

**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 17–18, 2005

The 56th meeting of the National Advisory Council for Nursing Research (NACNR) was convened on Tuesday, May 17, 2005, at 1:10 p.m. in Conference Room 6C6, Building 31, National Institutes of Health (NIH), Bethesda, Maryland. The first day of the meeting adjourned at approximately 4:10 p.m., at which time the open session also adjourned. The closed session of the meeting, which included consideration of grant applications, continued the next day, May 18, 2005, at 8:30 a.m., until adjournment at 11:50 a.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 56th meeting of the NACNR to order, welcoming all Council members, visitors, and staff. She noted that this is a momentous time for the National Institute of Nursing Research (NINR) as the Institute will celebrate its 20th Anniversary in 2006. Plans for a year-long celebration are underway. Dr. Grady welcomed new Council member, COL John Murray, U.S. Air Force, who is the Associate Dean of the Uniformed Services University of the Health

Sciences School of Nursing and consultant to the Surgeon General for nursing research. The slate of remaining new Council members has been approved and will be announced soon; they will join their colleagues at the next NACNR meeting. Dr. Grady also welcomed NINR's new Deputy Director, Dr. Mary E. Kerr, who serves as Executive Secretary of the NACNR.

Conflict of Interest and Confidentiality Statement

Dr. Kerr reminded attendees that the standard rules of conflict of interest are 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 either the open or the closed session of the meeting, Council members with a conflict of interest with respect to any topics or any application must excuse themselves from the room and sign a statement attesting to their absence during the discussion of that application. Dr. Kerr also reminded NACNR members of their status as special Federal employees while serving on the Council, and that the law prohibits the use of any funds to pay the salary or expenses of any Federal employee to influence members of the State Legislature or Congress. Specific policies and procedures were reviewed in more detail at the beginning of the closed session and were available in Council notebooks.

Minutes of Previous Meeting

Council members received a copy of the minutes of the January 25–26, 2005, Council meeting by electronic mail. No changes or corrections to the minutes of the January 2005 Council

meeting were suggested during the May meeting. A motion to approve the minutes of the January 2005 Council meeting as circulated was proposed and seconded.

Comments, corrections, and changes identified after the current meeting should be forwarded to Dr. Grady. The minutes of each quarterly NACNR meeting are posted on the NINR Web Site (<http://ninr.nih.gov/ninr>).

Dates of Future Council Meetings

Dates of future meetings in 2005, 2006, and 2007 have been approved and confirmed. Council members should contact Dr. Grady regarding any conflicts or expected absences.

2005

- September 13–14 (Tuesday–Wednesday)

2006

- January 24–25 (Tuesday–Wednesday)
- May 24–25 (Wednesday–Thursday)
- September 26–27 (Tuesday–Wednesday)

2007

- January 23–24 (Tuesday–Wednesday)
- May 22–23 (Wednesday–Thursday)
- September 25–26 (Tuesday–Wednesday)

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

The Director's report focused on updates since the last Council meeting and on current and impending activities and initiatives related to the budget, the Department of Health and Human Services (DHHS), NIH, and NINR.

Budget Updates—The President's proposed budget for FY2006 requests a 0.7 percent increase for the NIH overall and a 0.5 percent increase for NINR for a total allocation of \$138,729,000; approval of the FY2006 budget is pending. The slightly lower percentage for NINR, compared with the NIH overall, is due in part to core issues that Congress is addressing; however, NINR's proposed increase is consistent with most other institutes and centers (ICs). The FY2005 budget bill, which was signed into law on December 8, 2004, includes a 2.5 percent increase to NINR, compared with a 2.1 percent overall increase to the NIH. The total allocation to NINR for FY2005 is \$138,072,000. In comparing NIH and NINR funding from the last several years with the FY2005 and proposed FY2006 budgets, Dr. Grady noted that the economic landscape has changed considerably since 2002, the year that marked the completion of the doubling of the NIH budget. The NIH and much of DHHS as a whole are now in more of a steady-state budget period, and the trend of smaller incremental budget increases is expected to continue in the near future. The distribution of NINR's FY2004 budget, the most recent year for which all information is available, is consistent with previous years; allocations in FY2005 are expected to be similar to actuals for FY2004. Allocations of the FY2004 budget were reviewed Dr. Grady noted that NINR is consistently among the top three ICs with the highest percent of budget dedicated to training.

DHHS Updates—Mr. Michael Leavitt has been approved and installed as Secretary of DHHS. Mr. Leavitt previously served as Administrator of the Environmental Protection Agency (EPA); prior to his tenure at EPA, he was Governor of Utah. Mr. Leavitt recently announced a new initiative, the “500 Day Plan,” as one of his many priorities as DHHS Secretary. The vision of this plan involves six key themes: (1) transforming the health care system; (2) modernizing Medicare and Medicaid; (3) securing the homeland; (4) advancing medical research; (5) protecting life, family, and human dignity; and (6) improving the human condition around the world. The aims and mission of NINR are consistent with many of these themes, including advancing medical research, which can impact the health of Americans and our health care system; and research, strategies, and issues associated with improving quality of life across the lifespan and around the globe. More information on the plan may be found at <http://www.hhs.gov/500DayPlan/>.

