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

January 22-23, 2013

The 79th meeting of the National Advisory Council for Nursing Research (NACNR) was convened on Tuesday, January 22, 2013, at 1:00 p.m. in Conference Room 6, Building 31, National Institutes of Health (NIH), Bethesda, Maryland. The first day of the meeting was an open session and adjourned that same day at 4:23 p.m. The closed session of the meeting, which included consideration of grant applications, was convened on Wednesday, January 23, 2013, at 9:00 a.m. and continued until adjournment at 1:00 p.m. Dr. Patricia A. Grady, Chair, NACNR, presided over both sessions of the meeting.

OPEN SESSION

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

Dr. Grady called the 79th meeting of the NACNR to order, welcoming all Council members, visitors, and staff. Two Council members, Drs. Barbara J. Guthrie and Elaine Larson, were unable to participate in the open session, but were present at the closed session. Dr. Grady announced two visitors to the meeting, Drs. Cynthia Barnes-Boyd and Donna K. Hathaway.

Conflict of Interest and Confidentiality Statement

Dr. Ann Knebel, Executive Secretary, NACNR, and Deputy Director, National Institute of Nursing Research (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. She referred Council members to the Conflict of Interest and Confidentiality Statement and added that she would provide additional instructions on conflicts of interest and confidentiality during the closed session on January 23. She also reminded Council members of their status as special federal employees while serving on the Council and that as special employees, Council members cannot engage in lobbying activities while receiving payment from the government.

Dr. Knebel stated that any last-minute information to be shared with Council members would be uploaded to the electronic Council book under the "FYI" tab to be viewed on the provided laptops. FYI items

would not be discussed at the meeting unless Council members request further discussion. If any FYI items were determined to require action, they would be added to the meeting agenda.

Minutes of the Previous NACNR Meeting

Council members received the minutes of the September 18-19, 2012, NACNR meeting by email. A motion to accept these minutes was made, seconded, and approved unanimously. The approved minutes of each quarterly NACNR meeting become part of the Institute's permanent 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 Drs. Grady and Knebel about any conflicts or expected absences. The January 2014 meeting is scheduled over a holiday weekend and may be changed to a different date.

2013

September 17-18 (Tuesday-Wednesday)

2014

January 21-22 (Tuesday-Wednesday)

May 20-21 (Tuesday-Wednesday)

September 16-17 (Tuesday-Wednesday)

II. REPORT OF THE DIRECTOR, NINR—Dr. Patricia Grady, Director, NINR

The Director's report focused on the NIH and NINR budgets and on activities and news occurring within NINR, NIH, and the Department of Health and Human Services (HHS) since the last Council meeting.

Budget Update—Dr. Grady provided an update on the current status of appropriations for the NINR budget. Federal agencies are still awaiting progress on the fiscal year (FY) 2013 budget. The government is currently operating under a Continuing Resolution that will expire on March 27, 2013. Funding levels under the Continuing Resolution are at the same level as in FY2012.

Over the past several years, funding levels have been steady for NINR; however, due to inflation there have been decreases in real dollar amounts. Dr. Grady indicated that the increases in the NINR budget

over the past few years have been slightly above the mean increase for NIH overall. Although one of the smaller Institute budgets within NIH, NINR receives many accolades for its research efforts and achievements, which result in significant impact.

Dr. Grady reviewed NINR patterns of expenditures and noted that there were no major changes. Extramural programs consume the largest proportion of NINR funds in the form of research project grants (RPGs), centers, and P01 awards. Dr. Grady reminded the Council that the proportion of the NINR budget devoted to training is twice the average across NIH. The intramural program consumes 5 percent of the NINR budget, which is about half the average proportion for intramural programs across NIH.

HHS News—The Science of Eliminating Health Disparities Summit was originally an NIH initiative that expanded to encompass the entire Department. The 2012 Summit was held December 17-19, 2012, and brought together leaders, scientists, artists, and political movers who are all working to help eliminate health disparities.

There is a great deal of emphasis within the Department on information technology, particularly in regard to electronic patient information/records. The Federal Health Information Technology Strategic Plan is focused on protecting the confidentiality, integrity, and availability of health information. The initiative is designed to identify privacy and security best practices for mobile devices. This is of particular importance to NINR, which is funding a number of studies using mobile devices.

The HHS Innovation Fellows Program pairs External Fellows with internal HHS "innovators" to tackle complex healthcare problems and to establish innovation as a key process and core capability at HHS. The goal is to stimulate creativity in research. The External Fellows have backgrounds ranging from business and technology executives to lifelong entrepreneurs. The External Fellows were selected based on their expertise and demonstrated ability to innovate.

Dr. Grady highlighted areas of interest to Secretary Sebelius in the last several months: the Sandy Hook response, Worlds AIDS Day, diabetes month, Alzheimer disease, and breast cancer awareness month.

