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 28-29, 2003

The 49th meeting of the National Advisory Council for Nursing Research (NACNR) was convened on Tuesday, January 28, 2003, at 1:00 p.m. in Conference Room 10, Building 31, National Institutes of Health (NIH), Bethesda, Maryland. The first day of the meeting was adjourned at approximately 5:10 p.m. The open session of the meeting continued the next day, Wednesday, January 29, 2003, at 8:30 a.m. and continued until 10:45 a.m. on the same day. The closed session of the meeting, which included consideration of grant applications, continued the same day until adjournment at 12:50 p.m. 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 49th meeting of the NACNR to order, welcoming all Council members, visitors, and staff.

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 the 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 while serving 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 the Council notebooks.

Minutes of Previous Meeting

A motion to approve the minutes of the September 17-18, 2002 Council meeting without changes was proposed and seconded. The Council voted unanimously to approve the motion. The minutes of each NACNR meeting are posted on the NINR Web Site (www.nih.gov/ninr).

Dates for Future Council Meetings

Dates for meetings in 2003 and 2004 have been approved and confirmed. Council members should contact Dr. Grady or Dr. Leveck regarding any conflicts or expected absences.

2003

- 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 of activities related to the budget, NIH, and NINR.

Budget Updates

Dr. Grady reviewed the recent history of NINR and NIH budgets. In fiscal year (FY) 2001, the NINR budget was increased by 16.6 percent over the prior year's budget, bringing the Insitute's total funding to more than \$100 million for the first time. This increase compared favorably with the overall NIH budget increase of 14 percent. NINR's FY 2002 budget was increased by 14.5 percent and totalled approximately \$120 million; the overall NIH budget was increased by 14.7 percent for the same period. The current President's Budget for the NINR for FY 2003 includes a 7.9 percent increase, in contrast with a proposed 17 percent increase for the NIH overall. Under this proposal, the NINR budget for FY 2003 is approximately \$129 million. Dr. Grady noted that after accounting for funding for biodefense, the estimated 7.9 percent increase for the NINR is commensurate with proposed increases for most of the other Institutes and Centers (ICs) across the NIH. Final approval of the President's NIH budget for FY 2003 is still pending, and the Federal government is operating on a Continuing Resolution approved through Feburary 4. In providing points of reference, Dr. Grady noted that the FY 2001 budget was approved on December 21, 2000, and that the FY 2002 budget was signed into law on January 10, 2002.

The largest proportion of the NINR budget, approximately 75 percent in FY 2002, supports extramural research project grants (RPGs). Operating funds (i.e., grants management and review, workshops, and meetings) account for about 6 percent of the NINR budget; the R&D area and the intramural program each constitute 1 percent; training accounts for about 8 percent, which is roughly twice the NIH average; the Centers program consistutes about 6 percent; and other research activities (e.g., career awards, et cetera) represents 3 percent. Dr. Grady noted that with modest budget increases, the proportions allocated to each activity, program, or function are expected to remain relatively constant.

The training profile shows a steady increase in the total number of full-time training positions, from 219 in FY 2000 to 274 in FY 2002. This includes postdoctoral awards (T32, F32/33) and predoctoral awards (F31, T32). Annual stipends also have increased steadily since 1999, and a more steady-state for funding of training awards is anticipated for the near future, given budget considerations and the overall stipend increases.

Dr. Grady next discussed RPG success rates for the NINR and the NIH as a whole. The overall NINR success rate for competing applications for FY 2003 is projected to be approximately 21 percent, based on the President's Budget. The projected success rate for NIH overall is 30 percent. In the last few years, the success rates of competing RPGs for the NINR generally have been slightly lower than the rates for NIH overall. An exception to this general pattern was for FY 1999, when the NINR success rate was 14 percent, compared with an overall success rate of 32.4 percent for NIH. This much lower rate was due in part to a marked increase in the number of applications that was not accompanied by a commensurate increase in research funding. In contrast, in FY 2000, the NINR received the largest appropriation increase among all the ICs and had its highest success rate—31.6 percent—in several years; this rate also was slightly above the NIH mean. The RPG success rate for FY 2001 was 25.7 percent, and the success rate for FY 2002 is expected to be 25.4 percent; these rates compare with overall NIH rates of 32.1 percent and 31.3 percent for FY 2001 and FY 2002, respectively. Success rates computed by the NIH include new, competing continuation, and competing supplemental awards; a rate of approximately 30 percent is considered meritorious science by the NIH. Dr. Grady noted that the number of NINR applications has increased steadily in the last few years and has not fluctuated as it had in prior years; the growing cadre of committed nurse researchers is likely contributing to the steady growth of submissions.

Noncompeting applications comprise the bulk of awards, with awards being in place for an average of 4 years, as legislatively determined. Although the average cost for all research grants (i.e., all RPGs), including R03s, R01s, R15s, and others, has increased for the NINR and NIH overall, the mean cost of all NINR RPG grants (\$341,358 for FY 2002) remains below that of NIH (\$364,712 for FY2002). The average cost of an NINR-funded R01 is consistently higher (\$349,766 in FY 2001 and \$359,248 in FY 2002) than NIH-funded R01s overall (\$309,196 in FY 2001 and \$325,924 in FY 2002).

Dr. Grady noted that the maximum direct cost of NIH-wide AREA grants, which many new investigators receive, is now \$150,000, up from the previous maximum of \$100,000. Terms of eligibility for AREA awards also have changed for FY 2003 as follows: all schools/departments are eligible except those who received NIH funding totalling \$3 million or more per year in each of 4 or more of the last 7 years. Dr. Grady noted that all but six schools of nursing are eligible to be supported through the AREA grant mechanism (University of California- San Francisco, University of Illinois – Chicago, University of Michigan, University of North Carolina- Chapel Hill, University of Pennsylvania, and University of Washington).

