The 37th meeting of the National Advisory Council for Nursing Research (NACNR) was convened on Wednesday, January 20, 1999, at 1:00 p.m. at the National Institutes of Health (NIH), Bethesda, Maryland. The meeting was open to the public from 1:00 p.m. until approximately 5:30 p.m. on January 20, and from 9:30 a.m. until 10:30 a.m. the following day. A closed session was held for consideration of grant applications following the open session. The closed session continued until adjournment at 1:00 p.m. Dr. Patricia A. Grady, Chair of the NACNR, presided over both sessions.

OPEN SESSION, January 20, 1999

I. Call To Order And Opening Remarks

Dr. Patricia A. Grady, Chair, NACNR, called the 37th meeting of the NACNR to order, welcoming all Council members, visitors, and staff.

II. Council Procedures And Related Matters

Conflict of Interest and Confidentiality Statement

Dr. Mary Leveck, Executive Secretary of the NACNR, reminded attendees that the standard rules of confidentiality and conflict of interest apply throughout the Council meeting. She also reminded NACNR members of their status as special Federal employees while serving on the Council and that the law prohibits the use of funds to pay the salary or expenses of any Federal employee to influence State legislatures or the Congress. Specific policies and procedures were reviewed in more detail at the beginning of the closed session and were available in council notebooks.

Consideration of Minutes of Previous Meeting

The minutes of the September 17, 1998, meeting of the NACNR were approved. Dr. Grady noted that the minutes from the September Council meeting had already been distributed for comment and approval. The new expedited process allowed the minutes from the September meeting to be posted on the NINR Web site approximately 6 weeks earlier. Following a request for comments, Council members approved the new protocol.

Dates for Future Council Meetings

Dates for meetings in 1999 and 2000 have been approved previously; no major conflicts with the proposed meetings dates were noted. Planning for meetings during the year 2001 is underway.

1999

- May 18-19 (Tuesday-Wednesday)
- September 14-15 (Tuesday-Wednesday)

2000

- February 1-2 (Tuesday-Wednesday)
- May 23-24 (Tuesday-Wednesday)
- September 12-13 (Tuesday-Wednesday)

III. Report Of The Director

Dr. Grady provided an update of NINR-related activities and events since the last Council meeting.

Legislative Activities

Dr. Grady noted three changes in the FY1999 NIH Appropriations law:

- The Office of Alternative Medicine became the National Center for Complementary and Alternative Medicine, a free-standing Center with grant-making authority.
The National Institute of Dental Research, celebrating its 50th anniversary, is renamed the National Institute of Dental and Craniofacial Research (NIDCR).

New Freedom of Information Act (FOIA) requirements have been established. Under these new requirements, data from all Federally awarded grants, including unreported data retained by investigators, must be made available to the public. This issue and implementation of these new requirements, is discussed under section XI of these minutes, “Distribution of Data Under FOIA — New Legislation.”

The language of the House Subcommittee report urged expansion of the areas of juvenile diabetes, pediatrics, Alzheimer’s disease, and strengthening of population-based research to enhance behavioral interventions that would reduce health-compromising risks.

Budget Items

Dr. Grady profiled several aspects of the FY99 budget for NIH, which was approved on October 21, 1998, per Public Law (PL) 105-277. (The Federal government was supported through a series of short-term continuing resolution after the FY98 appropriations ceased on September 30.)

Dr. Grady explained that there are two funding appropriations for NIH, one to each Institute for non-AIDS research and a second to the Office of AIDS Research (OAR) for the portion of each Institute’s budget to be allocated for HIV/AIDS-related research. She noted that when NINR staff testify to Congress for NINR’s budget, they are testifying for the non-AIDS budget allocation. The AIDS research funds come through the OAR. The total NINR budget for FY99, $70.053 million, includes funding for both AIDS and non-AIDS research.

The NIH appropriation is $15.612 billion for FY99, representing a 14.9 percent increase over the FY98 NIH budget. Of those funds, the NINR appropriation is $70.053, a 10.2 percent increase over FY98 funding (Table 1).

Although one of the smallest Institutes with respect to allocated funds (Table 2), NINR has continued to grow since its establishment with approximately $16 million in 1986. Increases in funding to NINR have generally kept pace with appropriations to NIH as a whole. However, proportional increments built upon a small base have resulted in the same relative ranking with respect to the total NIH budget.

Dr. Grady then discussed research-related activity and mentioned that NINR continues to receive an increase in new and competing applications. NINR’s growth in this area is demonstrated by data showing that NINR is one of few institutes across NIH that shows a trend of growth in the number of applications over the last five years. NINR has kept close to the NIH average with respect to overall success rates. However, as time goes on and the scientific opportunities increase, a decrease in success rate has occurred and can be expected unless resources follow the same incremental trend. This information clearly shows NINR’s growth and points to an increasing pool of nurse researchers in the field who are poised and ready to take advantage of available opportunities.

NINR’s research portfolio also appears to be maturing, as evidenced by an increase in the number of non-competing grants and a relatively constant number of competing grants awarded from 1995 through 1998. Further evidence for the maturation of the NINR research portfolio is found in the increasing length and size of R01 competing awards

The increasing average costs associated with NINR’s awards are due, in part, to the greater emphasis on clinical research, which carries with it higher costs for researchers’ time and effort. Dr. Grady noted that clinical research accounts for approximately 88 percent of NINR’s research portfolio, in contrast with a smaller percent at most other Institutes.

NINR continues to monitor Congressional activities as Congress begins to develop budget requests for FY2000.

Training Update

As suggested in the outline of NINR’s overall budget, the Institute stresses the importance of research training opportunities and activities for nurse scientists. As part of the commitment to training, NIH and NINR recently increased stipend awards so that they are aligned more closely with the recommendations of the 1994 National Academy of Sciences (NAS) report, Meeting the Nation’s Needs for Biomedical and Behavioral Scientists. The new annual stipends are $14,688 for
predoctoral students (an increase from $11,700) and $26,256 for postdoctoral researchers (an increase from $21,000). In 1998, NINR provided for 199 training fellows totaling more than $4.7 million. This figure represents 149 predoctoral fellows and 50 postdoctoral fellows in both the individual and institutional programs (Table 3).