The Patient-Centered Outcomes Research Institute (PCORI) is an independent, nonprofit, nongovernmental organization. PCORI Funding Announcements (http://www.pcori.org/funding-opportunities) are designed to solicit applications for proposals to support a portfolio of clinical effectiveness research. Funding announcements aligned with the areas of Assessment of Prevention,

Diagnosis, and Treatment Options; Improving Healthcare Systems; Communication and Dissemination Research; and Addressing Disparities were released May 22, 2012. A fifth funding announcement, Improving Methods for Conducting Patient-Centered Outcomes Research, was released November 16. Cycle III opens January 15, 2013. NINR interacts with PCORI and is involved in many of their research opportunities. The first round of PCORI-approved awards which includes NINR funded nurse scientists, involved research areas such as reducing health disparities, rural health, chronic pain, and palliative and end-of-life care.

NIH News—Dr. Grady noted NIH's new logo, designed to be simpler and to reflect science pointing the way forward. There have been two new appointments at NIH—Dr. Christopher P. Austin was named Director of the National Center for Advancing Translational Sciences (NCATS) and Dr. Richard Nakamura was named Director of the Center for Scientific Review. Dr. Grady has met with both individuals and discussed areas of mutual interest and importance. NIH announced two senior scientific recruitments on January 10: the Chief Officer for Scientific Workforce Diversity and the Associate Director for Data Science.

The Office of Research on Women's Health (ORWH) held the Ninth Annual NIH Interdisciplinary Women's Health Research Symposium on November 12, 2012. The Symposium focused on two ORWH signature initiatives: the Specialized Centers of Research (SCOR) on Sex Differences and the Building Interdisciplinary Research Careers in Women's Health (BIRCWH) program.

Dr. Grady noted that Dr. Francis S. Collins started writing an NIH Director's blog; he currently blogs three times per week. Dr. Collins also received the Galien Foundation 2012 Pro Bono Humanum Award. The Pro Bono Humanum Award recognizes exemplary and innovative efforts in improving human health.

Dr. Grady also reported that:

- The NIH Office of Education began its 2013 Demystifying Medicine series on January 8. The course is designed to help bridge the gap between advances in biology and their application to major human diseases.

- There are two trans-NIH funding opportunities of interest to NINR: Multidisciplinary Studies of HIV/AIDS and Aging and the NIH Pathway to Independence Award.

- The Lasker Clinical Research Scholars Program, a joint effort between NIH and the Lasker Foundation, is in its second year. Dr. Jessica Gill, who worked in the NINR Intramural Research Program (IRP) as a fellow, received a Lasker Scholar Award last year.

NINR News—Dr. Grady acknowledged the loss of Senators Arlen Specter and Daniel Inouye, who were strong supporters of NIH and NINR. She also highlighted a few recent editorials. "The National Institute of Nursing Research: Delivering on the Promise" was published in *Applied Nursing Research* in November 2012. Authored by Dr. Grady, the editorial focuses on the evolution of NINR. A special issue of *Nursing Outlook* that focused on palliative and end-of-life care was released in November 2012.

Dr. Grady reported that Dr. Yvonne Bryan, Special Assistant to the Director, NINR, participated in a plenary session at the American Public Health Association's 140th Annual Meeting. She also announced that Ms. Ana Ferreira and Dr. Sussana Morales of NINR received the 2012 NIH Group Honor Award for their work in innovative methods of monitoring and procurement to help make NINR compliant with the NIH Procurement Act.

Dr. Grady noted important upcoming deadlines. The application deadline for the Summer Genetics Institute is March 18, 2013. The Institute will take place June 3-28 of this year. The NINR Fatigue/Sleep Methodologies Boot Camp—July 22-26, 2013—will be accepting applications April 1 to May 20. Dr. Grady noted that enrollment for these boot camps fills quickly. She highlighted selected funding opportunities in behavioral interventions to address the environment, healthy habits, health disparities, and early cognitive deficits. The Graduate Partnerships Program (GPP) will be accepting applications for 2013 until January 25. The GPP is a doctoral fellowship training program that coordinates training and funding for students attending a school of nursing. A qualified Ph.D. student at any university can now apply to the program. Dr. Grady encouraged Council members to view the YouTube video posted on the GPP website (https://www.ninr.nih.gov/training/trainingopportunitiesintramural/graduate-partnership-program) that features an alumna of the program, Dawn Betters, discussing how the GPP helped her advance her nursing research career. A recent graduate of the program, Sheeba Nadarajah, is now doing a postdoctoral fellowship focused on end-of-life care.

The Ninth Annual NIH Graduate Student Research Symposium: The Faces of Tomorrow's Science was held January 15. The Symposium communicated the scientific research being done at NIH and celebrated the successes of its graduate community. Dr. Grady shared the names of five NINR graduate students recognized at the symposium: Jennifer Dine, Kristin Filler, Alyson Hanish, Sheeba Nadarajah, and

Christina Slota. Dr. Grady closed her presentation by inviting Council members and visitors to visit the NINR website.