In response to interest by the Council, Dr. Grady highlighted features of the Research Supplements for Underrepresented Minority (RSUM) program, which the NIH and NINR uses to stimulate research and to attract new individuals to the field. Eligible applicants, ranging from high school students through faculty members, work with funded investigators, and the NINR provides supplemental funding for the minority individual's involvement. In terms of percent of budget devoted to this mechanism, the NINR tops all ICs by allotting approximately 1 percent of its eligible funds for RSUMs. Dr. Grady noted that the NINR is tracking individuals who participate in the program; initial findings suggest that the program is successful in recruiting and retaining individuals into research careers.

NIH Updates

Dr. Nora Volkow has been named new Director of the National Insitute on Drug Abuse (NIDA). Dr. Volkow, a psychiatrist, has expertise in imaging and molecular biology and the science of drug abuse. Most recently, she served as Associate Director at Brookhaven National Laboratory in Stonybrook, Long Island, New York. Dr. Volkow's appointment as NIDA Director will begin on or around April 15th.

NINR Updates and Outreach

Dr. Grady announced the retirement of three Council members: Dr. Margarethe Cammermeyer, Dr. Carmen Portillo, and Dr. Betty Smith Williams. A fourth member, Dr. Stephanie Ferguson, is departing from the Council to take a position at the World Health Organization. Dr. Grady thanked the members for their time, commitment, and contributions to NACNR.

Dr. Grady then reviewed the areas of research opportunity for the current fiscal year, which the Council helped to craft 2 years ago. Program Announcements (PAs) and/or Requests for Applications (RFAs) have been released for all of these areas of opportunity:

- <u>Chronic Illnesses or Conditions</u>
 - Long-term care recipients: Quality of life and quality of care research
 - Informal caregiving research for chronic conditions
 - Improving quality of life in mobility disorders
- Behavioral Changes and Interventions
 - Enhancing adolescent health promotion across multiple high-risk behaviors
 - Community-partnered interventions to reduce health disparities
- <u>Responding to Compelling Public Health Concerns</u>
 - Research to improve care for dying children and their families
 - NINR small grant research program (R03)
 - Research on clinical decision making

In other Institute news, the NINR in conjunction with NCMHD recently announced the funding of 17 P20 Partnership Centers Awards that partner a research-intensive school of nursing with a minority insitution. These awards serve as a follow-up to the pilot partnership program. The partnered institutions include Johns Hopkins University–North Carolina A&T State University, University of California at San Francisco–University of Puerto Rico, University of Michigan– University of Texas Health Science Center at San Antonio, University of North Carolina at Chapel Hill–North Carolina Central University and Winston-Salem State University, University of Pennsylvania–Hampton Unviersity, University of Texas at Austin–New Mexico State University, Las Cruces, University of Washington–University of Hawai'i at Manoa, and Yale University–Howard University.

Tracking the publication and dissemination of information from NINR-funded research studies to the larger nursing community and to the public is a key goal of the Institute, as indicated in its 5-Year Strategic Plan. In the past 3 years, the number of articles published by NINR grantees has approximately doubled. Papers have appeared in a variety of peer-reviewed journals.

Another activity in which the NINR has participated is the "End of Life Care" videotape series that incorporates nursing research, education, and care in the area of end of life. The six-tape series has aired three times to 1,640 hospitals, and about 250 sets and 100 single tapes have been sold. The series also is available to hospice providers. Three of the six tapes are among the finalists in the Media Festival, Joint Conference of the American Society on Aging and the National Conference on Aging, to be held on March 13–16, 2003. The NINR collaborated with the American Association of Academic Health Centers and the American Association of Colleges of Nursing (AACN) in developing this series.

In-house updates include the appointment of Dr. Jeffrey Chernak to the Office of Review and the departure of Dr. Karen Helmers. Dr. Chernak's background is in the neuroscience of aging and molecular biology; he comes to the NINR from the NIA. Dr. Helmers, who managed NINR's neurosensory portfolio, has transferred to the Center for Scientific Review (CSR), where she will be the Scientific Review Administrator for a newly established nursing study section.

Dr. Grady congratulated Council members Dr. Dorothy Powell, Associate Dean, College of Pharmacy, Nursing, and Allied Health Sciences, Howard University, and Dr. Betty Smith Williams, founding President, National Coalition of Ethnic Minority Nurse Assocations, both of whom are recognized in the 2003 African American History Calendar from the Aetna Corporation. In other honors, Dr. Grady received the first Centennial Achievement Medal for distinguished service from the Georgetown University School of Nursing and Health Studies. The award recognizes scholars and leaders in the field.

Upcoming NINR events include the Summer Genetics Institute (June 1–July 25, 2003), and the Symposim, "Linking the Double Helix With Health: Genetics in Nursing Research" (April 13, 2003). Online applications for the Summer Genetics Institute will be received through March 3, 2003, and a total of 18 students will be accepted. Additional information about both events may be obtained from Dr. Mindy Tinkle. NINR, together with more than 20 groups and coalitions, served as a co-sponsor for the State of the Science Congress held in September 2002, in Washington, DC, which drew more than 700 attendees. In conjunction with this Congress, the NINR supported a workshop on media training for investigators. The next State of the Science Congress will be held in September 2004. The Friends of NINR (FNINR) sponsored the annual Nightingala event, also in September, which was attended by more than 1,000 individuals.

Since the last Council meeting, NINR convened a Working Group on Ethics in End of Life Research, which was held on September 12–13, 2002. A summary of the meeting will be available soon on the NINR website.

Additional events and activities will build on the NIH "Roadmap" meetings that focused on developing NIH's vision for biomedical discovery. Themes emerged, including new pathways to discovery, multidisciplinary research teams of the future, and re-engineering the clinical research enterprise.

NINR convened five working groups as a followup to Council discussions to discuss research themes for the future. Multidisciplinary teams totalling approximately 75 to 80 scientists attended these meetings. Feedback is still being gathered, and areas to pursue are being refined and reframed. Some of the broad areas of interest that were explored include, Changing Lifestyle Behaviors for Better Health, Managing the Effects of Chronic Illness to Improve Quality of Life, Identifying Effective Strategies to Reduce Health Disparities, Harnassing Technologies to Serve Human Needs, and Enhancing the End-of-Life Experience for Patients and Their Families.

