



*Eunice Kennedy Shriver*

NICHD

National Institute of Child Health  
& Human Development

NATIONAL ADVISORY CHILD HEALTH  
AND HUMAN DEVELOPMENT  
COUNCIL

*MINUTES OF MEETING*

January 22, 2009

**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
PUBLIC HEALTH SERVICE  
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN  
DEVELOPMENT  
NATIONAL ADVISORY CHILD HEALTH AND HUMAN DEVELOPMENT COUNCIL  
SUMMARY MINUTES  
January 22, 2009<sup>1</sup>**

The National Advisory Child Health and Human Development (NACHHD) Council convened its one-hundred-thirty-seventh meeting at 8:10 a.m., Thursday, January 22, 2009, Building 31, Conference

Room 6, National Institutes of Health, Bethesda, Maryland. The meeting was open to the public from 8:07 a.m. to 12:40 p.m. As provided in Sections 552b(c)(4) and 552b(c)(6), Title 5, U.S.C., and Section 10(d) of Public Law 92-463, for the review, discussion, and evaluation of grant applications and related information, the meeting was closed to the public from 1:40 p.m. until 3:45 p.m.

Dr. Duane Alexander, Chair, NACHHD Council, and Director, *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, presided.

**Council members present:**

Dr. Enriqueta Bond  
Dr. Sandra Carson  
Dr. Sherin Devaskar  
Dr. Jonathan Gitlin  
Dr. Ralph Kauffman  
Dr. Perri Klass  
Dr. Ronald Lee  
Dr. Vivian Lewis

Dr. Gail Martin  
Dr. Robert Morris  
Dr. Mark Phillippe  
Dr. Margaret Stineman  
Dr. Rosemarie Truglio  
Dr. Steven Wolf, NABMRR Liaison  
Member

**Council members absent:**

Dr. Joseph Zanga

**Ad Hoc Participants (Pending Member Appointment)**

Dr. Robert Braun      Dr. Rebecca Craik  
Dr. Ann James Dr. Priya Kishnani

**Ex Officio members present:**

Dr. David Heppel, Maternal and Child Health Bureau, Health Resources and Services Administration  
Dr. Lynn Cates, Department of Veterans Affairs, Veterans Administration  
Dr. David S. Louder, III, Air Force Medical Operations Agency, Department of Defense

Council Roster (Attachment I)

<sup>1</sup>Members absent themselves from the meeting when Council discusses applications from their own institutions or when a conflict of interest might occur. The procedure applies only to individual applications discussed, not to en bloc actions.

**Invited speakers:**

Dr. Jack Fletcher, Professor, University of Houston, Houston, Texas.

Dr. Lynn Vernon-Feagans, Professor, University of North Carolina at Chapel Hill, Chapel Hill, North Carolina.

**Others present were:**

Dr. Mary Ann McCabe, Society for Research in Child Development

Dr. Amy Pollick, Association for Psychological Science

Dr. Katrina Gwinn, Baylor College of Medicine

Mr. Jeffrey Mize, Baylor College of Medicine

Mr. Rick Hunsen, Digicon Corporation

Ms. Meghan McGowan, Federation of Behavioral, Psychological, and Cognitive Sciences

Dr. Akbar Shahkolahi, Social Scientific Systems

Ms. Carolyn Huitema, RTI International

Ms. Angela Sharp, Consortium of Social Science Associations

Mr. Perry Kirkham, Purdue University

Ms. Karen Studwell, American Psychological Association

Mr. Ted Shaneck, Tennell Government Services

Michelle Rodreques, SRI

Mr. Emil Wigode, March of Dimes

Mr. David Scalzitti, American Physical Therapy Association

Members of Staff, NICHD

Members of Staff, NIH

Members of Staff, CSR

**I. INTRODUCTORY REMARKS**

Dr. Alexander welcomed Council members, guests, invited speakers, and staff and announced that the meeting would be open to the public on Thursday morning, January 22, and would be closed to the public in the afternoon for the consideration of grant applications.

Dr. Alexander stated that one of the challenges for the Institute and for the membership is the ability of the Council to continue its vital contributions to the NICHD mission in the face of time constraints, travel inconveniences, restricted budgets, and unexpected events. To meet this challenge and facilitate attendance at Council meetings, the Institute has initiated a pilot study of “virtual attendance” as an alternative to attending meetings in Bethesda. Virtual or computer-assisted meetings are becoming more common as technology advances and competing professional demands, travel budget limitations, and safety factors increase in importance. Additionally, having the technology in place will allow us to accommodate an individual member or to reconfigure an entire meeting to a completely electronic one

in the event of an emergency. In addition to allowing Council members to participate in the meeting through Adobe Connect technology, the general public was also invited to attend from remote sites. Dr. Alexander reviewed the virtual meeting guidelines to facilitate remote participation and to assure that remote Council member attendees be fully engaged in the discussion and deliberations of the Council meeting.