NIH Updates—The debate about *ethics policies* and *conflict of interest* (COI) at the NIH continues, and the discussion has received national attention among health care professionals and by the larger public media. Dr. Grady cited comments from Dr. Raynard Kington, Deputy Director, NIH, who stated that the “number one priority [of establishing new ethics rules] was to ensure the public’s trust in the integrity of the science of this institution,” which remains the foundation for guiding the development of NIH’s ethical standards and policies. The new policies, which have caused some senior researchers and others to leave or to consider leaving the NIH, may overreach and be too restrictive for the whole of the institute. To that end, HHS Secretary Leavitt has stated that the “new rules designed to prevent conflicts of interest among Federal scientists may have to be rolled back to stop researchers from moving to private institutions.” The NIH has received more than 1,000 comments on the new policies as it

continues to examine and reassess its rules and regulations. Additional information on this evolving discussion may be found at the NIH COI Information and Resources Web Site at http://www.nih.gov/about/ethics_COI.htm.

The Council of Public Representatives (COPR), one of two advisory groups to the NIH Director, has been working with the *NIH Public Trust Initiative* to engender the NIH as a trusted agency and a valued resource for and about clinical, biomedical, and behavioral health research. One of the key activities of this initiative, which is co-chaired by Dr. Grady and Dr. Yvonne Maddox, Deputy Director, National Institute of Child Health and Human Development (NICHD), was convening a comprehensive meeting with COPR in October 2004. The full-length report from that meeting, including recommendations for advancing public input into the clinical research enterprise, is available at the COPR and the Public Trust Initiative Web sites. As part of its ongoing efforts, the Initiative has sought information about public opinion and knowledge of the NIH and biomedical research in the United States. One national survey from Research!America indicated that most people (59 percent) know that the government and taxpayers are the largest contributors to medical research in this country; however, those polled did not appear to understand NIH's role in the research enterprise and its impact on medicine and public health. Dr. Grady noted that although the NIH cannot control the public's perceptions in the area of research, it can improve its communications and interactions with the public, for example, with the use of plain language and recognizing the importance of the immediacy of releasing critical information. The Initiative has sought feedback across ICs to develop an inventory of current NIH activities and to identify uniformity or clustering of data, target "publics" and determine how to reach them, and develop "exportable" programs that all ICs can share. The main inventory categories of types of activities include involving and protecting human participants,

including the public in IC business, promoting the visibility of the NIH, teaching and developing course materials for science education, and developing educational and outreach programs for extramural and intramural clinical and research communities. NINR is actively engaged in many of these activities, along with the COPR, review groups, and expert panels, which are key to achieving the Initiative's goals. The development of an NIH "ambassador" program may further facilitate these efforts. Target publics include the general public/community, clinical trial participants, the research advocacy community, the external scientific community, and the NIH internal scientific workforce. Dr. Grady described one project, the NIH Alaska Native Outreach Effort, which involved several ICs including NINR, and incorporated many of the Public Trust Initiative's goals. Through this effort, the NIH learned about how health care is delivered in Alaska; the challenges of providing health care and conducting research in largely rural, highly dispersed populations; and how traditional and complementary medicine may blend with Westernized medical care. Follow-up includes identifying and translating generalizable information to outreach and scientific efforts and programs. Information about the Public Trust Initiative may be found at <http://publictrust.nih.gov>.

Dr. Grady continued by noting that the *NIH Roadmap Initiative* recently celebrated its 1-year anniversary. Accomplishments and future directions were reviewed in a briefing on October 14, 2004, and in a commentary in *Nature* titled, "Early success claimed for Zerhouni's NIH Roadmap." One key component of the Roadmap is the annual NIH Director's Pioneer Award, a highly competitive program that recognizes innovative, high-risk, high-impact research. A total of nine Pioneer Awards were made in FY2004, with funds supporting mathematical modeling of neurons and neural networks, cellular reprogramming, understanding and manipulating metabolic cycles, exploring new approaches to AIDS vaccines, and nanoscale studies of cell

surface-environment interactions. Another Roadmap initiative, the Patient Reported Outcomes Measurement Information System (PROMIS), is designed to address the pressing need to better quantify clinically important symptoms and outcomes that currently are difficult to measure. In FY2004, PROMIS funded seven grants focused on improving assessment of patient-reported outcomes. One project will develop measurements of symptoms (pain, fatigue) and aspects of health-related quality of life with a focus on chronic diseases, and another is developing a publicly available system of Computerized Adaptive Tests. PROMIS and the Pioneer Award are just two examples of programs that distinguish the Roadmap from more traditional research initiatives and from other fields. Further information on the NIH Roadmap, including current and upcoming solicitations, may be found at <http://nihroadmap.nih.gov/>.

