# Department of Health and Human Services National Institutes of Health National Institute of Nursing Research Minutes of the National Advisory Council for Nursing Research

September 16-17, 2008

The 66th meeting of the National Advisory Council for Nursing Research (NACNR) was convened on Tuesday, September 16, 2008, at 1:00 p.m. at the Bethesda Marriott (Pooks Hill), Bethesda, Maryland. The first day of the meeting was an open session and adjourned that same day at approximately 5:38 p.m. The closed session of the meeting, which included consideration of grant applications, was convened on Wednesday, September 17, 2008, at 9:05 a.m. and continued until adjournment at 11:32 a.m. Dr. Patricia A. Grady, Chair, NACNR, presided over both sessions of the meeting.

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**OPEN SESSION** 

# I. CALL TO ORDER, OPENINIG REMARKS, COUNCIL PROCEDURES, AND RELATED MATTERS

Dr. Grady called the 66th meeting of the NACNR to order, welcoming all Council members, visitors, and staff. She extended a special welcome to new Council member Dr. Marion Broome, Dean, Indiana University School of Medicine.

# Conflict of Interest and Confidentiality Statement

Dr. Mary Kerr, Executive Secretary, NACNR, reminded attendees that the standard rules of conflict of interest applied throughout the Council meeting. Briefly, all closed session material is privileged, and all communications from investigators to Council members regarding any actions on applications being considered during the Council should be referred to National Institute of Nursing Research (NINR) staff. In addition, during either the open or the closed session of the meeting, Council members with a conflict of interest with respect to any topics or any application must excuse themselves from the room and sign a statement attesting to their absence during the discussion of that application. Dr. Kerr also reminded NACNR members of their status as special Federal employees while serving on the Council, and that the law prohibits the use of any funds to pay the salary or expenses of any Federal employee to lobby or otherwise influence state legislatures or Congress. Specific policies and procedures were reviewed in more detail at the beginning of the closed session and were available in Council notebooks.

# Minutes of Previous NACNR Meeting

Standing Council members received a copy of the minutes of the May 20-21, 2008, NACNR meeting by electronic mail. No changes or corrections to the minutes of the May 2008 Council meeting were suggested during the September meeting. A motion to accept the minutes of the May 20-21, 2008, Council meeting as circulated was proposed, seconded, and approved unanimously. Any comments, corrections, and changes to the May 2008 meeting minutes identified at a later time should be forwarded to Drs. Grady or Kerr. The approved minutes of

each quarterly NACNR meeting become part of the Institute's permanent record and are posted on the NINR Web Site (www.ninr.nih.gov).

# **Dates of Future Council Meetings**

Dates of future meetings in 2008, 2009, and 2010 have been approved and confirmed. Council members should confirm their calendars for these meeting dates and contact Drs. Grady or Kerr regarding any conflicts or expected absences.

### 2008

January 22-23 (Tuesday-Wednesday)

May 20-21 (Tuesday-Wednesday)

September 16-17 (Tuesday-Wednesday)

### 2009

January 27-28 (Tuesday-Wednesday)

May 19-20 (Tuesday-Wednesday)

September 22-23 (Tuesday-Wednesday)

### <u>2010</u>

January 19-20 (Tuesday-Wednesday)

May 18-19 (Tuesday-Wednesday)

September 14-15 (Tuesday-Wednesday)

II. REPORT OF THE DIRECTOR, NINR—Dr. Patricia Grady, Director, NINR; Ms. Elisa Gladstone, Communications Director, NINR

The Director's report focused on updates since the last Council meeting and on current and impending activities and initiatives related to the National Institutes of Health (NIH) and NINR budgets, the NIH overall, and the NINR.

**Budget Update**—Dr. Grady provided a brief history and current status of appropriations and projections for the NINR budget.

