

**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 27 – 28, 2004

The 52nd meeting of the National Advisory Council for Nursing Research (NACNR) was convened on Tuesday, January 27, 2004 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 adjourned at approximately 5 p.m. The closed session of the meeting, which included consideration of grant applications, began at 9 a.m. on Wednesday, January 28 and adjourned at 12:45 p.m. on the same day. Dr. Patricia A. Grady, Chair of the NACNR, presided over both sessions.

OPEN SESSION

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

Dr. Grady called the 52nd meeting of the NACNR to order, welcoming all Council members, visitors, and staff. She also welcomed Dr. Anna Alt-White an *ex officio* member of the NACNR representing the Department of Veterans Affairs, following Dr. Pauline Cournoyer's departure from the Council in May, 2003. Dr. Grady gave special thanks to retiring Council members Dr. Margaret Grey, Dr. Daniel Hanley, Dr. Rosanne Harrigan and Dr. Dorothy Powell.

Conflict of Interest and Confidentiality Statement

Dr. Claudette Varricchio, NACNR Executive Secretary, 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. Varricchio 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 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 Meeting

Council members received a copy of the minutes of the September 16-17, 2003, Council meeting by electronic mail. No changes or corrections to the minutes of the September 16-17, 2003 Council meeting were suggested during the January meeting. Comments, corrections, and changes identified after the current meeting should be forwarded to Dr. Grady or Dr. Varricchio. The minutes of each NACNR meeting are posted on the NINR Web Site at (<http://www.nih.gov/ninr/about/adv-council.html>).

Dates of Future Council Meetings

Dates of meetings in 2004 and 2005 have been approved and confirmed. Council members should contact Dr. Grady or Dr. Varricchio regarding any conflicts or expected absences.

2004

- ◆ January 27–28 (Tuesday–Wednesday)
- ◆ May 19–20 (Wednesday–Thursday)
- ◆ September 14–15 (Tuesday–Wednesday)

2005

- ◆ January 25–26 (Tuesday–Wednesday)
- ◆ May 17–18 (Tuesday–Wednesday)
- ◆ September 13–14 (Tuesday–Wednesday)

II. REPORT OF THE DIRECTOR, NINR (Dr. Patricia A. Grady, Director, NINR)

The Director's report focused on updates since the last Council meeting and on current and impending activities related to NIH, budget, and NINR.

Budget -- The pending FY 2004 Congressional Conference Budget Bill included \$134,701 million for NINR, a 3.3 percent increase. This is similar to other NIH Institutes and Centers (ICs) and greater than the 2.8 percent increase in the overall NIH budget. Approximately 76 percent of the NINR FY 2003 budget funded extramural research project grants (RPGs). Operating funds, such as working groups, meeting support and salaries, was 6 percent, research and development was 2 percent and the intramural program was 1 percent. Research training was 8 percent – more than twice the proportion other ICs' support of research training; the Centers program was 5 percent; and other research activities, such as career awards, were 2 percent.

The NINR RPG success rate for FY 2004 competing applications is projected to be 24 percent, compared to NIH's estimated 30 percent – a not unusual gap in recent years. For FY 1999, however, NINR's success rate was only 14 percent, compared to NIH's 32.4 percent, in part due to the marked increase in the number of applications to NINR in that year. In FY 2000, however, NINR received the largest appropriation increase among the ICs and had its highest success rate – 31.6 percent, slightly higher than the NIH mean. More recently, in FY 2001 through FY 2003, the NINR success rate was 25

– 27 percent, compared with NIH’s 31 to 32 percent. The growing cadre of nurse researchers is reflected by the increase in applications – from 210 in FY 1998 to 375 in FY 2003.