Additional information on issues presented by Dr. Grady may be found at the NINR Web Site at www.nih.gov/ninr.

Questions/Comments

Given that the mean for R01s is now greater than \$350,000, it may behoove the Council to revisit the question of what constitutes a high-budget proposal. Another issue that may need further examination is what appears to be a relatively low number of published studies compared with the large number of funded projects (approximately 250 to 300 investigators currently receive NINR funding). Whether this represents a cultural productivity issue or simply a lag in the fairly new publication tracking and monitoring system may be worth pursuing. The impact of budget restrictions on funding also was raised. To the last question, Dr. Grady noted that using the projected budget for FY2004 (e.g., a 2 % increase, as indicated by a recent FASEB report), the success rate for RPGs is projected to decrease by approximately 4 percent from the prior year.

III. UPDATE ON NIH'S IMPLEMENTATION OF THE HIPAA PRIVACY RULE (Dr. Della Hann, Office of Extramural Research, NIH)

The HIPAA (Health Insurance Portability and Accountability Act) Privacy Rule is very broad in scope and covers a number of aspects of health care. Among the key concerns for NIH is how the Privacy Rule affects the research community and NIH's conduct of business. The primary function of the Privacy Rule is the protection of individually identifiable health information. The Rule sets forth a series of conditions under which this information can and cannot be used or disclosed to others. "Covered entities" are among the parties that will be most affected by the Rule; these entities include health plans, health clearinghouses, and health care providers that perform or conduct "HIPAA level transactions," which basically may be translated as electronic billing for health care. The research community interacts most closely with health care providers and to a lesser extent with clearinghouses. Clinical research also often involves the collection, use, and or sharing of identifiable health information. Under most circumstances, individuals must provide written authorization for entities to disclose or use health information. 45 *CFR* 46,

which the NIH follows for the protection of human research subjects, remains untouched by this Rule. The Privacy Rule also does not alter NIH's application forms or process, peer review process, or funding decisions. Most covered entities must comply with the Privacy Rule by April 14, 2003.

The Office of Civil Rights, which has the authority to enforce the Privacy Rule, asked research agencies within the Department of Health and Human Services (DHHS) to develop educational privacy materials and resources for investigators with a unified message across agencies. The NIH has taken the lead in the cooperative effort with the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), the Agency for Healthcare Research and Quality (AHRQ), and the Office for Human Research Protections (OHRP). NIH's primary role in implementing the Privacy Rule is to reach out to the research community with information and resources, including a research-focused Web site, brochures for general as well as targeted audiences, speaking engagements, Listservs, and trained NIH staff.

Once finalized, all documentation about the Privacy Rule will be available online. The role of the Rule in clinical research should be clarified upon finalization. More general information about the Rule, including details about training sessions, currently is available at the Office of Civil Rights Web site (www.hhs.gov/ocr).

IV. SMALL BUSINESS INNOVATION RESEARCH (SBIR) AND SMALL BUSINESS TECHNOLOGY TRANSFER (STTR) PROGRAMS (Ms. JoAnne Goodnight, NIH SBIR/STTR Program Coordinator)

SBIR is a Congressionally mandated set-aside program for small business concerns to engage in Federal research and development, with the potential for commercialization. STTR is another set-aside program designed to facilitate cooperative R&D between small business owners and U.S. research institutions, with the potential for commercialization. The SBIR and STTR programs account for 2.5 percent and 0.15 percent, respectively, of the NIH's extramural R&D budget. More than \$1.6 billion is available through SBIR/STTR participating agencies in FY 2003. Ms. Goodnight noted that the Department of Health and Human Services is the largest civilian agency to participate in the SBIR/STTR program. In FY 2002, NIH funding through the SBIR/STTR program was nearly \$500 million, with approximately \$471 million going to SBIR projects and \$28 million to STTR projects.

Congress identified four major goals in establishing the SBIR program through the Small Business Innovation Development Act of 1982. These goals were to stimulate technological innovation, use small business to meet Federal R&D needs, foster and encourage participant by minorities and disadvantaged persons in technological innovation, and increase private sector commercialization innovations derived from Federal R&D. The primary goals of the STTR program, which was established through the Small Business Research and Development Enhancement Act of 1992, were to stimulate and foster scientific and technological innovation through cooperative R&D carried out between small business concerns and research institutions, and to foster technology transfer between small business concerns and research institutions. SBIR/STTR programs are structured using three phases. Phase I involves feasibility studies that are funded at up to \$100,000 over 6 months (SBIR) or 12 months (STTR). Following successful completion of Phase I, researchers may apply for Phase II support for full R&D studies. In Phase II, 2-year awards are made for up to \$750,000 (SBIR) and up to \$500,000 (STTR). Phase III represents the commercialization stage of a project, and investigators use non-SBIR/non-STTR funds to achieve the goals of this part of the program.

The SBIR program was reauthorized in 2000, with the program extending through September 30, 2008. The reauthorization included greater emphasis on output and outcome data (i.e., commercialization) and added the FAST Program for Federal and State partnerships. The National Research Council will be assessing the SBIR program, as mandated under the reauthorization. The STTR program was reauthorized in 2001. New features include an increased set-aside (from 0.15 to 0.30 %) starting in FY 2004, increased Phase II funding (to \$750,000), and an increased emphasis on outreach and information dissemination.

Small businesses can use the SBIR/STTR program to help NIH meet its mission, specifically to conduct innovative R&D that proposes solutions to improve patient health, speed the process of discovery, reduce the costs of medical care and medical research, and improve research tools. SBIR also helps to translate research from the bench into clinical practice, and it supports enabling technologies and disruptive technologies that have the potential to have significant societal impact. The program assists the NIH and other agencies in addressing critical research needs and national priorities in areas such as biodefense, nanotechnology, imaging, bioengineering, bioinformatics, and biomaterials.