The NINR has been experiencing small budgetary increases in 2007 (0.1%), 2008 (0.6%), and 2009 (0.1% projected). Despite a functional reduction of the budget when adjusted for inflation in terms of the biomedical research price index, the increases provide encouragement to the NINR in an environment of tight budgets. The President's Budget request for fiscal year (FY) 2009 includes \$137.609 million for the NINR, which represents a small decrease (0.4%) from the FY 2008 level. The House and Senate budgets each allocate an increase for the NINR: \$142.336 million (3%) and \$144.439 million (2.3%), respectively, which is perceived as a positive indicator from Congress. NINR budget projections for FY 2009 allocations remain close to current: research program grants (RPGs) (72%), training (7%), research management and support (7%), Centers (6%), intramural research (3%), research and development (3%), and other research (2%). The NINR allocates greater percentages of its budget to RPGs and training

than most other NIH Institutes and Centers (ICs), and its intramural program is largely devoted to training young investigators.

NIH News—Dr. Grady reported that enhancements to the NIH peer review process are underway with the intent to engage the best reviewers, improve the quality and transparency of reviews, ensure balanced and fair reviews across scientific fields and career stages, and develop a permanent process for the continuous evaluation of peer review. The NIH Roadmap for Medical Research has released a Transformative R01 Program to elicit from the scientific community creative and transformative ideas that address "grand challenges" and transform a specific field. In addition, the NIH has expanded the Clinical and Translational Science Awards (CTSA) Consortium to include 14 additional institutions; the CTSA Consortium is a unique network of medical research institutions working to reduce the time between laboratory discovery and patient treatment. Initial awards have been made by the NIH Public Trust's Partners in Research Program, which promotes more rapid translation of findings into practice and better informs scientists concerning the needs of the community; 37 awards were made from more than 200 applications.

An NIH summit entitled "The Science of Eliminating Health Disparities," sponsored by the National Center on Minority Health and Health Disparities (NCMHD), will be held December 16–18, 2008, in National Harbor, MD. The NIH John E. Fogarty International Center for Advanced Study in the Health Sciences has announced the Millennium Promise Awards: Non-Communicable Chronic Disease Research Training Program to help researchers fight chronic

diseases in developing nations. The NIH Pain Consortium held its Third Annual Symposium on Advances in Pain Research on May 22, 2008, and a Mechanisms and Management of Pain in the Elderly Workshop on June 30-July 31, 2008.

Dr. Grady also noted that in June, Dr. Anthony S. Fauci, Director, National Institute of Allergy and Infectious Diseases received the Presidential Medal of Freedom and addressed the United Nations General Assembly. Additionally, Dr. Francis S. Collins has retired as Director of the National Human Genome Research Institute, and Dr. Alan Guttmacher is serving as the Acting Director of that Institute. The Genetic Information Nondiscrimination Act of 2008, which prohibits health insurers and employers from discriminating based on genetic information, was enacted on May 21, 2008.

NINR Update—Dr. Grady welcomed new members of the NACNR: Dr. Maggie L. Richard, Captain, U.S. Naval Nurse Corps and Director, Human Research Protection Program, Department of the Navy, Bureau of Medicine and Surgery; and Dr. Marion E. Broome, Dean, Indiana University School of Medicine.

Dr. Grady received the Doctor of Science, *Honoris Causa*, from the State University of New York Downstate Medical Center on May 28, 2008. In addition, several of NINR staff recently received NIH Director's Awards for their work. The Friends of the NINR 2008 NightinGala, which will be held on October 1, 2008, in Washington, DC, is focusing on "Discovery and Recovery: Celebrating Mental Health and Nursing Research" and will feature former First Lady Rosalyn Carter as the keynote speaker. The 2008 National State of the Science Congress on

Nursing Research will occur October 2-4, 2008, at the Omni Shoreham Hotel in Washington, DC.

New staff within NINR's Division of Extramural Activities include: Dr. Yvonne Bryan, Chief, Office of Extramural Activities; Dr. Josephine Boyington, Program Director, End of Life and Long-Term Care; and Dr. Kathleen Jett, Program Director, HIV/AIDS and Oncology. A workshop on Integrating Cost-Effective Analysis into Clinical Research was held July 17-18, 2008. A Centers meeting on leveraging and sustainability topics occurred August 14-15, 2008. Two NINR Research Centers Requests for Proposals were published and expire on December 16, 2008: (1) Centers of Excellence in Symptom Management Research or Centers of Excellence in Health Promotion/Disease Prevention (P30); and (2) Centers in Symptom Management Research or Centers in Health Promotion/Disease Prevention: Building Research Teams for the Future (P20). The NINR Web Site now includes a section on frequently asked questions about the NINR Research Centers Program.