#### Review of Confidentiality and Conflict of Interest

Dr. Alexander reminded Council members that material furnished for review and discussion during the closed portion of the meeting is considered privileged information. Advisors and consultants serving as members of a public health advisory committee may not participate in situations in which any violation of conflict of interest laws and regulations might occur. Responsible staff shall ensure that a Council member does not perform duties or render advice which might have a direct and predictable effect on the interests of an organization or institution in which he/she has a financial interest. In particular, Council members should not participate in the evaluation of grant applications for federal support which will affect the interests of such organizations or institutions. At the end of the closed session of the meeting, all members were required to certify that they had not been involved in any conflict of interest situations during the review of grant applications.

#### Council Minutes - September 11, 2008, Meeting

The minutes were approved as written.

#### Future Meeting Dates

The following future meeting dates were agreed to:

June 11, 2009	(Thursday)
September 21, 2009	(Monday)
January 28, 2010	(Thursday)
June 3, 2010	(Thursday)
September 20, 2010	(Monday)
January 20, 2011	(Thursday)
June 2, 2011	(Thursday)
September 22, 2011	(Thursday)

## **II. INTRODUCTION OF NEW MEMBERS**

Dr. Alexander welcomed new Council members and requested that they introduce themselves. Each new member presented a brief overview of their research and professional interests and expressed their interest in serving on the Council and their enthusiasm for interactions with present Council members and NICHD staff.

Priya Kishnani, M.D., is Professor, Department of Pediatrics-Medical Genetics, Duke University Medical School, Durham, North Carolina. Dr. Kishnani's primary focus has concentrated on the translation of laboratory science into the clinical arena, especially in the areas of such therapeutic interventions as enzyme replacement therapy and small molecules.

Robert E. Braun, M.D., is Chair of Research and Associate Director, the Jackson Laboratory, Bar Harbor, Maine. His main area of expertise is in the developmental genetics of male reproduction. Dr. Braun has an interest in both male infertility and the development of male contraceptives.

Ann James, Ph.D., J.D., is Senior University Counsel at Stanford University, Stanford, California. Dr. James completed her Ph.D. degree in Medical Microbiology and Immunology and a J.D. degree from the University of Houston Law Center. Her career focus, both prior to and after her legal education, has been on health care.

Rebecca Craik, Ph.D., FAPA, is Chair and Professor, Physical Therapy Department, Arcadia University, Glenside, Pennsylvania. Dr. Craik earned her Ph.D. degree in Neuroscience and has dedicated her professional career to the advancement of medical rehabilitation with a concentrated focus on the development of a research agenda for physical therapy.

David S. Louder, III, M.D., has been appointed the new Department of Defense (DoD) *ex officio* representative. Dr. Louder currently serves as the Director, Medical Operations, Air Force Medical Operations Agency, DoD and Clinical Assistant Professor at the University of Maryland School of Medicine, Baltimore. Dr. Louder completed Residency training in Pediatrics at Keesler USAF Medical Center, Keesler AFB, Mississippi, and Fellowship training in Neonatal-Perinatal Medicine at Wilford Hall Medical Center, Lackland AFB, Texas.

Current member Ralph Kauffman, M.D., has been reappointed to serve a final fourth year on the Council. Dr. Kauffman retired in 2006 as the Chair of the Medical Research Department at Children's Mercy Hospital. Dr. Kauffman's scientific expertise has focused on Pediatric Therapeutics.

### **III. NICHD DIRECTOR'S REPORT AND DISCUSSION**

The Report of the Director, NICHD, (electronically posted on the Council Members Website prior to the meeting) is appended (Attachment II). Dr. Alexander provided a brief overview of personnel changes at NICHD and NIH. He shared with Council a legislative update since the last meeting.

### **IV. REPRODUCTIVE SCIENCES BRANCH TWO YEAR UPDATE**

Dr. Louis DePaolo, Chief, Reproductive Sciences Branch (RSB), Center for Population Research, reviewed the Branch's progress since the last report and presented the Branch's plans for the future. He also reported on progress of the Reproductive Medicine Network. His presentation covered the following topics.