Trans-NIH Activities

NINR continues to participate in a variety of trans-NIH activities, including ongoing workshops, meetings, working groups, and planning committees. Examples since the last Council meeting include:

- The NIH Consensus Development Conference on Rehabilitation of Persons with Traumatic Brain Injury.
- The proposed NIH Behavioral and Social Science Study Sections (for more information, and for a description of each of the study sections, go to http://www.drug.nih.gov/review/bss.htm on the Internet). Dr. Grady noted that review of all behavioral and social sciences research conducted at NIH has been completed and that NIH’s Center for Scientific Review (CSR) is in the implementation phase of this activity. The goals of this phase of the process are to: (1) ensure that CSR Behavioral and Social Sciences Study Sections reflect current, state of the science; (2) create a structure that can adapt to future developments in science; and (3) ensure high-quality peer review. The first set of grants will be reviewed by the new study sections in June, 1999.
- An expansion in the use of NIH’s Modular Grant Application and Award, as described on the Internet at www.nih.gov/grants/guide/notice-files/not98-178.html. The Modular Grant Application and Award program simplifies budget reporting and reduces the amount of time from application to awarding of the grant.

Outreach Activities

NINR’s outreach efforts take a variety of forms, including attendance at and participation in scientific meetings, collaborations with other research and professional organizations, and development and promotion of nursing research programs. Since the last Council meeting, NINR staff participated in meetings, conferences, or symposia including:

- Gerontological Society of America
- International Transplant Nurses Society
- National Coalition for Health Professional Education in Genetics
- Rehabilitation Nurses Association
- State of the Art and Science of Genetic Nursing
- Society for Neuroscience

NINR co-sponsored the conference, “Cutting Through the Clutter: Increasing Media Coverage of Nursing and Nursing Research,” held October 12, 1998. This day-long conference was designed to kick off a national effort to maximize media coverage of nursing and nursing research achievements at both the local and national levels. The morning panel included Dr. Bob Arnot, Chief Medical Correspondent at NBC-TV; Ms. Nancy Shute, from US News and World Report; Ms. Sally Squires, reporter for the Washington Post and National Public Radio (NPR); and Ms. Doreen Gentzler, TV news anchor in the Washington, DC. area. An afternoon panel of deans and public information officers from academic settings discussed case studies of successful media campaigns and tips for building effective working relationships with journalists. Panelists for the afternoon session included Dr. Norma Lang and Susan Greenbaum from the University of Pennsylvania; Dr. Patricia Stark...
and Pamela Lewis from the University of Texas Health Center at Houston; and Dr. Colleen Goode and Sarah Ellis from the University of Colorado Health Sciences Center.

Staff Updates

Dr. Grady made several announcements regarding NINR staff updates. The Associate Director for Scientific Programs now manages both the Division of Extramural Activities, which includes extramural programs, review, and grants management; and the Office of Science Policy and Public Liaison (OSPPL), which is responsible for planning, legislation, and information activities. The establishment of OSPPL is responsive to the Institute of Medicine’s (IOM’s) recommendations that each Institute and Center at NIH establish a public liaison.

Dr. Grady announced the following staff appointments: Dr. Mary Leveck has been named NINR’s Associate Director for Scientific Programs and Director of the Division of Extramural Activities; Dr. Carole Hudgings has assumed the duties of Acting Chief of the Office of Extramural Programs; and Daniel O’Neal has been appointed Chief of the Office of Science Policy and Public Liaison and serves as the NINR Public Liaison. The search for an Executive Officer is in its final stages, Dr. Grady reported.

Dr. Grady then introduced the following new members of NINR’s extramural staff:

- Dr. Janice Phillips, who received her Ph.D. in nursing from the University of Illinois, arrives from the University of Maryland. Dr. Phillips will be the Program Director for NINR’s Health Promotion and Risk Behaviors Portfolio.
- Dr. Karen Helmers, a graduate of the George Mason University School of Nursing, holds a Ph.D. in psychology and joins NINR from York University in Ontario, Canada. Dr. Helmers will serve as the Program Director for the Neurofunction and Sensory Conditions Portfolio.

Dr. Grady extended congratulations and a welcome to those cited. She also invited those in attendance to visit the Institute’s Web site at http://www.nih.gov/ninr.

Questions/Comments

Questions raised at the end of this presentation focused on the new FOIA requirements. Dr. Grady noted that representatives from all Institutes and Centers, including NINR, and other agencies as well are discussing and debating this issue and that concerns have been voiced about the new requirements. Additional queries on this topic were directed to the presentation to be made later during the Council meeting by Diana Jager from the Office of the Director, NIH.

IV. Report On The Meeting On Public Participation In NIH Activities

Council member Dr. Mary Lou de Leon Siantz provided a report on her participation with NIH to enhance interaction with the public. The Institute of Medicine’s (IOM’s) recent report, Scientific Opportunities and Public Needs: Improving Priority Setting and Public Input at the National Institutes of Health. As part of this initiative, NIH Director Dr. Harold Varmus invited 23 individuals representing a variety of NIH’s constituencies to attend a meeting on September 23, 1998, to discuss future activities and responsibilities of the key entities involved in public outreach, the to-be-formed NIH Director’s Council of Public Representatives (COPR) and the NIH Offices of Public Liaison (OPLs), located within each of NIH’s Institutes and Centers. Those attending the meeting included members of the business community, lawyers, educators, health-care providers, judges, and researchers in addition to individuals or family members with life-threatening and chronic illnesses. All had some knowledge of the NIH and recognized the importance and need for the public to have a basic familiarity with NIH’s impact at both the national and international levels.

Those attending the meeting generally agreed that the COPR would be filling dual roles to serve the needs of the NIH Director and the needs of the public it represents. The Director’s Council may consider establishing criteria for evaluating NIH performance, reviewing how well NIH’s messages are communicated and assessing NIH’s effect. The basic functions of the OPLs, outlined in part in the IOM report, include serving as a contact point for the public and the Congress, and as offices for outreach to constituency groups.

Dr. Varmus has indicated that the discussion from the September meeting would continue and welcomed further comments and suggestions from the invited participants and other members of the public.