III. ADVISORY COMMITTEE TO THE DIRECTOR WORKING GROUP ON DIVERSITY IN THE BIOMEDICAL RESEARCH WORKFORCE—Dr. Lawrence A. Tabak, Principal Deputy Director, NIH

Dr. Tabak discussed the results of the Advisory Committee to the Director (ACD) Working Group on Diversity in the Biomedical Research Workforce. He presented a graphic depicting the diversity of the NIH-funded research workforce. Compared with the 2010 United States Census, the number of minority NIH principal investigators (PIs) on RPGs is woefully underrepresented. If NIH wants to continue to fulfill its mission, it must recruit the best and brightest individuals from all segments of society. By 2020, minority populations will become the majority.

Race, Ethnicity, and NIH Research Awards, a published study commissioned by NIH, helped inform the Advisory Committee Working Group. The study revealed a scarcity of black applicants for R01 awards; of the 83,188 applications analyzed, only 1,149 came from black or African-American applicants. There is a disparity in the funding of RPGs in addition to a narrow pipeline of applicants. The Working Group was formed in June 2011 and the Race, Ethnicity, and NIH Research Awards article was published in August 2011. In June 2012, the Working Group provided recommendations to the ACD and the NIH Director. The recommendations were framed according to the following four elements: (1) pipeline; (2) mentoring; (3) infrastructure; and (4) peer review. The Working Group identified several challenges that need to be solved: (1) there is no one set of initiatives that will diversify the NIH-funded workforce overnight; (2) there is tremendous mistrust in many of the minority communities with which NIH must engage, and NIH must work hard to gain that trust; (3) any effort will require collaboration and cooperation of extramural partners; and (4) diversifying the workforce and ensuring fairness of the peer review process are collective responsibilities across NIH.

Dr. Tabak highlighted the two main goals of the Initiative to Increase the Diversity of the NIH-funded Workforce. The first is to increase the diversity of the NIH-funded workforce because there is compelling evidence that this will help NIH accomplish its mission. The second goal is to ensure that all applicants are treated fairly in the peer review system. Four interrelated approaches will be implemented to achieve these goals. Dr. Tabak noted that the full implementation plan can be viewed at: http://acd.od.nih.gov/Diversity-in-the-Biomedical-Workforce-Implementation-Plan.pdf.

The purpose of the NIH Building Infrastructure Leading to Diversity (BUILD) Program is to provide support to undergraduate students from diverse backgrounds and strengthen the likelihood that these students will succeed in science and transfer from a baccalaureate degree to a Ph.D. in disciplines relevant to biomedical research. The student support provided includes rigorous mentored research experience for two summers (in college) and up to two years postgraduation; tuition scholarships for up to two years as an undergraduate; and the possibility of loan repayment in graduate school. The faculty who train and mentor these students also will receive support, including salary offset and infrastructure support for key faculty responsible for undergraduate research training; resources for highly effective mentors to train new mentors; and support for "Innovation Space" to enable organizations to develop novel approaches to increase diversity of the student pool that enters the Ph.D. training pathway. The primary site eligibility for this program is institutions which receive less than $7.5 million of NIH RPGs annually and have at least 25 percent of undergraduate students receiving Pell Grants. Primary sites are encouraged to partner with pipeline-partner institutions and research-partner institutions (including the NIH intramural program) to complement strengths and participate in a nationwide BUILD consortium. A primary site may also partner with a "co-primary" institution that does not have an undergraduate program and meets the other inclusion criteria. A major indicator of whether undergraduate students pursue science careers is whether they have had hands-on experience that is meaningful and relevant.

Dr. Tabak reviewed the second approach to be implemented. The establishment of a National Research Mentoring Network (NRMN) will serve to create a nationwide consortium to connect students, postdoctoral fellows, and faculty to experienced mentors both in person and virtually. The NRMN will develop standards for good mentorship and provide training to individuals interested in learning how to become better mentors. The Network will provide or arrange for relevant workshops and training opportunities in grantsmanship (i.e., grant writing; mock study sections, feedback on grant applications) and career "survival" strategies. NRMN will link with the BUILD consortium primary institutions and all student participants. Ultimately, the network of students, postdoctoral fellows, and faculty will be plugged into the larger biomedical research community.

Dr. Tabak explained that support for the BUILD/NRMN consortium will come from the NIH Common Fund. NIH plans to issue planning grants in FY2013 and conduct regional technical workshops to aid applicant organizations that may wish to apply for these programs. Depending on fund availability and a sufficient number of highly meritorious applications, NIH plans to support about 10 primary site institutions with an ultimate steady stage of about 600 undergraduates in all program phases; one NRMN;

and one coordination and evaluation center for the entire program. NIH estimates the average yearly support over the initial life of the program to be about $50 million. There will be a continued search for partnerships with other funding sources to expand the program.

Dr. Tabak introduced the approaches that will be used to ensure fairness in the peer view system. NIH has a core responsibility to ensure that all applicants are treated fairly. NIH will form an expert ad-hoc subcommittee of the ACD Working Group on Diversity to examine multiple hypotheses, including the role of unconscious bias, related to disparities in research awards. Implicit bias and diversity awareness training will be implemented for both Scientific Review Officers (SROs) and members of review panels. NIH will pilot the anonymization of applications by removing identification of the applicant and/or the applicant organization. There will be enhanced feedback to applicants with applications that have not been discussed further for review. NIH will develop better SRO practices for highly discrepant reviews, provide more guidance to reviewers on using the additional comments section of the critique template, and provide Next Step information on every summary statement. The Early Career Reviewer Program Pilot also will be continued.