#### Research Programs and Staff

The mission of the RSB is to encourage, enable, and support scientific research aimed at alleviating human infertility, uncovering new contraceptive leads and expanding fundamental knowledge of processes that underlie human reproduction. To this end, the RSB provides funds for basic, clinical, and translational studies that will enable the development of more effective strategies for the diagnosis, management, and prevention of conditions that compromise reproductive health, with the goal of promoting a better quality of life for all individuals. This mission is supported by program areas in Reproductive Neuroendocrinology, Reproductive Endocrinology and Immunology, Reproductive Genetics and Epigenetics, Ovarian Biology, Pre-implantation Genetics and Development, Reproductive Medicine Gynecology, Reproductive Medicine Infertility, and Male Reproductive Health. Dr. DePaolo recognized the efforts of the Program Officers within the Branch.

#### Scientific Achievements

The Branch supports outstanding leaders within these portfolios. Two exemplary scientists who were honored by the President include Dr. Bert O'Malley, who received the nation's top scientific honor, the 2008 National Medal of Science, "For 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, including cancer." In addition, Dr. Kevin Eggan received the Presidential Early Career Award for Science and Engineering "For developing new approaches for reprogramming of patient cells into pluripotent stem cells and for developing and teaching new undergraduate curriculum in stem cell science." Dr. Eggan's work was recognized by Time Magazine as the top medical breakthrough of the year. Notably, Science identified reprogramming cells as the breakthrough of the year in 2008, which includes work supported by the Branch. Another RSB supported investigator, Dr. Rudy Jaenisch was also recognized for his work in reprogramming fibroblasts into induced pluripotent stem cells by being awarded the 2008 Meira and Shaul G. Massry Prize which is given annually to those making outstanding contributions to the biomedical sciences and the advancement of health.

#### Review of Panel/Council Recommendations

The panel recommended that the Branch relate its mission to overall public health, wellness, and quality of life across the lifespan to better publicize its mission to congress, scientists, and the public.

The mission of the Branch was revised (see above), and includes quality assessments in ongoing studies.

In response to the panel's recommendation to increase collaborations with other NICHD branches; NIH Institutes and Centers (IC), and Offices; Federal agencies; and the private sector, the Branch has developed programs that broaden its outreach in partnership with numerous groups. Through the Fertility Preservation Initiative, the Branch is working with seven ICs, the Centers for Disease Control and Prevention (CDC), Agency for Healthcare Research and Quality (AHRQ), National Institute for Occupational Safety and Health (NIOSH), and the National Aeronautics and Space Administration (NASA) and issued a PAR focused on technologies (R21), has issued with the National Center for Research Resources (NCRR) a RFA on Tools for Germplasm Cryopreservation, and plans a RFA on Fertility Preservation in FY 2010 (R01).

A joint conference, Preconception Care Workshop, was held in April, 2008 in collaboration with the Pregnancy and Perinatology Branch (PPB), NICHD; Office of Research on Women's Health (ORWH) NIH; Office of Rare Diseases (ORD), NIH; Centers for Disease Control (CDC); American College of Obstetricians and Gynecologists (ACOG); and the Society for Maternal-Fetal Medicine (SMFM).

A program on Assisted Reproductive Technology (ART) Outcomes was developed in collaboration with PPB, Demographic and Behavioral Sciences Branch (DBSB), Developmental Biology, Genetics and Teratology Branch (DBGTB), Child Development and Behavior Branch (CDB), and the Division of Epidemiology, Statistics and Prevention Research (DESPR) by issuing or planning the following: PAR on Female Health and Egg Quality (R01), PA on adverse outcomes (R01, P01), planned RFA (SBIR/STTR) on Noninvasive Assays of Human Oocytes and Preimplantation Embryos in FY 2010. The Branch plans a RFA on Developmental Epigenetics in FY 2010 (R21), is involved in the NIH Roadmap Initiatives on Epigenetics/Epigenomics, Fragile X Trans-NIH Blueprint (Premature Ovarian Insufficiency), and New Interventions for Menopausal Symptoms with the NIA Clinical Trial Network.

The Branch is collaborating with NICHD Intramural Program in the areas of Fragile X and Premature Ovarian Insufficiency, Uterine leiomyomas and adolescent health, and has sponsored several workshops and meetings in these program areas.