Questions/Comments

Dr. de Leon Siantz and other NACNR members noted several implications of these recommendations and initiatives to the nursing research community and NINR. First, the nursing community has two primary constituencies, the lay public and colleagues in practice. The nursing constituency has several subconstituencies, including practicing RNs, who serve as strong patient
and public advocates; nurse researchers and scientists. Thus, outreach to these different groups requires a variety of approaches such as attendance and presentations at a variety of professional associations; community forums; development of Web pages and other Internet forums; articles and editorials in professional journals; and interviews or contributions to television spots and programs and newspaper and magazine articles, among others. Use of the Internet in particular was noted as a significant means to increase access to a wide range of constituencies; increased awareness of electronic information and outreach is a related challenge. One suggestion was to link the NINR Web site to public Web sites.

Another issue raised was that the public still seems to see nurses in traditional roles and future outreach and communications efforts need to address this perception. The benefits of nursing research must be clearly communicated to all audiences.

V. Strategic Planning For The 21st Century

Dr. Grady noted that NINR, like other Institutes and Centers, continues to face challenges in its strategic planning for beyond the year 2000. NINR has been engaged in preliminary work to determine how best to position the Institute and the nursing research profession for the new century. Part of that preliminary work involves gathering, reviewing, and coordinating suggestions, ideas, and guidance from groups across the country.

NINR is assisted in these efforts by the NACNR Planning Work Group, whose mission is to coordinate Council meeting agendas, provide a forum for sensitive issues, and advise the NINR Director on issues of strategic planning. The Planning Work Group meets prior to the council meeting and via conference calls as needed. Current members of the Work Group include Drs. Karen Miller, Mi Ja Kim, Kathleen Buckwalter, Steven Finkler, Ellen Rudy, and Ada Lindsey in addition to Drs. Grady and Leveck.

Following the introduction by Dr. Grady, Dr. Miller, representing the Planning Work Group, provided a brief summary of the Work Group’s most recent discussions surrounding strategic planning for the 21st century. These discussions included looking back on NINR’s and NACNR’s accomplishments over the past 10 years as a springboard for setting future goals and direction. Through its interactions, the Work Group also developed a set of discussion points for consideration by the Council. Dr. Miller noted that many external factors, such as Federal appropriations and policies, impact NINR and nursing researchers. Although these issues are important, NINR and the nursing community need to be proactive in their own strategic planning, in light of and also independent of these external influences. For example, NINR must identify how to best position itself to optimize its outcomes given certain conditions.

Members of the Planning Work Group first reviewed NINR’s mission and then began to devise a simple action plan that would address the proposed discussion points and take the Institute into the next century. The overall goals suggested by the Work Group include:

- Increasing the impact of NINR with NIH
- Identifying scientific areas where we can achieve distinction
- Identifying future areas of research opportunity
- Communicating and disseminating research findings
- Enhancing capacity-building for the future development of researchers

Dr. Miller reported that the Planning Work Group would like to have a strategic plan in place by the end of 1999.

Comments/ Questions

As part of the strategic planning process, it may be helpful to identify those studies that produced the “greatest yield” with respect to impact on Congress, NIH, the public, the nursing community, and to determine the nature of these studies. Dr. Grady commented that each of NINR’s Program Directors are reviewing their respective science research portfolios for such examples. She called for feedback and direction in facilitating these reviews. Another approach is to identify and pursue those areas in which nurse researchers are highly experienced, such as chronic care, clinical care, and end-of-life issues.

Taking a step forward, the Council also should seek to identify new areas in which nurses could have an impact. The community might consider, for example, the role of nurses as public liaisons. The strengths and skills associated with some areas of nursing research that likely will be relevant to society in the future (e.g., end-of-life care) also should be considered. In this capacity, nurses play a critical role in their ability to translate clinical research findings to those who do not understand the science of those findings. An increase in the number of patents filed by nurse researchers, or resulting from research in the field, signal a maturation of the research community and increased opportunities for recognition of the accomplishments in this field. A comprehensive review that clearly documents such issues would be helpful.

The nursing research community also must identify its
constituencies: Are we trying to reach each other? Other scientists outside the field of nursing? The public? Patient advocacy groups? Professional advocacy groups? Young people? Seniors? It was noted that researchers in other disciplines often are not aware of the research being conducted by the nursing research community. Once audiences and their needs are identified, public service announcements (PSAs), press conferences, articles, and other tools with a broad or targeted message that attract attention while showing what nursing is all about could be developed. Several examples were discussed to highlight activities that could be undertaken. Council members also were reminded that the Ad Hoc Communications Committee is addressing many of these issues.

In summary, NINR and the larger research community must identify and balance its priorities, make opportunities to promote these issues, and take advantage of already existing situations to enhance and expand awareness of the accomplishments in this field of research. The dialogue on strategic planning for the 21st century is ongoing, and Council members and the Planning Work Group welcome feedback and input.

Summer Research Training Program

Before moving to the next presentation, Dr. Grady announced that the Summer Research Training program, co-sponsored by NINR and the Clinical Center Nursing Department, is now accepting applications. The program will run from July 20, 1999, until July 23, 1999. Interested parties can access the NINR Web site or contact Dr. Ann Knebel via e-mail at aknebel@nih.gov for more information. Minority applicants are encouraged to apply to the program; names of potential candidates for the program may also be submitted to Dr. Knebel.

VI. Discussion Of Fy2001 Areas Of Opportunity

Dr. Grady explained that the Council reviews potential areas of opportunity each January. Each of the proposed areas identified is assigned to two Council members, who provide a brief assessment and timeline for their area. Suggestions for possible areas of opportunity come from a variety of sources across the country, including NINR staff, NACNR members, members of the larger nursing research community, portfolio reviews, published findings, and workshop and conference presentations. Identifying possible areas of opportunity within the nursing research field assists NINR is its planning processes. Dr. Grady reminded the group that NINR, as part of the Federal government, is planning for and working with three fiscal-year budgets simultaneously.

There are several goals associated with identifying areas of opportunity. For example, developing areas for opportunity helps fill gaps in NINR’s research portfolios. As Dr. Grady noted, most identified and approved areas are developed further to become program announcements (PAs) for future study. In contrast, those areas that the Council believes are very early in development may, instead, begin with a workshop to explore the state-of-the-science and the projected importance of the area.