Increased engagement by all NIH leadership also will help ensure fairness in the peer review process. An NIH Steering Committee Working Group on Diversity will be created, thus making diversity a core consideration of NIH governance. A Chief Diversity Officer also will be recruited. This individual will coordinate NIH initiatives designed to enhance diversity of the NIH-funded research workforce, oversee a rigorous prospective evaluation of existing NIH programs designed to enhance diversity, and work collaboratively as a practicing scientist across NIH to increase the diversity of intramural investigators. Dr. Tabak closed his presentation by noting that Dr. Roderic Pettigrew, Director of the National Institute of Biomedical Imaging and Bioengineering (NIBIB), has stepped in to serve as the interim leader for diversity issues within NIH. Dr. Pettigrew is cochairing the search committee for the Chief Diversity Officer.

IV. WOMEN'S HEALTH RESEARCH AT NIH: PROMISES TO KEEP—Dr. Janine Clayton, Director, Office of Research on Women's Health

Dr. Clayton presented an overview of ORWH's vision and goals. The overall mission of ORWH is to promote women's health and sex differences research within and beyond the NIH scientific community. Examining the role of sex and gender and its effects on health and disease is critically important to improving women's health. The scientific community needs research specifically devoted to women's

health because of reproductive health and disease and sex differences related to how women experience disease (e.g., diabetes, musculoskeletal diseases, mental illness). Dr. Clayton asked Council members and those in the audience to remember two important questions from her presentation: If we don't remember to include sex and gender in our study design, hypothesis generation, analysis, and reporting, what are we missing? What harm are we doing by not including sex and gender in all levels of scientific investigation?

ORWH is leading the effort in implementing strategic priorities outlined in the NIH strategic plan *Moving into the Future with New Dimensions and Strategies for Women's Health Research: A Vision for 2020 for Women's Health Research.* The strategic plan identifies three crosscutting themes that provide a conceptual framework for integrating women's health within the biomedical research landscape: (1) advancing understanding of sex/gender differences in health and disease; (2) integrating sex/gender perspectives in emerging basic science fields and in translational research and technologies; and (3) fostering partnerships to improve the translation and dissemination of health information. Dr. Clayton stressed that the only way to expand the understanding of health and disease in women is through partnership. ORWH is aided by NIH Institutes and Centers and by the NIH advisory and coordinating committees on research on women's health in implementing these strategic priorities.

Dr. Clayton shared ORWH's most recent funding opportunity announcement (FOA), Administrative Supplements for Research on Sex/Gender Differences. This administrative supplement program is designed to support research that increases understanding of sex and gender differences in health and disease as part of the implementation of the NIH strategic plan. Dr. Clayton reviewed the six goals of the strategic plan:

- Increase sex differences research in basic science studies.

- Incorporate findings of sex/gender differences in the design and application of new technologies, medical devices, and therapeutic drugs.

- Actualize personalized prevention, diagnostics, and therapeutics for girls and women.

- Create strategic alliances and partnerships to maximize the domestic and global impact of women's health research.

- Develop and implement new communication and social networking technologies to increase understanding and appreciation of women's health and wellness research.

- Employ innovative strategies to build a well-trained, diverse, and vigorous health research workforce.

The question of why sex/gender matters in biomedical research has been around for quite some time. The 2001 Institute of Medicine (IOM) report entitled *Exploring the Biological Contributions to Human Health: Does Sex Matter?* coined the phrase "every cell has a sex"—meaning that every cell has its chromosomal complement. Dr. Clayton reviewed the NIH definitions of sex and gender. Sex is a biological element stemming from a chromosomal complement. Gender is a self-representation related to a person's sociocultural environment. Dr. Clayton presented a few health examples on why sex and gender differences are important research considerations. Chronic pain is much more common in women and narcotic analgesics are more effective in women than in men, yet nearly 80 percent of all published studies in the journal *Pain* tested male subjects exclusively during the queried time period. According to research published in the August issue of the *Journal of Clinical Nursing*, women have a poorer quality of life than men following a stroke. The study also revealed that female transient ischemic attack (TIA), or mini stroke, patients are as badly affected when it comes to quality of life as female stroke patients and need the same level of support after they are discharged from the hospital. For men, this difference did not exist. Additionally, women who suffer from migraines with aura have a higher risk of stroke, and women with a history of preeclampsia are more likely to have non-pregnancy-related stroke. Another study cited that women are more likely than men to not see their doctors or fulfill prescriptions due to financial barriers. Dr. Clayton reiterated that both sex and gender are critically important to understanding the health differences between women and men.

