

**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 15–16, 2012

The 77th meeting of the National Advisory Council for Nursing Research (NACNR) was convened on Tuesday, May 15, 2012, at 1:00 p.m. in Conference Room 6C, Building 31, National Institutes of Health (NIH), Bethesda, Maryland. The first day of the meeting was an open session and adjourned that same day at approximately 4:45 p.m. The closed session of the meeting, which included consideration of grant applications, was convened on Wednesday, May 16, 2012 at 9:00 a.m. and continued until adjournment at 1:00 p.m. Dr. Patricia A. Grady, Chair, NACNR, presided over both sessions of the meeting.

OPEN SESSION

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

Dr. Grady called the 77th meeting of the NACNR to order, welcoming all Council members, visitors, and staff. She introduced Dr. Ann Knebel as the new NINR Deputy Director. Dr. Knebel comes to NINR after serving for 20 years at the Public Health Service, where she retired at the rank of Rear Admiral. While at the PHS, Dr. Knebel helped to start the Office of Preparedness and Emergency Operations and served as Deputy Director there. She also has a history with NINR, having worked as a program official. Dr. Knebel brings a large amount of clinical experience, and her primary research area has focused on work with ventilators and weaning.

Dr. Grady also welcomed five new Council members:

- Dr. Julie Anderson is an associate professor of nursing at the University of North Dakota. She has extensive experience in neonatal intensive care nursing, and her primary research interests center around skin and wound care. Anderson has authored or co-authored over forty articles and several book chapters on topics ranging from venous, arterial, and pressure ulcers, pressure mapping, support surfaces, maggots and honey as wound treatments, and palliative wound care.
- Dr. Susan Gennaro is dean and professor of the Connell School of Nursing at Boston College. Her research focuses on the improvement of global perinatal health and the identification of causes of preterm birth in minority women in the U.S. Her research has been funded by the NIH for over 20 years and has also focused on improving nursing education through innovative programs to increase the number of minority nurse scientists who are trained to work with vulnerable populations.
- Dr. William L. Holzemer is professor and dean at the Rutgers University College of Nursing. His research examines quality of nursing education, quality of nursing care, outcomes research, variation in practice, self-care symptom management, and quality of life, with special emphasis on people living with and affected by HIV infection. He recently completed an R01 research project supported by the NIH's Fogarty International Center and the Health Resources and Services Administration (HRSA) on how stigma and discrimination impacts quality of life for Africans living with HIV/AIDS and quality of work life for AIDS patient nurses.

- Dr. Anne Rosenfeld is professor and associate dean for research at the University of Arizona College of Nursing. Her research focuses on symptom management for women with acute coronary syndrome. She has been principal investigator for a series of NIH- and American Heart Association-supported studies addressing women with acute coronary syndrome. She has served on the Behavioral Medicine, Interventions and Outcomes NIH Study Section. Rosenfeld has been principal investigator for HRSA projects to prepare primary care nurse practitioners for work in rural settings and has served as core faculty on several T32 and K12 training programs.
- Col. Bruce A. Schoneboom is the incoming commander for the Army Medical Research Institute for Chemical Defense at Aberdeen Proving Grounds, MD. He has been the principal investigator of numerous funded grants and has an established funding and publication record. His research interests include investigating neuro-immune responses of the central nervous system to viral pathogens with known bioterrorist capabilities and the development of new monitoring technologies with operational and garrison applications. Schoneboom is a member of several professional organizations including the American Nurses Association, the American Association of Nurse Anesthetists, the National Academy of Practice, Sigma Theta Tau International Honor Society of Nursing, and the American Academy of Nursing.