The *National Research Council (NRC)* report on training has been released by the Committee for Monitoring the Nation's Needs for Biomedical, Behavioral, and Clinical Personnel. A separate panel for nursing research identified two major areas of concern for nurse scientists, including: (a) career trajectory of research training, particularly related to the delayed entry of nurse scientists into advanced degree programs and research and the resulting 15 years of productive career time compared with 30 or more years for other fields; and (b) the need to enhance attraction and retention of nurse researchers from postdoctoral through career development opportunities. NINR shares these concerns and supports strategies to change the career trajectory of nurse scientists, such as efforts that enhance productivity (e.g., through publication) and respond to the shortage of nurse investigators (e.g., through fast-tracking of opportunities), and emphasizes research-intensive training environments, which will facilitate retention. The NRC report, which explores a range of issues such as the distinction between Master's and

doctorally prepared nurses compared with other fields may be found at <http://www.nap.edu/books/0309094275/html>.

Recent findings of the *Society for Women's Health Research* (SWHR) on extramural support for research on sex and gender differences at the NIH are summarized in the report titled "National Institutes of Health: Intramural and Extramural Support for Research on Sex Differences, 2000–2003" (<http://womenshealthresearch.org>). NINR is among the top three ICs supporting gender-based research, based on percentage of budget, with slightly more than 5 percent of its awards devoted to this research emphasis. The National Institute on Alcohol Abuse and Alcoholism (NIAAA) ranked the highest, with nearly 8 percent of its grant awards allocated to the study of sex and gender differences. With the release of this report, NINR and other ICs will begin a dialog about the possibilities of expanding the study of women's health, given that women account for approximately 50 percent of the population.

Dr. Grady participated in the 20-year anniversary celebration of the Johns Hopkins University School of Nursing. An expert panel discussion focusing on health disparities was held as a part of the celebration on May 3, 2005. Panelists included NIH Director Dr. Elias Zerhouni and NINR-funded nurse researcher Dr. Antonia Villarruel.

The opening of the Mark O. Hatfield Clinical Center in April was another landmark event on the NIH campus and has been described as a "technical marvel with a human heart."

NINR Updates and Outreach—The "top five" research advances forwarded to Congress last year demonstrate the breadth of investigations supported by NINR and the potential impact of

this research on public health. Advances focused on patient safety on hospital units as a correlate to adequate RN staffing, the impact of a nurse practitioner-led program to improve lifestyle and control of blood pressure among inner city black men with hypertension, early and acute signs of heart attack in men versus women, the role of nursing care in transition from hospital to home in lowering costs for elders with heart failure, and outcomes (palliative care, caregiver burden) associated with hospice enrollment and advance directives. Areas of research opportunity for FY2006 were reviewed during the January 2005 Council meeting and include research in a multicultural society with a focus on preventing and intervening in HIV/AIDS, increasing health promotion through studies on parenting capacity, biobehavioral methods to improve outcomes research, improving cognitive function in quality of life in central nervous system disorders, and providing end-of-life and palliative care in rural and frontier areas. The increased interest in end-of-life issues, for which NINR is the lead NIH IC, has led to renewed attention to palliative care and end-of-life decision making. The strong interest in this area was evident at the NIH State-of-the-Science Conference on Improving Life Care on December 6–8, 2004, which was attended by nearly 1,000 registrants, compared with the usual 200–300 participants. This area of research draws from a range of disciplines and lends itself to collaborative qualitative and quantitative investigations within and outside nursing. Findings of end-of-life research supported by NINR indicate that many patients at the end of life choose complementary approaches for pain relief; caregivers consistently report that decedents had pain, dyspnea, and other distressing symptoms, while caregivers themselves often felt drained, had high levels of stress, and were financially burdened. The consensus statement from the December conference is available at the NINR Web Site.

The NINR Centers meeting, held on April 26–27, 2005, brought together directors and principal investigators of the Institute’s three Centers programs: The P30 Core Centers program, the P20 Exploratory Centers program, and the P20 Partnership Centers on Health Disparities program. The theme of the meeting was “sustainability,” with discussions targeting ongoing self-evaluation; networking among centers; and identifying and sharing center resources, including expertise and funds. Dr. Grady also reported on the recent rural health care research center celebration on May 5, 2005, which focused on improved health care outcomes through rural health research. Since the last Council, meeting, staff have attended and participated in four regional nursing research conferences and several other scientific meetings to keep abreast of current science and to network and be available to investigators in the field.

In order to keep abreast of current science and to network with investigators in the field staff have attended and participated in four regional nursing research conferences, the International Stroke Conference, and the National Nursing Research Roundtable.