A variety of new tools are available for sex/gender differences research. To study the effects of chromosomal differences, researchers developed a "four-core genotypes" mouse model in which the gene determining gonadal sex is spontaneously deleted from the Y chromosome and, through transgenic technology, inserted into an autosome, so that the gonadal sex of the animal is no longer related to the chromosome complement. XX and XY no longer affect the gonads the animal develops, and four core genotypes result: XY gonadal males, XX gonadal males, XX gonadal females, and XY gonadal females. This allows for separation of the sex chromosome and gonadal hormone effects. Other tools to aid sex/gender differences research include computational approaches, Bayesian statistical approaches, adaptive clinical trial design, and incorporation of sex-specific analysis into systematic reviews.

ORWH recently supported an IOM workshop focused on sex-specific reporting in scientific journals. The workshop summary addressed important issues such as the need to promote sex differences in women from the beginning of life to the end of life and the inclusion of women in clinical trials. An examination of about five years of data revealed that for phase III clinical trials supported by NIH, roughly one-third reported primary outcomes measured by sex. To help achieve awareness of sex/gender differences in clinical research, ORWH is expanding its professional training curricula. In collaboration with the U.S. Food and Drug Administration, ORWH developed an online course on sex and gender differences that will be available this year. ORWH also collaborated with NINR on specific course lessons related to the neural basis of sex differences in pain.

Dr. Clayton noted the importance of personalized health. Personalized health considers biological sex, age, and health determinants from environmental, social, and cultural influences—a strategy that can help address health disparities. Global Burden of Disease Study 2010 data, recently published in *The Lancet*, revealed that despite spending more money on healthcare, the U.S. did not fair well compared with other countries. The study is a systematic effort to describe the global distribution and causes of a wide array of major diseases, injuries, and health risk factors. Dr. Clayton noted specific health disparities among women that require further research:

- The rate of black women who die from stroke before age 35 is twice the rate of white women.
- The rate of black women who die from coronary heart disease under the age of 75 exceeds the rate of white women.
- The death rates from breast cancer are highest in black women.
- Asian-American women have the highest rates of new stomach cancer compared with all other ethnic groups.

Race and ethnicity are important to consider in respect to sex/gender.

Dr. Clayton reported that ORWH recently developed a mobile application based on its publication, *A Primer for Women's Health: Learn about Your Body in 52 Weeks*. The primer aims to promote healthy lifestyles by offering practical strategies for women to use every day. To date, ORWH has distributed

over 100,000 copies of the publication. Dr. Clayton concluded her presentation by noting that there are a number of diverse scientific and health sex/gender issues that need to be addressed in a comprehensive way. In order to improve women's health, research, programs, and policies must effectively consider and integrate sex/gender differences.

V. UPDATE ON NINR WOMEN'S HEALTH RESEARCH PORTFOLIO—Dr. Xenia Tigno, Program Director, NINR

Dr. Tigno presented NINR's current and past research portfolio in women's health, highlighting NINR's efforts to advance the health of women and girls in both the United States and abroad. An IOM committee defined women's health broadly, encompassing health conditions that are specific to women, are more common or more serious in women, have distinct causes or manifestations in women, have different outcomes or treatments in women, or have high morbidity or mortality in women. The Director-General of the World Health Organization (WHO), Dr. Margaret Chan of the People's Republic of China, who was appointed to her position in November 2006, has identified many of the issues facing women today: "The obstacles that stand in the way of better health for women are not primarily technical or medical in nature. They are social and political, and the two go together." While life expectancy is higher for women, countless social factors combine to create lower quality of life. Health risks are higher for women than for men in the world today.

In 2010, an IOM committee published a report, *Women's Health Research: Progress, Pitfalls, and Promise,* wherein they identified various gaps in research related to women's health, including: insufficient research to examine the social and environmental factors that, along with biological risk factors, influence women's health and underlie multiple diseases; inadequate attention given to assessing quality of life in women, such as functional issues, issues with mobility or pain, or issues involving wellness; large disparities in disease burden that continue to exist among many groups of women; the need to accelerate translation of research findings into clinical practice and public health policies; and the need to enhance dissemination of findings so that research based messages are effectively communicated. A subsequent 2011 IOM report helped inform the provisions of the Affordable Care Act, which will incorporate a number of preventive services for the health care of women, including no deductibles or copays for mammograms, birth control, and cervical screenings; better care for pregnant women and nursing mothers; coordinated care for senior women; and comprehensive sex education for teens, so that by 2013 there will be improved access to care for lower-income women.

NINR participates, together with other NIH Institutes and Centers, in achieving ORWH and NIH goals for the health of women—closing the gaps in knowledge and opportunities for research in women's health. NINR has a long history of contributing to the science of women's health. As early as 1989, when women's health was still in its infancy, NINR already was funding a Center for Women's Health Research based at the University of Washington. In 1994, NINR joined ranks with ORWH and the National Institute on Aging to cofund the Study of Women's Health Across the Nation (SWAN); this study is still ongoing. The Center for Reducing Risks in Vulnerable Populations has funded many important studies related to the health of women. Dr. Tigno further explained the accomplishments of the above initiatives.

