OPEN SESSION

I. CALL TO ORDER, OPENING REMARKS, COUNCIL PROCEDURES, AND RELATED MATTERS—Dr. Patricia Grady, Director, NINR

Dr. Grady called the 81st meeting of the NACNR to order, welcoming all Council members, visitors, and staff. Council member Dr. Lyder was unable to participate in the open and closed sessions.

Conflict of Interest and Confidentiality Statement

Dr. Ann Knebel, Executive Secretary, NACNR, and Deputy Director, National Institute of Nursing Research (NINR), noted that the meeting would be recorded for purposes of the minutes and that audio recordings would be destroyed once the minutes were completed. She referred Council members to the Conflict of Interest and Confidentiality Statement and added that she would provide additional instructions on conflicts of interest and confidentiality during the closed session on September 18. She asked Council members to update their addresses on the meeting roster that would be circulated during the meeting. Dr. Knebel also reminded Council members of their status as special federal employees while serving on the Council and that as special government 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 May 17–18, 2013, NACNR meeting by email. A motion to accept these minutes was made, seconded, and approved unanimously. The approved minutes of each NACNR meeting become part of the Institute’s permanent record and are posted on the NINR website (www.ninr.nih.gov).

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

2014
January 21-22 (Tuesday-Wednesday)
May 20-21 (Tuesday-Wednesday)
September 16-17 (Tuesday-Wednesday)

2015
January 27-28 (Tuesday-Wednesday)
May 19-20 (Tuesday-Wednesday)
September 15-16 (Tuesday-Wednesday)

Dr. Grady encouraged all attendees to view the research posters in the adjoining meeting rooms during the break and at the close of the open session.

II. NIH AND BIOMEDICAL BIG DATA—Dr. Eric Green, Director, National Human Genome Research Institute (NHGRI)
Dr. Green gave an update on the National Institutes of Health’s (NIH) response to the changing landscape of the biomedical research enterprise. Propelled by technological advancement over the last decade, the acquisition of “big data” is coming to the forefront of the biomedical research enterprise. Myriad data types, including genomics, other ‘omics, imaging, phenotypic, exposure, and clinical, represent the big data problem. The acquisition and influx of a large amount of biomedical data have led to the need for more effective and efficient data management and analysis.

A Data and Informatics Working Group (DIWG) was asked to provide the Advisory Committee to the Director (ACD) and the NIH Director with expert advice on the management, integration, and analysis of
large biomedical data sets. The Working Group released recommendations in June 2012 in the following areas: research data spanning basic science through clinical and population research; administrative data related to grant applications, reviews, and management; and management of information technology (IT) at NIH. The overarching themes of these recommendations are that NIH is at an institutional risk of failing to capitalize on technological advances; cultural changes at NIH are essential; new opportunities need to be developed for data sharing, analysis, and integration; and long-term NIH commitment is required. Among the major problems to be solved are locating the data; getting access to the data; extending policies and practices for data sharing; organizing, managing, and processing biomedical big data; developing new methods for analyzing biomedical big data; and training incoming and mid-career researchers who can use biomedical big data effectively.

NIH leadership approved implementation of the DIWG’s recommendations. The following are the three major, integrated elements of the implementation plan:

- **New leadership:** A new position, the Associate Director for Data Science (ADDS), was created. The ADDS is the strategic leader and reports to the NIH Director. Data science encompasses big data, bioinformatics, computational biology, biomedical informatics, information science, biostatistics, and quantitative biology. Dr. Green is the Acting ADDS; however, a permanent appointment is expected.

- **New internal governing group:** A high-level internal NIH group, the Scientific Data Council (SDC), was created to provide programmatic leadership and coordination of data science activities. The ADDS chairs the SDC and it will have trans-NIH representation. The SDC will oversee the Big Data to Knowledge (BD2K) initiative, provide long-term NIH strategic planning in data science, and play a key role in data-sharing policy development and oversight.

- **New programmatic activity:** The BD2K initiative aims to be catalytic and synergistic in achieving its overarching goal—by the end of 2020, enable a quantum leap in the ability of the biomedical research enterprise to maximize the value of the growing volume and complexity of biomedical data.