The 6th annual Summer Genetics Institute (SGI) is slated to be held June 6–July 29, 2005 (the registration deadline was March 1). Approximately 100 “students” will have graduated from the program by the end of this year’s course. One graduate, Karen Whitt, wrote about her experiences from the 2004 SGI in the February 2005 issue of *Policy, Politics, and Nursing Practice*. Dr. Grady reported that SGI graduates have been very successful in translating their experiences from the SGI into funding and publishing in the area of genetics. Dr. Mindy Tinkle and her staff continue to monitor and track the activities of those who have participated in the program.

NINR Staff Updates and Transitions—Dr. Mary Kerr, NINR’s new Deputy Director, received the Distinguished Alumna Award from Case Western Reserve University in Cleveland, Ohio. Dr. Mindy Tinkle recently moved into the position of Special Assistant to the NINR Director, where she will direct and oversee crosscutting events and activities, including NINR’s upcoming 20-year anniversary celebration. Dr. Jeff Toward is a new Program Director of Extramural Research responsible for managing the science for Chronic Illness and Aging. He comes to NINR from NIAAA; prior to his tenure at the NIH Dr. Toward was on the faculty of the University of Texas School of Nursing. He Mr. Mark Waldo, who worked as a photographer and writer in NINR’s public liaison office, recently left the Institute for a position as pastor in Oxford, Mississippi. Mr. Brian Albertini has joined NINR as a Branch Management Chief.

Recent and Upcoming NINR Publications—Dr. Ellen Rudy and Dr. Grady have co-authored an article titled “Biological researchers: building nursing science,” which will appear in an upcoming issue of *Nursing Outlook*. The article traces the career paths of nurse scientists in the field of biological research who received funding from NINR several years ago and is based on interviews and follow-up on these investigators. Other co-authored publications include a paper by Dr. Kerr titled “A comparison of gastric and rectal CO₂ in cardiac patients,” in *Biological Research for Nursing*; Dr. Smothers’ paper, “Drinking patterns and body mass index in never smokers: National Health Interview Survey, 1997-2001,” in the *American Journal of Epidemiology*; Dr. Bakos’s manuscript, “Palliative wound care at the end of life,” in *Home Health Management and Practice*; and Dr. Huss’ article, “A+ asthma rural partnership coloring for health: an innovative total asthma teaching strategy,” in *Pediatric Nursing*. Dr. McCarthy had two papers highlighting intramural research on cachexia published in a recent issue of *Research in Nursing and Health*. The May supplement to the *American Journal of Obstetrics*

and Gynecology includes papers from the 2003 NINR Working Group on Optimizing Pregnancy Outcomes in Minority Populations, which was organized by Dr. Bryan.

NINR Events and Activities—NINR’s 20th Anniversary celebration kicks off with a symposium at the CANS Conference in October 2005. Friends of the NINR (FNINR) has already begun to promote the anniversary. Registration for the October 11, 2005, NightinGala at the Omni Shoreham Hotel in Washington, DC, is available through the Friends’ Web site. The theme of this year’s NightinGala is “Nursing Research: Advancing the Health of America.”

Questions/Comments

Regarding a question about the public perception of funding of medical research, Dr. Grady commented that the public appears to have a good understanding of the actual proportion of funds contributed by various categories (e.g., government, industry, consumers). Those polled were fairly close to estimating the government’s financial contribution, which is approximately 50 percent of all biomedical and clinical research funding. However, only 2–5 percent of the public were aware of NIH’s role and activities; there was better recognition of, for example, the role of the Centers for Disease Control and Prevention (CDC) in public health because of the connection with immunization but not as a research funding agency. It was noted that pharmaceutical companies have been contributing an increasing amount of monies to research over the past decade.

III. 1st ANNIVERSARY UPDATE OF ROADMAP INITIATIVE (Dr. Lauren Aaronson, Senior Advisor to the Director and NINR Liaison for the NIH Roadmap Initiative and the NIH Public Trust Initiative)

The NIH Roadmap Initiative (<http://nihroadmap.nih.gov>) is designed to transform the Nation's medical research capabilities, speed the movement of research discoveries from the bench to the bedside, and initiate research from the bedside to the bench. The Roadmap is defined through three overarching themes to overcome roadblocks to transformation and translation: New pathways to Discovery, Research Teams of the Future, and Re-engineering the Clinical Research Enterprise. Each theme, in turn, is associated with a series of working groups to address specific issues related to that theme. The first round of Roadmap awards has been made, and plans for future activities and research initiatives are underway. Funding for each theme-driven component of the Roadmap is scheduled to increase incrementally through FY2009; total funding for this initiative accounts for less than 1 percent of the NIH budget.

