

**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, 2002

The 47th meeting of the National Advisory Council for Nursing Research (NACNR) was convened on Tuesday, May 21, 2002, at 1:05 p.m., in Room E1/E2, Building 45, National Institutes of Health (NIH), Bethesda, Maryland. The meeting was open to the public until approximately 5:45 p.m. The closed session of the meeting, which included consideration of grant applications, continued the next day, Wednesday, May 22, 2002, at 9:30 a.m. until adjournment at 1:30 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 47th meeting of the NACNR to order, welcoming all Council members, visitors, and staff. She then welcomed and introduced four new Council members, whose tenure began with the current meeting: Dr. Peter Buerhaus, Senior Associate Dean for Research at the School of Nursing at Vanderbilt University; Dr. Louis Burgio, Director of the Applied Gerontology Program and Professor of Clinical Psychology at the University of Alabama at Tuscaloosa; Dr. Stephanie Ferguson, Associate Professor at the George Mason University College of Nursing and Health Science; and Dr. Dolores Sands, Dean of the School of Nursing (SON) at The University of Texas at Austin.

Conflict of Interest and Confidentiality Statement

Dr. Mary Leveck, 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 Council should be referred to NINR staff. In addition, during the closed session of the meeting, Council members with a conflict of interest with respect to any application must excuse themselves from the room and sign a statement attesting to their absence during the discussion of that application. Dr. Leveck also reminded NACNR members of their status as special Federal employees at the council meeting 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 approved the minutes of the January 16–17, 2002, Council meeting by electronic mail. No additional corrections or additions to the January 2002 minutes were suggested during the May Council meeting. The minutes from each NACNR meeting are posted on the NINR Web Site (www.nih.gov/ninr).

Dates for Future Council Meetings

Dates for meetings in 2002 through 2004 have been approved and confirmed. Council members should contact Dr. Grady or Dr. Leveck regarding any conflicts or expected absences.

2002

- September 17–18 (Tuesday-Wednesday)

2003

- January 28–29 (Tuesday-Wednesday)
- May 20–21 (Tuesday-Wednesday)
- September 16–17 (Tuesday-Wednesday)

2004

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

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

The director's report focused on updates related to NIH, budget, Congressional testimony, and NINR.

NIH Updates

Dr. Grady reported on key activities across the campus since the last Council meeting.

On May 2, 2002, the U.S. Senate approved the nomination of Dr. Elias Zerhouni as the 15th NIH Director. Dr. Zerhouni, a radiologist, comes to the NIH from Johns Hopkins University, where he most recently was Executive Vice Dean of the School of Medicine, Chair of the Russell H. Morgan Department of Radiology and Radiological Science, and Martin Donner Professor of Radiology and Professor of Biomedical Engineering. Dr. Zerhouni received his medical degree from the University of Algeria; shortly after receiving his degree, he emigrated to the United States. He has been a member of the National Academy of Sciences' Institute of Medicine since 2000 and has served on NCI's Board of Scientific Advisors since 1998. He has pioneered the development of several advanced technologies used to diagnose and differentiate certain types of tumors, components, and diseases of the cardiovascular system. Among his many accomplishments, Dr. Zerhouni established, with community-based radiologists, a company

specializing in the delivery of outpatient, high-tech imaging services that subsequently was acquired by the American Radiology Services Corporation. He also established an interdisciplinary research group—the Institute of Cell Engineering, to pursue advances within the emerging fields of proteomics and stem cell research. Dr. Zerhouni was sworn in as the new NIH Director on May 20, 2002.

Dr. Ruth Kirschstein, NIH Deputy Director, served as Acting NIH Director for nearly 2 1/2 years, from January 2000 through May 2002, since the departure of the previous permanent director. The NIH community expressed its gratitude to Dr. Kirschstein for continuing to carry the Institute forward during that time.

In other NIH news, Dr. Roderic I. Pettigrew has been named as the first permanent director of the newly established National Institute of Biomedical Imaging and Bioengineering (NIBIB). Dr. Pettigrew is currently a Professor of Radiology, Medicine and Bioengineering at Emory University School of Medicine in Atlanta, Georgia.

Budget Update

Dr. Grady noted that the first few months of each year are particularly active because of annual Congressional hearings at which she and the directors of NIH institutes and centers (ICs) provide testimony in support of the President's proposed budget.

Data were presented for the past two fiscal years. NINR received a 16.6 percent increase in FY 2001 compared to the 14 percent overall NIH increase. In FY 2002, the NINR budget increased 11.9 percent while the NIH budget increased by 13.5 percent. The proposed President's Budget for the upcoming fiscal year (FY 2003) provides an 8.3 percent increase for NINR compared with an overall NIH increase of 15.5 percent. Dr. Grady pointed out that most of the other ICs also are slated to receive approximately 8 percent increases in their budgets, according to the President's proposed plan. The ICs that are proposed to receive larger increases include the National Institute of Allergy and Infectious Diseases (NIAID), for biodefense and bioterrorism research, and the newer ICs, such as the National Center on Minority Health and Health Disparities (NCMHD). The National Cancer Institute (NCI) also is proposed to receive a proportionately larger increase than other ICs in FY 2003.

