor
Tel: (613) 798-5555 (ext. 15231)
Fax: (613) 761-5402
E-mail: jgrimshaw@ohri.ca
www.eroc.cochrane.org

REQUESTS FOR APPLICATIONS

- Title:** **RFA-HD-08-009: Translational Research in Female Pelvic Floor Disorders (R03)**
- Receipt Date(s):** October 30, 2008
- Sponsor/Co-Sponsor(s):** NICHD
- Purpose:** This RFA solicits applications from institutions/organizations that propose to enhance collaborative research among basic scientists and clinician researchers in female pelvic floor disorders. The purpose of the RFA is to attract more basic scientists into the field of female pelvic floor disorders, to establish relationships between clinicians and basic scientists, and to promote research that has the greatest clinical applicability for addressing unknown aspects of physiology and pathophysiology of pelvic function.
- Title:** **RFA-HD-08-010: Using Proven Factors in Risk Prevention to Promote Protection from HIV Transmission (R01)**
- Receipt Date(s):** December 11, 2008
- Sponsor/Co-Sponsor(s):** NICHD
- Purpose:** This RFA solicits research project grant (R01) applications that propose studies designed to develop, implement, and evaluate new or improved HIV prevention programs that incorporate proven elements from positive youth development, risk behavior prevention, and drug abuse prevention programs. These programs should be designed for use in high-risk, urban American minority preadolescents and early adolescents in elementary and middle schools or in after-school programs. The goals of these prevention programs are to 1) reduce exposure to HIV by preventing, delaying, or protecting against the negative outcomes of risky behaviors, 2) enhance resiliency in the target population, and 3) improve knowledge, behavior, and health in youth.
- Title:** **RFA-HD-08-014: Women's Reproductive Health Research (WRHR) Career Development Program (K12)**
- Receipt Date(s):** March 27, 2009
- Sponsor/Co-Sponsor(s):** NICHD
- Purpose:** The purpose of this RFA is to build a national capacity of junior investigators in women's reproductive health research, provide junior faculty with state of the art training in women's reproductive health research in an academic setting, stimulate women's reproductive health research over a variety of disciplines,

and secure an outstanding research experience for junior faculty leading to a career as a successful independent investigator.

Title: **RFA-HD-08-020: Limited Competition for Data Sharing for Demographic Research Infrastructure Program (U24)**

Receipt Date(s): December 2, 2008

Sponsor/Co-Sponsor(s): NICHD

Purpose: The purpose of this limited competition is to advance population research by enhancing and expanding the use of existing demographic data sets in a cost effective manner, while ensuring appropriate confidentiality and protection of the respondents in the data sets. Specifically, the Data Sharing for Demographic Research (DSDR) infrastructure program is intended to: (1) expand secure archiving of data and meta-data of interest to the demographic research community and by providing assistance on data archiving to the demography research community directly and by providing assistance on data archiving to data producers throughout the community; and (2) provide tools, training, and expertise that support access to and the effective use/analysis of these data by researchers in the demographic community.

Title: **RFA-HD-08-023: Innovative Computational and Statistical Methodologies for the Design and Analysis of Multilevel Studies on Childhood Obesity (R01)**

Receipt Date(s): November 28, 2008

Sponsor/Co-Sponsor(s): NICHD, OBSSR

Purpose: This RFA solicits Research Project Grant (R01) applications from institutions/organizations that propose to develop, refine, and apply innovative statistical or computational methods for the analysis of multilevel determinants of childhood obesity or for the design of multilevel interventions. Multilevel observational and intervention studies include those that consider the range of biological, family, community, socio-cultural, environmental, policy, and macro-level economic factors that influence diet and physical activity in children. This RFA aims to encourage the development and application of novel methodologies, using secondary or simulated data, that can simultaneously examine factors of energy balance that span more than 3 levels of influence in children.

Title: **RFA-HD-08-025: Collaborative Pediatric Critical Care Research Network (U10)**
Receipt Date(s): March 31, 2009
Sponsor/Co-Sponsor(s): NICHD
Purpose: The purpose of this RFA is to maintain infrastructure to support the Collaborative Pediatric Critical Care Research Network (CPCCRN) by establishing and maintaining the infrastructure required for a network of academic centers to perform clinical trials and pertinent descriptive and translational research for children who are critically ill. This network, by rigorous use of appropriate scientific methodology, can study the required number of patients and provide answers more rapidly than individual centers acting alone.