Dr. Tigno gave an overview of NINR's current women's health portfolio. A large number of the NINR studies focused on women's health are in the training category of grants, roughly 40 percent. Women's health research at NINR fulfills the mission areas of the NIH strategic plan for women's health. In the area of health promotion and disease prevention, an outstanding example would be SWAN—a multicenter, multiethnic longitudinal study designed to characterize the physiological and psychosocial changes that occur in women during the menopausal transition. The goal of SWAN's research is to help scientists, health care providers, and women learn how midlife experiences affect health and quality of life during aging. Between 1996-1997, 3,302 premenopausal women not receiving hormone therapy between the ages of 42 and 52 were enrolled in the study. Currently, 79 percent of those women are still participating in SWAN. Some of the most important findings of this study include:

- SWAN helped define the stages of reproductive aging.

- The age of menopause was found to be earlier for Hispanic and African-American women, contributed to by cultural and socioeconomic factors.

- Health-related quality of life during the menopausal transition is mediated not only by health status, but by sociodemographic characteristics. Quality of life is further modified by anxiety and mood disorders, sleep, and health behaviors.

- Bone mass density loss starts one year prior to the final menstrual period.

Other women's health research at NINR fulfills the health promotion and disease prevention mission in capacity areas such as preterm birth, obesity, and physical activity. One study is addressing obesity problems of midlife and older rural women in Nebraska with a weight loss or weight maintenance program delivered through the Internet. Findings after the first three months of the intervention demonstrated a dramatic decrease in weight among women in all of the intervention groups. Another study addressing weight gain in Latinas following pregnancy is being conducted in Arizona. Initial findings indicate that social support obtained by involving community partners, or *promotoras*, during weekly walking sessions can increase walking activity and prevent postpartum weight gain in this population.

NINR also supports women's health research in the area of symptom management. The Promoting Effective Recovery from Labor Urinary Incontinence (PERL) study and the ongoing Translating Unique Learning for Incontinence Prevention (TULIP) study seek to improve urinary incontinence in postpartum women and elderly women, respectively. In TULIP, a self-instructional DVD on bladder health, which can be made available at annual gynecological checkups or adapted for the Web via podcasts, is compared with face-to-face delivery. These self-management interventions appear to improve urinary incontinence in both groups of women. A training grant in the area of caregiving—specifically, daughters as caregivers to their parents with dementia—explores the concept of compassion fatigue and its potential outcomes. Long-term objectives of the grant are to develop and test personal interventions to reduce compassion fatigue in adult child caregivers and eliminate the corresponding negative consequences for care receivers.

A recently concluded study presented at the 2012 AIDS Conference used video-capable cell phones to target a young population of African-American urban women at high risk of contracting HIV through risky sexual behaviors. The study evaluated a video-based intervention consisting of soap operas to reduce risky sexual behaviors. The outcome was a decline in HIV sexual risk behaviors at both three and six months post intervention.

Specific areas of women's health research that could be further advanced at NINR include women and aging—particularly in areas of chronic diseases, disabilities in cognitive function, and caregiving; women in health disparities, which would include geospatial analysis and ethnocultural diversity; epigenetics; maternal and infant health; unintended pregnancy, elective delivery, and Caesarean birth; and global women's health. Dr. Tigno closed her presentation by summarizing NINR's research achievements in women's health. NINR's portfolio in women's health not only fulfills the various mission areas of NIH,

but in many instances is ahead of the curve in addressing the gaps in women's health identified by the IOM. NINR's role is critical to women's health researchers to further refine, expand, and disseminate findings through various venues in the United States and abroad.

VI. ETHNIC DIFFERENCES IN PREDICTING PRETERM BIRTH AND LOW BIRTHWEIGHT: A BIOBEHAVIORAL PROFILE OF RISK—Dr. Jeanne Ruiz, Associate Professor, The Ohio State University College of Nursing

Dr. Ruiz presented her NINR-supported research examining the role of ethnic differences in predicting preterm birth (PTB) and low birthweight. Premature birth—delivery before 37 weeks gestational age—remains a significant problem in the United States. In 2009, there were about 500,000 preterm babies born in this country. Preterm birth is considered the most significant problem in maternal and child health today. Preterm birth is an important indicator of how the baby will grow, including cognitive ability, lung and gut development, and risk of hemorrhage. The rate of prematurity has not decreased in the last several years. The Hispanic population is of particular importance to study because the number of births within this population is going to dramatically increase in the coming years—Hispanics comprise the fastest-growing ethnic minority group in the United States.

Dr. Ruiz reported March of Dimes data on preterm births from 2007-2009. Black and African-American women had a premature birth rate of 17-18 percent and Hispanic women had a rate of 12 percent. Dr. Ruiz explained the epidemiologic phenomenon known as the Hispanic Paradox—newly immigrated, poor Hispanic women have better physical and mental health outcomes than do Hispanic women who are born in the United States with the same socioeconomic status. As part of her research, Dr. Ruiz hypothesized that health behaviors, risk factors, and outcomes (particularly prematurity and low birthweight) worsen the longer a woman stays in the United States and becomes acculturated. Acculturation is defined in the psychology literature as a multidimensional process involving changes in practices, values, and identification from the heritage culture; changes into the receiving culture; or a combination of both cultures interacting.