Conflict of Interest and Confidentiality Statement

Dr. Bryan noted that the NACNR meeting would be taped for purposes of the minutes and that tapes would be destroyed once the minutes are completed. She referred Council members to the

Conflict of Interest and Confidentiality Statement. Briefly, Council members should determine whether they have a tangible role in the proposal, a vested interest in the proposal (for example financial gain), or an appearance of a conflict in deciding whether they should review applications. To avoid conflicts of interest, or even the perceptions of such, Council members should leave the room during a discussion of applications submitted by their institutions, family members, close associates, or persons with whom they have had longstanding differences. The Conflict of Interest and Confidentiality Statement also notes that material furnished for review purposes and discussion during the closed session is privileged and can only be discussed with NINR staff under appropriate circumstances.

Dr. Bryan added that she would provide additional instructions on conflicts of interest and confidentiality during the closed session on May 16. She also reminded Council members of their status as special Federal employees while serving on the Council and that as special employees, Council members cannot engage in lobbying activities while receiving payment from the government.

Minutes of the Previous NACNR Meeting

Council members received the minutes of the January 17–18, 2011 NACNR meeting by email. A motion to accept these minutes was forwarded, seconded, and approved unanimously.

Dates of Future Council Meetings

Council members were asked to confirm their calendars for the following meeting dates and to contact Drs. Grady and Bryan about any conflicts or expected absences.

2012

September 18–19 (Tuesday–Wednesday)

2013

January 22–23 (Tuesday–Wednesday)

May 21–22 (Tuesday–Wednesday)

September 17–18 (Tuesday–Wednesday)

2014

January 21–22 (Tuesday–Wednesday)

May 20–21 (Tuesday–Wednesday)

September 16–17 (Tuesday–Wednesday)

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

The Director’s report focused on the NIH and NINR budgets and on activities and news occurring within NINR, NIH, and the Department of Health and Human Services (HHS) since the last Council meeting.

Budget Update—Dr. Grady noted that budget hearings have been held but, it is not certain that a budget will be in place by the end of the fiscal year. In light of recent history and the current fiscal situation, however, the budget is unlikely to have substantial increases. Dr. Grady pointed out that even though NIH has received very modest increases in recent years, the agency is still doing comparatively well.

The appropriation for NINR has remained slightly above the mean for NIH, but it remains one of the smaller budgets at NIH, representing 0.5% of the total NIH budget. The largest amount of NINR funds are allocated to extramural research, primarily through research project grants. NINR also supports a small centers program at 3% of its budget, and although program projects are housed within research project grants, NINR considers them part of the centers line. Other research funds, including career development awards, constitute 2% of the budget, training constitutes 6%, and the Intramural Research Program (IRP) constitutes 4%. Dr. Grady added that the proportion of the budget devoted to IRP is moving toward 5% and that NINR aims to eventually increase that proportion to approximately 10%, which is the average across NIH.

Dr. Grady noted that the majority of the open session would center on IRP, which focuses primarily on preparing the research workforce of the future.

HHS News—Health care reform legislation requires insurers and other providers to use plain language in describing their health plan benefits, coverage, and other products. Accordingly, HHS offers plain-language training to government workers. Dr. Grady also announced the Strong Start Initiative, which aims to increase the number of healthy deliveries and reduce the number of pre-term births. Approximately \$40 million has been dedicated primarily to the Centers for Medicare and Medicaid Services to fund research projects and test care models. In addition, President Obama has announced new steps to fight Alzheimer’s disease, and additional funds will be available in that area in 2012 and 2013.

NIH News—Dr. Grady announced that Dr. Gary H. Gibbons has been selected as the new director of the National Heart, Lung, and Blood Institute. Dr. Gibbons comes to NIH from Morehouse School of Medicine, where he served as Director of the Cardiovascular Institute and as Chairman of the Physiology Department. Dr. Grady also announced that Dr. M. Roy Wilson has been named Deputy Director for Strategic and Scientific Planning and Program Coordination at the National Institute of Minority Health and Health Disparities. Dr. Wilson has served as Chancellor at the University of Colorado, Denver, as Dean of the Medical School and Vice-President at Creighton University, and as President of the Texas Tech University Health Sciences Center.

