

Department of Health and Human Services

National Institutes of Health

National Institute of Nursing Research

Minutes of the National Advisory Council for Nursing Research

May 21–22, 2019

The 98th meeting of the National Advisory Council for Nursing Research (NACNR) was convened on Tuesday, May 21, 2019, at 1:00 p.m. in Conference Room 620/630, Building 35, Porter, National Institutes of Health (NIH), Bethesda, Maryland. The first day of the meeting was an open session that started at 1:00 p.m. and adjourned that same day at 4:13 p.m. The closed session of the meeting, which included consideration of grant applications, was convened on Wednesday, May 22, 2019, at 9:00 a.m. and continued until adjournment at 1:00 p.m. Dr. Ann Cashion, Acting Chair, NACNR, presided over both sessions of the meeting.

OPEN SESSION

I. CALL TO ORDER, OPENING REMARKS, COUNCIL PROCEDURES, AND RELATED MATTERS—Dr. Ann Cashion, Acting Director, National Institute of Nursing Research (NINR)

Dr. Cashion called the 98th meeting of the NACNR to order and welcomed all Council members, visitors, and staff. She introduced new Council members Drs. John Lowe and Joanne Wolfe and noted the absence of new Council member Dr. Peter A. Lewin. Dr. Cashion acknowledged Lt. Col. Jennifer Hatzfeld for her service on the Council; Lt. Col. Hatzfeld will be stepping down following this Council meeting.

Conflict of Interest and Confidentiality Statement

Dr. Nara Gavini, Acting Executive Secretary, NACNR, and Chief, Office of Extramural Programs, NINR, noted that the meeting would be recorded for purposes of the minutes and that audio recordings would be destroyed once the minutes were completed. He reminded attendees that NIH is a smoke-free campus.

Dr. Gavini asked Council members to update their addresses on the meeting roster circulated during the meeting. Dr. Gavini referred to the conflict of interest and confidentiality statements provided in the Council materials and indicated that specific instructions would be provided at the beginning of the closed session on Wednesday.

Minutes of the Previous NACNR Meeting

Council members received the minutes of the January 29–30, 2019, NACNR meeting via the Electronic Council Book. A motion to accept these minutes was made, seconded, and approved unanimously. The approved minutes of each NACNR meeting become part of the Institute’s official record and are posted on the NINR website (www.ninr.nih.gov).

Dates of Future Council Meetings

Council members were asked to confirm their calendars for the following meeting dates and to contact Dr. Nara Gavini about any conflicts or expected absences.

2019

September 17–18 (Tuesday–Wednesday)

2020

January 14–15 (Tuesday–Wednesday)

May 19–20 (Tuesday–Wednesday)

September 15–16 (Tuesday–Wednesday)

2021

January 26–27 (Tuesday–Wednesday)

May 18–19 (Tuesday–Wednesday)

September 14–15 (Tuesday–Wednesday)

II. NINR DIRECTOR’S REPORT—Dr. Ann Cashion, Acting Director, NINR

The Director’s report focused on activities and news from the Department of Health and Human Services (HHS), NIH, and NINR since the Council met in January. Highlights of Dr. Cashion’s report included:

Budget Update—Dr. Cashion reviewed recent appropriations history. The Fiscal Year (FY) 2019 budget included a 3.1 percent increase for NINR, and a 4.7 percent increase for NIH, much of which was allocated to large initiatives such as Brain Research through Advancing Innovative Neurotechnologies (BRAIN), Alzheimer’s disease (AD) research, and the “All of Us” program.

NINR distribution of funds for FY2018 (the most recent completed FY) shows the Institute’s strong commitments to investigator-initiated research as well as training awards that enable scientists to be trained to conduct independent nursing research. The 8 percent allocated to funding NINR’s highly active intramural research program is slightly below the 10 percent average across NIH Institutes.

HHS and NIH News—Dr. Cashion reported that Dr. Norman Sharpless has been named Acting Commissioner of the Food and Drug Administration. He previously served as Director of the National Cancer Institute (NCI); NCI Deputy Director Dr. Douglas Lowy is serving as NCI’s Acting Director.