This year, the Council was asked to consider the seven areas of opportunity for NINR for FY2001, as outlined below. These may be linked to the six FY2000 NIH areas of emphasis: the biology of brain disorders, new approaches to pathogenesis, new preventive strategies against disease, new avenues for the development of therapeutics, genetic medicine, and computers and advanced instrumentation. For NINR, the proposed FY2001 areas of opportunity include:

Area 1: Nursing Management of Normal Labor and Birth

Management of labor and birth are issues that are of relevance to consumers, health care practitioners, and the nursing community. Some of the potential research areas include determining which noninvasive and nonpharmacological care measures are effective in improving a range of patient outcomes and increasing patient satisfaction; determining which clinical variables are predictive of abnormal progress in labor or poor labor outcomes; exploring whether noninvasive approaches (e.g., continuous support in labor) reduce costs and the need for increased intervention; and examining the effects of technologic measures such as telemedicine on care during labor.

Discussion

Some Council members, while recognizing the continued importance of this area to nursing and the cadre of NINR-funded scientists researching this subject, questioned whether this represented a truly new area of opportunity. It was pointed out that this is an area with some components, such as the use of telemedicine and telemonitoring, that have not been studied in depth and might lend themselves to future investigation. There was mixed support for this research area as presented, and a subsequent draft outlining the rationale for making this a research area of pursuit will be prepared.

Area 2: Patient Decision Making Under Conditions of Uncertainty

This submission addresses opportunities for nurses to participate in the patient decision-making process.
Several changes that would strengthen the current proposal were identified. First, the area should not be restricted to "conditions of uncertainty;" in many cases, the patient prognosis is well known. Thus, the area should consider patient decision making under conditions of certainty and uncertainty. Second, the role of nursing interventions regarding the point of uncertainty should build on already existing data. Third, based on such information, the agenda for this area should take such data into account in asking the next order of questions, for example, which nursing interventions help with patient decision making. Fourth, this area should push past the descriptive realm. Thus, a statement requesting studies of the impact of specific, structured nursing interventions or tools that assist patients in decision making (e.g., patient education, family discussion and clarification) should be added to the list of potential research areas under this topic. Outcomes, including cost benefits of various interventions, should be included. Fifth, the reviewers questioned whether the last point, which recommends studying the role of alternative psychosocial options among patients who decline participation in support groups, may not fit in this category. Other points that should be incorporated into this proposal include genetics, specifically, genetic risk assessment; cost-benefit or cost-outcome studies or analyses in relation to how nursing interventions affect patient decisions; and cultural considerations.

Also relevant to this area of opportunity is the informed consent process and recent shifts in what is considered "reasonable" to the patient, the nurse, the doctor, and the family. Many patients and their families do find it easier to communicate with nurses about a variety of issues, and nurses, in turn, are more available to patients than physicians; thus, the nursing community should not forfeit this opportunity.

Discussion

Because the field of genetics changes so rapidly, the content of this area should continue to be revised and updated, as needed, through its implementation in 2001. Another comment suggested some overlap between this area of opportunity and the previous area (i.e., regarding nursing interventions in patient decision making) with respect to the advent of genetic tests that are being used to predict risk for certain diseases.

Dr. Grady took time during this discussion period to announce an 8-week summer training program, named the Summer Genetics Institute, to be held in the year 2000. This course will offer lectures and both clinical and hands-on laboratory experiences in clinical genetics. Students in the course will also have the opportunity to work one-on-one with mentors. NINR is the lead Institute for this program in collaboration with the NHGRI and NCI. NINR’s Division of Intramural Research is developing the curriculum and securing expert instructors for the course. Dr. Annette Wysocki is the contact person for the program.

Area 4: Managing Symptoms of Congestive Heart Failure

Congestive heart failure (CHF) is an important public health problem, affecting an estimated 5 million Americans. It is the number one reason for hospital admissions among older adults. The reviewers recommended that this submission be refined somewhat so that the proposed research areas identified are based more on testing the effectiveness of interventions that will facilitate self-management of symptoms associated with CHF. Because research is already underway in this area, however, a question whether this area would still be...
considered new in 2001 was raised. The importance of this research is not expected to diminish over the next two years because of the prevalence of the problem.

Discussion

One attendee noted that this issue has strong implications for telemedicine, particularly with clients in rural America, with respect to monitoring of symptoms and exercise.

Area 5: Model Strategies for Self-Management Across Chronic Diseases

This area of opportunity proposes testing the effectiveness of interventions across chronic illnesses and across specific subgroups of chronic illness. It would identify and then test models of effective self-management intervention strategies for these groups. The reviewers considered this a much-needed area of research that should elicit some solid proposals. It is a good example of a cross-cutting area of research for which interventions are available. Implementation of research founded on this area would be expected to increase generalizability of self-care management interventions.

Some suggestions to expand this area were offered: (1) identifying and testing strategies that caregivers use to enhance self-management by the patient; (2) acknowledging the roles of alternative and complementary medicine in self-care management, which could lead to partnering with NCCAM; (3) expanding telehealth strategies to assist in the use of self-care management, which would complement the previous area of opportunity; (4) testing of evidence-based guidelines that would need to be modified across various settings; (5) examining nursing administrative or care coordination systems that foster self-care management; and (6) analyzing secondary data sets and conducting meta-analyses to identify and evaluate effective strategies as they are applied to different settings or different diseases.

Discussion

This proposal was greeted with enthusiasm and support. Incorporation of the study of caregiver strategies was of particular interest. The importance of this area was stressed, as was the timeliness of the issue that makes it difficult to delay implementation of the initiative.

Area 6: Diabetes Self-Management in Minority Populations

The reviewers were positive about this submission, which focuses on Native Americans, African Americans, and Hispanics. They recommended that this area of opportunity be given high priority. This submission goes beyond differences in minority populations and addresses cultural (in addition to racial and/or ethnic) differences in managing chronic disease. Such differences can also include whites or persons from rural areas that are at a low socioeconomic level. Many of the fundamental principles included in this area probably are, or will be found to be, translatable to other chronic illnesses.

Discussion

This area responds to emerging issues and opportunities and efforts of the trans-NIH committee and the Diabetes Research Working Group and speaks to NIH’s efforts to raise awareness of health disparities across various populations. Because it also relates to other areas of opportunity, specifically to issues of self-management, it may be worthwhile to consider pooling resources across these areas.

One component lacking from this proposal, however, is the absence of studies that would investigate the economic implications of chronic diseases in relation to issues such as self-management, employability, socioeconomic status (SES), and ability to pay for medical care. Attendees acknowledged that capturing and measuring cost outcomes is difficult but possible. A workshop to share methods for cost measure and analysis in nursing studies may be of great benefit.