The NIH Roadmap – The NIH Roadmap, spearheaded by NIH Director Elias Zerhouni, was developed by more than 300 experts from a variety of backgrounds and settings as a way to promote more effective, novel approaches to solve scientific and health issues. The Roadmap is designed to transform medical research capabilities and speed research discoveries from the bench to bedside and back to improve the health of the American people. Sixteen implementation work groups met last year and developed three major research themes: New Pathways to Discovery; Research Teams of the Future; and Re-engineering the Clinical Research Enterprise. The FY 2004 funding level planned for the NIH Roadmap is \$128.3 million, and projected growth is up to \$508 million by FY 2009. Although the budget may appear large, it is but a small percentage of the overall NIH Budget. The goal of the Roadmap is to enhance rather than take away funds from individual ICs. Dr. Dushanka Kleinman is the new Assistant Director for NIH Roadmap program activities. Additional information may be found at <http://www.nihroadmap.nih.gov>.

NINR was the first to establish an implementation- working group to address Roadmap issues. The purpose was to identify gaps in science areas that nursing research can address; to identify areas NINR is already addressing; to develop strategies to advise scientists about implementing the Roadmap; and to stimulate the NINR community to participate in Roadmap initiatives. NINR’s senior Advisor for the Roadmap is Dr. Lauren Aaronson.

Publication of Findings – NINR-supported researchers’ publications are increasing steadily, from 114 articles in FY 2000 to 365 in FY 2003. Of note is that 52% of all articles captured in FY 2003 from NINR-funded investigators were published in non-nursing journals. This is an indication of the increasing reach of our science.

Upcoming Events – Upcoming NINR events include: the 5th Summer Genetics Institute from June 7 to July 30, 2004; a Cost Effectiveness Analysis Conference on August 4 – 6, 2004; and the NIH State of the Science Conference on Improving End-of-Life Care on December 6 – 8, 2004. NINR, along with 16 other nursing organizations, is cosponsoring the State of the Science “Congress on Nursing Science: Working Toward a Healthier Nation,” on October 7 – 9, 2004. The Friends of the NINR NightinGala, with the theme “Nursing Research: Enhancing the Public’s Trust,” will be October 6, with Dr. Zerhouni as guest speaker. A Behavioral Research Workshop is also planned for 2004.

III. NIH UPDATE: OFFICE OF RESEARCH ON WOMEN’S HEALTH (Dr. Vivian, Director)

In the past 10 plus years, “women’s health” has moved from being used chiefly by women’s reproductive advocacy groups to the concept of a “new mosaic” for women’s health. This shift has research as a focal point that informs standards of care, education and dissemination of research findings to healthcare providers and consumers. Women’s health is important not only to women, but to the men in their lives, as well as to researchers of both genders.

ORWH was established in 1990 to address concerns that medical research did not include women – or minorities – in clinical research, a necessity in order to identify similarities and differences between

genders and across populations. Now the United States stands alone in the world in enacting a law that requires their inclusion. New questions arise, however, such as why more women (about 67%) than men participate in clinical studies, and why certain ethnic groups are underrepresented. The Office's mandate includes establishing a research agenda at NIH on women's health, and participating on trans-NIH committees to ensure that grants comply with the requirements for women and minorities. The most current "Agenda for Research on Women's Health for the 21st Century" is contained in an eight-volume report. The report covers women across the lifespan and focuses on sex and gender disparities and similarities, and factors contributing to disparities among women.

Two major ORWH priorities overlap with the NIH Roadmap -- interdisciplinary research and interdisciplinary career development. ORWH's efforts are funded through the Building Interdisciplinary Research Careers in Women's Health (BIRCWH) Programs established in 2000, which provide institutional career development awards having a strong mentoring component. Barriers to entry into science and medicine careers are also studied, and mentoring is considered critical to overcoming these barriers. ORWH has also facilitated development of Specialized Centers of Research on Sex and Gender Factors, funded through interdisciplinary research awards. Each Center receives about \$1 million a year for 5 years.

A research initiative for which ORWH was directly responsible was the Women's Health Initiative, now moved to the National Heart, Lung and Blood Institute. Findings released so far regarding menopause and hormone replacement therapy have received significantly more coverage than other women's health research projects. The ORWH home page is <http://www4.od.nih.gov/orwh/>.