Dr. Debara Tucci has been named Director of the National Institute on Deafness and Other Communication Disorders (NIDCD) and is expected to join NIH in September.

Dr. Noni Byrnes has been selected as the new Director of the NIH Center for Scientific Review (CSR).

NIH has established a permanent office for the trans-agency Helping to End Addiction Long-term (HEAL) effort to speed solutions to stem the national opioid public health crisis.

Dr. Cashion mentioned a selection of NIH funding opportunities in which NINR participates; topics include prevention in mid-life adults, age-related microbiota changes in chronic disease, clinical trials for AD and age-related cognitive decline, diet and physical activity assessment methods, and chronic overlapping pain conditions. Announcements are available at <http://grants.nih.gov/grants/guide>.

NINR News—Dr. Cashion announced upcoming NINR Director’s Lectures featuring Dr. Jean McSweeney (September 17) and Dr. Patricia Stone (November 19). Videos of spring Director’s Lectures—Dr. Arlene Butz and Dr. Eun-Ok Im—are available on the NINR YouTube channel.

NINR recently added a women’s health research webpage that highlights how nursing research informs women’s health and how NINR helps advance the careers of women scientists.

NINR’s updated Data and Safety Monitoring (DSM) of Clinical Trials Policy is available on the NINR website. NIH requires each Institute and Center (IC) to have a system for oversight and monitoring conduct of clinical trials (CTs) to ensure participant safety and the validity and integrity of CT data. The updated NINR policy includes guidance on CT data validity and integrity as well as new information on CT research experience for career development and training awards.

The 2019 National Nursing Research Roundtable (NNNR) focused on “The Value and Importance of PhD Research Scientists to Health Outcomes.” The January 2019 *Journal of Nursing Scholarship* featured papers from the 2018 NNNR on the topic of promoting state-of-the-art biobehavioral approaches in symptom science through collaborations.

In March, NINR K awardees attended the NIAID Research Career Development Workshop that provided opportunities for information exchange to help inform and propel K participants into independent research careers, transition to R01s, and sustain research independence.

On June 27, NINR will host a scientific symposium to mark the launch of the NINR-led Symptom Science Center. Dr. Michael Gottesman, NIH Deputy Director for Intramural Research, will present the

keynote address, followed by an introduction to the Center and panel presentations on cancer-related symptoms, symptom clusters in concussions, and patient-reported outcomes and symptom science at the NIH Clinical Center.

Dr. Cashion was featured on a recent episode of the “All about Nursing” radio show where she provided personal advice on research careers and described NINR-supported research. She was one of several nursing organization leaders who presented comments at a public session for the Committee for the Future of Nursing 2020–2030, which is examining challenges in developing recommendations for nursing in the next decade. Her remarks highlighted the work of NINR scientists and emphasized that the primary focus of nursing science is on improving quality of life at any age, not necessarily on curing disease.

The NINR-supported Palliative Care Research Cooperative (PCRC) received the 2019 Presidential Citation Award at the annual American Academy of Hospice and Palliative Medicine/Hospice & Palliative Nurses Association Assembly. The award recognized PCRCs commitment to advance hospice and palliative care research.

Dr. Jessica Gill, Deputy Scientific Director of NINR’s Division of Intramural Research and Chief of the NINR Brain Injury unit, served on the congressionally mandated Committee on VA Examinations for Traumatic Brain Injury (TBI). In April, the National Academies of Sciences, Engineering, and Medicine released the Committee’s report entitled “Evaluation of the Disability Determination for Traumatic Brain Injury in Veterans,” which provides recommendations to the Department of Veterans Affairs (VA).

NINR is participating again in efforts of the National Institute on Aging (NIA) to incorporate an AD focus into existing NINR awards via one-year supplements. During FY2018, NIA funded 15 administrative supplements to NINR awards totaling over \$5 million.

NINR is seeking candidates for a Director of the Division of Extramural Science (DES), which develops proposals for new research initiatives and manages funding programs that support nursing research.