Area 7: Telehealth Interventions to Improve Clinical Nursing Care

This area of opportunity describes the many forms that telehealth or telemedicine can take (e.g., via still images, video, use of teleconferences, telephone interventions, the Internet). Because nurses are at the center of communications strategies in the health care setting, they often are responsible for monitoring communication or other digital devices. Thus, through this area, nurses can choose to be, as they have in the past, on the cutting edge of the interface between technology and medicine.

NINR scientists have conducted studies that support the benefits of several telehealth applications, such as providing telephone consults, developing of computer- and Web-based health information and educational models, and overseeing the use of home-monitoring devices that transmit data electronically to practitioners at distant sites. Some additional issues related to telehealth that may also be pursued through nursing research include accessibility, cultural sensitivity, and expansion of the technologies beyond disease-based
practice.

It is clear that this form of communication is here to stay and will continue to grow and advance. The reviewers suggested that this area be “fast-tracked” to push it ahead of the FY2001 schedule.

Discussion

Attendees suggested that the various telehealth prototypes be evaluated carefully before being brought into practice. Licensing, training, confidentiality, and privacy are other very important issues with respect to electronic and technological advances in medicine and health.

VII. NINR Research Activities: HIV/AIDS

Dr. June Lunney, Program Director and AIDS Coordinator, NINR, highlighted NINR’s HIV/AIDS portfolio. HIV/AIDS is a worldwide problem. Cultural, social, and economic variations, however, have contributed to very distinct and disturbing differences in both the spread and treatment of HIV in global regions. The U.S. research community has begun to respond by prioritizing those projects that are expected to have both international and local benefits. For example, in recent months, the NIH Office of AIDS Research has spearheaded major efforts toward vaccine development. Dr. Lunney noted that although NINR has not yet become involved in HIV/AIDS vaccine research, it is important nonetheless to pay close attention to research trends in this field. Further, in the United States, the profile of HIV-infected persons has shifted, from a group of highly educated and motivated gay men to a very vulnerable population that includes disproportionate numbers of minorities and increasing numbers of women. Targeted prevention methods must be identified and researched to stop this trend, and modifications in treatment and prevention methods must be tested to accommodate varying cultural and behavioral factors that should be considered if we are to successfully treat these vulnerable populations. Finally, although some breakthroughs in treatment regimens have occurred in recent years, no simple treatments exist. Treatment is daunting and complex.

The NINR has maintained steady growth in its AIDS research budget, starting with an allocation of $600,000 in FY88 to more than $6 million in FY99. Funds for AIDS research are appropriated separately from non-AIDS research funding. To ensure that these funds support high-quality research, NINR seeks applications from nurse scientists and interdisciplinary teams that ask questions that are designed to improve nursing practices.

NINR-supported studies form clusters according to several areas of interest. For example, in 1994, NINR released an RFA seeking small-scale studies examining symptom management of persons infected with HIV. This was followed by a second RFA in 1996 for full-scale symptom management studies. Results of the small-scale studies are highlighted below. Results from the second initiative should be available in the next 2 to 3 years. Other past initiatives included collaborative PAs on behavioral research in support of AIDS prevention and understanding and improving adherence to retroviral treatment regimens.

Efficacy has been demonstrated for the interventions tested in three of the projects funded as a result of the first RFA. Dr. Barbara Smith, from the University of Alabama at Birmingham, was the principal investigator for one of these studies, which demonstrated the benefits of exercise on symptom management in HIV-infected persons. (Results of Dr. Smith’s study are presented in the next section, “Effects of Exercise on Symptoms of HIV Infection.”) Another ongoing project addresses fever management. A sample of AIDS patients within this project who had fevers greater than 102° demonstrated that insulated wraps and draft control were more effective in reducing fever in this population than more traditional techniques such as ice packs and cooling blankets. Draft control and insulated wraps also improved thermal comfort; reduced shivering, fatigue, and metabolic costs of fever; and produced lower body temperatures. These findings are being incorporated into the major HIV nursing textbooks.

In another study, Dr. Ann Williams at Yale University compared standard care with two nurse-prescribed prophylactic regimens. The goal of this study was to reduce the incidence of vaginal candidiasis among HIV-infected women without using systemic antifungal agents in an already heavily medicated group. Preliminary results indicate that both nurse-prescribed interventions reduced the incidence of vaginitis by more than 50 percent. A case-control analysis of the predictors of vaginitis is now underway to identify which HIV-infected women would benefit most from this intervention.

A former Council member, Dr. Loretta Jemmott, has completed a randomized clinical study of 365 African-American women attending a family planning clinic in a low-income, inner city community. The researchers compared a social-cognitive intervention that included skills building with an information-only HIV prevention-intervention and a control comprising a generic health promotion program. The two experimental interventions were studied in both a small-group setting and as a one-on-one experience. The skill-building interventions resulted in significantly increased condom use,
fewer self-reported risk-taking behaviors, and fewer clinically documented sexually transmitted diseases (STDs). The details of this study will be published in the near future.

In another study, Dr. Linda Aiken from the University of Pennsylvania collected comprehensive, high-quality data from 20 hospital in 12 cities across the United States. The data set included detailed information on more than 1000 AIDS patients and nearly 1,000 nurses. The study found that patients in the nursing units dedicated to the care of AIDS patients were significantly more satisfied with their nursing care than patients in other units. Dr. Aiken’s team also found that the creation of specialized AIDS units resulted in better outcomes for nurses. Specifically, nurses’ perceived job status was enhanced, job autonomy was increased, and interactions with physicians were improved; nurses also reported experiencing less burnout.

Ongoing studies concerned with symptom management include:

- Dietary interventions to reduced diarrhea in HIV-infected persons,
- A sleep hygiene program to lessen fatigue, and
- Information and communication skills-building interventions to improve pain management in AIDS patients.

Studies seeking to identify or test interventions to improve adherence to treatment regimens include:

- A community-based project testing the impact of a self-efficacy-based intervention on adherence. Evidence from other populations indicates that increasing patients’ skills and confidence in their ability to control the symptoms and disabilities associated with their illness is useful in promoting self-management of symptoms and active participation in self-care and decision making.