Approval of the final budget bill for FY 2003 is pending. Dr. Grady noted that budget bills for the prior 2 fiscal years were signed into law between the end of December and middle of January of the fiscal year which had already started on October 1.

The success rate is an important parameter for NINR because we are still developing our nursing research workforce. In the last two years, the success rates of competing RPGs for NINR have been lower than the rates for NIH overall. The approximate success rates in FY 2001 and FY 2002 were or are expected to be 25.7 and 25 percent, respectively, and the projected success rate for FY 2003, using the President's proposed budget, is estimated at 21 percent. The overall success rates for NIH for FY 2001, 2002, and 2003 were or are expected to be 32.1 percent, 31 percent, and 30 percent (estimate), respectively. The lower estimated success rate for FY 2003 is based on the proposed President's budget and the expected number of applications.

Approximately 65-75 percent of an institute's budget is in the commitment base for continuing grants. The increase in funds available for new and competing research equals the increase over the existing appropriation to the NINR plus the turnover from completed grants.

Dr. Grady also provided information on nursing research funding from ICs other than NINR. FY 2001 data from the 50 nursing schools receiving the most NIH funding indicated that investigators at these schools received a total of \$70.6 million from NINR awards. An additional \$41.8 million were received by these nursing schools from other NIH sources. Clearly nurse researchers are being successful at NINR and in other ICs at the NIH.

Congressional Testimony

Dr. Grady's testimony before the second session of the 107th Congress included the House budget hearing on March 13, 2002, a House theme hearing on April 16, and the Senate budget hearing on March 21. The budget hearings consisted of a consolidated NIH appropriations testimony to the committees. In addition, a series of theme hearings focused on various scientific topics. NINR participated in the fourth theme hearing, which was an active, well-attended panel hearing that focused on prevention and health promotion. It was the only hearing televised live on C-SPAN. The testimony may be found at <http://www.nih.gov/ninr/info.html>.

Testimony given to the House and Senate, officially known as the Congressional Justification, describes scientific activities and advances that have been achieved in previous years and that may be expected in future years given the President's proposed budget. Dr. Grady's testimony included a story of discovery, a description of recent science advances, and an outline of areas of research opportunity for the proposed budget increase. The story of discovery presented at this year's NINR testimony focused on caregiving research, which is an area that the NINR is looking to expand. Scientific advances include results of completed studies that have moved science forward with respect to public health impact, translatability, and other factors. Projected areas of opportunity are those discussed during the January Council meeting the year before they are presented to Congress.

One of the four scientific advances presented to Congress this year involved NINR-funded research showing an increased risk of uterine rupture in future pregnancies in women who previously delivered via Cesarean section (Lydon-Rochelle, *New Engl J Med* 2001;435:3-26). The study, which examined records of more than 20,000 women, found that women with a prior C-section were 3.3 times more likely to have a uterine rupture with a future spontaneous delivery than women who had a repeat C-section without labor. Inducing labor without prostaglandins increased the relative risk of uterine rupture to 4.9, whereas inducing labor with prostaglandins increased risk by more than 15-fold. Because C-sections account for approximately 20 percent of all deliveries in the United States, these findings could impact a large number of women. The results of these studies suggest a possible change in practice, which at a minimum would include informing women of the potential outcomes of their decisions.

Another scientific advance presented to Congress involved an intervention for transplant recipients that can reduce re-hospitalizations for immunosuppressant drug reactions and toxicities by almost 50 percent (Hathaway R01: Carter et al., *Prog Transplantation* 2000;10:204-

208). Costs also were reduced by about 20 percent. These findings have important public health implications, particularly in light of the increase in the number of transplants performed each year in this country and the increased longevity of transplant recipients over the past 10 years.

Dr. Grady also described the community-developed and -based Lead Awareness Program in North Philadelphia, which has been successful in increasing awareness of the health problems associated with exposure to lead-based products and reducing lead poisoning among urban youth (Rothman et al., *Holistic Nurs Prac* 1999;14:47-58). The NINR-supported nurse researchers formed a partnership with an academic nursing center and a nearby community of primarily African Americans. The program that was tested included education, awareness, and behavior modification strategies that focused on adults and children. One year after the intervention, lead levels of the intervention group were decreased by 11 percent versus a 3 percent decrease in the control group. The study received the National Environmental Education Achievement Award for its work.

Additional NINR-funded research has identified and successfully implemented interventions that control blood pressure in high-risk young African-American men (Hill, NINR symposium presentation, October 24, 2001). This community-based study found that a three-pronged intervention reduced the increase in blood pressure in the experimental group. After 36 months, 44 percent of the experimental group had their blood pressure under control; in comparison, the NHANES III control rate for patients on treatment is 29 percent. The intervention included education about hypertension among African-American men, increased access to care, and lifestyle changes.

Dr. Grady continued her presentation by describing another study that utilized “talking circles” to promote wellness in American Indian communities in North Dakota (Hodge et al., *J Transcultural Nurs* 2002;13:6-11). Talking circles is a form of storytelling that uses oral tradition in groups to carry prevention messages, in this case, about diabetes prevention and management. The study found that the use of talking circles affected a change in attitude toward diabetes and improved health outcomes (e.g., as indicated through various blood measures and reduced weight gain). The high motivation of several of the participants in the study led them to bring the program back to their communities, where the positive impact of the talking circles has moved well beyond the initial study. Another unanticipated outgrowth of the study is the development of a cookbook of traditional Native American dishes that were modified to be much healthier from a diabetic and cardiovascular standpoint.