Dr. Grady also reported that:

- The National Center for Advancing Translational Sciences has launched a pilot program with industry and researchers to spur therapeutic development. The program, which involves companies such as Pfizer and Eli Lilly, will start with old molecules that have been shelved but might have some utility. Thus this collaboration aims to take advantage of work that has already been done.
- NIH is participating in a new Interagency Pain Research Coordinating Committee, which includes 6 Federal members, 6 public members, and 6 representatives of constituency groups or professional organizations. At the Committee's first meeting in April, members reported on work that is already under way with respect to pain. The Committee aims to meet twice a year, with working groups meeting in between. Dr. Grady reminded Council that health care reform legislation includes several aspects related to pain.

- NIH has launched a new online resource in behavioral and social science research. This resource is the result of a collaboration headed by the NIH Office of Behavioral and Social Science Research.
- NIH has launched a website, Clinical Trials and You, as a resource for individuals who want to learn about and participate in clinical trials. Aimed toward the knowledgeable consumer, the site explains what clinical trials are, why they are important, and why individuals might be interested in participating.
- The Seventh Annual Pain Symposium will be held May 29–30 and address treatment of chronic pain. The symposium will be held as an adjunct to the Food and Drug Administration’s workshop on pain.
- A new biography, *Always There*, tells the life story of Dr. Ruth L. Kirschstein, who with her husband has devoted more than 50 years of service to NIH and the surrounding community. The biography is available for free on the NIH website, in several versions including Kindle.

With regard to review of applications, language in the President’s proposed FY2013 budget, addresses special consideration for principal investigators receiving \$1.5 million or more in annual costs for research. The language suggests that Councils review pending applications for those investigators and use specific criteria to determine whether those applications receive funding. Dr. Grady informed the Council that more information would be given and that Council would have an opportunity to provide feedback about the process.

NINR News—The National Nursing Research Roundtable brings together presidents, executive directors, and chief executive officers of research-oriented nursing organizations to address

timely issues. NINR co-hosted with the Eastern Nursing Research Association the 2012 Roundtable, which focused on symptom management in an era of technology. Dr. Grady described one Roundtable presentation, which showed a miniature laboratory on a chip. The M-Chip, which has been field-tested in Rwanda, facilitates rapid, early detection of HIV/AIDS. A video describing this project has been posted to YouTube.

Dr. Grady also reported that NINR has two requests for applications, one focused on mild cognitive impairment and the other on caregiver and symptom management for individuals with Alzheimer's Disease, with due dates of May 21–22, 2012. In addition, NINR has created a video of a grantsmanship workshop and posted it to its website. This video compiles information presented to new or early investigators at regional meetings during NINR's anniversary celebration.

Dr. Grady announced that Dr. Mary Engler has been named Training Director in IRP. A scientist best known for her work in vascular biology and her pioneering work on omega-3 fatty acids, Dr. Engler will oversee all IRP training programs. Dr. Grady also reminded NACNR that the Summer Genetics Institute will be held June 4–29, 2012 and that NINR will hold a boot camp focused on methodologies in fatigue and sleep research.

Dr. Grady closed her presentation by referring Council members to a handout on NINR outreach activities and by inviting them to visit the NINR website.

III. OVERVIEW OF THE INTRAMURAL RESEARCH PROGRAM—Dr. Raymond Dionne, Scientific Director, Intramural Research Program (IRP)

Dr. Dionne described training opportunities offered by the IRP, both for extramural and intramural scientists. Research Methodology Boot Camps, which are administered by the Foundation for Advanced Education in the Sciences (FAES), offer to extramural scientists 1-week courses of didactic and laboratory training. Topics rotate based on interest: the past few boot camps have focused on pain research, whereas the upcoming boot camp, as reported by Dr. Grady, will focus on sleep and fatigue. The boot camps have garnered highly positive evaluations and enthusiasm from speakers and students. Extramural scientists can also participate in the Summer Genetics Institute, which is now an intense, 1-month, full-time experience on campus. The Institute, which is also administered by FAES, has trained more than 230 nurse trainees from 2000 through 2011, and Institute alumni have published more than 65 peer-reviewed publications based on research supported by NIH grants. NINR is obtaining clearance from the Office of Management and Budget (OMB) to conduct an evaluation, including a survey of all past trainees.