Dr. Ruiz reported the results of her first study "Psychoneuroimmunology (PNI) Preterm Birth in Hispanics," which took place from 2008 to 2012. She looked at the effect of psychological factors or emotional distress (stress, anxiety, and depression) on endocrine factors, including stress hormones, reproductive hormones, and immune factors. The study recruited 470 self-identified pregnant Hispanic women at 22-24 weeks gestation in south Texas. The women ranged in age from 14-40 years and did not

exhibit any major medical issues predictive of prematurity (e.g., hypertension or diabetes). All of the women were of low socioeconomic status and the majority had a 12th grade education or less. Validated self-report questionnaires were used to assess acculturative distress and psychosocial protective factors. Numerous stress and reproductive hormones, inflammatory cytokines in the blood, and gene polymorphisms were measured. Maternal and infant outcomes were assessed through a review of medical records. Acculturation was modeled as a latent variable using three indicators: English proficiency, residence index (years in the United States minus age), and generational status.

Previous studies have shown a Hispanic Paradox in which relatively less-acculturated Hispanics with intact social relationships exhibit better than expected health outcomes, despite low socioeconomic status. Dr. Ruiz's study supports this and indicates a preterm birth rate of 13.4 percent for the more-acculturated women compared with a PTB rate of only 4.7 percent for the less-acculturated women. Mental health deteriorated across generations, with worsening depression, anxiety, and stress with successive generations. Stress and reproductive hormone levels decreased across generations, whereas body mass index and number of sexual partners increased. The study also observed interactions between undetectable interleukin (IL)-10 levels and years in the United States and undetectable IL-10 levels and being born in the United States in models predicting preterm birth. Follow-up probes of these interactions suggested that when IL-10 was undetectable, preterm birth became more likely as time living in the United States increased. These data provide potential biobehavioral explanations for the relationship between acculturation and declining health among Hispanic women in the United States.

Dr. Ruiz reported on the outcomes of her second study "Mechanisms Underlying Preterm Birth in Minority Women," in which 517 women were examined. This study involved women who were more acculturated than those in the first study. Additional data analyses are confirming the results of the first study. Based on the findings, three risk profiles were developed for the Hispanic population involved in the study to help target intervention strategies. Moving forward, Dr. Ruiz would like to test a cognitive behavioral therapy intervention in a pilot study to prepare for full-scale implementation. She would like to screen women using three identified profiles of risk prospectively to best determine the accuracy and predictability of the best biomarkers. She will use this to target interventions for the psychological and acculturation variables identified for the highest-risk profile. The interventions will be tailored so that the women most at risk receive the most intensive intervention. The targeted behavior skills-building intervention will be conducted in conjunction with the prenatal visit, focusing on mental health and infant outcomes, in a randomized trial to improve anxiety, stress, coping, depression, health outcomes, and cost

savings for hospitals. Dr. Ruiz concluded her presentation by noting that more-effective, innovative interventions that target psychosocial and cultural risk, as well as medical risk factors, are needed.

Questions, Comments, and Discussion Points Included:

- In response to the question how smoking and eating/diet behavior played a role in preterm births and low birthweight in the study, Dr. Ruiz responded that by the third generation of living in the United States, women have reached overweight and obese weight levels. Generally, smoking was low in the population of women studied. The high number of sex partners in this population is alarming. Some of the identified preterm birth risks in the Hispanic population will be the same for African-American women.

- In 2006, the number-one reason for hospitalization in the United States was childbirth and the number-one operation was Cesarean delivery. Over the past 20 years, maternal mortality has increased.

- Dr. Ruiz indicated she did not look at the household composition (i.e., the number of generations within the household not acculturated) when determining risk profiles.

- If Dr. Ruiz were able to predict women at highest risk for prematurity and low birthweight, it would be easier to determine the best method of intervention.

- It was asked whether Dr. Ruiz collected information on provider types. Dr. Ruiz responded that the women in the first study received care at either community clinics or from private doctors; women in the second study all received care from private doctors.

- It was asked whether there are any studies that examine the composition and effect of vaginal microbial flora of these women and the risk of preterm birth. Does the microbial flora change the longer a woman lives in the United States? It was noted that bacterial vaginosis increases the risk of preterm birth; however, treating the infection does not change the risk level.

- Corticotropin-releasing hormone (CRH) was the only biomarker that directly predicted preterm birth outcomes; however, a panel of biomarkers is needed to determine the most predictive markers.

VII. REVIEW OF THE MEMORANDUM OF UNDERSTANDING AND REVIEW OF THE INCLUSION OF WOMEN AND MINORITIES—Dr. Anne Knebel, Executive Secretary, NACNR

Dr. Grady reminded the Council that the Memorandum of Understanding (MOU) serves as a contract between NINR and Council members about what is presented during the closed session. She also noted that NINR and NACNR must review the MOU each year. Dr. Knebel reported that the only change to the MOU resulted from a change in NIH policy that requires that applications from investigators receiving $1 million or more in direct costs be brought to Council. Otherwise, the MOU remains the same. The Council moved, seconded, and unanimously approved the motion to accept the revised MOU.