### Future Directions

Dr. DePaolo described the areas the Branch plans to develop over the next few years including development of technologic resources; encouraging the development of new investigators and retention of physician-scientists in their research careers; development of programs to promote research on etiology and early diagnosis of female reproductive and gynecologic diseases; support of research that examines gene-environment interactions, epigenetic modifications and potential intergenerational effects; promotion of the concept of male reproductive health to include clinical issues beyond infertility and contraception; encouraging research on all aspects of stem cell biology; pursuing

investigations at the intersection of the immune and endocrine systems; and encouraging research using systems and integrative biology approaches which is essential to enable understanding of diseases with multifactorial etiologies such as PCOS and endometriosis.

Dr. DePaolo then presented a progress report on the Reproductive Medicine Network (RMN) that had been requested by Council.

The RMN is a multicenter clinical trials network started in 1990, whose goals are to conduct large multi-center clinical trials to improve the management of infertility, and to investigate the etiology of reproductive diseases and disorders. The third re-competition was held in 2007 which identified seven clinical sites including University of Pennsylvania, University of Colorado Denver Health Science Center, Penn State (Hershey) Medical Center, Wayne State University, University of Michigan at Ann Arbor, University of Texas Health Science Center at San Antonio and the University of Vermont College of Medicine. The Data Coordinating Center is located at Yale University. All the sites work collaboratively with the Chairperson of the Steering Committee and the NICHD Team.

The RMN has developed five protocols that have been approved by the Advisory Board and Data and Safety Monitoring Board; two female infertility, two male infertility, one IVF protocol. Planned studies include Pregnancy in Polycystic Ovary Syndrome II\* (in progress), Comparison of Standard Oxygen Tension Regimens (5 percent, 20 percent) on Clinical IVF Outcomes\*, Microsurgical Varicocelectomy vs. Intrauterine Insemination and Timed Intercourse for Treatment of Male Partners with Palpable Varicocele and Abnormal Semen Analysis\*, Can the Rate of Multiple Gestations after Ovulation Stimulation with Gonadotropins Be Reduced?\*, and Clomiphene Citrate Treatment of Infertile Men with Non-Obstructive Azoospermia. Four of these studies (\*) are comparative effectiveness research.

RMN resources and enhancements include the development of a Central Repository for Biologic Specimens and Data, a resource for future investigations, the establishment of a Registry of Pregnancies Conceived in RMN Trials, standardization of case report forms and the assessment of quality of life measures in each of the protocols. Plans for collaboration and integration of the efforts of the SCCPIR and RMN sites are being undertaken as a way to bridge the translational blocks between basic research, human studies and clinical trials.

Council members praised the accomplishments and efforts of the RSB. Dr. Mark Phillippe inquired regarding the publications of the RMN. In the last funding period there were approximately 12 publications.

## **V. REPORT OF THE SUBCOMMITTEE ON PLANNING AND POLICY**

Dr. Enriqueta Bond, Chair of the Subcommittee on Planning and Policy, reported on the January 8, 2009, teleconference meeting. Meeting topics included Dr. Bond's review of the NIH

Council of Councils meeting of November, 2008, which addressed, among other topics, three "Roadmap" concepts that were then in development. The concepts were (1) Clinical IMPACT Awards Program; (2) Mechanism-associated Phenotypes for Genetic Analysis; and (3) Library of Integrated Network-based Cellular Signatures. The Council generally supported the concepts except that several

members expressed reservations about the third concept. Dr. Yvonne Maddox, Deputy Director, NICHD, reported on the NICHD's piloting of computer-assisted attendance at Council meetings and the NIH Academic Community Partners in Research Program. Ms. Mona Rowe, Associate Director, Office of Science Policy, Analysis and Communication, reported on the new NIH Research, Condition and Disease Categorization (RCDC) system, a Congressionally-mandated initiative to institute uniform reporting across the NIH of annual funding obligations for 215 disease categories. Dr. Eugene Hayunga, Director, Office of Extramural Policy, presented the NICHD's portion of the biennial report to Congress on compliance with the statutory requirement to include women and minority subjects in NIH-supported research. Dr. Bond said that the report indicated that the NICHD is doing a very good job of ensuring inclusion of these populations in its supported research. She said that the Subcommittee recommended that the Council certify the NICHD's report and the Council concurred with this recommendation.