Intramural training opportunities include post-baccalaureate training, where trainees serve 1 to 2 years as research associates and receive didactic, hands-on, and mentored training in the laboratory and on a clinical protocol. Expected outcomes for post-baccalaureate training include authorship on an abstract and one or more manuscripts, as well as admission to graduate school. Also offered is postdoctoral training, which is the traditional intramural training mechanism. Postdoctoral trainees in the NINR IRP serve 2 to 3 years as associate investigators and receive didactic, hands-on, and mentored training with an emphasis on molecular genetics methods.

These trainees are expected to go on to research positions and become change agents. Following postdoctoral training, scientists in the IRP can become assistant clinical investigators, with independent resources for personnel and supplies, and exceptional trainees can enter the tenure track, a rigorous, 5- to 8-year process in which they develop an independent research program and undergo interim and final evaluations by a board of scientific counselors. The Lasker Scholar Program is a new program that aims to attract the highest quality of clinical investigators. This program offers up to 5 years of support, with the expectation that trainees will move on to positions in academia.

Dr. Dionne described the organization of IRP and noted its interests in the areas of tissue injury, symptom management, and biobehavior. He emphasized that the IRP complements the work of the extramural community; it does not replicate or compete with that work.

Within the area of symptom management, IRP investigators study the biologic mechanisms underlying symptoms, the measurement of symptom intensity and its effects on patients, clinical interventions to reduce the burden of illness and treatment and improve quality of life, and the molecular genetics that contribute to individual variations in symptoms. Specifically, the Program aims to develop next-generation nurse scientists who use molecular genetics methods to study underlying mechanisms, develop prognostic and diagnostic tools and innovative interventions to meet unmet needs currently managed by nurses and nurse practitioners, and quantify patient-reported outcomes to identify subgroups for genomic studies and individualized interventions. Specific projects include:

- Unbiased target identification, using laboratory methods on RNA taken from patient specimens.
- Genomic approaches to identify genetic and epigenetic changes associated with chronic diseases and environmental influences.
- Differential gene expression associated with traumatic brain injury and post-traumatic stress disorder in soldiers post-deployment.
- Epigenetic changes associated with cancer-related fatigue.

Dr. Dionne closed by emphasizing the IRP's approach in gathering well-characterized phenotypic data, applying genomic methods to identify altered molecular pathways, and identifying patient subgroups. The ultimate goal of IRP research is to facilitate care models in which clinicians can measure patient symptoms, obtain profiles of their symptoms, and address the underlying molecular changes.

IV. IMMUNO-GENETIC MECHANISMS IN GASTROINTESTINAL SYMPTOM DISTRESS—Dr. Wendy Henderson, Intramural Research Program, NINR

Up to 20% of the United States population report digestive or gastrointestinal symptoms. Of these, abdominal pain is one of the top 10 reasons for outpatient visits and accounts for approximately \$30 billion in annual costs. Abdominal pain of unknown origin usually develops after acute illness and is more often reported by females. The evidence that genetics plays a role in symptom presentation is growing; however, it is poorly understood. Dr. Henderson, a tenure-track investigator in IRP, aims to describe the mechanisms involved in symptom distress related to digestive disorders, specifically the biobehavioral relationships between inflammation and

patient symptoms and genetic or other biologic or physiologic factors that might predict patient-related clinical outcomes.