IV. NINR RESEARCH ACTIVITIES: WOMEN'S HEALTH (Dr. Janice Phillips, Program Director, NINR)

NINR's portfolio on Women's Health Research targets six areas:

- Health Promotion in Women Across the Lifespan: exercise in midlife and older women; enhancement of health in rural, minority and vulnerable populations
- Prevention and Risk Reduction in Women Across the Lifespan: prevention of falls; reduction of HIV risk among Latinas; prevention of depression in single mothers; promotion of healthy bones during puberty
- Managing Chronic Illness in Women: shaping cognitive representations in hypertensive women; enhancing quality of life for breast cancer survivors; providing online support for rural chronically ill women
- Pregnancy, Postpartum, and Reproductive Issues: influence of lactation on postpartum stress and immunity; support for low-income breast feeding – the costs and the outcomes; moderate exercise to prevent preeclampsia
- Menopausal Health: bibehavioral models of symptoms; Study of Women Across the Nation; study of women in transition – in the years before menopause
- Sex and Gender Differences in Health: establishing a P30 Center for Women's Health Research; the interaction of estrogen/platelets in cardiovascular disease.

Other research focuses on societal issues, such as the health and stress of women leaving welfare, and women who thrive following abuse. Two new initiatives for FY 2004 include low birth weight in minority populations and health promotion in underserved and minority women.

V. RESEARCH PRESENTATION: OVARIAN AGING IN A MULTIETHNIC COHORT OF MID-LIFE WOMEN (Dr. Mary Fran Sowers, University of Michigan)

The Study of Women's Health Across the Nation (SWAN) examines the period between 40 and 60 years of age – the menopausal transition -- an area where scientific data is limited. SWAN is cosponsored by NINR and the National Institute on Aging, and was first funded in September 1994. The project has seven clinical sites, an endocrine laboratory in Michigan and a cardiovascular risk factors laboratory in Kentucky. SWAN is a multi-phase prospective, longitudinal study of the natural history of menopause and the change in ovarian function.

The study began with a survey of 16,063 women between 40 and 55 years of age. About 450-500 women per site were recruited for the longitudinal study. Five ethnic groups were represented, and retention in the study is currently about 80%. Findings so far indicate that:

- Asian women are more likely to be premenopausal at ages 40 to 55.
- African-American women are more likely to have undergone surgical menopause (30%); Asian women least likely (7%). Peak age for surgery was 36 – 40 for African-American women and 41-45 for Caucasian women.
- Vasomotor symptoms were greatest for African-American women (50%), whereas Japanese women had the lowest rate (20%).
- Four of the five groups reached menopause at 51 – 51.5 years of age. Japanese women reached menopause later.
- Women reporting heart disease had reached menopause 2 years earlier than women without the disease.
- Non-smokers reached menopause at 52; smokers at 50 years of age.

Although there were confounding factors, descriptive findings were discussed regarding hormones and body mass index (BMI). The findings included: follicle stimulating hormone (FSH), which communicates between the ovary and the brain, the ovarian product estradiol, linked strongly to menopausal transition, testosterone, and sex hormone binding globulin. Each was shown to vary by certain factors, such as body composition, age, day of cycle, and body composition, but they do not all vary by the same factors or concentrations. Moreover, Chinese had lower mean and less variable estradiol concentrations, whereas Caucasian and African-American women have similar concentrations. The prevalence of hot flashes doubles as FSH increases to about 100. African-Americans have markedly higher levels of FSH and are more likely to have menopausal symptoms, including hot flashes, than other women. Higher concentrations of estradiol indicate less frequent hot flashes – 35% of the women did not have frequent hot flashes. A noticeable increase in estradiol occurs just prior to perimenopause, thus hormonal changes occur well before the one year amenorrhea that precedes post menopause.

Hormonal changes affect bone mineral density (BMD) and osteoporosis. Femoral neck BMD is inversely related to FSH levels but is not related to estradiol levels. Lumbar spine BMD does not appear

to be affected in pre- and early perimenopausal women. The greatest loss in lumbar BMD occurs in late perimenopause. African-American women have the highest levels of BMD. When limiting the analysis to those weighing less than 70 kgs, all had similar BMD except for Caucasians, who have the lowest measures. Thus body size and hormones appear to be driving bone health status.