- A phone-based intervention to test the benefits of a program of 12 independent telephone sessions designed to improve daily drug-taking habits through the development of self-assessment and problem-solving skills. This intervention, if efficacious, could provide a cost-effective means of extending provider support of HIV-infected patients.

- A home-based intervention with an emphasis on dialogue and subjective actions, in contrast with the passive receipt of information. This approach takes into account the environment in which the patient lives.

The NINR has also been active in developing and supporting research that will reduce high-risk behaviors and increase the use of interventions that will stop the transmission of HIV. Recently funded projects in this area include:

- A school-based prevention program for pregnant and parenting minority adolescents.
- A community based, parent-teen education program for middle school children.
- Programs incorporating culturally sensitive interventions for inner-city Latinas.

Other current and future NINR research efforts and endeavors focus on:

- Collaborations with the World AIDS Foundation to facilitate information exchange among nurses in developing nations. Solicitation of concept letters for small grants in support of AIDS research and education in developing countries is underway.
- Collaborations with the Clinical Trials Networks.
- The FY99 Initiative, Neuroimmunological Effects of Behavioral Interventions.
- End-of-life research.
- Behavioral issues associated with vaccine development.

VIII. Effects Of Exercise On Symptoms Of HIV Infections

Dr. Barbara Smith, who holds the Marie O’Koren Endowed Chair in Nursing at the University of Alabama (UAB) at Birmingham, presented results of her study, “Aerobic Exercise and Symptom Management in HIV,” which was one of the initial four NINR-funded studies to investigate symptom management of HIV/AIDS. The co-PI of the study was Dr. Judith Neidig. The study was a collaborative effort that drew on expertise in nursing, psychiatry, exercise physiology, pulmonary medicine, internal medicine, biostatistics, and immunology. The AIDS Clinical Trial Unit provided additional support for the study, particularly for supplemental laboratory work.

The specific aim of the study was to measure the impact of regular aerobic exercise on participants’ (1) physical symptoms (including weight and body composition), (2) immune status (including viral load and sev-
eral T-cell and other markers, such as CD4, CD8, and CD56 counts), (3) psychological health (including depression and mood), and (4) aerobic capacity (i.e., \( VO_{2\max} \)). Study participants included men and women 18 to 50 years old who had tested positive for HIV.

Individuals exercised in a controlled setting on campus for 12 weeks; follow up continued for up to 60 weeks after completion of the study. The exercise regimen included interval training on a bicycle, treadmill, or track three times a week. Each exercise session lasted for 60 minutes, during which time participants worked at heart rates equivalent to 60 to 80 percent of their \( VO_{2\max} \); this measure of exertion was modified throughout the study as capacity improved (or lessened). The two-group design included pre- and posttest measures. Efforts were made to control for a variety of confounding factors that could influence or compromise physical and mental health status of the participant, such as alcohol and tobacco use, cognitive function, concurrent medicine use, nutrient intake, nutritional status, cardiac output, pulmonary function, and stress hormone levels.

Results of the study are encouraging. The regular aerobic exercise regimen produced significant improvements in time on treadmill, aerobic capacity, and vigor and reductions in fatigue, anger level, and depression. Exercisers also saw significant increases in percent body fat without weight gain. Measures of immune status, specifically, CD4 count, CD4 percent, and viral load, remained unchanged, indicating that regular physical activity did not harm immune function. The exercise program outlined in this study thus seemed to have an overall positive effect on the physical health and mental status of HIV-positive persons. The program could be implemented with relative ease for many individuals and may be translatable to clinical practice as an intervention. As with other regimens, monitoring and compliance are critical to success.

Future studies will incorporate ways to obtain a more accurate measure of weight loss or gain and body composition among those who exercise. Because wasting is a common symptom of AIDS, interventions that counter such effects are particularly important.

**IX. Inclusion Of Women And Minorities In Research**

Dr. Gertrude McFarland, from NIH’s Center for Scientific Review (CSR), discussed the inclusion of women and minorities in NIH- and NINR-funded clinical research, per implementation of the 1993 NIH Revitalization Act (PL 103-43) mandating that NIH ensure that women, minorities, and their subpopulations be represented appropriately in all its human subject research studies. Although some exceptions are allowed under this Act, research projects proposing to exclude women and/or minorities must provide a clear and compelling rationale for their exclusion. In Phase III trials that evaluate the impact of an experimental intervention, it is important that sufficient numbers of women and minorities must be included to ensure meaningful statistical analysis of results. Dr. McFarland noted that the full complement of directives and policies may be found at CSR’s Web site, as indicated in the PHS 398 grant application kit.

Through its Tracking and Inclusion Committee, the NIH has developed a variety of strategies to ensure uniform implementation of the 1993 guidelines across the NIH. In assessing compliance with the 1993 mandate, reviewers are instructed to evaluate the proposed gender and minority composition of the study population and its appropriateness to the study objectives of the application under review. If the representation in the study design is inadequate to answer the questions posed, and a justification for this inadequacy is not provided or is insufficient, the deficiency can be factored into the score of the application.

NIH is now able to monitor demographic data for study populations on an NIH-wide basis through a computerized tracking system. Dr. McFarland noted that of NIH proposals in January 1995, 5,392 applications included human subjects. Of those, only 4.3 percent received a “gender unacceptable” code, and 6.9 percent had a “minority unacceptable” code. In May 1995, 5,677 applications included human subjects; of those, 4.6 percent were deemed gender unacceptable, and 6.7 percent received a minority unacceptable code.

The Nursing Study Section of CSR reviews the majority of applications on which NINR is the primary institute. Data from the November 1998 review of submissions to the CSR study section showed that of 57 R01s submitted that received a score, two were coded minority unacceptable, three were gender and minority unacceptable, and 14 were gender unacceptable. These figures are higher than the NIH average. Program and review staff will work with the scientific community on this issue.

Descriptive data from critiques of applications provides insight into some of the problems in the reviewed proposals. For example, the applicants often state in their proposals that a study will include equal numbers of men and women, or a representative distribution of minorities, but then offer no further information. Reviewers also note that many proposals do not discuss minority recruitment, or recruitment in general, whereas others exclude some minority groups without reason. Still other applications provide no information or data regarding the representative nature of the population(s) expected to be included in the study.
The following suggestions are provided by reviewers for investigators to improve gender and minority representation in human research studies:

- Include on the research team women and minorities who have experience with the populations to be included in the study.
- Explore the extent to which universities provide resources for efforts to recruit and retain women and minorities.
- Include relevant local, regional, and national statistics.
- Describe changes in protocol, study design, and/or rationale, any problems that surfaced during preliminary investigations.
- Monitor compliance at the level of the Institutional Review Board (IRB).