Each IC has its own SBIR/STTR budget, and most applications are reviewed by CSR Special Emphasis Panels, which include scientists from academia and industry. In addition to the standard peer review research project review criteria, review criteria for Phase II applications include demonstrated feasibility in Phase I, presentation of a commercialization plan, and a high degree of commercial potential. In FY 2002, approximately 27 percent and 33 percent of Phase I NIH SBIR and STTR applications, respectively, were funded. Approximately 48 percent of Phase II SBIR applications also were funded, while 63 percent of Phase II STTR applications were awarded. NIH SBIR/STTR success stories may be found at http://grants.nih.gov/grants/funding/sbir successes/sbir successes.htm.

V. NINR RESEARCH ACTIVITIES: SBIR AND STTR OVERVIEW (Dr. Hilary Sigmon, Program Director, NINR)

The NINR participates in the SBIR/STTR program through a variety of individual and collaborative activities with other ICs. The NINR provides annual input into SBIR/STTR scientific solicitations, participates with other ICs in regular "town meetings," yearly orientations, and co-sponsors Program Announcements (PAs). For example, the NINR is a co-sponsor of the PA, "Bioengineering Nanotechnology Initiative" (PA-02-125), which uses the SBIR mechanism.

Supporting small business research projects is consistent with NINR's mission, which in part is " . . . to ensure a comprehensive approach to research on health promotion, illness, and disabling

conditions . . ." Technologies that manage symptoms and technologies that improve nursing care form the backbone of NINR's small business program. The Institute's small business portfolio includes programs of research that have wide applications for many disorders, settings, and atrisk populations. Small business technologies span clinical and basic sciences, and investigators on these projects often establish multidisciplinary teams that include nurse researchers.

The NINR-funded small business projects involve the research and development of technologies to promote the alleviation, adaptation, or management of symptoms include technologies used in hospitals, hospices, or home settings to assess chronic illness; devices to improve nursing care; smoking cessation devices; assessment devices targeting childhood asthma in homes and schools; and diagnostic devices to detect early symptoms of chronic obstructive pulmonary disease (COPD) in young adults. For example, one NINR-funded Phase I SBIR grantee tested the feasibility of the Info/Med Board (IMB) as a medication organizer to improve compliance among older patients, who are at increased risk for poor compliance.

Another area in which technology and nursing research interface involves technologies to enhance self care and clinical care, such as technologies to improve adherence in patients with chronic conditions, telehealth technologies to improve delivery of care, technologies to treat chronic wounds that fail to heal, and monitoring technologies for preterm infants. An example in this area is an NINR-funded Phase I SBIR feasibility study that tested an interactive multimedia (IMM) kiosk system designed to identify risks for coronary heart disease (CHD) and to suggest behavioral modifications that will lower risk in worksite employees. Positive Phase I rled to a Phase II SBIR study.

Commercialization of a wound skin intelligence system represents another success story that can be attributed to NINR-funded SBIR. The feasibility phase of this project tested an electronic interface designed to alert staff about excessive skin pressure. In the Phase II project examining the commercial potential of the device, a nurse researcher with expertise in wound healing is assisting with the clinical study in nursing homes.

Another successful Phase I SBIR project focused on testing the feasibility of an automated pressure sore status tool, a standardized assessment instrument used in the field to track and describe status changes in chronic wounds. This tool formed the groundwork for the wound skin intelligence system being developed and tested further with support from Bristol-Myers-Squibb. Dr. Sigmon concluded by noting that the SBIR mechanism is appropriate for several FY 2003 NINR areas of opportunity, including community-partnered interventions to eliminate health disparities, adolescent health promotion activities, and end-of-life research such as pain relief for palliative care.

VI. REVIEW OF NINR TRAINING EVALUATION ACTIVITIES (Dr. Carole Hudgings, Assistant Director, DEA, NINR, presenter; Drs. Margaret Grey and Carmen Portillo, Council Discussants)

The primary purposes of the training programs' evaluation are to inform the components of the NINR strategic planning that are designed to train nurses for research careers and to provide indicators that are useful in the planning and improving of research training programs for nurse

scientists. The evaluation also contributes to NINR's accountability of its investment in nursing research training.

The NINR currently offers two primary mechanisms to support training of nurse scientists: Research Training Awards, which collectively are known as National Research Service Awards (NRSA), and the Career Development Award Program, also referred to as K awards. NRSA funds predoctoral and postdoctoral training grants and fellowships. Awards to individuals include the F31 for predoctoral students, the F32 for postdoctoral students, and the F33 for senior scientist investigators. The T32 is an institutional award made to a college or university; and the funds are used to support pre- and postdoctoral students in a particular area of research. Career Development mechanisms of support include K series grants such as the K01 and the K22. Two new awards, the K23 and K24, support patient-oriented training. These and the previously offered K07 and K08 awards are included in the evaluation.

Five overarching questions guide the evaluation:

- What training support trajectories are used by the individuals supported by these awards?
- What are the outcomes (e.g., subsequent funding, publications) for pre- and postdoctoral and research career development for each of the trajectories?
- What is the pattern of NINR funding for pre- and postdoctoral training at T32 versus non-T32 institutions?
- What are the key research training characteristics of institutions for typical trajectories?
- Are trajectories and outcomes similar to those in the Pion Study, which evaluated all of NIH's research training programs?

The evaluation is a descriptive study that covers the 10-year period from 1992 to 2001, except where noted. When available, historical data from 1986 are included in the evaluation. Primary data sources include NIH databases, grant files, and schools of nursing. The study population includes individuals as well as institutions. Data are available to provide beginning answers for the first three questions.

Highlights of the findings to date include the following:

<u>Individual vs. Institutional Research Training Positions</u>: More fellows were supported by individual awards in the initial years (i.e., from 1986 into the early 1990s). However, since 1994 the number of fellows supported by institutional training grants (T32s) has exceeded the number supported by individual awards. The majority of postdoctoral fellowships are supported by institutional grants. During NINR's 15-year history, there has been a preponderance of support at the predoctoral level, with some gain in the proportion of postdoctoral awards in recent years.