NINR Update

Dr. Grady noted three recent scientific meetings sponsored by the NINR whose purpose was to convene experts to provide the Institute with ideas and advice on moving its research programs forward. One of the meetings, held on November 5–6 2001, focused on community-partnered interventions to reduce health disparities. The second meeting, held on March 18–19, 2002, involved uniting resources to address health disparities; this was a followup to the coalition meeting held in June 2000. Another recent meeting, held on May 14–15, 2002, sought to identify opportunities in bioterrorism; Dr. Joan Shaver was the Council representative at this

meeting. The first two meetings were discussed further during the current Council meeting (see Section IV).

Dr. Grady also reported on NINR Web Site usage; data show steady increases in the number of visitors to the site and the number of files sent (i.e., downloaded) over the past 4 years. In March 2002, more than 800,000 files were downloaded, compared with about one-half that amount (i.e., 424,000 files downloaded) just 2 years earlier, in March 2000. Nearly 18,000 people visited the Web site in March 2002, which again is approximately twice the number of visitors in March 2000. More information on Web site usage may be found at <http://www.nih.gov/stats/ninr>.

In other NINR news, video and audio presentations from the **NINR 15th Anniversary Symposium** are available through the NINR home page (www.nih.gov/ninr). The Web site includes additional information about the Symposium and the gala event celebrating NINR's anniversary.

Also newly available through the NINR Web Site are video and audio versions of the Institute's annual course, **Research Training: Preparing Nurse Scientists**. The 5-hour course on grantsmanship and research career development can be used for review or as teaching modules; videos of the guest speakers may be purchased at cost. CEU credits are available for the online Research Training course; the course does not need to be completed at one setting. The course this summer will be held on July 16–19, 2002. Because this course is now on the website, it is thought that this will be the last on-campus offering.

Upcoming NINR events include the **Summer Genetics Institute**, a 12-week, full-time academic course that includes classroom and laboratory instruction and training that will run from June 1–July 26, 2002. A total of 18 students are expected to participate in this course.

Finally, NINR, along with nearly 20 research groups, is a co-sponsor of the **State of the Science Congress** in Washington, DC, to be held on September 26–28, 2002. The focus of this year's meeting is advancing nursing practice excellence.

Dr. Grady announced the appointment of Dr. Martha Hare as Program Director of the NINR's Immune Responses and Oncology research portfolio. Most recently, Dr. Hare served for 10 years as a senior scientist at the Batelle Institute.

III. HUMAN SUBJECTS PROTECTIONS ISSUES: DATA SAFETY AND MONITORING (Dr. Lawrence Friedman, Assistant Director for Bioethics and Clinical Research, National Heart, Lung, and Blood Institute; Council Discussant, Dr. Daniel Hanley)

One of the primary functions of the NIH is to initiate and sponsor large-scale, multi-center clinical trials. Oversight and management of clinical studies initiated by the NIH has always fallen under the purview of the NIH; this oversight includes data and safety monitoring. Historically, however, the NIH has not been involved in data and safety monitoring of extramural research. In recent years, NIH's role and responsibilities in this area have begun to evolve and become more formalized, particularly in connection with investigator-initiated trials.

The NIH has several responsibilities with respect to data and safety monitoring of clinical research. One responsibility includes overseeing peer review of the scientific and safety aspects of a protocol; a drawback of this process, however, is that the peer reviewers may not have an opportunity to review the full or final protocol, in part because institutional review board (IRB) approval is not necessarily required prior to submitting a proposal. The NIH is responsible for assuring that IRB approval is in place and that a data and safety monitoring board (DSMB) is in place, where needed.

Ongoing data and safety monitoring allows investigators and the NIH to address ethical issues that are associated with or that may arise during the conduct of a study; to maintain the scientific integrity of a protocol; and to address medical and public health issues as they arise. A variety of individuals and entities usually are involved in monitoring the data and safety of a study. These include investigator(s), the IRB, the sponsor (e.g., NIH), regulatory bodies (e.g., FDA), and DSMBs or a similar entity established for the purpose of following the conduct and findings of a study.

The types of clinical research for which an NIH data monitoring policy is available include intervention studies (i.e., early phase and late phase clinical trials) and other types of studies (e.g., gene transfer studies). With respect to early phase clinical trials, NIH policy outlined on June 10, 1998, states that, "It is the policy of the NIH that each Institute and Center (IC) should have a system for the appropriate oversight and monitoring of the conduct of clinical trials to ensure the safety of participants and the validity and integrity of the data for all NIH-supported or conducted clinical trials." The policy also notes that, "Monitoring should be commensurate with the risks..." and that there should be "... a continuum from monitoring by the principal investigator or NIH program staff in a small phase I study to the establishment of an independent data and safety monitoring board for a large phase III clinical trial."