Working groups under the New Pathways to Discovery theme include molecular libraries and imaging probes; building blocks, biological pathways, and networks; structural biology; bioinformatics and computational biology; and nanomedicine. An overview of program initiatives associated with molecular biology and imaging was summarized in the November 2004 issue of *Science* magazine; among the FY2004 awards was funding for a molecular libraries small molecule repository, establishment of the NIH Chemical Genomics Center; P20s for high resolutions probes for cellular imaging; and R03s for the development of high-throughput molecular screening assays. FY2005 RFAs expand and build on the research initiatives from the prior year. Four National Centers for Biomedical Computing were funded in

FY2004; an RFA for National Centers was re-announced, with applications due in January 2005. Plans for programs to develop partnerships between individuals and National Centers are underway. The nanomedicine program supports highly specific molecular scale medical intervention to cure disease or repairing damaged tissue and funded 20 Center Concept Development Awards in FY2004. Five to eight Nanomedicine Development Centers are planned for funding in the next 2 years.

Initiatives under the Research Teams of the Future theme provide mechanisms for interdisciplinary research, high-risk strategies, and public-private partnerships. FY2004 funding supported research focused on curriculum development (K07s), interdisciplinary research training (R13s, T32s), methodological innovations in the behavioral and social sciences (Type 3 supplementals to R01s/P01s), meetings and networks for methods development (R13s, R21s), and training for a new interdisciplinary workforce (T90s). Twenty-one Exploratory Centers (P20s) for Interdisciplinary Research across the country were funded in the first year of the Roadmap; these planning centers provide cross-disciplinary opportunities to think about and address key and complex problems in the biomedical and health sciences. Two of the Interdisciplinary Research Exploratory Centers include the Behavioral Epidemiology Center at UC-Berkeley and the Antimicrobial Center at Columbia University. The second phase of development of the Exploratory Centers was launched in FY2005; further information may be found in NOT-RM-05-006 (*cf* February 4, 2005 *NIH Guide*). An RFA for the second phase is to be released in January 2006. The program anticipates funding 8 to 10 Interdisciplinary Consortia at approximately \$3 million/year and gives non-P20 Centers an opportunity to compete for support. A two-phase review will include evaluation and scoring of white papers (due May 2006) followed by invitations by the NIH Implementation Group to submit full proposals.

Information on administrative supplements to behavioral and social and biological sciences research grants (R01s, R37s, P01s, U01s with at least 1 year of funding remaining as of 9/30/05) may be found in NOT-RM-05-007 (*cf* February 4, 2005 *NIH Guide*); applications must be received by June 15, 2005. Response to the P20 announcement in FY2004 was very strong, and funding was highly competitive with an 8 percent success rate. Dr. Grady serves as Co-Chair of the Interdisciplinary Research Working Group, which reported a 25 percent success rate in its initial year.

Initiatives under the Re-engineering the Clinical Research Enterprise theme address new strategies to enhance infrastructure and capacity for clinical research and to re-energize the clinical research network through creating better integrated clinical research networks, preparing the clinical research workforce, and developing technologies and policies. Integration of clinical research networks will be achieved through linking existing networks to allow for the more effective conduct of clinical studies and trials and to ensure that patients, providers, and scientists form true communities of research. The FY2006 NECTAR (Network of Elective Clinical Trials and Research) will be launched at 12 sites with pilot projects that will have contract support for inventory, survey, and networking functions. The National Center for Complementary and Alternative Medicine (NCCAM) staff and Council reviewed 55 applications for Regional Translational Research Centers in May 2005, and 20 awards of \$100,000 each are anticipated. A second-round RFA to assess the planning and status of sites is slated for June 2005. Phase I of the Translational Research involves funding of small-scale/pilot-phase basic research cores; phase II will involve three types of centers, specifically, clinical services provided regionally, core technologies provided nationally and combined centers. About 20 phase II planning grants

per year are expected to be funded in FY2005 and FY2006; about eight Centers will be funded each year between FY2006 and FY2008.

The Roadmap Initiative PROMIS encompasses six primary research sites and one statistical coordinating center and which anticipates nurse researchers among its primary end-users.

Another initiative is a coordinated national multidisciplinary clinical research career development program housed in seven academic institutions across the country. This apprenticeship program will offer salary support to 20–25 scholars per site and is funded through the K12 mechanism. A predoctoral clinical research training program (T32) designed to increase the number of well-trained clinical researchers is targeting physicians, dentists, nurses, and other allied health care professionals who will assume leadership roles in patient-oriented investigations. A National Clinical Research Associates certification program is under development; to assess feasibility in target audiences. A meeting on enhancing the discipline of clinical and translational research will focus on how the NIH can foster the clinical and translational sciences into a new academic discipline and related issues; the meeting, which will be held on May 23, 2005, at the DoubleTree Crystal City National Airport Hotel in Virginia, may be viewed at <http://www.videocast.nih.gov>.