Title: **RFA-HD-08-027: Data Coordinating Center for the Collaborative Pediatric Critical Care Research Network (U01)**
Receipt Date(s): March 31, 2009
Sponsor/Co-Sponsor(s): NICHD
Purpose: The purpose of this RFA is to solicit applications for a centralized Data Coordinating Center (DCC) that will support the activities of the CPCCRN. The funded DCC will cooperate with the NICHD CPCCRN Principal Investigators and the NICHD Project Scientist in identifying research topics of high priority and in designing protocols appropriate to the evaluation of optimal management in these areas. The DCC will have primary responsibility for data management and analysis for Network research in collaboration with the CPCCRN Steering Committee.

CO-SPONSORED REQUESTS FOR APPLICATIONS

Title: **RFA-CA-09-003: Replication and Fine-Mapping Studies for the Genes Environment and Health Initiative (GEI)(R01)**
Receipt Date(s): December 1, 2008

- Sponsor/Co-Sponsor(s):** NCI, NEI, NHGRI, NHLBI, NIA, NIAAA, NIAID, NIAMS, NIBIB, NICHD, NIDA, NIDCD, NIDCR, NIDDK, NIEHS, NIGMS, NIMH, NINDS, NINR, NLM
- Purpose:** The purpose of this RFA is to provide support for replication and fine-mapping studies of genetic regions that are putatively associated with common complex traits, primarily those identified by genome-wide association studies (GWAS). The proposed projects should aim to enhance the identification of causal variants influencing complex diseases. Any phenotype may be appropriate for these projects (i.e., studies need not be oriented on cancer or cancer-related phenotypes). This RFA will not support recruitment of human subjects, collection of human specimens, collection of medical or phenotype data, studies using animal models, or discovery genome-wide association efforts.
- Title:** **RFA-DK-08-012: Closed Loop Technologies: Clinical and Behavioral Approaches to Improve Type 1 Diabetes Outcomes (R01)**
- Receipt Date(s):** March 19, 2009
- Sponsor/Co-Sponsor(s):** NIDDK, NICHD
- Purpose:** The purpose of this RFA is to solicit applications for human studies to develop a highly reliable, easy to operate system linking continuous glucose monitoring to insulin delivery in a closed loop system. The goal is to address barriers that limit progress toward a closed loop system and specifically to 1) address behavioral factors that limit use of these systems, 2) use the technologies as tools to advance understanding of the pathophysiology of glucose regulation in patients with Type 1 diabetes and 3) test and improve the safety, reliability and utility of these technologies in humans. Research goals include improved metabolic control with decreased glycemic excursions, increased lifestyle flexibility and improved quality of life in patients with diabetes. Only human studies will be considered responsive to this RFA.
- Title:** **RFA-DK-08-013: Closed Loop Technologies: Pilot and Exploratory Clinical and Behavioral Approaches to Improve Type 1 Diabetes Outcomes (R21)**
- Receipt Date(s):** March 19, 2009
- Sponsor/Co-Sponsor(s):** NIDDK, NICHD
- Purpose:** See RFA-DK-08-012
- Title:** **RFA-DK-09-001: Small Business Innovation Research to**

Develop New Therapeutics and Monitoring Technologies for Type 1 Diabetes (T1D) Towards an Artificial Pancreas (SBIR) [R43/R44]

Receipt Date(s): April 15, 2009
Sponsor/Co-Sponsor(s): NIDDK, NIBIB, NICHD
Purpose: This RFA is intended to support cutting edge research conducted by a small business leading to the development of innovative technologies that may advance progress toward an integrated, long term, automated, glucose regulated insulin delivery system (artificial pancreas). This announcement has two main purposes: a) promote technical innovation and b) promote pre-clinical or clinical testing of single or combined components of a closed loop system.

Title: **RFA-RR-09-004: Research on Integrity in Collaborative Research (R21)**

Receipt Date(s): March 17, 2009
Sponsor/Co-Sponsor(s): NCRR, NICHD
Purpose: The purpose of this exploratory/developmental grant program is to foster research on research integrity in areas of collaborative research that have little published data. The proposed project must challenge existing paradigms, be developed around an innovative hypothesis or address critical barriers to progress in understanding the multiple factors that underlie deviation from integrity in collaborative research. The sponsoring agencies are particularly interested in research focused on integrity in collaborative research that will provide clear evidence (rates of occurrence and impacts) of problem areas in community standards, self-regulation, practice norms, and non-adherence to accepted codes of conduct. The application must address the societal, organizational, group, or individual factors that affect integrity in collaborative research, both positively and negatively. Applications must have relevance to health sciences research including, for example, those biomedical, behavioral health sciences, or health services research areas having particular positive or negative collaborative research integrity issues. Applicants must address problems or issues that have relevance to the specific interests of the Office of Research Integrity (ORI) or NIH Institutes and Centers.