Dr. Henderson and her team have identified a link between unexplained abdominal pain and serotonin, mast cell activation, and pro-inflammatory mediators. Pilot data from the Brain-Gut Natural History Study further indicate that an inflammatory mechanism, specifically chemokine CCL-16 is upregulated in patients with chronic abdominal pain of unknown origin. These findings are consistent with other studies showing upregulation of CCL-16 in patients with ulcerative colitis. Other work in Dr. Henderson's laboratory has identified a microRNA signature that distinguishes between wellness and irritable bowel syndrome or chronic abdominal pain. This signature maps back to the colorectal miRNAome and might identify potential treatment targets. Dr. Henderson and colleagues are also exploring the molecular genetics underlying the relationship between stress and chronic abdominal pain.

As part of the Brain-Gut Natural History Study, and in collaboration with investigators from the NIH Clinical Center, the National Institute of Diabetes and Digestive and Kidney Diseases, the University of Washington, and Psychology Software Tools, Inc., Dr. Henderson's team has created the Gastrointestinal Pain Pointer (GIPP) to address the need for improved characterization of pain and real-time subjective and objective pain assessments. The GIPP utilizes an interaction touch-screen personal computer which allows the patient to identify where their pain is occurring and how intense that pain is, all in real time. The computer captures this information using existing pain descriptors, and devices attached to the computer take readings on sympathetic and parasympathetic factors such as heart rate and blood pressure. Dr. Henderson and colleagues have shown the GIPP to be a valid and reliable instrument. Thus GIPP offers

clinicians an integrated way to capture patient-related outcomes and perhaps address Joint Commission accreditation criteria for assessment of pain.

V. ADVANCING FATIGUE RESEARCH THROUGH CLINICAL AND BIOLOGICAL INVESTIGATIONS—Dr. Leorey Saligan, Intramural Research Program, NINR

Fatigue, which affects quality of life for a wide range of patients with chronic disease, remains an unmet clinical need. Up to 96% of cancer patients report fatigue, even at the time of diagnosis, and \$9.1 billion in productivity is lost because of chronic fatigue syndrome (CFS). The management of fatigue remains difficult, because the etiology of fatigue remains unknown and the diagnosis of fatigue syndromes remains complex. Thus patients with fatigue often see multiple practitioners. The Centers for Disease Control and Prevention and the National Comprehensive Cancer Network have issued practice guidelines for the management of fatigue, and both recommend that nurses and nurse practitioners educate patients with specific strategies to manage their fatigue. But the lack of evidence related to specific mechanisms that these strategies are targeting makes education difficult.

Previous genomic studies have found no differences between CFS patients and healthy controls in gene expression specific to adrenergic receptors, ion channel receptors, cytokines, or immune cell production. However, single nucleotide polymorphism (SNP) and microarray studies have found differential expression of genes related to glutamatergic neurotransmission and circadian

rhythms, and other studies have found that several classes of immune cells and inflammatory markers such as IL-6 are in fact elevated in patients with fatigue.

Dr. Saligan, a tenure-track investigator in the IRP, aims to describe the behavioral, molecular, and genetic correlates of fatigue in different patient populations; investigate potential peripheral and central targets for fatigue; conduct clinical trials to manage fatigue; and use scientific evidence to address the limitations of the practice guidelines. He and his colleagues have conducted gene expression studies on samples from patients with fibromyalgia, CFS, and from patients undergoing radiation therapy for cancer. They have observed differential expression of several genes, many of which are associated with homeostasis, immune response, iron synthesis, and neurodegeneration. These gene expression profiles have allowed Dr. Saligan and his colleagues to identify clusters of fatigued patients with contrasting intensities of behavioral symptoms. Work is under way to confirm their results through proteomic and genomic approaches and to determine whether central or peripheral mechanisms underlie fatigue. This work could facilitate tailored interventions for fatigue in the future.

VI. IMPROVING INFORMED CONSENT—Dr. Jerry Menikoff, Office of Human Research Protections, HHS

Dr. Menikoff reported that for the first time in two decades, the Office of Human Research Protections (OHRP) and the White House Office of Science Policy have proposed changes to regulations regarding human research subjects. OHRP and the Office of Science Policy are now evaluating more than 1,100 comments received during the public comment period.