IV. UPDATE: PRESENTATION OF INTRAMURAL PROGRAM (Dr. Melinda Tinkle, Intramural Program Director for Research and Training and Special Assistant to the Director, NINR)

The Symptom Management Laboratory within NINR's Division of Intramural Research seeks to identify biological mechanisms underlying symptoms or clusters of symptoms associated with

disease conditions and states, measure symptom intensity and its effect on patients, and assess patient responses to interventions that reduce the burden of illness and treatment and improve quality of life. Key laboratory staff include Dr. Donna McCarthy, Acting Laboratory Chief; Dr. Ned Ramsay, Laboratory Manager; Dr. Jane Fall-Dickson, Investigator; Dr. Sue Marden, Clinical Nurse Scientist; and Laboratory Technicians Ms. Erin Graves and Ms. Jodi Penn.

Unit Programs within the laboratory are associated with three areas of research: cachexia (Dr. McCarthy), oral mucosal injury (Dr. Fall-Dickson), and quality of life (QoL) issues (Dr. Marden). The cachexia unit includes studies of biological mechanisms of tumor-induced cachexia, characterized primarily by weight loss and muscle wasting, and related symptoms in a mouse model; additional research focuses on protective effects on pro-inflammatory cytokines, indomethacin, and ibuprofen. The oral mucosal injury unit includes studies of the effect of topical thalidomide for the treatment of stomatitis in patients with chronic graft-versus-host disease, and of entercept (embrel) chemotherapy-induced stomatitis. Dr. Marden has been the PI on a range of studies examining the QoL in patients with HIV infection receiving intermittent versus continuous HAART, hematological diseases undergoing allogeneic bone marrow transplant, advanced melanoma, or hypertrophic cardiomyopathy. Dr. Marden is currently investigating technology dependence and QoL in patients with implantable defibrillators. Investigators in the Symptom Management Laboratory publish extensively in peer-reviewed journals.

The Division of Intramural Research is engaged in several training activities, including general research training such as the “Developing Nurse Scientists” and the “Level II” Nurse Scientists courses; pre- and postdoctoral training such as the Graduate Partnership Program (GPP) Pilot

Project and K22 Transition Awards; and long-term targeted training such as the Summer Genetics Institute. The Developing Nurse Scientists course is a Web-based program initiated in April 2002 following several years as an in-person course. To date, more than 4,500 individuals have completed the course for 5 contact hours. The course is consistently rated excellent in evaluations. Updates and revisions to the course are underway in the development of a second-level course (“Level II” Nurse Scientists), which will include new modules, including instruction on how to build research programs.

The GPP is an intramural program that links NIH researchers and laboratories to academic institutions for the purpose of training Ph.D. students. The program boasts approximately 400 participants from 70 universities conducting graduate research projects in association with 21 of the ICs, including NINR. NINR’s GPP Pilot Project involves development of a consortium of schools to participate in the program in three focal science areas: symptom management, genetics, and end of life. Schools in the consortium are selected based on funded research and appropriateness of matching, geographic distribution, and the balance of small versus larger schools. Six academic institutions are currently in the consortium. Students accepted into the program complete their coursework during the first 1–2 years of graduate school; they usually move to the NIH during their second year, when they go through research rotations, take additional courses, and have further learning experiences. The program provides a stipend, tuition assistance, health insurance, and travel monies. NINR currently has three GPP scholars, each at different stages of the program. NINR also supports K22 Career Transition Awards, which provide recent postdocs with intramural research training at the NIH for 2–3 years, after which the awardees transition to an extramural institution using funding from the K22 for up to 2 additional years. Most continue their research through the R01. NINR has three K22

investigators, one in the intramural phase and two who have transitions to the extramural phase of their awards. Awardees have been mentored by investigators at the National Institute of Neurological Diseases and Stroke (NINDS), National Institute of Aging (NIA), and National Cancer Institute (NCI).

NINR's Summer Genetics Institute (SGI) is a 2-month intensive research training held on the NIH campus. It includes lectures, case studies, seminars, hands-on laboratories, and special activities. The goals of the SGI are to develop and expand research capacity in genetics, expand the basis for clinical practice among advanced practice nurses, and build an institutional research infrastructure based on experience from the SGI. Graduates of the program include faculty, graduate students, and advanced practice nurses. As a group, they are very productive, as indicated from outcomes of graduates of the 2000–2004 courses. Their accomplishments include more than 70 publications, a highly successful grant award rate (more than 50 of 75 submitted research proposals funded), and numerous research presentations. Graduates have worked to implement innovative curriculum and practice projects based on their experience and training at the SGI, which has served as a springboard for further training and professional activities. Many are now in leadership roles in professional organizations and policy groups.

The NINR Intramural Program is in a growth mode, and future directions include expanding research opportunities in the Program's laboratories, ongoing recruitment of a Scientific Director, and further development of activities comprising the research training arm of the Institute. Dr. Tinkle noted that the intramural Web site has been redesigned, and she encouraged everyone to visit the new site at <http://ninr.nih.gov/ninr/>.