NINR's Division of Intramural Research sponsored the Summer Genetics Institute from June 8 to August 1, 2008. Two students from the NINR Graduate Partnerships Scholars recently published articles in the *Neurosurgery Quarterly* (T. Barr) and *Biological Research for Nursing* (E. Kurnat-Thoma).

Issues, Accomplishments, and Milestones—Dr. Grady reported that the NINR funded Center for Nursing Outcomes Research will co-direct a European Union nursing study called RN4CAST. Additionally, Dr. Victoria Champion, Indiana University School of Nursing, was

appointed as a member of the National Cancer Institute's National Cancer Advisory Board.

Dr. Grady expressed sadness at the passing of Dr. Michael DeBakey.

NINR Outreach—Ms. Elisa Gladstone described recent research dissemination efforts, including an NINR annotated bibliography published in *JOGNN* (May/June), *Nursing Outlook* (September/October), a monthly feature study in *AJN*, and monthly summaries of "Nursing Research" in *Medscape Today*. The NINR and NINR-funded research were covered in various press and media, including *Medscape*, *Science Daily*, *Sun Sentinel*, *PR Newswire*, *Boston Herald*, *The Shreveport Times*, and *Pine Bluff Commercial*. Ms. Gladstone noted that the NINR continues to build a relationship with the press and encouraged Council members to share press stories with the NINR.

III. BMI, NUTRITION, INFLAMMATION, AND HEART FAILURE OUTCOMES—

Dr. Terry Lennie, Co-Director, RICH Heart Program, and Associate Dean, Ph.D.

Program, College of Nursing, University of Kentucky

Dr. Lennie to the Council reported on a study on nutrition, inflammation, and heart failure outcomes. Studies in 2002 found—contrary to beliefs held across the heart industry—that heart failure patients who were obese lived longer than those who had a lower body mass index (BMI). Dr. Lennie's study proposed to determine differences in morbidity and mortality outcomes, as well as quality of life, among normal weight, overweight, and obese patients with heart failure. Among these groups, it also examined the effects of nutritional deficiencies on morbidity and mortality outcomes, differences in proinflammatory cytokine activity, and relationships among

serum lipoproteins, endotoxin, and proinflammatory cytokine levels. The protocol involved a 4-day food diary, blood specimen analyses, and monthly follow-up for 1 year. This investigation is the first to study the interplay between nutrition, inflammation, and outcomes, and uses a biobehavioral approach to compare biological, behavioral, and psychological factors among the BMI groups. It is expected to produce the largest data set of nutritional intake and body composition of patients with heart failure. Preliminary results have indicated that nutrition makes a difference in the outcome of patients with heart failure. In addition, there is evidence that being overweight and obese is related to improved morbidity and mortality and some psychosocial outcomes in heart failure, and that the effects of obesity involve a complex interaction among biological, behavioral, and psychological factors. In closing, Dr. Lennie provided examples of the extensive synergy among investigators, and acknowledged the important role that NINR training opportunities, particularly predoctoral and postdoctoral fellowships, have played in his and other researchers' careers.

IV. TRANSFORMATIVE R01—Dr. Elizabeth Wilder, Director, Division of Strategic Coordination, Office of Portfolio Analysis and Strategic Initiatives

Dr. Wilder provided information about the NIH Roadmap for Medical Research's new Transformative R01 Program. The concept for a transformative program has been discussed within the NIH for some time, including during the initiation of the Roadmap. One of the Roadmap's original missions was to foster innovative approaches. The concept reemerged through a workshop in December 2007. One recommendation from the community concerning enhancements to the peer review process was that the NIH should have set-aside funds for

outside-the-box thinking to allow greater flexibility for investigators. The reauthorization of the NIH in 2006 established authority for the NIH to conduct high-risk, high-reward (HRHR) research projects; the HRHR Demonstration Group that was convened following the reauthorization confirmed this approach. The Transformative R01 Program will support projects with the potential to create or overturn fundamental paradigms through inventive, innovative, or unconventional approaches. Projects are expected to have a major impact in biomedical or biobehavioral sciences. The program is open to all scientific fields of interest to the NIH. Potential areas of need have been indentified, including human behavior change, 3-dimensional tissue models, functional variation in mitochondria in disease, acute to chronic pain transitions, novel protein capture reagents, and evidence base for pharmacogenetics.