NINR received \$1 million from the NIH Office of AIDS Research for FY2019 in response to initiatives developed by Dr. Rebecca Henry, a program director in the DESP. These funds support NINR participation in the NIH Multi-Center AIDS Cohort Study and Women’s Interagency HIV Study Combined Cohort Study, the NIH Centers for AIDS Research, and an NIH-wide, NINR-led initiative: “Strengthening the Impact of Community Health Workers on HIV Care and Viral Suppression.”

NINR-Funded Science Advances—Dr. Cashion highlighted two recently published findings from research conducted by NINR extramural grantees. A nested case-control study found seven bacterial taxa were significantly associated with spontaneous preterm birth (sPTB), with a stronger effect in African-American (AA) women. Higher vaginal levels of β -defensin-2 lowered the risk of sPTB, a finding that

holds promise for identifying women at risk for sPTB. The second publication reported findings from a study on risk factors for poor health-related quality of life (HRQL) in multi-morbid adult cancer survivors. Worse HRQL outcomes were associated with having more diagnoses, seeing more physicians in the past six months, having a mental health diagnosis, not having self-management routines, low health literacy, low self-efficacy, and low social support. Standardized assessment of these factors could help healthcare teams identify survivors who need additional supports and inform more personalized treatment approaches.

Dr. Cashion noted the range of NINR-sponsored funding opportunity announcements available at www.ninr.nih.gov/ResearchAndFunding/DEA/OEP/FundingOpportunities/.

NINR Training Opportunities—Dr. Cashion described two upcoming NINR training activities: the Summer Genetics Institute (June 3–28, 2019) and the NINR Methodologies Boot Camp (July 15–29, 2019) “Precision Health: Smart Technologies, Smart Health.” The Boot Camp will explore state-of-the-art digital health data and smart technologies and strategies for incorporating them into research programs.

NINR Graduate Partnership Program Fellow Delia Djalilova received a 2019 Oncology Nursing Society Foundation Research Doctoral Scholarship, took first place in the NIH Graduate Student Research Symposium’s annual “elevator pitch” competition, and received an NIH Graduate Student Research Award for her poster entitled “Role of Exosomes in Cancer-Related Fatigue.”

Staff News—Dr. Cashion announced that Dr. Nicolaas Fourie, a longtime member of the NINR Intramural Research Program, died suddenly in February. Dr. Wendy Henderson is the first nurse scientist to be selected to participate in the highly competitive American Gastroenterological Association (AGA) Future Leaders Program. Dr. Paule Joseph has accepted a tenure-track position in the NINR Division of Intramural Research.

The search for an NINR Director is ongoing. Dr. Cashion expects that the position will be filled in fall 2019 at the earliest.

III. OVERVIEW OF THE NINR SYMPTOM SCIENCE AND PRECISION HEALTH

PORTFOLIO—Dr. Michelle Hamlet, Program Director, NINR

Dr. Hamlet presented an overview of the NINR precision health and symptom science portfolio, which includes R01s, Center grants, Fellowships, and Career Development Awards. She defined precision health approaches to disease prevention and treatment and symptom science and described an integrated model of precision health and symptom science that serves as the foundation for NINR-supported research in this area.

Three recently funded grants in the NINR symptom science and precision health portfolio are as follows:

- “Genomic Underpinnings for Breast Cancer Treatment-Induced Nausea and Vomiting” (TINV) aims to assess the impact of genetic variability on TINV. Identifying patients who are at higher risk of severe TINV would support steps toward early intervention.
- “Omic-based Intervention to Treat Pain” in children with functional abdominal pain gastrointestinal disorders (FGIDs) proposes conduct of a randomized controlled trial to test the hypothesis that individuals with abnormal markers in their gut microbiome composition respond better to diet and those without abnormal markers respond better to cognitive behavioral therapy.
- “Extending Sleep to Reverse Metabolic Syndrome in Middle-Aged Adults” will explore whether a sleep-extension intervention not only affects sleep duration but also improves outcomes for other symptoms such as fatigue and health behaviors.