Dr. Knebel also reviewed the 2013 NINR Report on the Inclusion of Women and Minorities in Clinical Research. This report is a requirement that must be done every two years. Dr. Knebel highlighted findings of the report. For extramural protocols, there was an overall decrease in enrollment, but the percentages of ethnic minorities and women remained relatively constant, with approximately 30 percent of participants reporting being minorities and approximately 60 percent reporting being female. These data are consistent with data reported in 2011 in the broader NIH inclusion reports. For intramural protocols, there was a small increase in the number of studies, but the percentages for minorities and women were consistent with those for 2011. The Council moved, seconded, and unanimously approved the motion to accept the report.

Following these discussions, Dr. Grady thanked participants and attendees for their time and interest and adjourned the open session of the meeting.

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 130 research and training grant applications on which NINR was the primary Institute; these applications requested a total of $33,792,227 (direct costs year 01). The Council also considered 512 applications on which another Institute/Center was primary and NINR was secondary. These applications requested a total of $125,644,861 (direct costs year 01). The Council concurred with the IRG recommendations on these 642 applications.

ADJOURNMENT

The 79th meeting of the NACNR was adjourned at 1:00 p.m. on January 23, 2013.

CERTIFICATION

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

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Patricia A. Grady, Ph.D., R.N., F.A.A.N
Chair
National Advisory Council for
Nursing Research

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Ann R. Knebel, Ph.D., R.N., F.A.A.N.
Executive Secretary
National Advisory Council for Nursing Research

MEMBERS PRESENT

Dr. Patricia A. Grady, Chair
Dr. Ann Knebel, Executive Secretary
Dr. Anna Alt-White, *Ex Officio*
Dr. Julie Anderson
Dr. Glenna Dowling
Dr. Everette Freeman
Dr. Susan Gennaro
Dr. William Holzemer
Dr. Kenton Kaufman
Dr. Courtney Lyder
Dr. Kathleen Potempa
Dr. Anne Rosenfeld
COL Bruce Schoneboom, Ph.D., *Ex Officio*
Dr. Gail Stuart
Dr. James Tulsky
Dr. Janet Williams

MEMBERS OF THE PUBLIC PRESENT

Dr. Cynthia Barnes-Boyd, University of Illinois at Chicago
Dr. Donna Hathaway, University of Tennessee Health Science Center

FEDERAL EMPLOYEES PRESENT

Mr. Brian Albertini, NINR/NIH
Dr. Noreen Aziz, NINR/NIH
Dr. David Banks, NINR/NIH
Ms. Melissa Barrett, NINR/NIH
Ms. Karen Bashir, NINR/NIH
Mr. Brian Beckham, NINR/NIH
Dr. Yvonne Bryan, NINR/NIH
Dr. Ann Cashion, NINR/NIH
Ms. Andi Cimino, NINR/NIH
Dr. Janine Clayton, ORWH/NIH
Dr. Marguerite Engler, NINR/NIH
Ms. Crystal Esler, NINR/NIH
Ms. Ana Ferreira, NINR/NIH
Dr. John Grason, NINR/NIH
Dr. Amanda Green, NINR/NIH
Mr. Kevin Green, NINR/NIH
Ms. Jennifer Greene, NINR/NIH
Dr. Chris Hafner-Eaton, NINR/NIH
Dr. Lynda Hardy, NINR/NIH
Dr. Rebecca Hawes, NINR/NIH
Dr. Karen Huss, NINR/NIH
Mr. Doug Hussey NINR/NIH
Ms. Deborah Jennings, NINR/NIH
Ms. Mary Kelly, NINR/NIH
Dr. Weiqun Li, NINR/NIH

Dr. Yujing Lui, NINR/NIH
Dr. Sue Marden, NINR/NIH
Ms. Angela Marshall, NINR/NIH
Dr. Donna Jo McCloskey, NINR/NIH
Dr. Arthur Meltzer, NINR/NIH
Ms. Archana Mohale, NINR/NIH
Ms. Mary Murray, NINR/NIH
Dr. Mario Rinaudo, NINR/NIH
Mr. Charles Rose, NINR/NIH
Mr. Mark Schaaf, NINR/NIH
Ms. Candice Scott, NINR/NIH
Ms. Tara Schwetz, NINR/NIH
Mr. Shawn Stocking, NINR/NIH
Mr. Roberto Tellez, NINR/NIH
Dr. Chelvi Thyagarajan, NINR/NIH
Dr. Xenia Tigno, NINR/NIH
Dr. Catherine Timura, NINR/NIH
Dr. Lois Tully, NINR/NIH
Dr. Linda Weglicki, NINR/NIH
Mr. Kevin Wilson, NINR/NIH
Mr. Ronald Wolff, NINR/NIH
Mr. Bryson Young, NINR/NIH