The proposed changes aim to strengthen protections for human research subjects and to accommodate changes in the way research is done, particularly with respect to the number of players, the amount of information collected during studies, and new research technologies. In line with this aim, the revised regulations would:

- Consider the use of a central institutional review board (IRB) for multicenter studies. When the regulations were implemented decades ago, most large studies were conducted at single institutions, and requiring review of a study by a local IRB was appropriate. Now, however, many studies are conducted at multiple sites, and the requirement for a local IRB review from each site can sometimes hinder the research. For example, in some cases, if a local IRB delays a protocol, the study team might choose to remove that site from the study.
- Modify the regulations such that IRBs are required to focus more on riskier studies, such as clinical trials, rather than relatively low-risk studies with little possibility of harm to subjects. This change would increase protections for human subjects by allocating time and effort in a more efficient and effective way.
- Create basic privacy protections that are applied across studies, rather than requiring IRBs to review those protections for each study. This is especially warranted with the increase of information collected from study subjects.
- Expand the scope of the regulations by broadening the criteria by which participants are defined as human research subjects and subject to Federal regulations. At present, these regulations apply only to research that affects products or devices regulated by the Food and Drug Administration or to research conducted by agencies subject to the Common Rule. Proposed changes could, for example, apply Federal regulations to any institution that accepts Federal funding for research that includes human subjects.

The majority of Dr. Menikoff's presentation focused on improving informed consent, particularly the consent form. He emphasized that the consent form is an important part of the consent process because it serves as documentation that volunteers received the key pieces of information they needed when deciding whether to participate in a study. Thus the consent form should be clear and understandable to potential research subjects. However, investigators and study participants have often complained that consent forms are too long (sometimes as many as 30 pages), that the language is often too legalistic, that consent forms often function more as sales documents than as decision aids, and that the forms frequently fail to include the most important pieces of information that could help someone make an enlightened decision. Thus the proposed rules aim to:

- Prescribe the appropriate content that must be included in the form, perhaps with greater detail and specificity than the current regulations provide.
- Restrict the content that would be inappropriate to include.
- Limit the acceptable length of various sections of the form.
- Prescribe how information should be presented, for example what information should be presented at the beginning of the form and the type of information that should be included in appendices.
- Reduce institutional boilerplate language that is usually included to protect institutions from litigation, rather than to inform study subjects.
- Provide standard consent form templates that could be used to satisfy the new regulations.

Questions, Comments, and Discussion Points included:

- Questions about the use of informed consent in emergency medicine. Dr. Menikoff noted that the current regulations include a waiver allowing emergency research without consent. He did not think that this waiver had been changed.
- Observations about the economic burden of regulations and IRB requirements on investigators, particularly those conducting low-risk research. Dr. Menikoff stated that issues of burden were key in discussions about improving consent and shifting effort to where it should reside.
- Questions about an increase in the number of research categories exempt from administrative review. This issue is still under debate. Dr. Menikoff noted, for example, that OHRP had proposed implementing web-based decision trees to determine whether a study should undergo administrative review, but several institutions balked at the proposal.
- Questions about how to operate when there is evidence of cognitive impairment. The proposed rules do not directly address issues of vulnerable subjects. Dr. Menikoff assured Council that everyone recognizes the need to address these issues. However, he also pointed out that these are large issues requiring further discussion and that OHRP did not want them to take away from the initial overall effort to begin revising regulations.
- A reminder about next steps. Once the evaluation of the initial public comments is complete, a Notice of Proposed Rulemaking, which will include proposed language for revised regulations, will be posted for public comment. Dr. Menikoff was optimistic that these efforts would continue to move forward, but he acknowledged that the system is complex, and he could not say how long these steps would take.