# V. UPDATE ON EXTRAMURAL AND INTRAMURAL TRAINING OPPORTUNITIES—Dr. Karen Huss, Program Director, NINR Training Coordinator

Dr. Huss provided an update on NINR's extramural and intramural training opportunities.

National Research Service Awards (NRSAs) for research training are available as F31 and F32 grants for individuals and T32 grants for institutions. Training recommendations in 2006 suggested the creation of the T32 Program to expedite training and changed the trajectory of research careers by emphasizing F32 and K awards. From FY 2003 through 2007, the NINR budgetary allocation to training exceeded the NIH average. The NINR provides more predoctoral but fewer postdoctoral awards than the NIH overall; the ratio between predoctoral and postdoctoral awards for the NINR for FY 2007 was 2.9:1 versus 1.4:1 for the NIH as a whole. Dr. Huss presented specific an analysis of NINR's F31, F32, and T32 awards, describing

the number of predoctoral and postdoctoral awards during the past decade and their subsequent productivity. Analyses thus far reveal that a) individual pre and postdoctoral fellowships are more productive than institutional pre and post doctoral fellowships, b) those who do postdoctoral fellowships are more productive earlier than those who do only predoctoral fellowships. Future directions include the tracking of predoctoral and postdoctoral awardees' research progress through a database, focusing training in areas of scientific deficit, increasing individual awards, increasing the postdoctoral to predoctoral ratio, and proactively guiding trainees to apply for future research support early.

The NINR also supports several types of career development or "K" awards, including the K01, K22, K23, K24, and K99/100. The greatest number of these awards made by both the NINR and the NIH overall are for K01 and K23 grants. The strategic plan areas most emphasized in these grants include quality of life and biobehaviors. Dr. Huss shared data that compared the number of applications and awards made by each IC for K01, K23, and K24 grants in FY 2007. NINR's intramural program promotes career development primarily through K22 grants, the Graduate Partnership Program, and the Summer Genetics Institute.

Future directions for the NINR include increasing the number of K awards and emphasizing research in topics such as health promotion/disease prevention, end of life, health disparity, methodology, technology, and HIV.

VI. PRESENTATION OF CONCEPTS—Dr. Yvonne Bryan, Chief, Office of Extramural Activities, NINR

Council members reviewed and discussed eight new concepts during the September 2008 NACNR meeting

Genetic and Epigenetic Predictors of Symptom Burden (Dr. Kathy Mann Koepke,
 NINR; Dr. Sharon Tennstedt, discussant)

**Discussant Comments:** This is an important concept that NINR is well positioned to support. It recognizes the current empirical data on experiential response to treatment and moves that into the differential experience in response to symptoms. Questions were raised about the focus on prototypical symptoms, such as pain, fatigue, and depression. It is hoped that the focus on symptom burden shows recognition of clustering symptoms and the fact that symptoms do not usually occur in isolation. The issue of symptom phenotypes recalls past frameworks that recognize that symptoms can be experienced and expressed differently by different genders and cultural/ethnic groups.

• Chronic Comorbid Conditions in HIV-Positive Adults on Highly Effective Anti-Retroviral Therapy (HEART) (Dr. Kathleen Jett, NINR; Dr. Michael Counte, discussant)

Discussant Comments: The concept was viewed favorable in its potential to advance
HIV research. The concept includes a partially epidemiological approach, in which area
there are many unknowns; hence a potential collaborator could be the Centers for Disease
Control and Prevention. Another consideration should be the forecast of AIDS in the

elderly. The concept's strong support of a multidisciplinary focus and its encouragement of comparative research was viewed favorable.