Dr. Friedman noted that all NIH-sponsored late phase (phase III) clinical trials require external DSMBs. Policy for early phase clinical trials from June 2000 stated that, "... investigators must submit a monitoring plan for phase I and II clinical trials to the funding Institute and Center (IC) before the trial begins." These monitoring plans must be approved prior to initiation of the study. The elements of the plan and the entity or person doing the monitoring of early phase trials depend on several factors: the nature of the study, potential risks to subjects, and the complexity of the study design and intervention. Although not mandated by the NIH, monitoring by a person or group other than the PI is strongly encouraged for early phase trials. DSMBs in early phase trials are recommended if the study is multicenter, blinded, or involves high-risk interventions, procedures, or vulnerable populations. DSMBs generally are the only group that would be allowed to see unblinded results.

DSMBs are composed of experts in the field who are independent from the study and who are not part of the investigation team. The members of the DSMB should be free of financial and other conflicts of interest associated with the study; they should have no vested interest in the outcome of the study. The DSMB serves as an advisory group to the investigator, IC, or institution that appointed the board.

With respect to data monitoring, NIH staff are responsible for reviewing applications to assess the adequacy of the proposed monitoring plan. In this role, staff may address questions such as:

- ◆ Has a DSMB been formed when necessary? Should the IC or the PI appoint the board? To whom should the board report? These decisions should be guided by the nature of the study and other relevant factors.
- ◆ Does the data monitoring person or group have relevant experience?
- ◆ Is the planned frequency of monitoring adequate for the condition or the intervention?
- ◆ Does the monitoring plan include stopping criteria for adverse events or for benefits?
- ◆ Are there procedures for written communication of recommendations and decisions?
- ◆ Is there a plan for rapid reporting of serious adverse events?

NIH staff also should document the adequacy of a plan before funding a study; receive regular data monitoring reports; receive reports of serious, unexpected events and actions taken in response to such events; and receive reports of any actions taken by the PI, IRB, and the DSMB. NIH policy dated June 11, 1999, states the following: “. . . all multi-site trials with data safety monitoring boards are expected to forward summary reports of adverse events to each IRB involved in the study.” NIH staff are to ensure that a summary of the DSMB’s recommendations and adverse event reports are communicated to the IRBs. In most cases, the speed of the communications will depend on the nature of the recommendations.

With respect to other types of clinical research, the PI and local institution traditionally have been responsible for the conduct of research and for ensuring subject safety. A role for the NIH or other organization or agency in this process is not clearly defined at this point; however, this issue is being examined.

IV. REPORTS ON RECENT NINR WORKSHOPS

Community-Partnered Interventions to Reduce Health Disparities (Dr. Toni Tripp-Reimer, University of Iowa)

Dr. Tripp-Reimer provided highlights of the NINR- and NCMHD-sponsored meeting, “Community Partnered Interventions in Nursing Research to Reduce Health Disparities,” held November 5–6, 2001. The meeting co-chairs were Dr. Janice Phillips, Dr. Patricia Grady, and Dr. Tripp-Reimer. The 20 invited participants included scientists, practitioners, and community leaders with expertise in community-based partnerships.

The purposes of the meeting were to assess the state of the science of community-partnered research activities in addressing health disparities; identify components of effective interventions; and recommend future directions for nursing research in this area. The rationale for the conference was based on the growing recognition of the increasing disparities in the health of Anglo and minority populations, the inadequacy of the current research paradigm to address these issues, and the need for increased research.

Dr. Tripp-Reimer noted that the first day of the meeting focused on the state of the science in community-partnered research. Nurse scientists described models of successful community-

partnered interventions, the costs constraints of these projects, and lessons learned. Community leaders also provided strong recommendations to scientists on how best to proceed in future community-based research endeavors. The identified requirements for success included community involvement in all phases of the research, beginning with the planning phase; demonstrated long-term commitment, investment, and involvement from the investigator and the research team; clear reciprocity demonstrating tangible benefits to the community in funding, services, or training; sharing of power between the scientists and the community; plans for sustainability of the programs, interventions, or services from the start of the project; willingness or ability to identify areas of tension with standard scientific models; and demonstration of investigator competence.

On day 2 of the meeting, participants joined working groups to formulate sets of recommendations under three areas: research topics, research methods, and training. Recommendations for research topics included taking a broader focus rather than a disease-specific approach to studying health promotion and chronic illness; emphasizing appropriate environmental and cultural considerations; using culturally anchored versus Eurocentric interventions; investigating innovative service delivery models; studying variations in disparities across groups; integrating culture into all phases of research; and evaluating the interplay of culture, socioeconomic status (SES), and racism.

Recommendations for the conduct of research included increased support for formative and preliminary research, which was considered significant to community-based studies in which instrument development and refinement generally are not part of the study design. Other recommendations discussed included consideration of alternatives to randomized clinical trials; increased efforts by NINR to partner with groups such as private foundations, the Centers for Disease Control and Prevention (CDC), and the Agency for Healthcare Research and Quality (AHRQ) for joint initiatives; and requiring evidence of or plans for partnerships and sustainability in calls for proposals for community-based.

Training recommendations included increasing support for training and technical assistance in the areas of cultural competence, community-partnered research, and training of and with community partners; increasing the number of minority nurse scientists and promoting fast-track B.S.N.-Ph.D. programs; and partnering with minority organizations such as minority-serving institutions and minority nursing groups.