## **VI. LOAN REPAYMENT PROGRAM UPDATE**

Dr. Eugene Hayunga presented an overview of the NIH Loan Repayment Program (LRP) in which successful applicants, in return for a two year commitment to a research career, receive up to \$35,000 per year toward qualifying educational debt plus an additional 39 percent toward federal tax obligations and additional amounts to cover state tax obligations. Dr. Hayunga described the three programs in which the NICHD participates and their eligibility requirements: the Clinical Research Program; Pediatrics Research Program; and the Contraception and Infertility Research Program. Dr. Hayunga also described the timeline, review criteria, and the award process for these programs.

Dr. Steven Kaufman, Medical Officer, Contraception and Reproductive Health Branch, presented data on the success of the NICHD Loan Repayment Program over the past three years with particular emphasis on the 2008 program. Type 1 success rates for 2008 for all three NICHD participating programs combined were 19 percent for Ph.Ds, 44 percent for Pediatricians, 47 percent for Ob/Gyns, and 29 percent for other M.D.s. The success rates for Type 2 applications for 2008 were 53 percent for Ph.Ds, 52 percent for Pediatricians, 75 percent for Ob/Gyns, and 69 percent for other M.D.s. NIH-wide success rates were 40 percent for new applicants (Type 1s) and 70 percent for renewals (Type 2s), with no differences among male and female applicants. Additional NIH data indicate that successful applicants were more likely to apply for subsequent RPG or Career Development (K) awards than unsuccessful applicants.

The presentation concluded with questions from Council members who were primarily interested in knowing whether follow-up data have been collected to indicate how successful this program has been

in keeping successful applicants in research careers. Council members seemed highly supportive of the LRP and requested more in-depth information in the future, especially with regard to the Contraception and Infertility Research (CIR) program.

## VII. CHILD DEVELOPMENT AND BEHAVIOR BRANCH PRESENTATION

Dr. Peggy McCardle, Chief, Child Development and Behavior Branch (CDB), provided an overview of the Branch mission, program areas for supported research, and major findings of researchers. The Branch's mission is to study the behavioral, neurological, and genetic aspects of child development. CDB-supported researchers are investigating the early cognitive abilities of infants, the biological correlates of early behavioral development, and the impact of the social and emotional context and how that interacts with genetics to predict later outcomes. For example, researchers have demonstrated through studies of infant eye-gaze and attention that as young as 10 to 11 months, infants can infer the intentions of adults, and this can be used as an indicator of social emotional development and can predict later language development. In addition, both early temperament and correlated physiological markers such as cortisol or brain wave asymmetry are strongly associated with later development. Caregiver support has been shown to modify genetic risk of shyness by middle school age in children with a specific genetic condition.

Studies of executive function (that is, cognitive planning, organizational abilities, attention, and memory) is a current hot topic across many areas of developmental science. Primate and human studies of "uncertainty" have given rise to a new theoretical model of attention development which accounts for the interaction of environment, experience, and success in these executive function processes. In addition, animal models are helping us track development and have revealed a trajectory of typical development that progresses from a reactivity and distractibility to more purposeful, effective attention and learning. Studies of the neurobiology of reading have informed us about both reading disabilities and typical reading development. Beginning readers activate specific left hemisphere (anterior and temporal) brain regions as shown on fMRI scans while reading. As their skills improve there is more involvement of the left occipitotemporal region. Individuals with reading disabilities do not tend to show this developmental trend; but recent findings suggest that children with reading disabilities can show similar shifts to more left OT involvement following successful reading intervention.

In the area of biliilingualism, CDB-funded research has demonstrated that a specific reading intervention with struggling English Learner (EL) readers, presented in either Spanish or English, was more effective than that same intervention had been for monolingual English struggling readers, presumably due to the

additional supports provided in the EL adaptation (added gestures, more time and encouragement for verbal responses); researchers are exploring using those same adaptations for monolingual struggling readers. As with reading, the branch is supporting work to understand how children learn math and what goes wrong when they do not. Researchers demonstrated that early number sense and growth trajectory in math achievement are good predictors for identifying kindergarteners at risk for math difficulties later in primary school.

Among the many findings of The Study of Early Child Care and Youth Development are these: higher quality pre-K care is associated with higher vocabulary scores in fifth grade; those sixth graders who spent more time in center-based care were a bit more likely to be disobedient, to argue or to get into

fighters, but parenting quality is a better indicator of child outcomes than type, amount or quality of child care. Children's social and emotional development is an integral part of their becoming healthy, happy adults and to their learning. Researchers have identified both behavioral and physiological measures to help identify factors impacting development; we know that parents' marital conflict affects children's adjustments, and that children's experiences and perceptions of those experiences in the home have an impact on their own adult experiences and parenting.