Dr. Hamlet summarized recently published findings from the portfolio. A study of “Microbiome Composition and Extraintestinal Pain in Irritable Bowel Syndrome” (IBS) found that decreased microbial diversity was linked to severity of extraintestinal pain in women with IBS. “Cancer Fatigue-Regulated Transcription Factor Activity” found that individuals suffering from cancer treatment-related fatigue in head and neck cancer match the “conserved transcriptional response to adversity” profile: increased transcription of proinflammatory genes and decreased transcription of antiviral genes in individuals suffering from fatigue. Patients with human papillomavirus (HPV)-related head and neck cancer experience low fatigue, and their transcription profiles are the opposite. Further study is needed to explore whether this differential regulation points to a molecular mechanism that ties fatigue to the inflammatory pathway of gene expression.

NINR-supported early stage investigators in the portfolio are studying the effects of genomic testing on fear of cancer recurrence among breast cancer survivors; the microbiome-gut-brain axis in psychoneurological symptoms in children with solid tumors; and DNA methylation, preterm birth, and blood pressure in African-American children.

Nurses and nurse-scientists play a critical role at the forefront of patient interactions, and NINR is leading the charge by supporting research employing precision health approaches.

IV. ANNOUNCEMENT OF VISITORS

Dr. Cashion announced the names of visitors and encouraged attendees to take advantage of the upcoming break to meet them.

V. OBSTRUCTIVE SLEEP APNEA IN MEN AND WOMEN: BRAIN CHANGES LINKED WITH SYMPTOMS—Dr. Paul Macey, Associate Professor, University of California, Los Angeles (UCLA) School of Nursing

Dr. Macey presented an overview of his research on obstructive sleep apnea (OSA), with an emphasis on brain changes, mechanisms of injury, gender differences in brain and symptoms, and interventions. Clinical problems with OSA include many physical and psychological comorbidities that the treatment of choice, Continuous Positive Airway Pressure (CPAP), does not resolve.

Dr. Macey's early research focused on structural damage in the stress and blood pressure control regions of the brain. Magnetic resonance imaging (MRI) from a large population study showed differences in hippocampus volume of OSA patients versus controls. Roughly half of patients with OSA report depressive symptoms; studies revealed that those with depressive symptoms have markers of brain changes not present in those with normal mood.

Animal model studies identified sex differences in cellular and symptom responses to intermittent hypoxia. Human imaging studies found sex differences in white matter alterations accompanying OSA.

Dr. Macey conducted a study to assess whether neural changes in OSA might result from alterations in neurotransmitter levels. Novel MRI techniques enabled measurement of concentrations of GABA and glutamate in the brain and identified an association between OSA and low GABA and high glutamate in the insular cortex.

Several studies have suggested that brain injury in OSA is probably reversible to some degree. A cross-sectional study conducted at UCLA indicated that CPAP resolves cognitive deficits in females and males as measured by the Montreal Cognitive Assessment (MoCA). CPAP improves depressive symptoms in males but not in females.

Dr. Macey described an OSA intervention, Inspiratory Muscle Training (IMT), designed to improve muscle tone of the tongue. Participants practiced breathing in against resistance for one set of 30 breaths daily over a period of six weeks. Preliminary results indicate a decrease in sleepiness but an inconsistent effect on sleep and blood pressure. Dr. Macey noted that participants reported feeling more positive.

Next steps focused on mechanisms will include testing behavior and pathology models, determining sex-specific pathways, and distinguishing intervention targets. Intervention-focused steps will explore specific interventions for specific symptoms such as CPAP complements and alternatives as well as sex-specific interventions.

VI. NIH ALL OF US RESEARCH PROGRAM/PRECISION MEDICINE INITIATIVE—

Dr. Stephanie Devaney, Deputy Director, All of Us Research Program

Dr. Devaney summarized the purpose and current progress of the All of Us Research Program, which was funded by Congress in 2016 and officially launched May 6, 2018. The Program’s mission is to accelerate health research and medical breakthroughs, enabling individualized prevention, treatment, and care for all of us. The mission is being operationalized by nurturing relationships with 1 million partners from all walks of life over decades toward delivering the largest, richest biomedical dataset and catalyzing a robust ecosystem of researchers and funders hungry to use and support it. Participants reflect the rich diversity of the U.S. population, have access to their information, and are partners in every step of program development—from what data to collect to what research is conducted. Key values include transparency, security, and privacy.