An Executive Summary of the meeting is on the NINR Web Site at <http://www.nih.gov/ninr/news-info/meetings.html>.

National Coalition of Ethnic Minority Nurse Associations Workshop (Dr. Betty Smith Williams, Council Member, Professor Emerita, California State University, Long Beach)

NCEMNA joined NINR, National Center for Minority Health and Health Disparities (NCMHD), National Institute of General Medical Sciences (NIGMS), and the University of Texas at Austin School of Nursing Core Center in sponsoring a 2-day workshop titled, “Uniting Resources to Address Health Disparities,” on March 18–19, 2002. Thirty participants from the five ethnic minority nurses associations that make up NCEMNA, other experts, and NIH representatives

attended the workshop. The five associations include the National Association of Hispanic Nurses, the Asian American Pacific Islander Nurses Association, the National Black Nurses Association, the National Alaska Native American Nurses Association, and the Philippine Nurses Association of America. Dr. Smith Williams noted that NCEMNA, a not-for-profit incorporated 501(3)(c) organization, is interested as an entity and through its individual members in pursuing funding opportunities.

The main objectives of NCEMNA are to increase the number of minority researchers in the United States, to increase the amount of research conducted relative to ethnic minorities, and to increase the ability of other researchers interested in working with ethnic minorities to have appropriate knowledge and cultural awareness. The previous NCEMNA meeting, which was sponsored by NCEMNA, NINR, and NCMHD, was held in June 2000. Five state-of-the-art nursing research commentaries corresponding to the five ethnic nursing associations at the meeting in 2000 were published in *Nursing Outlook*.

On the first day of the workshop, the presidents of each of the nursing associations summarized their organizations' research agendas and strategic plans. The five associations together represent approximately 350,000 nurses nationwide in 150 community-based chapters in 30 states with a combined 60-plus years of experience in conference planning and evaluation. NCEMNA offers a national mechanism for communicating with ethnic nurses via newsletters, e-mail, journals, conferences, and chapter meetings; and nurse members with experiential, theoretical, and practical knowledge of their respective ethnic groups. NCEMNA also offers linkages with consumer organizations in their respective communities and advocacy programs for each represented ethnic group. NCEMNA therefore comprises an extensive and diverse network of minority nurse researchers and supporting resources. Some of the research needs identified during the meeting included the funding of programs in education and career development to build the pipeline of minority nurse researchers, advocacy, and community education and outreach.

Following the presentations, discussion groups convened to identify and discuss funding opportunities. The small group discussions generated an array of ideas and three major recommendations, including:

- ◆ Develop curricula for culturally competent nursing practice.
- ◆ Develop strategic conferences to increase numbers of ethnic minority researchers.
- ◆ Develop culturally based minority nurse research mentoring/career development programs.

V. UPDATE ON ACTIVITIES OF THE NINR OFFICE OF SCIENCE POLICY AND PUBLIC LIAISON (Mr. Daniel J. O'Neal, III, Chief, OSPPL, NINR)

The work of the NINR Office of Science Policy and Public Liaison (OSPPL) focuses on NINR communications; public affairs; planning and evaluation activities; and briefings, reports, and other opportunities as they arise. The OSPPL staff includes Mr. Daniel O'Neal, Chief; Ms. Linda Cook, Public Affairs/Legislative Officer; Dr. Ann Knebel and Ms. Genevieve deAlmeida-

Morris, Program Analysts; Mr. Ray Bingham and Mr. Mark Waldo, Technical Writers; and Mr. Walter Reid, Secretary.

Among its many responsibilities, OSPPL monitors short- and long-term science policy issues and activities. For example, OSPPL staff track activities in progress and their products in an array of Federal administration offices, such as the President's Office of Science and Technology and the Office of Management and Budget (OMB). It also monitors and analyzes activities to and from science- and health-related Congressional committees and relevant policy groups, such as the Institute of Medicine (IOM), RAND, and the Brookings Institute. OSPPL also monitors important global health and other science and technology issues in terms of priority setting, resource allocation, and impact.

Activities focused on positioning NINR for the future include developing an array of resources for NINR supported research findings; disseminating relevant findings; assessing the contributions of findings to science and practice; and coordinating special events. Specifically, OSPPL seeks to access all NINR-funded findings and publications using automated journal searches of databases such as PubMed, CINHALL, and Web of Science. Articles are catalogued by investigator and by area of science. Staff then sort through the findings for articles that may be of media interest or that appear to target certain audiences, including consumers. Findings are briefly summarized; these science capsules are then shared with the *American Journal of Nursing*, *Nursing Spectrum*, and *Medscape-Nursing*, an online journal with more than 100,000 subscribers, mostly advanced practice nurses. OSPPL also has begun to circulate the capsules to specialty nursing groups. Other OSSPL products include the *FOCUS* series and "Making a Difference," which describes example studies of NINR-supported investigators.