NICHD ITEMS OF INTERESTClinical Research Program

On November 5-6, 2008, Dr. Steven Hirschfeld, Associate Director for Clinical Research, spoke at a workshop sponsored by the Endocrine Society and the Lawson Wilkins Pediatric Endocrine Society. The workshop was co organized by former NICHD Clinical Director Lynette Nieman on “Regulation of Clinical Research”. The workshop was intended to bring together researchers and policymakers to improve the state of U.S. clinical research. Among the issues discussed was the use of healthy children for controls in clinical research and what criteria define a condition. The outcome of the workshop is a planned White Paper on the perceptions and types of risk in pediatric research.

Additional activities of the NICHD Clinical Research Program include an updated NICHD policy document on Clinical Monitoring including a charter template for Independent Data Monitoring Committees, development of a redesigned web based system for Certificates of Confidentiality applications that will become the NIH Portal for application submission, and collaboration with the National Center for Research Resources Clinical and Translational Science Awards program for two conferences. The first will occur on February 26, 2009, on the topic of determining specifications for collaborative research for child health. The second is scheduled for March 20, 2009, on comparative models for Institutional Review Board review for multi-institutional studies. Both conferences will take place on the NIH campus.

Global Network

A child development center in honor of Dr. Linda Wright, Deputy Director, Center for Research for Mothers and Children, was inaugurated at Metgud Hospital in Bailhongal, India, during a recent site visit to the Global Network’s site at the Jawaharlal Nehru Medical College, Belgaum, India. This is the first such Center to be opened in a rural Indian community; it will be used initially to train counselors to teach parents to provide early infant stimulation and to provide developmental interventions to area toddlers. The child development center is an outgrowth of the BRAIN HIT trial (Waldemar Carlo, Principal Investigator) which was jointly funded by the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development; the National Institute of Neurologic Diseases and Stroke, and the Fogarty International Center as part of the Brain Initiative. The BRAIN HIT trial is being conducted at four Global Network sites in Belgaum, India; Lusaka, Zambia; Kirachi, Pakistan; and Chimetanango, Guatemala. Counselors at intervention sites teach mothers of asphyxiated infants enrolled in the FIRST

BREATH resuscitation study (versus normal infants who receive standard care) how to provide home-based early stimulation in order to optimize their infants' developmental outcome. The trial will follow the infants until 36 months for cognitive, motor and social development compared to a normal control group which has received standard care.

Dr. Patricia Hibberd, a new Principal Investigator in the Global Network for Women's and Children's Health Research, and a Professor of Pediatrics, Medicine and Public Health at the Tufts University School of Medicine, has been chosen by the Paul G. Rogers Society for Global Health Research, as one of their 25 new Society Ambassadors. Society Ambassadors are highly respected "citizen scientists" and advocates committed to making global health research a higher national priority. In consultation with Research!America, they engage policy makers, thought leaders, the media and the public on the value and importance of global health research. The Rogers Society is comprised of 50 scientific leaders representing a broad spectrum of medical and public health research.

AWARDS

All NICHD FY 2008 staff awards can be viewed at the following link:

http://www.nichd.nih.gov/about/overview/advisory/nachhd/upload/2008_NICHD_Awards_Ceremony_Program_20081008.pdf

Dr. Bert W. O'Malley, long-term grantee of the NICHD, has been awarded the National Medal of Science, the nation's highest award in science. President Bush presented the award to Dr. O'Malley in recognition of his pioneering work on the molecular mechanisms of steroid hormone action and hormone receptors and coactivators, which has had a profound impact on our knowledge of steroid hormones in normal development and in diseases such as cancer, diabetes, and reproductive disorders. In 1965, Dr. O'Malley joined the NCI as a Clinical Associate, and was later appointed head of the Molecular Biology Section of the Endocrine Branch. From 1969 to 1973, he directed the Reproductive Biology Center at Vanderbilt University School of Medicine and received the first center grant in the reproductive sciences awarded by the NICHD. Since 1973, Dr. O'Malley has been Chairman of the Department of Cell Biology at Baylor College of Medicine. Dr. O'Malley is a member of the National Academy of Sciences and Institute of Medicine, is a past president of the Endocrine Society and has received numerous awards and honors. He has published over 600 papers and holds 20 patents in the field of gene regulation, molecular endocrinology and steroid receptor action. His laboratory has trained over 250 students and fellows.

Dr. Kevin Eggan, Assistant Professor at Harvard University and NICHD grantee has been named a recipient of the 2007 Presidential Early Career Award in Science and Engineering. This award recognizes outstanding young investigators who carry out innovative research at the frontiers of science and technology as well as community service demonstrated through scientific leadership, education or community outreach. He has received many other awards including the prestigious John D. and Catherine T. MacArthur Foundation Fellowship in 2006. Dr. Eggan's research is on stem cells, epigenetic reprogramming, embryo development and the use of various stem cell approaches to study human disease processes and to develop novel therapeutics.