<u>Number of T32 Awards</u>: The number of active institutional training awards has remained relatively constant from 1992 through 2001, with NINR supporting 24 T32s in 2001.

<u>Individual Awards</u>: Most individual awards were for F31 (predoctoral) fellows rather than F32 (postdoctoral) fellows. Although a small number of K awards are made, the number has increased in recent years.

<u>Individual Awards at T32 vs. non-T32 Institutions</u>: Since FY 1996, non-T32 institutions consistently have received more F31 awards than institutions with T32s. Similarly, non-T32 institutions have received more K awards than T32 institutions in the last 7 years. The sponsor-candidate match plays a critical role in the success of these applications.

<u>Duration of Support</u>: About one-half of both F31 fellows and T32 predoctoral fellows were supported for approximately 2 years.

<u>Subsequent Funding</u>: Preliminary data show that a small number of F31 fellows received subsequent support for research projects (R series) and/or career development (K series) awards. A higher proportion of F32 awardees received subsequent funding. Data revealed that fewer T32-supported fellows received subsequent funding. Recipients of K series awards appear to have greater success in securing subsequent R series funding.

Potential next steps include collecting additional data for T32 individuals and institutions, comparing NINR results to NIH data, collecting and analyzing data for Minority K01 awardees, collecting and analyzing similar information for RSUM recipients, and continuing to gather data for these and subsequently funded fellows to support regular periodic evaluations.

Questions/Comments

Council members congratulated the NINR on the effort put forth to conduct this evaluation, and they recognized the challenges involved in the task.

In response to a question on the cost benefit of the predoctoral program with respect to productivity and yield, it was noted that several additional analyses that are planned need to be completed before decisions about or changes in the research training programs are discussed or made. The data are still largely preliminary, and the group should consider the temporal relationship between the training and the outcomes presented.

Some issues related to the current structure of T32s that may need to be addressed include assessing criteria to identify who is administering the T32 (e.g., are they active, productive researchers) and to determine the range of activities included in research training (e.g., grantsmanship, research publications). It also may be instructive to examine certain qualitative indicators, such as the factors that contribute to the success of particular institutions.

Council members suggested that the NINR consider collecting additional data including particularly in T32 applications: other funding and awards (e.g., foundation grants, private funding); age at time of award; and type of employment following training. Other suggestions include exploring more fully the K series, especially with respect to successes and subsequent funding; expanding to include funding sources other than the NINR; and gaining a better understanding of the factors associated with the various success stories among awardees (e.g., academic environment, mentoring). Also consider more direct data collection methods by recommending that this information be included in T32 applications.

Pipeline issues, such as the impact of a relatively older age of investigators at the time of entry into the field and the increasing scarcity of doctoral-level nurse researchers to teach and train baccalaureate nursing students, also were raised. Identifying other mechanisms of support for mentors (e.g., merit awards) and developing specialized postbaccalaureate and postdoctoral training programs (e.g., M.S. in clinical research) were discussed as well.

Dr. Grady noted that the NINR is already pursuing some of these issues, and that many of the issues raised by the Council will be considered and pursued further. The evaluation of the training program is ongoing, and the NINR will present additional data as the analysis continues and evolves.

DISCUSSION OF PROPOSED 2005 AREAS OF OPPORTUNITY (Assigned Council

Discussants; Dr. Mary Leveck, Moderator)

The Council reviewed eight proposed areas of research opportunity for FY 2005. Some areas build on prior programs, others fill gaps in the investigative arenas that may be worthy of exploration, and still others address emerging public health issues of interest or emerging interest.

1. Prevention Strategies To Decrease Obesity in Infants and Young Children (Drs. Harrigan and Ward, Discussants)

Childhood obesity has been a long-standing public health problem in the United States, but recent increases in the prevalence of obesity in children of all ages and backgrounds have reached near-pandemic levels. This initiative is designed to stimulate research that focuses on risk and protective factors in the prevention of obesity in infants and young children up to 5 years old. Prevention strategies that rely heavily on a multidimensional systems approach to the prevention of obesity infants and young children are fundamental to this research opportunity.

The Council discussants strongly supported the need to develop interventions to help stem this serious public health problem in American youth. There was some concern, however, regarding the state of the science and the readiness to engage in intervention research focused on prevention without sufficient descriptive studies in place, particularly in multicultural populations with health disparities. A request was made to add descriptive studies in special populations (e.g., culturally competent prevention, epidemiologic correlates) and to clarify the language in the objective that refers to "critical periods when infants and young children are most vulnerable."

2. Management of Symptom Clusters in Cancer and HIV/AIDS (Drs. Portillo and Shaver, Discussants)

The term symptom cluster has been defined as "concurrent symptoms that influence one another." This initiative builds on a body of research that has been stimulated in large part by nurse scientists in the past decade, and seeks to elucidate the presence of symptom clusters in HIV/AIDS, their management, and the impact of such management on patient outcomes,

particularly quality of life. To date, symptom cluster research has focused largely on pain, depression, and fatigue in cancer. The initiative will expand current research to better identify clusters, design and test interventions, and develop knowledge about the presence and management of symptom clusters in relation to a variety of endogenous and exogenous factors such as age, gender, type and stage of disease, cultural affiliation, and family constellation.

The Council discussants fully supported this initiative, noting that there is a significant gap in the clinical knowledge and the science of symptom clusters in HIV/AIDS. This initiative might serve as a model for studying other illnesses and conditions. Additional suggestions and comments included to consider adding objectives to examine the differences and commonalities in the interpretation of individual, family, and community responses to symptoms in diverse racial and ethnic groups; to characterize symptom clusters in clinical populations; and to identify symptom clusters related to health disparities in diverse groups. Other comments suggested including objectives that focus on the underlying physiologic mechanisms driving the symptoms and placing greater emphasis on symptom amelioration.