The Program will start by collecting a limited set of standardized data; data types will grow and evolve. The current protocol includes participant enrollment, consent, and authorization of access to electronic health records (EHRs); answering of surveys; collection of physical measurements; provision of biosamples; and usage of wearable and digital apps. Genomics plans include genotyping and whole-genome sequencing for all of the 1 million participants. Results return processes will be piloted with 40,000 diverse participants, beginning with medically actionable genomic results via the Genetic Counseling Resource.

The All of Us scientific framework aims to enable research that will increase wellness and resilience and promote healthy living; reduce health disparities; develop improved risk assessment and prevention strategies; provide earlier, more accurate diagnoses; and improve health outcomes and reduce disease impact through improved treatment and precision interventions. The public data browser provides summary statistics from the database so that participants can understand the cohort composition and researchers can view characteristics of the participant population, explore available data types, and plan research questions. A restricted researcher workbench is under development.

More information is available at ResearchAllofUs.org and AllofUs.nih.gov.

INTRODUCTION OF CONCEPT PLANNING PROCESS—Dr. Cashion, Acting Director, NINR

Dr. Cashion provided an overview of the concept planning process, noting that NINR seeks Council guidance on future initiatives to pursue. Concept development is an annual deliberative process to identify gaps in the portfolio, emerging problems, and opportunities for innovation.

VII. CONCEPT PRESENTATION AND DISCUSSION—Dr. Nara Gavini, Chief, Office of Extramural Programs, NINR

Dr. Gavini facilitated discussion of four concepts. Each Council member assigned as a lead discussant provided a brief concept overview and remarked on its importance and relevance to the NINR mission. Discussion by the entire Council followed.

Concept 1. Palliative Care in Home and Community Settings

The proposed concept would support studies aimed at determining needs and best practices for integration of palliative care into home and community settings. Council members noted that the concept lacked a strong focus on the role of nurses in these settings. Community health workers playing a role in care are often directed by nurses. Others commented on the need to find appropriate ways to share information with caregivers who do not have a formal relationship with patients (e.g., partners, significant others).

Concept 2. Patient Activation for Self-Management of Chronic Illness

The proposed concept aims to promote clinical research that expands evidence-based interventions concerning the influence of patient activation (i.e., an indicator of patients' knowledge, skills, abilities, and willingness to manage their health and healthcare) on self-management. Council members noted the need to clarify how patient activation differs from self-efficacy and recommended expanding the model to incorporate physiological aspects such as brain and hormonal phenotypes, adding the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) as a potential collaborator, and exploring self-management as a patient-oriented goal.

Concept 3. Omic-Guided Biobehavioral Interventions for Improved Health Outcomes

The proposed concept aims to harness advances in genomics and other omics and incorporate them into non-pharmacological interventions designed to improve health. Council members noted that the concept raises awareness and offers an avenue for nurse scientists to develop objective ways to demonstrate effectiveness of interventions. Council members recommended including an objective related to use of existing resources and datasets.

Concept 4. Strategies to Improve Health Outcomes and Reduce Disparities in Rural Populations

The proposed concept aims to promote research into and development or adoption/adaptation of interventions that can reduce health risks faced by rural Americans and encourages the research community to use a wide range of methodological approaches to enhance access to and

acceptability of interventions in rural settings (e.g., telehealth, community-based prevention research). Council members noted the timeliness of the concept and the need to expand Advanced Practice Registered Nursing and interprofessional collaboration. Potential research focus areas include addiction and mental health as well as diverse rural subpopulations.

Dr. Gavini thanked Council members for their thoughtful discussion. Concepts will be revised in response to Council feedback.

VIII. ADJOURNMENT—Dr. Ann Cashion, Acting Director, NINR

Dr. Cashion thanked meeting attendees and adjourned the open session of the meeting at 4:13 p.m.