<u>Intervening in Multiple Comorbid Illnesses in the Elderly</u> (Dr. Karen Huss, NINR;
 Dr. David Dinges, discussant)

**Discussant Comments:** The concept was deemed interesting but questions raised about its focus in terms of intervention. It appears to be an intervention to manage the disorder. It is hard to carry out this program without understanding the functional consequences of multiple illnesses and what matters to the elderly person; this is about managing polypharmacy and symptoms. Quality of life should be emphasized in the concept, and both socioeconomic and ethnic issues should be considered. In addition, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) might be a suitable collaborator.

<u>Early Identification of Heart Failure in Older Adults</u> (Dr. Karen Huss, NINR; Dr.
 Jean McSweeney, discussant)

Discussant Comments: Support was expressed for the concept, noting that it offers the opportunity to impact health care costs and improve quality of life with early intervention. Most current promising interventions are associated with large health care centers that attract mostly urban patients who have health insurance. The technology component is especially important to begin ensuring that health care professionals have access to technology so that all patients benefit, including those who live in rural areas or are confined to their homes.

Intervening to Prevent Secondary Disorders Among Persons with War-Related
 Traumatic Injuries and their Families (Dr. Karen Huss, NINR; Dr. Kevin Frick, discussant)

**Discussant Comments:** It was noted that this population has grown and has the potential to grow larger. Regarding the concept's relevance to the Strategic Plan, it was unclear whether specific methods were recommended. Additionally, "cost and benefits" are not included in the objectives, which raises the issue of how the word "efficient" is used. This also provides an opportunity to discover better measures of family quality of life; good metrics on this topic are not widespread in the current literature.

Biomarkers Metabolic Syndrome Underserved Populations (Dr. Paul Cotton, NINR;
 Dr. Kevin Frick, discussant)

Discussant Comments: Anything that can be done to reduce health disparities usually is worthwhile research. The timing of this concept was questioned given that metabolic biomarkers have not been defined in the larger population. Regarding the order of the objectives, the second objective listed ("Develop and test reliable biomarkers") should be answered first for the general population because these conditions are devastating for anyone. Determining what the biomarkers are and how to use those biomarkers for interventions and whether those interventions need to be modified or made suitable or culturally appropriate for underserved and vulnerable populations would be a useful set of steps. It is unclear, however, how much of the basic research has been carried out, or how different biomarkers would be for vulnerable and underserved populations.

Advancing Palliative Care Research for Children Facing Serious Illness or
 Experiencing Bereavement (Dr. Josephine Boyington, NINR; Dr. J. Randall Curtis, discussant)

**Discussant Comments:** Support was expressed for the concept. It responds to an important need pointed out by the IOM and the NINR. It is inclusive of families. This is an area where there has been some science but it has been limited, particularly in terms of the development of interventions. The last objective could be broadened to include families and their experiences as well as the children. Potential collaborators (e.g., NHLBI) could be broadened.

<u>Developing Biobehavioral Interventions to Improve Palliative Care in Life-</u>
 <u>Threatening Disorders</u> (Dr. Josephine Boyington, NINR; Dr. J. Randall Curtis, discussant)

**Discussant Comments:** This concept addresses an important need that is included in NINR's Strategic Plan. It focuses on primary care, comorbid diseases, and families, as well as interventions and "keys to translationals," which means getting advances into practice in the lives of patients and families. Potential collaborators could be expanded to other ICs.

VII. UPDATE ON COST EFFECTIVENESS WORKSHOP—Dr. Kevin Frick, Associate
Professor, Department of Health Policy Management, Johns Hopkins Bloomberg School
of Public Health

Dr. Frick reported on the NINR-sponsored Workshop on Integrating Cost-Effective Analysis into Clinical Research, which was held July 17-18, 2008, on the NIH campus in Bethesda, MD. The workshop was intended to increase understanding of cost-effectiveness analyses and identify tools to integrate such analyses into clinical research. The goals were to discuss current knowledge related to cost effectiveness and develop recommendations to promote a research agenda on incorporating cost-effectiveness analysis in clinical interventions. This agenda will be a critical step in shaping future policy initiatives to support the allocation of health care resources for the treatment of rare diseases.