3. Maintaining Wellness and Preventing Disease Progression in Patients With Moderate Cardiac Dysfunction (Drs. Naylor and Schempp, Discussants)

This initiative proposes to stimulate biobehavioral intervention research in patients with a diagnosis of moderate cardiovascular disease (CVD) and their families. Interventions are needed to assist patients in maintaining the highest physical and psychological functioning for their disease state across the life span. The initiative seeks to determine which interventions maintain wellness through lifestyle management and which interventions may prevent the onset of kidney failure, cerebrovascular accidents, second myocardial infarctions, end-stage congestive heart failure (CHF), and diabetes mellitus type 2 in patients with CHF.

The Council discussants considered this initiative important to nursing research, because very little work has been done in this area of secondary prevention. Council members made suggestions including clarifying whether the primary focus of this research is to improve intermediary outcomes (e.g., adherence, knowledge) or longer term outcomes (e.g., regression of atherosclerosis); encouraging individual, family, and community involvement; addressing environmental conditions and social circumstances as they relate to behavioral choices and health outcomes; including diverse groups with respect to racial and ethnic minorities as well as older populations; and identify interventions for multiple risk factors. Other comments related to considering the inclusion of nutritional factors, herbal remedies, and supplements and determining whether initial efforts should focus on cardiovascular disease or take a broader scope to include other conditions affected by the CV system.

4. Opportunities in Genetics and Nursing Research II (Drs. Hanley and Burgio, Discussants)

This initiative seeks to continue the integration of genetics research and nursing research. Multidisciplinary teams, collaborations, and consortia promoting strategies to manage illness, prevent disorders, and maintain health will be encouraged. Possible areas of interface include gene-environment-behavior interaction, bioimaging and biotechnology sensing devices to further validate psychological interventions, phenotype markers to decrease symptoms and treat or diagnose illness, and functional application of proteomic discoveries. This initiative, if approved, will update PA-97-047, titled "Opportunities in Genetics and Nursing Research," which was released on March 21, 1997.

Genetics is an important area of interest in NINR's strategy and research portfolio, and the Council discussants supported this initiative as a means of expanding these efforts and activities. The initiative could have a stronger emphasis on studying, evaluating, and better identifying the phenotype/phenotypic markers and expression.

5. Opportunities for Nursing Research in Biodefense (Drs. Schempp and Cammermeyer, Discussants)

The NINR and other ICs at the NIH recognize the need to increase nursing research in the area of natural disasters and emergencies, particularly in the areas of infrastructure building, research training, and programs of research. Nursing research can add new knowledge to this area by answering clinical questions that address problems of early symptom management and the prevention of complications after exposure to chemical, biological, and viral agents. Of particular note, the NINR could add behavioral and clinical expertise to the proposed regional centers of excellence in biodefense and emerging infections that are being funded by NIAID.

The Council discussants noted that this important opportunity represents an area of anticipatory research. Additional feedback on this initiative included to consider strengthening the third objective, which addresses allaying fear and responding to end-of-life issues during emergency responses, by drawing from international experiences on community, infrastructure, and nursing response. Perhaps separating this into two separate objectives (fear, end of life) would be helpful. Other suggestions were to include both short- and long-term effects and responses, as well as national versus local impacts and responses; to identify underlying biological mechanisms, such as immune system functioning and response to stress; and to include identifying methodological needs for the symptom cluster area of opportunity that overlap with acute symptoms that may occur with a bioterrorism attack.

6. Chronic Disease Self-Management: State of the Science Workshop (Drs. Grey and Buerhaus, Discussants)

The purpose of this initiative is to assess the state of the science in chronic disease selfmanagement and related health outcomes and to identify directions for new research. This workshop, proposed for the spring of 2004, will assist in the development of future NINR initiatives in this research area. The target audience for the workshop will be investigators in the field of behavioral studies related to chronic disease populations. Presenters will be experts in the field of self-management and behavioral studies.

The Council discussants identified this initiative as important for the cross-fertilization of ideas and strategies in this area of research, and a opportunity to help move investigators away from more traditional disease-specific approaches. Additional points to consider include ensuring that family, particularly spouses/partners, are involved in the interventions as well as considering the role of caregivers; identifying and targeting the initiative to the chronic disease states that are most prevalent and that would be expected to have the greatest impact on public health; and emphasizing both the novel research goals identified in the initiative and the quality-of-life endpoints, as well as economic endpoints.

7. Chronic Disease Self-Management in Understudied Populations (Drs. Dunbar-Jacob and Cournoyer, Discussants)

More knowledge is needed about factors affecting self-management of chronic diseases in certain populations. Further study also is needed to determine whether interventions tested in mainstream populations translate into understudied groups. Such populations include but are not limited to the geographically isolated, the unemployed or uninsured, the oldest of the elderly, persons with modest incomes, persons with a non-heterosexual orientation, and persons with physical disabilities including sensory impairment. The goals of this initiative are to advance chronic disease self-management science about understudied populations and to stimulate the testing of established mainstream interventions in these populations.

The Council discussants supported this highly-relevant initiative, noting that NINR staff may want to delay finalization of this initiative until after the state of the science workshop, so that the initiative can be focused based on the workshop findings. It also was suggested to have a subgroup of the workshop focus on the issues raised in this initiative. The final objective is relatively broad, and it could be rewritten with greater focus on specific behaviors and outcomes in relation to underserved populations. Council members recognized that solid, well-designed studies in this research area are necessary but costly.

8. Reducing Health Disparities Among Minority and Underserved Women (Drs. Smith Williams and Sands, Discussants)

The purpose of this initiative is to stimulate research aimed at reducing health disparities among racial minority and underserved women, as defined in the NINR's strategic plan on reducing health disparities. More specifically, this initiative is designed to solicit applications to test culturally and linguistically appropriate health-enhancing interventions to reduce health disparities among minority and underserved women age 21 and older. Included are low literacy, rural, and low-income populations; other groups may include older minority women, lesbians, and migrant female workers.