In CDB's expert panel review and strategic planning activity, advisors made many recommendations in the broad area of cognition, learning and learning disabilities, in math and science, the role of comorbid problems, of executive function and translation of basic findings to practice. The Branch will include an examination of new areas such as the role of pets in child development, through our recently established public-private partnership with the Mars Corporation. The Panel suggested other areas of study: the impact of bereavement, natural disasters and other traumatic events (including war and violence), as well as stress and adjustment problems. The Panel urged continued and expanded work on behavioral phenotyping and on animal models and various types of epigenetic studies and on brain development, using current and future neuroimaging tools and integrating the various imaging modalities with each other and with cognitive behavioral measures. The Panel also encouraged the Branch to include the study of the various contexts and settings within which today's children develop to support multi-level, longitudinal studies of growth over time and even across generations, and to consider international perspectives, especially on such issues as the role of culture and the impact of disasters such as war and famine. In all areas, work on measurement and methods are needed, and the panel encouraged continuation and expansion of our interagency collaborations.

Two researchers funded by the Child Development and Behavior Branch presented their work.

Dr. Jack Fletcher, Professor, University of Houston, presented information on the history of learning disabilities identification, including work funded by the NICHD which contributed to significant education legislation that has paved the way for more children to receive preventive services that can

prevent educational failure. He outlined research which he and his team in Houston and collaborators at other NICHD-supported Learning Disabilities Research Centers are currently conducting, which includes work on the neural differences between good and poor readers, and how that changes with successful intervention. He made the important points that reading, math, and writing are heritable traits, that in reading, heredity accounts for 50 to 80 percent of variance in outcomes, that there are no genes specific to poor development (e.g., no dyslexia genes) although there are several reliable loci. A strong understanding of neural systems is crucial, and research has shown a network of occipital temporal, temporal parietal, and frontal regions that is malleable. The field is moving away from "bad-gene, bad brain" theory to the idea that genes cause brains to be at risk and risk is modified by environment. Dr. Fletcher described randomized trials currently being conducted by the Texas Center for Learning Disabilities, which succeeded through remedial intervention in reducing the proportion of "non-responders" from 20 percent of the school population to 5 to 10 percent.

Dr. Lynne Vernon-Feagans, Professor, University of North Carolina in Chapel Hill, presented information about the Family Life Project, a study of 1,290 children living in rural poverty in

Appalachia (Pennsylvania) and the rural south (North Carolina). The study looks at the multiple interacting processes in early childhood that may be the causal mechanisms linked to later academic and social adjustment in children living in low-wealth rural communities. The findings are categorized according to four areas: cumulative risk, parenting and cognitive development at 15 months; chaos and early childhood development with a focus on predictors of 36 month language development; cortisol reactivity and early behavior focusing on maternal and child contribution to cortisol response and emotional arousal; and prenatal exposure to smoking and temperament with a focus on neurobehavioral consequences of prenatal exposure to smoking at 6 and 8 months. This research team has found based on data collected in the first 5-year funding period that “chaos” (a composite measure of instability of the number of people and caregivers present in the home), and household disorganization represented by number of TV hours, neighborhood noise, etc., poverty and parenting in infancy and early childhood predict a child’s later language development. They measured cortisol reactivity to stress at age 15 months, and find this to be related to family income/needs ratio and maternal engagement with the infant. In the second 5-year funding period, they will continue this multidisciplinary study, following this cohort of children as they make the transition to kindergarten and elementary school, continuing to examine behavioral, physiological and contextual factors and their influence on the children’s academic performance, health and development.

In a question and answer section following the presentations, Dr. Ralph Kauffman asked Dr. Fletcher whether his work was affecting current education policy and strategies. Dr. Fletcher discussed the profound effect of his and his colleagues’ research findings on policymakers, noting discussions that were held in Congress as well as presentations that he made to subcommittees on education.

Dr. Fletcher noted the impact of this work on No Child Left Behind and Reading First legislation. He stated that in the past there was a tendency to reject science in favor of other epistemologies based on beliefs and anecdotal evidence. Dr. McCardle added that No Child Left Behind made use of evidence-based practice, especially in reading, based on the National Reading Panel report which had been supported by the NICHD and which drew upon much of the reading research supported by the Institute. She also cited examples of public/private partnerships with the Branch and MARS Inc., as well as IRA (International Reading Association) which include efforts to disseminate research information developed by scholars such as Dr. Fletcher.