V. SYMPTOM MANAGEMENT LAB: CLINICAL TRIAL PROTOCOLS IN PATIENTS WITH ORAL STOMATITIS (Dr. Jane Fall-Dickson, Investigator, Symptom Management Laboratory, NINR)

Dr. Fall-Dickson has transitioned within the NIH from a Clinical Research Fellowship with the National Institute of Dental and Craniofacial Research (NIDCR) between 2001 and 2004 to a tenure-track investigator with the Symptom Management Laboratory. Criteria to reach tenure at the NIH include the creation, development, and dissemination of novel, high-risk research. The basic research track is approximately 6 years, and the clinical research track is 8 years. Dr. Fall-Dickson's primary area of investigation involves elucidating the pathogenesis of oral complications of cancer treatment and related symptomology (i.e., stomatitis and oral complications of chronic graft-versus-host disease [cGVHD]), with a focus on patients experiencing solid and hematologic cancers as well as hematologic diseases and those exhibiting the conditions and symptoms associated with the trajectory of peripheral blood stem cell transplantation (PBSCT) treatment process.

Stomatitis is the most debilitating treatment side effect of PBSCT, and it is associated with extreme acute oral pain, which has an adverse impact on the patient's clinical status and recovery and the efficacy of treatment plans.¹ Stomatitis can also have a significant economic impact, increasing hospital costs by up to \$43,000 among PBSCT patients with oral ulceration compared with patients without ulceration.¹ Despite an extensive list of agents that have been used to treat stomatitis, only a few have been studied in clinical trials; further, an optimal treatment regimen(s) for oral mucosal injury and related negative sequelae has not been established.

¹ Avritscher et al., *Sem Onc Nursing* 2004; 20:3-10.

Approximately 80 percent of patients with extensive cGVHD have serious oral manifestations such as tissue atrophy and erythema, lichenoid changes, and pseudomembranous ulceration.

To address these clinical research questions and problems, Dr. Fall-Dickson has established multidisciplinary collaborations within and outside the NIH through intramural and/or extramural programs at the National Heart, Lung, and Blood Institute (NHLBI), NIDCR, NCI, and NIH's Pain and Palliative Care Service. The unique aspect of her research on treatment of oral manifestations in cancer and transplantation patients is to examine the relationships among clinical signs, symptoms, QoL, and cytokine levels in saliva, plasma, tissue, and buccal epithelial cells. These research activities have been supported through two NINR grants for clinical protocols. One award has funded a 1.5-year pilot study (n=232) on the effectiveness of methods to assess TNF- α from buccal mucosal cells in chemotherapy (entercept)-related mucosal injury. Preliminary findings from this study indicated that stomatitis and oropharyngeal pain were a clinically significant ($p < .001$) problem for the cohort. Elevated salivary, but not plasma, TNF- α levels suggest a local mucosal inflammatory response, which provides a target for topical interventions. A second grant is funding a two-phase oral cGVHD study: a pilot study to test proof of concept (i.e., evaluation of a 0.1 percent thalidomide mouthwash for amelioration of cGVHD stomatitis) and, with success of the pilot assessment, expansion to a larger scale study of a topical thalidomide ointment or mouthwash (versus placebos) and other ICs and health care settings. The primary endpoint of the pilot study is healing of oral ulcers, defined as a minimum 80 percent reduction in ulcer size from baseline; primary outcomes in the main study include healing of oral ulcers and reduction in ulcer-related pain after healing.

In closing, Dr. Fall-Dickson stated that the program is positioned for sustainability, owing to several issues, notably the addressing of important clinical research questions to advance the science and promote patient health; the commitment of intramural, extramural, trans-NIH, and multidisciplinary researchers and establishment of collaborations with these investigators; and partnering with the NCI-sponsored Community Clinical Oncology Program (CCOP).

VI. FATIGUE RESEARCH IN HIV/AIDS (Dr. Joachim Voss, NINR K22 Trainee)

Dr. Voss is an NINR K22 trainee mentoring with NINDS researcher Dr. Marinos Dalakas. He has worked with HIV/AIDS patients in a variety of capacities since 1987 and was involved in the field during the transition of HIV/AIDS from an acutely lethal disease to a chronic illness. A research plan for the K22 should provide for novel research that develops and expands skills and knowledge in, as applicable, basic and clinical research. Dr. Voss' research goals are to test the biobehavioral relationships between subjective symptom experiences and objective biological measures in HIV/AIDS patients, expand symptom research on fatigue in these patients, and develop biomarkers for fatigue and mitochondrial toxicity in HIV/AIDS patients on antiretroviral treatments (ART). He noted that to date, there is no way to determine which patients on ART may develop mitochondrial fatigue, or to monitor the condition with assurance. Outcomes include review of research on mitochondrial intoxication in HIV/AIDS, hands-on training in relevant laboratory techniques and protocols, develop and implement a collaborative clinical protocol (n=75) between NINDS and the National Institute of Allergy and Infectious Diseases, and develop a customized microarray chip as a tool to identify and measure approximately 5,000 mitochondrial and nuclear genes. Dr. Voss' proposed research plans and outcomes span the first 2 years of his award.