Another OSPPL activity involves disseminating findings through press releases, which are developed in conjunction with the investigators and their home institutions and can be found on the NIH portion of the American Association for the Advancement of Science (AAAS) Web Site known as Eurekalert. Mr. O'Neal commented that many of the recent NINR press releases posted on Eurekalert have gotten 800 to 1,000 visits each. OSPPL also works closely with media contacts at various nursing research publications, such as *Nursing Research* and *Research in Nursing and Health*, to identify NINR-funded research that may be especially newsworthy.

OSPPL also is involved in the Johnson and Johnson Campaign for Nursing's Future designed to enhance the image of nursing and nursing research. OSPPL is exploring the development of a photo essay exhibit of nurse investigators and their clients that could be used in conjunction with the campaign at conferences, as a traveling exhibit, or as an online event. The exhibit may be useful in attracting students and nurses to the field of nursing research.

OSPPL efforts also have been targeted at encouraging investigators to develop or improve relationships with the media. In 1998, NINR and other nursing organizations co-sponsored a workshop on how investigators can integrate positive images and findings related to nursing and nursing research into the media. A similar workshop was held at the last State of the Science conference; another media workshop is planned for this year's State of the Science conference in September. On campus, this interactive media training is provided at <http://videocast.nih.gov> by going to the Past Events and linking to "Making Today's Research Tomorrow's Headlines and

Success Stories from the Field,” Tuesday, September 19, 2000. OSPPL staff also have focused on expanding internal public affairs networks within the NIH community by working with information officers; public liaison officers; legislative, planning, and bioethics offices; science education programs; and international or visiting nurse researchers.

Evaluation activities within OSPPL focus primarily on GPRA (Government Performance Results Act), which emphasizes streamlining and accountability within government offices via strategic plans and goal setting. OSPPL helps facilitate NINR’s evaluation reports in addition to participating in collaborative evaluations across campus. A related activity being undertaken by OSPPL is the creation of a comprehensive database of research publications dating from NINR’s founding as a Center to the present.

Among the many NINR special events coordinated and promoted by OSPPL across campus have been end-of-life research meetings, including scientific workshops as well as an open forum for consumers; the National Nurses Week, which was held in conjunction with the Clinical Center; and the October 2001 NINR’s 15th Anniversary Symposium. These activities have helped raise the visibility of NINR and heighten the Institute’s role. NINR also has collaborated with AACN and AAHC on a series of six educational tapes focusing on end-of-life research and care. Recent Capitol Hill events in which NINR participated included the dedication of the Safra Lodge at the NIH, Hispanic Nurses Day on Capitol Hill, and the NINR testimonies to Congress.

Future OSPPL activities include continued and further evaluation of NINR products; developing new avenues for outreach to a range of nursing groups; compiling findings for journals of specialty nursing; and developing health literacy products, particularly Web-based products.

VI. REPORT OF THE NINR CENTERS MEETING (Council discussants, Dr. Margaret Grey, Dr. Jacqueline Dunbar-Jacob)

To develop the nursing research infrastructure, NINR uses two different centers mechanisms to support university-based Research Centers. The P30 Core Centers program currently supports nine interdisciplinary, collaborative nursing research programs at established research institutions. The P20 Exploratory Centers target nursing schools in the process of developing their research programs, helping to expand beginning research efforts, and helping to centralize resources. The NINR currently supports nine P20 Centers.

Drs. Grey and Dunbar-Jacob provided a brief background of the Centers Program and highlighted items of interest and concern from the May 20, 2002 P20/P30 Center Directors meeting. Principal Investigators of each of the 18 centers met to discuss and evaluate the Centers Program, identify challenges and successes of the centers, and describe common themes across the centers. Dr. Dunbar-Jacob noted that each center has a broad topic or area of research focus, with very little overlap across the 18 centers. The duration of the centers varies from relatively new P20s with about 1 year of funding to P30s in either their first or second cycle of 5-year funding or in their second cycle of 5-year funding following a P50. A listing of all the centers may be found at <http://www.nih.gov/ninr/research/dea.html>. Examples of research areas include vulnerable populations, chronic disorders, symptom management, biobehavioral research, health promotion, injury mechanisms, and outcomes research.

Dr. Grey outlined the stated goals of the P20s and the P30s. The goals of the P20 Exploratory Centers are to promote the development of infrastructure, to centralize resources and facilities in a specific scientific area, to enhance the research productivity of investigators, and to foster interdisciplinary research. Goals of the P30 Core Centers are to promote programs of research related to NINR program goals, to foster interdisciplinary research, and to provide a mechanism for the delivery of research results into clinical practice.

The PIs attending the P20/P30 Center Directors Meeting spent much of their time on the following questions: Are the centers meeting the stated objectives and goals? and What have the centers accomplished with their funding that they would not have been able to do otherwise?

Dr. Grey commented that the PIs were in agreement that one of the major contributions of the NINR Centers funding has been the ability to transition to “big science.” Most of the centers initially conducted relatively small, exploratory studies and then moved to more sophisticated studies (e.g., intervention studies) that seek to understand the complex nature of human problems facing nurses. The centers were able to make this transition by bringing in new staff, by networking, by building a critical mass of investigators working in a specific area, by building interdisciplinary synergism from across their institutions, and by developing crosscutting areas of research for the conduct of multiple studies to address a range of issues associated with a particular research theme.