The natural history of the menopausal transition suggests that the most rapid, significant changes occur prior to the final menstrual period. This is an important finding, since most clinical interventions target later perimenopausal and postmenopausal women. Body size was more important than anticipated; and there were more ethnic similarities than differences, although the hormone differences indicate that the hypothalamic-pituitary-ovarian hormone patterns differ by ethnic group.

Future plans of SWAN call for studies of the genetic components of hormone synthesis during the menopausal transition, including examining enzymes in the metabolic pathways leading to the production of androgens and estradiol.

VI. WORKSHOP ON MOVING THE RESEARCH AGENDA FORWARD FOR CHILDREN WITH CANCER (Council discussant: Dr. Frances Munet-Vilaro, Associate Dean, Administration and Planning, School of Nursing, UMDNJ)

The above interdisciplinary workshop took place on August 5 – 6, 2003, and was convened by NINR in partnership with the NIH Office of Rare Diseases. The group believed that the pediatric research focus should be broadened from the disease to child and family needs, and include diverse ethnic groups. This expansion is important, since new cases are increasing each year and more children and adults are survivors of childhood cancers. The group recommended a research agenda that includes biobehavioral and sociocultural dimensions. They concluded that moving from “cure to life course” is a paradigm shift requiring interdisciplinary training of researchers. They recommended further study of the nature of caring, particularly at the end of life. They also stressed that the voice of the child needs to be heard. Next steps include identifying areas of scientific priority, fostering collaborative interventions, and identifying funding mechanisms. Papers from the workshop will be published in a special edition of the *Journal of Pediatric Oncology Nursing*. The executive summary will be posted on the NINR website.

VII. THE PEER REVIEW PROCESS AT NIH (Dr. Brent Stanfield, Acting Director, Center for Scientific Review)

The Center for Scientific Review (CSR) is the focal point for the initial review of grant applications at the NIH. NIH receives more than 66,000 applications annually. There is a two-level system for review. The first level involves a Scientific Review Group (SRG), which determines initial scientific merit of applications, rates them, and recommends a level of support and duration of award. The second review level involves the IC Advisory Councils, which advise IC staff on funding, program priorities and relevance. Each study section has 12 to 24 members primarily from academia and may review as many as 60 to 100 applications.

When selecting reviewers and establishing a study section, CSR considers expertise, seniority, and diversity with respect to sex, race, ethnicity, geographic distribution, and institutional affiliation. The CSR Reviewer Training Committee has identified best practices that include annotated sample critiques that address and prevent review problems – such as a focus on minor technical issues, a lack of candor about uninteresting ideas; and insufficient detail or unclear language. There is a CSR premeeting

package, and a CSR video “Inside the NIH Grant Review Process” that may be viewed online at <http://www.csr.nih.gov>. To improve the peer review process, CSR is placing copies of applications on CDs, which avoids making paper copies and mailing large packets of materials to reviewers. There is also an online Internet-Assisted Review that facilitates informed discussion among study section members and expedites generation of summary statements after the meeting.

A concern is that, although recruitment of reviewers has been satisfactory over the past 5 years, there has been increased difficulty recruiting clinical reviewers, in part because loss of patient contact time translates into financial loss for the reviewers. The number of applications to be reviewed is another concern. Seventy is about right for a study section workload, but 100 to 120 seriously challenge reviewers. SRGs are observed every 5 years by a subgroup of the CSR Advisory Council. Reports of NINR study sections, part of CSR’s biobehavioral and social science SRGs, will be available on the CSR website.

VIII: REPORT OF THE T32 DIRECTORS MEETING (Council discussant: Dr. Delores Sands)

The T32 Directors meeting was held on December 11-12, 2003 to focus on development of future investigators. NINR currently funds 28 T32s in 18 schools of nursing. T32s attract students who otherwise could not afford their education and represent 21 percent of all nursing doctoral programs in the U.S. They also enhance scholarly productivity and mentorship. In response to NINR’s strategic plan to increase T32 postdoctoral fellows, between 1991 and 2001, postdoctoral T32s have increased by 12 percent. In reviewing the program, it was found that researchers benefited from multiple mentors, and mentors considered their role a rewarding experience, one that included an additional source of research topics, new questions, and new methods. Markers of success included publications, individual research grant awards, progress in research ability, and movement toward more equal relationships.