CLOSED SESSION

This portion of the meeting was closed to the public in accordance with the determination that this session concerned 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

NACNR members considered 106 research and training grant applications on which NINR was the primary Institute; these applications requested a total of \$34,565,995 (direct costs year 01). The Council also considered 270 applications on which another Institute/Center was primary and NINR was secondary. These applications requested a total of \$111,756,948 (direct costs year 01). The Council concurred with the Institutional Review Group recommendations on these 376 applications.

ADJOURNMENT

The 98th meeting of the NACNR was adjourned at 1:00 p.m. on Wednesday, May 22, 2019.

CERTIFICATION

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

Ann Cashion, Ph.D., R.N., F.A.A.N.
Acting Chair
National Advisory Council for Nursing Research

Nara Gavini, Ph.D., M.Phil.
Acting Executive Secretary
National Advisory Council for Nursing Research

COUNCIL MEMBERS PRESENT

Dr. Ann Cashion, Acting Chair
Dr. Nara Gavini, Acting Executive Secretary
Dr. Kathryn H. Bowles
Dr. Yvette Conley
Dr. Audwin Fletcher
Dr. Jennifer Hatzfeld, *Ex Officio*
Dr. Jeffrey A. Kelly
Dr. Deborah Koniak-Griffin
Dr. John Lowe, *Ad hoc*
Dr. Ida M. Moore
Dr. Shirley M. Moore
Dr. Nilda Peragallo-Montano
Dr. Rita H. Pickler
Dr. JoEllen Wilbur
Dr. Joanne Wolfe

MEMBERS OF THE PUBLIC PRESENT

Ms. Lisa Blair, University of Virginia
Ms. Amber Cassady, Lewis-Burke Associates LLC
Ms. Marlena Fisher, Johns Hopkins School of Nursing
Ms. Mary Ann Fullon, Social & Scientific Systems, Inc.
Mr. Nick Giordano, University of Pennsylvania
Ms. Melissa Hearrell, Sylvana Research
Dr. Sarah Jo Iribarren, University of Washington School of Medicine
Ms. Marjorie Kelley, Ohio State University
Dr. Robert McLinden, SSS
Ms. Marliese Nist, Ohio State University
Dr. JoAnne Robbins, University of Washington School of Medicine and Public Health
Ms. Kathy Sedgwick, NOVA Research Company
Dr. Paula Tanabe, Duke University School of Medicine

FEDERAL EMPLOYEES PRESENT

Dr. Lynn Adams, NINR/NIH
Dr. David Banks, NINR/NIH
Ms. Catherine Blumhorst, NINR/NIH
Dr. Yvonne Bryan, NINR/NIH
Dr. Edmond Byrnes, NINR/NIH
Mr. Aaron Condon, NINR/NIH
Dr. Augie Diana, NINR/NIH
Ms. Ana Ferreira, NINR/NIH
Dr. Nara Gavini, NINR/NIH
Dr. Michelle Hamlet, NINR/NIH
Dr. Wendy Henderson, NINR/NIH

Dr. Rebecca Henry, NINR/NIH
Dr. Karen Huss, NINR/NIH
Mr. Doug Hussey, NINR/NIH
Dr. Paule Joseph, NINR/NIH
Dr. Emma Kurnat-Thoma, NINR/NIH
Ms. Alison Lemon, NINR/NIH
Dr. Weiqun Li, NINR/NIH
Ms. Reena Masih, NINR/NIH
Dr. Martha Matocha, NINR/NIH
Dr. Jeri Miller, NINR/NIH
Ms. Cathy Mutta, NCI/NIH
Dr. Cheryl Nordstrom, CSR/NIH
Dr. Ananya Paria, NINR/NIH
Dr. Rebekah Rasooly, NINR/NIH
Dr. Louise Rosenbaum, NINR/NIH
Dr. Pamela Tamez, NINR/NIH
Dr. Lois Tully, NINR/NIH
Mr. Kevin G. Wilson, NINR/NIH
Dr. Sue Wingate, NINR/NIH
Dr. Lichen Xiang, NINR/NIH