VII. MECHANISMS OF STROKE-INDUCED IMMUNE SUPPRESSION AND IMPLICATIONS FOR STROKE RECOVERY—Dr. Taura Barr, Assistant Professor, West Virginia University

Stroke is the third leading cause of death in the United States and a common secondary outcome of chronic cardiovascular disease. Poor recovery from stroke is often caused by infection, septicemia, or depression, and these outcomes are mediated by stroke-induced immune suppression characterized by lymphocytopenia, inactivation of macrophages, increased production of serum inflammatory signals, decreased T-cell proliferation, and atrophy of primary and secondary lymphoid organs. Dr. Barr, an alumna of the Graduate Partnership Program (GPP), is further exploring post-stroke immune response and its implications for recovery.

During her time as a student in the GPP, Dr. Barr identified a gene expression profile specific to stroke and found that the majority of genes affected in this profile were involved in innate or adaptive immune responses. Further work identified the Toll-like receptor (TLR) signaling pathway, which regulates pro- and anti-inflammatory signals as well as growth and neurotrophic factors, as a primary pathway for response to stroke. Dr. Barr and her colleagues have identified environments and immune system factors that underlie differential responses to TLR signaling and can predict post-stroke outcomes, and they are exploring whether their findings can be used to identify cardiovascular profiles that might predict post-stroke depression. She works with many clinicians on her study protocols, with the ultimate goal of providing evidence to improve clinical care of stroke patients.

VIII. REPORT SLEEP DISTURBANCE AND IMPAIRMENT: MELATONIN

PRODUCTION AND PAX6—Ms. Alyson Hanish, University of Iowa; Graduate Partnership Program, NINR

WAGR syndrome is a genetic disorder characterized by Wilms tumor, aniridia, genitourinary anomalies, and cognitive impairment. *Genetic* mutations (*PAX6*) have been associated with isolated aniridia, an autosomal dominant disease characterized by eye abnormalities, and with absence or hypoplasia of the pineal gland, which produces melatonin and regulates circadian rhythm and sleep. Ms. Hanish, a GPP student, is working to characterize the non-ocular phenotype of *PAX6* mutations by examining the pineal gland, melatonin production, and sleep behavior in healthy controls and in patients with WAGR syndrome. She presented preliminary data from her studies. These studies will be important in patients with WAGR Syndrome and may lead the way to addressing the effects of similar mechanisms in other neglected genetic disorders.

IX. Gene REGULATION IN BREAST CANCER—Ms. Jennifer Dine, University of Missouri at Columbia; Graduate Partnership Program, NINR

Suppression of *BRCA1*, a critical tumor suppressor gene integral to genomic stability, is common in sporadic breast disease, even in women with no family history or genetic predisposition to breast cancer. Alteration in the gene for signaling protein (*FGFR2*) have been associated with higher risk for breast cancer and higher levels of *FGFR2* in human breast tumor fibroblasts, suggesting a role for *FGFR2* in *BRCA1* suppression and promoting breast malignancy. Ms. Dine,

a GPP student, is further exploring interactions between FGFR2 and *BRCA1*. She presented preliminary results from her work.

Following these presentations, Dr. Grady thanked participants and attendees for their time and engagement and adjourned the open session of the meeting.

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, U.S. 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 153 research and training grant applications on which NINR was the primary Institute; these applications requested a total of \$37, 063,463 (direct costs year 01). The Council also considered 480 applications on which another Institute/Center was primary and NINR was secondary. These applications requested a total of \$122, 129, 764 (direct costs year 01). The Council concurred with the IRG recommendations on these 633 applications.

ADJOURNMENT

The 77th meeting of the NACNR was adjourned at 1:00 p.m. on May 16, 2012.