The Council discussants found this initiative to be very important for reducing health disparities. The emphasis on behaviors and interventions in relation to a broad range of underserved populations is a strength of the proposal. The inclusion of descriptive components will allow for collection of additional definitive data to assist in the development and testing of interventions. One suggestion was to lower the age of eligibility to 18, or perhaps younger, to target high-risk behaviors in adolescents. However, inclusion of girls and younger women would likely shift the focus of the initiative. The initiative builds on NINR's portfolio on women's health, and refines the research on much-needed prevention modalities directed toward underserved groups.

VI. PROGRESS INDICATORS FOR FY 2002 STRATEGIC PLAN GOALS (Dr. Leveck)

Dr. Leveck reviewed the four scientific goals of NINR's Strategic Plan and highlighted progress indicators for year 3 of the plan. The 5-year plan runs from 2000 through 2004. Measurable progress indicators are evaluated at three time points—in 2000, 2002, and 2004. Baseline data were collected in 1997, 1998, and 1999.

The first scientific goal is for the NINR to support scientific opportunities to achieve scientific distinction and to contribute to health with the objectives of leading research activities in selected areas of science, pursuing collaborative opportunities across the NIH, and increasing grant funding in specific fields of research. The NINR exceeded the year 3 target for serving as primary sponsor as well as co-sponsor of PAs and RFAs. In 2002, the NINR served as primary sponsor on 8 PAs and 4 RFAs and co-sponsor on 14 PAs and 6 RFAs. The Institute also exceeded grant funding targets of 20 percent over baseline funding for eight research areas, including chronic illness, end-of-life research, genetics, health promotion/disease prevention, health disparities, quality of life/quality of care, symptom management, and telehealth. NINR staff and nurse researchers have served on 65 trans-NIH committees and 20 trans-agency committees, and have participated in 12 trans-agency activities.

The second scientific goal of the Strategic Plan is to support future areas of opportunity to advance research and to contribute to the scientific base for nursing practice, with the objectives of identifying promising areas of science, obtaining broad input into future research needs and gaps, and expanding the NINR intramural research program. Again, the NINR exceeded the objectives established under this goal for year 3. The Institute presented seven areas of opportunity to the NACNR, sponsored four workshops, and co-sponsored nine workshops to identify new areas of opportunity. In addition, NINR staff participated in and/or presented at 40 meetings to obtain input into its programs from a wide range of constituents and audiences, used the NINR Web Site to facilitate communication between investigators and the public regarding research opportunities, and held 5 Research Themes meetings. Regarding expansion of the Intramural Research Program, the NINR has two protocols in the Symptom Management Lab underway instead of the anticipated six protocols. However, the Institute has met its year 3 objective of supporting three mentoring awards, including two full-time K22 appointments and a third appointment pending.

Scientific goal 3 of NINR's Strategic Plan includes communicating and disseminating research findings, collaborating in sharing information, maintaining media relations programs, and communicating program announcements by e-mail. In year 3, summaries of three research reports were placed on the NINR Web Site, and capsules of 127 capsules of research findings were published on the MedScape Web Site. In meeting the objective of piloting avenues of dissemination of results of nursing research studies to consumers, particularly minorities, the Institute participated in three NIH-wide fairs that focused on minority health issues. The NINR produced a range of documents focused on research findings, including 16 new "Making a Difference" vignettes and four Research Focus documents. It also was involved in the development of the CenterNet video series on end-of-life care, which aired in 1,640 hospitals; in addition, 248 copies of the series have been sold. Four press releases were developed in the year,

rather than the projected six. To expand nurse researchers' knowledge of media and public relations, the NINR cosponsored a media training workshop as part of the State of the Science program. Dr. Leveck reported that the NINR Web Site receives approximately 1.5 million hits each month by nearly 50,000 visitors. Dissemination of news from the NINR is expanding, with 17 announcements made in year 3. NINR staff also prepared 145 research capsules for the MedScape Web Site and the *American Journal of Nursing*, and tracked and listed 227 NINR-funded publications in science journals. In addition, 68 media reports of NINR-funded research reports were identified.

The fourth scientific goal focuses on enhancing the development of nurse researchers through training and career development. Objectives include increasing training opportunities and the proportion of postdoctoral fellowships, expanding the Core Centers Program, and maintaining training and intramural fellowship opportunities. Dr. Leveck reported that in year 3 of the Strategic Plan, the NINR increased funding for training fellowships by 48 percent and increased the overall number of positions by 25 percent. The proportion of postdoctoral fellows to predoctoral fellows increased by 27 percent, nearly meeting the target of 28 percent. Results of the Institute's evaluation of the training and career development program were presented to the NACNR at the Council's January 2003 meeting. A total of 35 career development awards were made, and 9 career awards for minority nurse researchers were made. Dr. Leveck noted that the dollar amounts awarded under the minority K01 awards program have changed because the progress indicators were established due to the transition of the Office of Research on Minority Health to a Center; the NINR and NCHMD now co-sponsor these awards. The Centers Program targets for funding and for the number of centers have been exceeded, and the NINR has joined with NCMHD in the development of a Minority Partnership P20 program. The NINR met the goals of developing a Core Centers evaluation plan and reporting on Center accomplishments and on the Centers Directors' meeting to the Council in May 2002. The Nurse Scientist Training Program enrolled the targeted 40 students during the final onsite course in Summer 2002; since being launched as an Internet course in April 2002, the Nurse Scientist Training Program has enrolled 593 students, with 127 registrants completing the 5-hour online course thus far. Eighteen investigators were enrolled in the third annual Summer Genetics Institute on the NIH campus in 2002, somewhat below the anticipated enrollment due of laboratory space limitations.

In summary, the NINR has met or exceeded most of the progress indicators set forth in the 5-Year Strategic Plan. Monitoring and evaluating the Institute's progress has proved to be a useful exercise and helps keep the Institute on track in meeting its goals. The next progress review is slated for FY 2004.