Recommendations for the future included increased emphasis on inter-institutional collaborations; annual or biannual T32 fellows conferences that involve pre-and post doctoral fellows, their mentors, and T32 Directors and Co-Directors; lengthening the awards, especially for BSN and PhD students; involve postdoctoral fellows in the mentor’s RO1; promote establishment of interdisciplinary research teams of students; provide training for faculty to be mentors, perhaps through a short course by NINR; and consider funding non-nurse postdoctoral fellows.

IX: DISCUSSION OF PROPOSED 2006 AREAS OF OPPORTUNITY (Council discussants)

Each year, NINR staff present to Council for concept clearance areas identified as particularly interesting and important for research. Two Council members presented a review of each area to their fellow members.

Chronic Disease Self-Management: Model Testing in NINR Core Research Centers. (Drs. Margaret Gray and Louis Burgio)

Although a number of strategies and interventions to enhance chronic disease self-management have been developed and tested, translation into practice will need further testing in large, diverse cohorts at multiple sites. A possible setting would be NINR’s nine core nursing research centers. Center supplements could be the mechanism to achieve this goal. These centers already have networks for

research, and trials can be conducted relatively quickly because the infrastructure already exists. Specific interventions will be identified by a NINR's sponsored multidisciplinary "Chronic Disease Self-Management Workshop" in FY 2004. This initiative will help NINR move to Phase 3 and 4 clinical trials. Interventions to be tested could include problem solving and coping skills training. Partner ICs, such as the Office of Behavioral and Social Sciences Research and the National Institute of Dental and Craniofacial Research, could be included in the initiative.

Increasing the Parenting Capacities of Vulnerable Families (Drs. Roseanne Harrigan and Jacqueline Dunbar-Jacob)

This initiative addresses parenting of vulnerable families who are marginalized because of poverty, ethnicity and social status. These families are at high risk for ineffective parenting practices that have a harmful impact on their adolescent children, such as deficient parental monitoring and supervision, lack of parent-child bonding, and negative discipline methods. The initiative targets parents and caregivers of children 10 – 16 years of age to reduce family risk factors and build on protective factors. In discussion, it was suggested that adding the use of multiple sites by partnering with the National Children's Study Group would add statistical power to the initiative. A focus on substance abuse would provide opportunities for funding with other ICs and agencies.

Improving Psychiatric and Neurological Patient Physical Health (Drs. Mary Naylor and Daniel Hanley)

The central purpose of this initiative is research on improving health behaviors and decision making and improving quality of life in patients with non-dementing neurological and psychiatric disorders. Examples include migraine, multiple sclerosis, Parkinson's disease, phobias, stress, and sleep disorders, where subtle changes in cognitive and affective functioning may occur. First a scientific foundation must be built and research topics prioritized. In discussion it was pointed out that "non-dementing disorders" is an unclear term. "Improving healthy behaviors in the psychiatric and neurologic patient" might strengthen the title. Initiative language could also be more inclusive and clear about populations to be studied – for example, children and post-war populations could be included. Research on quality of life measures, which are underdeveloped, should be encouraged.

Following this discussion, Dr. Grady adjourned the open session of the meeting and thanked those in attendance for their participation.

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, US 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 279 research and training grant applications requesting \$5,972,350 in direct costs (Data obtained from IMPACII//QVR on January 15, 2004; includes all primary and dual applications and excludes F31, F32, F33, R03, and L series applications.

OTHER ITEMS FOR CLOSED SESSION: EXECUTIVE SESSION

ADJOURNMENT

The 52nd meeting of the NACNR was adjourned at 1 p.m. on January 28, 2004.

CERTIFICATION

I hereby certify that the foregoing minutes are accurate and complete

Patricia A. Grady, PhD, RN, FAAN
Chair
National Advisory Council for Nursing
Research

Claudette Varricchio, DSN, RN, FAAN
National Institute of Nursing Research