**VIII. UNIVERSITY OF IOWA COLLEGE OF NURSING: FAMILIES LIVING WITH
OSTEOGENESIS IMPERFECTA** (Anne Letocha, M.S.N., R.N.; NINR Graduate
Program Partnership Scholar Doctoral Student)

Ms. Letocha, a Master's prepared pediatric nurse practitioner, participated in the SGI, in 2001. This experience challenged her to think as a nurse researcher, with a focus on clinical practice, and to learn more about molecular genetics. After completing the SGI, Ms. Letocha was hired by NICHD as a pediatric nurse practitioner, where she coordinated longitudinal protocols for the Osteogenesis Imperfecta (OI) program, studied the genetics of OI. At the 8th International OI Conference, she presented molecular and clinical data that suggested an association between COL1A1 and A2 and hearing loss in children as young as 2–3 years old through the teen years. These findings prompted recommendations to start screening children with OI much earlier for hearing loss.

The data also showed similar prevalence rates of hearing loss for the COL1A1 and COL1A2 mutations (40 versus 45.5 percent for the COL1A1 and A2 mutations, respectively) countered the commonly held idea that individuals with COL1A1 mutations are more likely to have hearing loss than persons with COL1A2 mutations. Ms. Letocha has continued her education at the doctoral level. She was accepted into the GPP and the University of Iowa College of Nursing. Her NIH mentor is NICHD investigator Dr. Joan Marini. Ms. Letocha is developing dissertation topics and may focus on the transition to adult health care for rare genetic diseases, using OI as a paradigm against the background of genetic nursing research. In response to a question, Ms.

Letocha stated that the information presented at the OI Conference has not been published yet and that further investigation of mutations and polymorphisms associated with OI are underway.

Following this presentation, Dr. Grady thanked participants and attendees for their time and interest. She adjourned the open session of the meeting and invited Council members to join Dr. Tinkle and Dr. Clair Hastings, Chief, Nursing and Patient Care Services, for a tour of the NINR's Intramural Program and clinical staff located in the Mark O. Hatfield Clinical Research Center.

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 69 research and training grant applications on which NINR was the primary Institute; these applications requested a total of \$15,209,850 (direct costs year 01). The Council also considered 214 applications on which another Institute/Center was primary and NINR was secondary; these applications requested a total of \$58,250,590 (direct

costs year 01). The Council concurred with the IRG recommendations on these 283 grant applications.

ADJOURNMENT

The 56th meeting of the NACNR was adjourned at 11:50 am on May 18, 2005.

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

MEMBERS PRESENT

Dr. Patricia A. Grady, Chair
Dr. Mary Kerr, Executive Secretary
Dr. Joan Austin
Dr. Peter Buerhaus
Dr. Louis Burgio
Dr. Kathleen Dracup
Dr. Jacqueline Dunbar-Jacob
Dr. Joyce Newman Giger
Dr. Sandra Millon-Underwood
Dr. Gary Morrow
Dr. Frances Munet-Vilaro
Dr. Dolores Sands
Dr. Joan Shaver
Dr. Anna Alt-White, *Ex Officio*
Dr. John Murray, *Ex Officio*

MEMBERS OF THE PUBLIC PRESENT

Ms. Mary Cerny, SCG, Inc.

Dr. Jan Dorman, University of Pittsburgh

FEDERAL EMPLOYEES PRESENT

Dr. Lauren Aaronson, NINR/NIH

Mr. Brian Albertini, NINR/NIH

Dr. Alexis Bakos, NINR/NIH

Ms. Diane Bernal, NINR/NIH

Mr. Ray Bingham, NINR/NIH

Dr. Yvonne Bryan, NINR/NIH

Mr. Lawrence Haller, NINR/NIH

Dr. Martha Hare, NINR/NIH

Ms. Renee Harris, NINR/NIH

Dr. Karin Helmers, NINR/NIH

Dr. Karen Huss, NINR/NIH

Ms. Anne Letocha, NINR/NIH

Dr. Donna McCarthy, NINR/NIH

Dr. Trudy McFarland, CSR/NIH

Ms. Mary Miers, NINR/NIH

Mr. Lanny Newman, NINR/NIH

Mr. Chuck Sabatos, NINR/NIH

Ms. Christian. Shaw, NINR/NIH

Ms. Arlene Simmons, NINR/NIH

Dr. Barbara Smothers, NINR/NIH

Ms. Allisen Stewart, NINR/NIH

Dr. Mindy Tinkle, NINR/NIH

Dr. Jeff Toward, NINR/NIH

Ms. Kay Valeda, NINR/NIH

Dr. Joachim Voss, NINR/NIH