Following this update, Dr. Grady thanked participants and attendees for their time and interest and adjourned the open session of the meeting at 5:10 p.m.

#### CLOSED SESSION

This portion of the meeting was closed to the public in accordance with the determination that this session was concerned with matters exempt from mandatory disclosure under Sections 552b(c)(4) and 552b(c)(6), Title 5, U.S. Code, and Section 10(d) of the Federal Advisory Committee Act, as amended (5, USC Appendix 2). Members absented themselves from the meeting during discussion of and voting on applications from their own institutions or other applications in which there was a potential conflict of interest, real or apparent. Members were asked to sign a statement to this effect.

### **REVIEW OF APPLICATIONS**

The members of the NACNR considered 85 research and training grant applications on which NINR was the primary Institute; these applications requested a total of \$ 16,601,216 (direct costs year 01). The Council also considered 259 applications on which another Institute/Center was primary and NINR was secondary; these applications requested a total of \$53,722,242 (direct costs year 01). The Council concurred with the IRG recommendations on these 344 applications.

### **ADJOURNMENT**

The 66th meeting of the NACNR was adjourned at 11:00 a.m. on September 17, 2008.

### **CERTIFICATION**

I hereby certify that the foregoing minutes are accurate and complete.

Patricia A. Grady, Ph.D., R.N., F.A.A.

Chair

National Advisory Council for Nursing

Research

Mary Kert, Ph.D., R.N., F.A.A.N.

Executive Secretary

National Advisory Council for Nursing

Research

### **MEMBERS PRESENT**

Dr. Patricia A. Grady, Chair

Dr. Mary E. Kerr, Executive Secretary

Dr. Marion Broome

Dr. Michael Counte

Dr. J. Randall Curtis

Dr. David Dinges

Dr. Stanley Finkelstein

Dr. Kevin Frick

Dr. Diana Lake

Mr. James Linn

Dr. Jean McSweeney

Capt. Maggie Richard, Ex Officio

Dr. Marla Salmon

Dr. Sharon Tennstedt

Dr. King Udall

Dr. Anna Alt-White, Ex Officio

### MEMBERS OF THE PUBLIC PRESENT

Dr. Terry Lennie, University of Kentucky

Dr. Tam Nguyen, Johns Hopkins University

Ms. Darlene Summers, Consolidated Solutions and Innovations

### FEDERAL EMPLOYEES PRESENT

Mr. Brian Albertini, NINR/NIH

Mr. David Alperin, NHLBI/NIH

Ms. Melissa Barrett, NINR/NIH

Mr. Raymond Bingham, NINR/NIH

Dr. Josephine Boyington, NINR/NIH

Dr. Yvonne Bryan, NINR/NIH

Dr. Paul Cotton, NINR/NIH

Dr. William Duval, OD/NIH

Mrs. Linda Fitzwater, NINR/NIH

Ms. Elisa Gladstone, NINR/NIH

Dr. John Grason, NINR/NIH

Dr. Rebecca Hawes, NINR/NIH

Dr. Karen Huss, NINR/NIH

Ms. Deborah Jennings, NINR/NIH

Dr. Kathleen Jett, NINR/NIH

Ms. Ellie Johnson, NINR/NIH

Dr. Kathy Mann Koepke, NINR/NIH

Dr. Mary Frances Kordick, NINR/NIH

Dr. Weigun Li, NINR/NIH

Dr. Yujing Liu, NINR/NIH

Mrs. Angela Marshall, NINR/NIH

Ms. Mary Miers, NINR/NIH

Ms. Sussana Morales, NINR/NIH

Ms. Mary Murray, NINR/NIH

Ms. Kelli Oster, NINR/NIH

Ms. Tanesia Randall, OD/NIH

Dr. Mario Rinaudo, NINR/NIH

Dr. Barbara Smothers, NINR/NIH

Ms. Cheryl Stevens, NINR/NIH

Dr. Mindy Tinkle, CSR/NIH

Ms. Tonya Truesdale-Young, NINR/NIH

Ms. Jane Webb, NINR/NIH Dr. Elizabeth Wilder, OPASI/NIH, NIDDK/NIH Mr. Kevin Wilson, NINR/NIH