Dr. Bond expressed her concern about children labeled as having Attention Deficit Hyperactivity Disorder (ADHD) and learning disability who are given medication as opposed to good instructional programs and asked Dr. Fletcher his thoughts about the use of drugs versus the right education. Dr. Fletcher responded that in his work he often talks to practitioners about the use of drugs or stimulants over the value of monthly visits and contacts with children while they are at school. Dr. Fletcher stated his uncertainty about the impact of stimulants on academic performance but doubted the effectiveness of drug therapy alone in treating some forms of ADHD and learning disorders.

Council members commented on the activities of the Branch. Dr. Perri Klass commended the breadth, depth, and intellectual significance of the work funded by the Branch, citing particularly the health, socio-emotional and cognitive dimensions of the portfolios. She remarked that the work of the Branch

has impacted public discourse as well as clinical practice. Dr. Klass also highlighted the importance of Dr. Fletcher's work in bringing research information to bear on early childhood development and health and the role of the Branch generally in taking the lead in early childhood education, bringing the science to bear on issues such as executive function and learning disabilities. She commented on the Branch's commitment to all aspects of learning, including typical learning as well as problems related to learning. She stated that the neuro-imaging tools presented by Dr. Lisa Freund, CDBB, are convincing and dramatic in demonstrating the underlying dynamics at play. She applauded the Branch's work on adolescence and the use of biomedical standards of rigor and lessons from biomedical approaches.

Dr. Robert Morris remarked on his amazement at the growing influence of the Branch since his involvement in the early 80s. He noted some of the contributions the Branch has made, including heightening awareness that early growth and development is important in and of itself. He noted that Branch-supported work on atypical development has led to important findings on identification of risk factors and treatment/interventionism as well as to increasing understanding of the multilevel and interactive nature of cognition/learning and socio-emotional aspects of development. Dr. Morris commended the sophistication of the Branch in pulling diverse researchers together with different areas of expertise (neuro-imaging, bilingualism, cultural measurement), and forcing them to talk to one

another, focusing on the important interactions and interfaces of all these areas. He also stated that one of the biggest assets of the Branch is the scholarly credentials of the program staff, given their own lists of publications which serve to provide information about funded research findings to the field and to the public.

Dr. Rosemarie Truglio remarked on the Branch's impressive portfolio and the range of domains/disciplines covered. She highlighted the Branch's in-depth attention to conflict and the level of dissemination of its publications. She stressed the need to focus more on deciphering findings in ways that have more influence on policymakers and especially parents, whom she states are the real first agents for change. She expressed excitement about the work on reading and in math/science education generally, pointing out that the U.S. is a nation at risk because of its lower ranking in math/science. She stated that the relevant questions to ask are: 1) What does it mean to be prepared for the 21st century?

2) What are critical thinking skills? and 3) What are interventions necessary to advance critical thinking. Dr. Truglio also reflected on the need to focus on the positive and negative effects of media exposure, in particular, the range of types of media available and accessible to children today. She urged the Branch to make even more effort in disseminating the positive results of their work, such as the NICHD Study of Early Child Care and Youth Development (SECCYD), for which the popular media often highlights only the negative findings; she urged creation of a booklet of research-based information for parents highlighting the findings of the SECCYD and other child care research.

Dr. McCardle noted the need for the Branch to update its parent booklet and pointed out that Branch staff Drs. Valerie Maholmes and Lynne Haverkos are paying attention to research on media and will certainly take the suggestions made into consideration.

Other Council members provided observations. Dr. Sherin Devaskar praised the Branch report noting the work on translation in education. She raised a question about the influence of genetics as well as smoking on prenatal development. Dr. McCardle expressed the Branch's intention to work with the Pregnancy and Perinatology as well as the Intellectual and Developmental Disabilities Branches on these issues and others, such as following the development of premature children and those born as a result of assisted reproduction.

Dr. Margaret Stineman raised the question of traumatic brain injury and Dr. McCardle responded that the Branch would be looking into that area to see where the interfaces reside, including collaborations with the National Center for Medical Rehabilitation Research, NICHD.

### **VIII. MERIT AWARD MECHANISM OVERVIEW**

Dr. Louis DePaolo provided an overview of the NIH Merit Award. MERIT, he explained, stands for "Method to Extend Research in Time." The Award program was initiated by the National Institutes of Health in FY 1986. Since that time, the MERIT Award has become a symbol of scientific achievement in the research community.