The PIs identified a range of benefits of the Centers Program, including:

- ◆ Defining new areas of nursing research that have filtered into other areas in the schools, such as the curriculum. Several of the P30s and a few of the P20s reported this benefit.
- ◆ Recruiting new faculty within a particular research area, allowing investigators and faculty to identify strategic needs, and recruiting pre- and post-docs.
- ◆ Using the Centers as a research dissemination vehicle. The Centers also allow for the development of new evidence-based practice models.
- ◆ Bringing the school of nursing into the “larger” campus or university. The existence of the Centers helps bridge gaps between disciplines, departments, and faculty, and gives faculty members a vehicle to take risks that previously might not have been feasible.
- ◆ Strengthening and expanding community linkages, especially among the P30s.
- ◆ Leveraging more research funding from the university as a result of establishing a Center on campus.

The major contribution of the Centers is the ability to build synergism among investigators that otherwise would not have been brought together. This outcome of the Centers Program, in turn, is facilitating the advancement of nursing research.

Dr. Dunbar-Jacob described the challenges identified by the Center PIs. These challenges are shared across the Centers but may vary depending on the development stage of an individual center.

- ◆ Devising adequate mentorship strategies and establishing a group of core mentors. For P20s, the key issue was mentoring for the developing investigators; for the P30s, mentoring for mid-career researchers and sustained leadership were key issues.
- ◆ Accruing and maintaining adequate resources remains a challenge for the centers, even though the centers are receiving NINR and other support.
- ◆ Allowing adequate time for the Centers to achieve the stated goals. For P20s in particular, the 3-year lifespan may not be sufficient to develop the research base and infrastructure needed to transition to a P30. For P30s, this challenge is related more to the expansion and depth of the science.
- ◆ Sustaining leadership and a core faculty within the Centers.

Questions for the Council

Dr. Grey posed several questions to the Council members as the presentation was opened for general discussion: Is the Centers Program meeting its objectives? Are the Centers adequately covering key areas of science that are of interest to NINR? Are the Centers meeting their own scientific objectives? What should be the future for the Centers Programs?

Council members and others in attendance provided a great deal of feedback in response to these questions, in addition to having further questions about the program.

- ◆ The Centers Program overall appears to be a solid model, especially for research-intensive institutions. The Centers facilitate and foster the advancement of research, the recruitment of faculty, interdisciplinary networking and partnerships, the ability to secure additional funding, and the development of nursing curriculum. Center PIs acknowledged that this program has allowed research programs, faculty, and students to prosper in many ways; the universities at-large and non-nursing faculty also have benefited from the Centers Program.
- ◆ Regarding the awards made to the centers, the Centers Program grants are relatively small, fixed-rate grants. Young investigators can use pilot funds to P20s and P30s for exploratory research. The Centers Program accounts for approximately 5 percent of the total NINR budget, which is proportionately lower than the amount allocated by many other ICs. One suggestion was that NINR consider increasing the funding to this program, whose return is significant relative to the investment.
- ◆ A critical issue to the Centers, as well as to the nursing community, is the “graying” of the nursing research faculty and deans, which calls into question the sustainability of the Centers. This issue also underscores the need to focus on mentoring at all levels, including mentoring for leadership roles for the existing and for future centers. At the other end of the pipeline is the need to recruit young talented students at all levels of undergraduate, graduate, and postgraduate education and training and encourage them along a trajectory toward an academic research career. Anecdotal evidence suggests that students at schools with B.S.-M.S.-Ph.D. tracks and an NINR-funded Center move more quickly to advanced degree programs, including the Ph.D., than students at other schools because of the opportunities to participate in research activities offered through the

centers. Predoctoral students also appear to be more readily recruited to the former institutions.

- ◆ Council members discussed the importance of capturing and evaluating the array of outcomes and impacts of the Centers Programs. This issue, including which data to collect and how to evaluate the data collected, was discussed at length during the Center Directors Meeting on May 20, 2002. The centers currently collect a range of data, such as the number of pilot studies that turn into R01s or other major funding, how many publications were generated, and how many presentations have been made. The PIs agreed that they need to take the evaluation further by determining the larger impact of the centers; for example, what is the impact of a center's research, or of the research performed collectively by all the centers on an area of science or on public health. Identification of broader evaluation strategies is the next step in this process. Dr. Naylor stated that the Hartford Foundation has researched the paradigm of synergy across its Centers for Gerontological Nursing Excellence; the foundation also has evaluated the impact of its centers' research on several outcomes, including policy setting and the dissemination and incorporation of ideas and research findings among scientists and consumers. Positive as well as neutral and negative outcomes were assessed. The Council and NINR may wish to review this information further.
- ◆ Another task for the centers to pursue is to increase synergy among the centers. For example, some of the centers are addressing different aspects of similar problems; thus, collaborations among center researchers would facilitate the advancement of certain research activities and areas and reduce redundancy.

Several issues surrounding the future of the Centers Program were discussed.