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

Yvonne E. Bryan, Ph.D.
Acting Executive Secretary
National Advisory Council for Nursing
Research

MEMBERS PRESENT

Dr. Patricia A. Grady, Chair
Dr. Yvonne Bryan, Acting Executive Secretary
Dr. Anna Alt-White, *Ex Officio*
Dr. Julie Anderson
Dr. Glenna A Dowling
Dr. Everette Freeman
Dr. Susan Gennaro
Dr. Barbara Guthrie
Dr. William Holzemer
Dr. Kenton Kaufman
Dr. Elaine Larson
Dr. Courtney Lyder
Dr. Anne Rosenfeld
COL Bruce Schoneboom, Ph.D., *Ex Officio*
Dr. Gail Stuart
Dr. James Tulsy

Dr. Janet Williams

MEMBERS OF THE PUBLIC PRESENT

Dr. Taura Barr, West Virginia University
Ms. Nancy Steffan, Catholic University

FEDERAL EMPLOYEES PRESENT

Mr. Brian Albertini, NINR/NIH
Mr. David Alperin, NHLBI/NIH
Dr. David Banks, NINR/NIH
Ms. Melissa Barrett, NINR/NIH
Ms. Karen Bashir, NINR/NIH
Ms. Adrienne Burroughs, NINR/NIH
Dr. Ann Cashion, NINR/NIH
Dr. Pei-Ying Chuang, NINR/NIH
Dr. Paul Cotton, NINR/NIH
Dr. Arseima Del Valle-Pinero, NINR/NIH
Ms. Jennifer Dine, NINR/NIH
Dr. Raymond Dionne, NINR/NIH
Dr. Marguerite Engler, NINR/NIH
Dr. Mary Engler, NINR/NIH
Ms. Ana Ferreira, NINR/NIH
Dr. John Grason, NINR/NIH
Dr. Amanda Green, NINR/NIH
Dr. Chris Hafner Eaton, NINR/NIH
Ms. Alyson Hanish, NINR/NIH
Dr. Lynda Hardy, NINR/NIH
Dr. Rebecca Hawes, NINR/NIH
Dr. Wendy Henderson, NINR/NIH
Dr. Chao-Pin Hsiao, NINR/NIH
Dr. Karen Huss, NINR/NIH
Mrs. Deborah Jennings, NINR/NIH
Ms. Ellie Johnson, NINR/NIH
Ms. Mary Kelly, NINR/NIH
Dr. Hyunh Suk Kim, NINR/NIH
Mi Rim Kim, NINR/NIH
RADM Ann Knebel, DHHS
Ms. Hyunhwa Lee, NINR/NIH
Dr. Weiqun Li, NINR/NIH
Dr. Yujing Liu, NINR/NIH
Mr. Ryan Longchamps, NINR/NIH
Ms. Nada Lukkahatai, NINR/NIH
Mr. Benjamin Majors, NINR/NIH
Dr. Sue Marden, NINR/NIH

Mrs. Angela Marshall, NINR/NIH
Ms. Angela Martino, NINR/NIH
Dr. Donna Jo McCloskey, NINR/NIH
Dr. Arthur Meltzer, NINR/NIH
Dr. Jerry Menikoff, OHRP/HHS
Ms. Michelle Millwood, NINR/NIH
Dr. Mario Rinaudo, NINR/NIH
Mr. Charles Rose, NINR/NIH
Dr. Denise Russo, NINR/NIH
Dr. Leorey Saligan, NINR/NIH
Ms. Lindsay Scattergood-Keeper, NINR/NIH
Dr. Lena St. John, NINR/NIH
Mr. Shawn Stocking, NINR/NIH
Ms. Lela Strong, NINR/NIH
Dr. Xenia Tigno, NINR/NIH
Dr. Catherine Timura, OD/NIH
Dr. Lois Tully, NINR/NIH
Dr. Amy Wang, NINR/NIH
Dr. Dan Wang, NINR/NIH
Dr. Joan Wasserman, NINR/NIH
Dr. Linda Weglicki, NINR/NIH
Mr. Kevin Wilson, NINR/NIH