Dr. DePaolo said that only Principal Investigators on an existing NIH grant are eligible for the award, and that they cannot apply for the award, but must be nominated for it, by either program staff or by a Council member. Only principal investigators on an individual research award are eligible. Investigators on large program projects are not eligible. Dr. De Paolo added that the award is given to "investigators who have demonstrated superior competence and outstanding productivity during their previous research endeavors." The MERIT Award is intended to provide up to ten years of research support to relieve awardees of the need to prepare frequent renewal applications.

Dr. DePaolo announced that an NICHD committee had been formed to explore the use of the award in the future, in light of the need to balance the funding needs of both established and new investigators. He then responded to questions about how the award is administered.

### **IX. CONCEPT CLEARANCE REVIEW AND DISCUSSION**

The following three concepts were discussed and unanimously endorsed by the Council.

- Noninvasive Assays of Human Oocytes and Preimplantation Embryos

The purpose of the proposed RFA is to stimulate research by small businesses and collaborations between small businesses and universities or other institutions on this urgent topic that would be of high importance to the assisted reproduction technology field. Small businesses are well-suited for the types of approaches expected for this technology-intensive and highly focused initiative that has specific targeted goals. The major objective is to design and test novel methodologies that will permit evaluation of the quality and developmental potential of human oocytes and pre-implantation embryos

without doing them any harm. This approach should lead to the increased use of single embryo transfer in the assisted reproduction clinics and thereby reduce complications that occur to the mother and the offspring as a result of multiple pregnancies.

- Safe and Effective Instruments and Devices for Use in the Neonatal ICU

Although neonatal intensive care is heavily dependent on modern technology, there is a paucity of efforts in research and development (R&D) directed at improving existing technologies, or in developing innovative devices and instruments for use in the neonatal ICU. The purpose of the proposed RFA is to foster collaborative research between bioengineering and biomedical scientific

communities that can lead to improvements in existing technologies, as well as introduction of innovative instruments and devices that are safe and effective. Devices and instruments developed for use in the sick newborn infants should be based on sound bioengineering principles and tested appropriately in clinical settings for their safety profiles and accuracy of functioning. The objective is to foster continued collaboration between biomedical and bioengineering communities in the field of pediatric device development, leading to a set of safe and effective instruments and devices that can be used while caring for sick newborn infants.

- Pediatric HIV-AIDS Cohort Study (PHACS)

The proposed RFA is a competing renewal, using the U01 mechanism, to provide support for continuing the observational cohorts developed during the first competitive funding cycle. These cohorts address two critical issues in HIV research: the long-term safety of in utero exposure to multiple antiretroviral drugs in HIV-exposed but uninfected children, and the interactive effects of HIV and its treatments on perinatally infected children and adolescents. PHACS includes 2 distinct cohorts: 1) HIV-exposed but uninfected infants and children and 2) HIV-infected children and adolescents. The goals of the PHACS network: 1) acquire more definitive information regarding long-term safety of antiretroviral drugs used during pregnancy and in infancy on HIV-exposed but uninfected children, and to estimate the upper bounds of risk to children associated with in utero exposure to antiretroviral drugs and 2) understand the effect of HIV and its treatment on various domains including cardiovascular risk, bone health, sexual maturation, pubertal development, and mental health, in perinatally HIV-infected children and adolescents.

## **X. REVIEW OF APPLICATIONS**

A total of 1198 applications were initially assigned to the Institute. Applications that were transferred out, withdrawn, noncompetitive, unscored, or were not recommended for further consideration by the initial review groups were not considered by the Council. Council reviewed 503 applications requesting \$157,184,746 in total costs. Council favorably recommended 503 new, renewal, supplemental research and training grant applications with requested total costs of \$157,184,746.

**XI. ADJOURNMENT**

There being no further business, the meeting was adjourned at 3:45 p.m. on Thursday, January 22, 2009. The next meeting is scheduled for June 11, 2009.

Attachments: Council Roster (Attachment I)  
Report of the Director (Attachment II)

I hereby certify that, to the best of my knowledge, the foregoing minutes and attachments are accurate and complete.<sup>2</sup>

\_\_\_\_\_  
Duane Alexander, M.D.  
Chair, National Advisory Child Health  
and Human Development Council  
Director, *Eunice Kennedy Shriver* National Institute  
of Child Health and Human Development

\_\_\_\_\_  
Date

Mary Plummer  
Committee Management Officer, NICHD

<sup>2</sup>These minutes will be formally considered by the Council at its next meeting, and any corrections or notations will be incorporated in the minutes of that meeting.