Approaches that the reviewers thought NIH could initiate to improve recruitment and retention of women and minorities in clinical research included:

- Providing a sample write-up of a gender/minority section of an application on the NIH Web site.
- Placing more specific, user-friendly instructions in the PHS 398 grant application.
- Distributing publications and materials that describe this mandate.
- Giving examples of successful strategies for recruitment and retention of women and minority volunteers.

Dr. McFarland closed her presentation by noting that, up to this point, the Nursing Study Section was included in an IRG called Health Promotion and Disease Prevention, which has been dissolved. The Nursing Study Section is now housed in the IRG entitled Social Sciences, Nursing, Epidemiology and Methods.

In discussion, it was suggested that CSR develop a special Web site devoted to developing and/or identifying well-developed, successful strategies and models for recruitment and retention of women and minorities to clinical research studies. Collaborations with the Office of the Director and/or the Office of Extramural Research may help facilitate this process.

Annual Council Review of NINR Data on Women and Minority

Dr. Carole Hudgings, Acting Chief of NINR’s Office of Extramural Programs, provided data for the annual council review of minorities and women in NINR research. Overall, the data indicate that NINR appears to be relatively strong in its ability to recruit these populations in clinical studies. Some attendees commented that this is noteworthy and should be promoted across NIH and also within the nursing community.

X. Annual Statement Of Understanding

Dr. Leveck provided an update on the statement of understanding between NINR staff and the NACNR on a variety of proceedings, policies, and protocols. This statement is reviewed annually and updated, as needed, by NINR staff member Mr. Jeff Carow. Dr. Leveck noted that no changes to the statement were recommended this year. Council members had no comments on the statement, and it was agreed that the statement of understanding will continue as written for the coming year. The next update will be presented to the Council in January 2000.

Xi. Distribution Of Data Under Foia — New Legislation

Dr. Grady reminded attendees of the new legislation concerning confidentiality and availability of information from Federally funded research including clinical trials and studies under the Freedom of Information Act (FOIA). This new legislation, which has raised questions and concerns within the research community, was discussed in more detail by Ms. DianaJaeger, Acting Director, Office of Policy of Extramural Research Administration, and Director, Division of Grants Policy, Office of the Director.

Ms. Jaeger’s presentation highlighted various aspects of the new legislation, including some background and history of FOIA. She began by noting that in the Omnibus 1999 Appropriations bill, Congress directed the Office of Management and Budget (OMB) to amend OMB Circular A-110 (Uniform Administrative Requirements for Grants and Other Agreements with Institutions of Higher Education, Hospitals, and other Non-Profit Organizations) to extend the FOIA to require Federal awarding agencies to ensure that all data produced under an award will be made available to the public under the [FOIA] . . . If the agency obtaining the data does so solely at the request of a private party, the agency may authorize a reasonable user fee equaling the incremental cost of obtaining the data. (Statutory language from HR 4328, Title III: PL 105-277 10/21/98)

OMB Circular A-110 prescribes the general administrative requirements to Federal agencies, including the NIH, in their awarding of grants and cooperative agreements. Each agency, in turn, implements the circular through its own regulations. NIH’s implementation occurs through the Department of Health and Human
Services (HHS), CFR Part 74, Title 45, which is applied as a term and condition of every NIH award.

As Ms. Jaeger noted, the content of the few lines quoted above is an extremely complex and sensitive policy matter. NIH endorses the strategies that support the sharing of data but remains sensitive to this issue and is concerned that the current language does not address several important concepts. These concepts, the NIH and other agencies argue, must be clarified to ensure that data sharing can be undertaken while ensuring the integrity of the data, the confidentiality of participants (especially those in clinical trials), the investments of researchers and institutions in the research, and the continuance of important research activities.

Because this legislation extends an existing statute (i.e., the FOIA), it is useful to recall that FOIA does allow for some exemptions, for example, propriety data and confidentiality of human subjects. However, the FOIA applies only to records that the Federal government possesses. The new language extends these procedures to data that grantees hold.

Some of the issues and concerns that NIH has raised thus far include:

- What are data? How do we define data? What is the basic definition of data?
- When do data have to be released? An obvious point of release is with publication of the data. However, many studies result in a series of publications, each of which involves subsets of the larger data set. Would publication of any data require the release of all data?
- Is privacy of individual subjects protected? The protection that might be afforded individuals under current FOIA exemptions must be questioned. Even if individual identifiers have been removed from study data, if persons participating in a trial could seek to obtain data, then questions arise regarding the protection of blinded trials. Depending on the nature of the data released, participants could decide to leave a study, thereby directly influencing the outcome of the study based on their FOIA request. Such decisions could potentially invalidate a trial.
- How far-reaching is this new legislation? The present language applies to data funded wholly or in part by the Federal government. This phrasing raises concerns for researchers whose studies are funded by multiple sources and limited Federal support.
- How long must the data be available? The current OMB regulations have a 3-year record retention policy in place (i.e., data must be retained for 3 years after submission of the final expenditure report.
- How is compliance assured? What measures will be used to ensure compliance with the new regulations? Who will determine and carry out penalties for noncompliance? Who will bear the burden of the cost of these activities?
- Are there ways to assure appropriate release of data? NIH has suggested that, given the wide variety of types of data that might be involved in this process, agencies might elect to develop their own data-sharing policies that encompass the specific circumstances they expect to encounter.

NIH has already taken several steps to address the new legislation. For example, it has established a working group, chaired by Dr. Wendy Baldwin. The working group is preparing a document that raises many of the questions, issues, and concerns posed here. The final document will be available at some point in the future to the public for review. In the interim, comments can be sent to the NIH Deputy Director at dder@nih.gov.

OMB will propose changes to OMB Circular A-110 in an upcoming issue of the Federal Register as a Notice of Proposed Rule Making. Once the Notice is published, the public, including NIH, has 60 days to comment on the proposed changes. NIH will work closely with other agencies and Institutes/ Centers to gain a broader perspective of the issue but plans to prepare a single comment in response to OMB’s FR notice. Ms. Jaeger noted that the full text of OMB Circular A-110 can be found on the Internet at www.whitehouse.gov/WH/EOP/OMB/html/circular.html. The statutory language amending OMB Circular A-110 can be found at the Library of Congress’s Web site at http://thomas.loc.gov.