Dr. Constantine Stratakis, Senior Investigator, Section on Endocrinology and Genetics, Division of Intramural Research (DIR), is the 2009 recipient of the Endocrine Society's Laureate Ernst Oppenheimer Award. The award is the premier honor to a young investigator in recognition of meritorious accomplishments in the field of basic or clinical endocrinology.

Dr. Steven J. Suomi, Chief, Laboratory of Comparative Ethology, DIR, is the recipient of the American Psychological Association Presidential Citation. The award was presented to him in August 2008 in recognition of his lifelong service to the field of developmental psychology through his research using nonhuman primates. It also recognized him for his devotion to his students and focus on mentoring those under his charge resulting in the successful placement of students and postdoctoral candidates to various major university, government, and private sector appointments.

PUBLICATIONS

Health Behaviors in School-Age Children (HBSC) 2005/2006 Survey: School Report

This scientific report describes the findings from the 2005-2006 survey of the Health Behavior of School-Age Children (HBSC) project, a World Health Organization cross-national study of adolescent health, health behaviors, and the family, school, and social-environmental contexts for these health behaviors. This item is available online only through the NICHD Web site at http://www.nichd.nih.gov/publications/pubs_details.cfm?from=&pubs_id=5723 or at <http://www.nichd.nih.gov/about/org/despr/studies/behavior/HBSC.cfm>.

Innovations: Future Solutions Now—An E-Update from the NCMRR (Winter 2008-2009)

This e-update—released electronically by the NICHD National Center for Medical Rehabilitation Research (NCMRR), recognizes the accomplishments of NCMRR grantees, outlines funding opportunities for those doing research in rehabilitation research, and describes some of the many

projects and programs supported by the NCMRR. This item is available online only through the NICHD Web site at

http://www.nichd.nih.gov/publications/pubs_details.cfm?from=&pubs_id=5722.

Pregnancy and Perinatology Branch (PPB), NICHD, Report to the NACHHD Council, September 2008

This scientific report describes research and research training supported by the NICHD's PPB as of 2008 that relate to high-risk pregnancy, fetal pathophysiology, preterm labor and birth, disorders of the newborn, and sudden infant death syndrome (SIDS). The report also describes the activities of Branch-supported networks, including the Neonatal Research Network, the Maternal-Fetal Medicine Units Network, the Stillbirth Collaborative Research Network, and the Maternal-Fetal Surgery Network, just to name a few. The final section of the report outlines recommendations for the Branch's future research directions that resulted from a Branch-convened meeting with an expert panel, which reviewed the Branch portfolio and activities.

The above items are available from the NICHD Information Resource Center (1-800-370-2943) and/or through the NICHD Web site at <http://www.nichd.nih.gov/publications>.

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT
Status of FY 2008 and 2009 Budgets
(Dollars in thousands)

Includes AIDS

Mechanism	FY 2008		FY 2009	
	Actuals		President's Budget Requested	
<u>Research Grants</u>	No.	Amount	No.	Amount
<u>Research Projects</u>				
Noncompeting	1,250	\$507,720	1,191	\$492,745
Administrative Supplements	(40)	8,636	(55)	4,464
Competing	455	139,003	452	145,625
Subtotal	1,705	655,359	1,643	642,834
SBIR/STTR	94	28,728	100	29,061
Subtotal, RPG	1,799	684,087	1,743	671,895
<u>Research Centers</u>				
Specialized/Comprehensive	47	64,845	50	63,505
Clinical Research	0	0	0	0
Biotechnology	0	238	0	234
Comparative Medicine	0	300	0	0
Res. Centers in Minority Instit.	0	0	0	0
Subtotal, Centers	47	65,383	50	63,739
<u>Other Research</u>				
Research Careers	283	49,214	294	49,535
Cooperative Clinical Research	79	40,624	96	41,232
Other	119	22,300	143	22,479
Subtotal, Other Research	533	112,138	533	113,246
Total Research Grants	2,327	861,608	2,326	848,880
<u>Training</u>	<u>FTTP</u>		<u>FTTP</u>	
Individual	93	4,034	103	4,682
Institutional	745	32,354	769	33,918
Total Training	838	36,388	872	38,600
Research & Develop. Contracts (SBIR/STTR)	204 (0)	140,211 (0)	294 (0)	145,727 (0)
Intramural Research		162,752		165,029
Res. Management & Support		58,476		57,684
Total, NICHD		1,259,435		1,255,920