- ◆ The length of the P20s (i.e., 3 years, currently nonrenewable) was debated as to whether it allows sufficient time for a center to meet the goals as stated and then compete for a P30, especially with well-established P30s. Council members recognized that the P20s will be at different stages of development and that not all will be ready to compete for a P30 at the end of the 3-year period. On the other hand, the P20 grant is designed to serve as a springboard or support to begin to develop the center infrastructure and to leverage additional funding and resources; it is not designed to be an exclusive funding mechanism. One possible solution to this issue is for NINR to consider a one-time renewal of the P20 mechanism. Another suggestion is to consider establishing different criteria for institutions competing for a P30 grant; that is, established P30s would have to meet an additional set of criteria. Some Council members supported maintaining the P20 and P30 mechanisms as is.
- ◆ Other modifications to the current Centers Program were suggested. The idea of "sunsetting" P30s was discussed, as was the offering of other mechanisms, such as the P50. Expanding the Centers Programs funding, or shifting some of the P30 funds to the P20 grants, was suggested. Another suggestion was to have NINR relax the requirement of allowing only one center (i.e., either a P20 or a P30, but not both) per academic institution.
- ◆ It is important that planning occur so that opportunities are available for new schools to compete for the developmental centers.

Council members agreed that the discussion and evaluation of these issues and the Centers Program is ongoing. Dr. Grady noted that NINR will consider all of the Council's points.

At the end of 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 108 research grant applications requesting \$88,511.838 in total costs. The council recommended 74 applications requesting \$67,077,445 in total costs.

OTHER ITEMS FOR CLOSED SESSION: EXECUTIVE SESSION

The closed session concluded with a discussion of personnel and proprietary items.

ADJOURNMENT

The 47th meeting of the NACNR was adjourned at 1:30 p.m. on May 22, 2002.

CERTIFICATION

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

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

Mary Leveck, Ph.D., R.N.
Executive Secretary
National Advisory Council for Nursing
Research

MEMBERS PRESENT

Dr. Patricia A. Grady, Chair
Dr. Mary Leveck, Executive Secretary
Dr. Peter Buerhaus
Dr. Louis Burgio
Dr. Margarethe Cammermeyer
Dr. Jacqueline Dunbar-Jacob
Dr. Stephanie Ferguson
Dr. Margaret Grey
Dr. David Hanley
Dr. Roseanne Harrigan
Dr. Mary Naylor
Dr. Carmen Portillo
Dr. Dorothy Powell
Dr. Dolores Sands
Dr. Joan Shaver
Dr. David Ward
Dr. Betty Smith Williams
Dr. Paulette Cournoyer, *Ex Officio*
Dr. Catherine Schempp (COL), *Ex Officio*

MEMBERS OF THE PUBLIC PRESENT

Dr. Ruth Anderson, Duke University
Mr. Keren Bener, Johns Hopkins School of Nursing
Dr. Doris Bloch, Windows on Nursing
Mr. Carolyn Branson, Analytical Sciences, Inc.
Ms. Kathryn Chouaf, Johns Hopkins School of Nursing
Dr. Elizabeth Clipp, Duke University
Ms. Mary Cerny, The Scientific Consulting Group, Inc.
Dr. Judith Erlen, University of Pittsburgh School of Nursing
Dr. Eileen Fowles, Illinois State University
Dr. Deborah Koniak Griffin, UCLA School of Nursing
Dr. Eleanor McConnell, Duke University School of Nursing
Dr. Adey Nyamathi, UCLA School of Nursing
Ms. Kathy Parker, Emory University
Dr. Kenneth Phillips, University of South Carolina
Dr. Linda Pugh, Johns Hopkins School of Nursing
Dr. Phyllis Sharps, Johns Hopkins School of Nursing
Dr. Joyce Stechmiller, University of Florida School of Nursing
Dr. Toni Tripp-Reimer, University of Iowa
Dr. Grace Willard, Westat, Rockville, Maryland
Dr. Carolyn Yveta, University of Florida

FEDERAL EMPLOYEES PRESENT

Dr. Nell Armstrong, NINR/NIH
Mr. Ray Bingham, NINR/NIH
Dr. Yvonne Bryan, NINR/NIH
Ms. Linda Cook, NINR/NIH
Ms. Janet Craigie, NHLBI/NIH
Dr. Susan Dorsey, NCI/NINR/NIH
Ms. Diane Drew, NINR/NIH
Ms. Marianne Duffy, NICHD/NIH
Ms. Robin Gruber, NINR/NIH
Dr. Martha Hare, NINR/NIH
Mr. Lawrence Haller, NINR/NIH
Dr. Karin Helmers, NINR/NIH
Dr. Carole Hudgings, NINR/NIH
Ms. Kay Johnson, NINR/NIH
Dr. Ann Knebel, NINR/NIH
Ms. Cindy McDermott, NINR/NIH
Dr. Gertrude McFarland, CSR/NIH
Ms. Tara Mowery, NINR/NIH
Mr. Daniel O'Neal, NINR/NIH
Dr. Janice Phillips, NINR/NIH
Mr. Eddie Rivera, NINR/NIH
Ms. Siobhan Robinson, NINR/NIH
Ms. Rachel Schiffman, NIDA/NIH
Dr. Hilary Sigmon, NINR/NIH
Ms. Arlene Simmons, NINR/NIH
Dr. Claudette Varricchio, NINR/NIH
Mr. Mark Waldo, NINR/NIH
Ms. Kimberly Witherspoon, NINR/NIH
Ms. Sally York, NINR/NIH