Comments/ Questions

It was noted that this new legislation was a Congressional initiative and was not generated by OMB. (See Science, 6 November 1998, p. 1023.) Current legislation pending in the House (HR 88), sponsored by Rep-
representative George Brown of California, would repeal this initiative.

Attendees agreed that this is a high-priority issue and strongly supported implementing a broad marketing effort that would reach professional organizations and associations and academic medical institutions across the country. Ms. Jaeger reported that this issue has already received, and will continue to receive, a great deal of press. The Council on Governmental Relations, for example, prepared a white paper on this issue soon after the appropriations bill was released. In addition, Ms. Jaeger has addressed the new legislation at the Federal Demonstration Partnership, an organization of 65 institutions and 11 Federal agencies. Further, the HHS Data Council will be preparing a response to OMB’s FR Notice. In addition, several associations have contacted NIH requesting presentations that address the specifics and implications of this legislation. Thus, momentum and interest surrounding the legislation are growing.

XII. Closing Remarks

Dr. Grady ended the open session by thanking those present for their time and participation.

CLOSED PORTION OF THE MEETING

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.

XIII. Review Of Applications

The members of the National Advisory Council for Nursing Research considered 133 research, career development, and training grant applications requesting $105,335,721 in total costs. The Council recommended 87 applications with a total cost of $72,826,836.

XIV. Other Items For The Closed Session

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

XV. Adjournment

The 37th meeting of the NACNR was adjourned at 1:00 p.m. on January 21, 1999.

CERTIFICATION

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

__________________________________
Patricia A. Grady, Ph.D., RN, FAAN
Chair
National Advisory Council for Nursing Research

_____________________________________
Mary D. Leveck, Ph.D., RN
Executive Secretary
National Advisory Council for Nursing Research

Council Roster (please click here for current council roster)
<table>
<thead>
<tr>
<th>Members Present</th>
<th>Federal Employees Present</th>
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<tbody>
<tr>
<td>Dr. Patricia A. Grady, Chair</td>
<td>Dr. Nell Armstrong, NINR/ NIH</td>
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<tr>
<td>Mr. Gene A. Blumenreich</td>
<td>Mr. Jeff Carow, NINR/ NIH</td>
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<tr>
<td>Dr. Dorothy Brooten</td>
<td>Ms. Harriet Carroll, NINR/ NIH (ret.)</td>
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<td>Dr. Kathleen C. Buckwalter</td>
<td>Ms. Colette Carter, NINR/ NIH</td>
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<td>Dr. Mary Lou de Leon Siantz</td>
<td>Ms. Linda Cook, NINR/ NIH</td>
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<td>Dr. Betty R. Ferrell</td>
<td>Ms. Janet Craigie, NHLBI/ NIH</td>
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<td>Dr. Steven A. Finkler</td>
<td>Dr. Karin Helmers, NINR/ NIH</td>
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<td>Dr. Judith H. LaRosa</td>
<td>Dr. Carole HUDGINGS, NINR/ NIH</td>
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<td>Dr. Ada M. Lindsey</td>
<td>Ms. Diana J. aeGER, OPERA/ OER</td>
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<td>Dr. Karen L. Miller</td>
<td>Ms. Ann Knebel, NINR/ CC Nursing</td>
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<td>Dr. Curtis L. Patton</td>
<td>Dr. Cara Krulewitch, NINR/ NIH</td>
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<td>Dr. Ellen B. Rudy</td>
<td>Dr. Mary Leveck, NINR/ NIH</td>
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<td>Ms. Sarah J. Sanford</td>
<td>Dr. J.une Lunney, NINR/ NIH</td>
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<td>Mr. John Martin, NINR/ NIH</td>
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<td>Dr. Susan Mattson, NINR/ NIH</td>
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<td>Dr. Gertrude McFarland, CSR/ NIH</td>
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<td>Ex Officio members:</td>
<td>Mr. Daniel O’Neal, NINR/ NIH</td>
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<td>Mr. Eddie Rivera, NINR/ NIH</td>
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<td>Ms. Chris Rhatigan, NINR/ NIH</td>
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<td>Dr. Hilary Sigmon, NINR/ NIH</td>
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<td>Ms. Arlene Simmons, NINR/ NIH</td>
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<td>Dr. Mary Stephens-Frazier, NINR/ NIH</td>
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<td>Ms. Lisa Strauss, NINR/ NIH</td>
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<td>Mr. Mark Waldo, NINR/ NIH</td>
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<td></td>
<td>Dr. Annette Wysocki, NINR/ NIH (open session only)</td>
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<td>Ms. Wendy Blakey, The Johns Hopkins University</td>
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<td>Dr. Doris Bloch, Windows on Nursing</td>
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<td>Ms. Kathleen Boyden, University of Virginia</td>
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<td>Dr. Cheryl Bourguinon, University of Virginia</td>
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<td>Dr. Jacqueline Campbell, The Johns Hopkins University</td>
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<td>Ms. Mary Cerny, Scientific Consulting Group, Inc.</td>
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<td>Ms. Paula Chiplis, The Johns Hopkins University</td>
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<td>Ms. Barbara Cross, University of Virginia</td>
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<td>Ms. Jean Gaines, The Johns Hopkins University</td>
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<td>Ms. Rebecca Harmon, University of Virginia</td>
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<td>Dr. Chris Kasper, The Johns Hopkins University</td>
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<td>Dr. Louise Jenkins, University of Maryland</td>
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<td>Mr. R. Kevin Mallison, The Johns Hopkins University</td>
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<td>Ms. Janice Montgomery-Preston, University of Virginia</td>
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<td>Mr. Al Nugent, Midwest Research Institute</td>
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<td>Dr. Barbara Parker, University of Virginia</td>
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<td>Dr. Dawn Rigney, University of Virginia</td>
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<td>Dr. Barbara Smith, University of Alabama at Birmingham</td>
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<td>Ms. Xiao Xu, The Johns Hopkins University</td>
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<td>Ms. Kristin Zawacki, The Johns Hopkins University</td>
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## Training Update

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