Questions/Comments

Council members congratulated the NINR on its progress and successes and on meeting and exceeding many of the plan's goals and objectives. They encouraged staff to disseminate the findings across the nursing research community and also to consider future directions, in light of changing budgetary issues and scientific priorities. The NINR and the Council should begin to evaluate the steps and factors for developing the next strategic plan, including identifying qualitative outcomes measures and impacts and determining how to build on the advances already made in various areas of opportunity. Another issue to consider is that of identifying any

barriers that may impede achieving the remaining goals and objectives of the current plan and strategies to overcome the identified barriers. Dr. Grady noted that the current Strategic Plan was developed over an 18-month period when the budget was not anticipated to be robust; further, the Council provides guidance based on scientific merit, with consideration of budget issues. Thus, planning is based on a balance of science and available resources.

VII. REVIEW OF COUNCIL DOCUMENTS (Dr. Hudgings, Dr. Leveck, and Ms. Cindy McDermott)

Biennial Data for Gender Minorities

Dr. Hudgings highlighted data for compliance with gender and minority inclusion criteria for FY 1999 and 2000. In FY 1999, approximately 44 percent of the research subjects enrolled in NINR clinical studies were minorities. The number of minority study participants exceeded the NIH percentage guidelines for American Indians, Asian-Pacific Islanders, Blacks, and Hispanics. However, the percentage of Asians was below the NIH average. Also in FY 1999, more men than women were enrolled in NINR-funded clinical research trials, compared with the overall NIH average percentages. Although the raw numbers of minority subjects included in all NINRsupported studies increased between FY 1999 and FY 2000, the percentages dropped because of the marked increase in the total number of participants in all NINR clinical research studies following the implementation of several large-scale trials that have relatively larger proportions of white enrollees. Dr. Hudgings pointed out that guidance from the Council has assisted the NINR in remaining attentive to ensuring that gender and minority inclusion policies are followed. She noted further that the initial review groups (IRGs) and study groups are responsible for identifying problems and concerns regarding gender and minority inclusion on applications. This information is placed on the summary statement, and program staff work with the investigator to resolve these issues. Resolutions, in turn, are submitted to the Council.

Annual Statement of Understanding

The Statement of Understanding (SOU) between the NINR staff and the NACNR is reviewed and renewed each year. Dr. Grady noted that one of the key issues that may require further discussion by the Council is what constitutes a high-budget item. Dr. Leveck and Ms. McDermott briefly summarized the SOU and suggested maintaining the memorandum with minor editing and the addition of the R21 as a mechanism for expedited review. the R21 as a mechanisms for expedited review bullet.

In response to a query, Dr. Leveck clarified that R03s are in the under-\$50,000 category of applications, which do not require Council review. These applications will be brought to Council's attention for information, however.

A motion to approve the SOU with the suggested changes was proposed and seconded. The Council unanimously approved the SOU as discussed.

Following this final 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 231 research and training grant applications requesting \$56,217, 951 in direct costs. (Data obtained from IMPAC II / QVR on January 27, 2003; includes all primary and dual applications; excludes F31, F32, F33 applications.)

OTHER ITEMS FOR CLOSED SESSION: EXECUTIVE SESSION

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

ADJOURNMENT

The 49th meeting of the NACNR was adjourned at 12:50 p.m. on January 29, 2003.

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. Margaret Grey Dr. David Hanley Dr. Rosanne 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

Ms. Linda Bennington, Virginia Commonwealth University (VCU) Ms. Chantira Chiaranai, VCU Ms. Rachel Cobb, VCU Ms. Denise Crosson, VCU Dr. Martha Engelke, ECU Dr. Gillian Foruus, Illinois State University Dr. Eileen Fowles, Illinois State University Ms. Sandra Gossler, VCU Dr. Mary Jo Grap, VCU Dr. Pauline Green, Howard University Ms. Debra S. Hall, COPR Member Ms. Janet Herr, VCU Ms. Carline Jean-Gilles, VCU Dr. Deborah Jefferson, VCU Dr. Beatrice Kelly, Howard University Ms. Sanchol Lanigit, VCU Ms. Cynthia Little, VCU Dr. Cindy Munro, VCU Ms. Patcharin Nintochan, VCU Dr. Rita Pickler, VCU Ms. Kathli Putna, VCU Dr. Gayle Roup, VCU Ms. Pataporn Saengkhiew, VCU

Ms. Angela Sharpe, Consortium of Social Science Associations Dr. Nelma Shearer, Arizona State University Ms. Sasamon Srisothisak, VCU Ms. Sangthong Terathongrum, VCU Ms. Wantana Thinganjana, VCU

FEDERAL EMPLOYEES PRESENT

Dr. Nell Armstrong, NINR/NIH Mr. Ray Bingham, NINR/NIH Dr. Jeffery Chernak, NINR/NIH Ms. Linda Cook, NINR/NIH Ms. Janet Craigie, NHLBI/NIH Ms. Genevieve deAlmeida-Morris, NINR/NIH Ms. Diane Drew, NINR/NIH Ms. Angela Falwell, NINR/NIH Ms. JoAnne Goodnight, NIH OD Ms. Robin Gruber, NINR/NIH Ms. Debra Hall, COPR/NIH Dr. J. Taylor Harden, NIA/NIH Dr. Martha Hare, NINR/NIH Mr. Lawrence Haller, NINR/NIH Dr. Karin Helmers, CSR/NIH Dr. Carole Hudgings, NINR/NIH Ms. Samantha Jarvis, NINR/NIH Ms. Kay Johnson, NINR/NIH Ms. Kai Lakeman, NINR/NIH Dr. June Lunney, 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 Mr. William Rosano, NINR/NIH Dr. Hilary Sigmon, NINR/NIH Ms. Arlene Simmons, NINR/NIH Dr. Mindy Tinkle, NINR/NIH Mr. Mark Waldo, NINR/NIH Ms. Sally York, NINR/NIH