  - The four major programmatic areas of BD2K are:
    - facilitating broad use of biomedical big data;
    - developing and disseminating analysis methods and software for biomedical big data;
    - enhancing training for biomedical big data; and
    - establishing Centers of Excellence for biomedical big data.

  - Despite the current fiscal challenges, NIH has developed an initial seven-year funding plan for the initiative to begin in fiscal year (FY) 2014. Sequestration has slowed and reduced budget building.

  - A trans-NIH working group focused on the initiative comprises about 125 members representing 24 ICs and several Offices. The working group is holding BD2K workshops in the areas of:
o broad use of big data;
o software;
o training; and
o Centers of Excellence to elicit expertise from the research community.

Three BD2K requests for information (RFIs) have been launched and the first funding opportunity announcement (FOA) was released for investigator-initiated Centers of Excellence for big data computing in the biomedical sciences. The BD2K website (bd2k.nih.gov) is now live, featuring videocasts from the workshops, RFIs, and the FOA.

Dr. Green closed his presentation by stating that the biomedical research enterprise is undergoing a major “phase change” with respect to big data and data science. It is a trans-NIH problem needing trans-NIH solutions that will include multifaceted cultural changes.

Questions, Comments, and Discussion Points Included:

- **Are there similar big data efforts being conducted outside of NIH?**
  
  Within the federal government, the White House Office of Science and Technology Policy is conducting a similar effort, as well as several private foundations and international research organizations. There are many opportunities for collaboration in this area.

- **Will the cultural change needed to address the big data problem impact other areas of NIH?**
  
  Broadened data sharing is one of the major cultural changes that needs to take place, especially with the extramural community. NIH funds data generation, but not enough is devoted to the translation of those data. Another example of a cultural shift in this area would be evaluating an investigator based on his/her track record of sharing data as a criterion for a funding decision.

- **Substantial expertise on big data exists in the private sector (e.g., Google, Facebook) and at the National Security Agency (NSA). Are there any plans for NIH to interface with other organizations?**
  
  There is a lot of interest around cloud computing within NIH. Currently, NIH has a major collaboration on microbiome data with Amazon, and has had discussions with Google and Microsoft on clinical data.

- **Are there any mechanisms in place for emerging scholars to become involved with the BD2K initiative?**
  
  One component of the initiative is focused on training and curriculum development in data science.
• The current electronic health record (EHR) platform is not equipped to support large biomedical data sets. How will the BD2K initiative merge with EHRs?

There are a lot of activities and discussions on linking with EHRs. NHGRI is very interested in how to link genomic data with EHRs, but it is not a simple problem. Linking with EHRs would be an obvious area for a big data Center of Excellence to address. Privacy is another issue that needs to be addressed when working with data in the clinical setting. How close is NIH to having the necessary safeguards in place to facilitate clinical data sharing? Some of the cloud pilots are addressing this issue, but it requires further policy development.

• How will the quality of data be controlled?

Software development will address this issue—better tools to clean and protect the quality of data. Standards need to be developed for data and how to measure data quality. One of the workshops is on better defining data standards and measuring data quality.

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

The Director’s report focused on activities and news from the Department of Health and Human Services (HHS), NIH, and NINR since the last Council meeting. Several highlights included:

Budget Update—In FY2013, NINR received a 5.2 percent budget cut due to sequestration, but with transfers, the actual decrease was closer to 6 percent. Dr. Grady reviewed NINR patterns of investment and cuts to its budget. About 84 percent of the NINR budget goes to the extramural program for research grants and training. The intramural program comprises approximately 5 percent of the NINR budget. Funds to support infrastructure (grants review and management, Council, travel, etc.) comprises approximately 10 percent. Budget cuts were applied to noncompeting projects, the Centers program, and career budgets. No cuts were made to training. Internally, NINR cut travel costs, supplies, and equipment; postponed staff hires; and limited its outreach.

HHS News—HHS Secretary Kathleen Sebelius visited the NIH campus for a town hall meeting. She encouraged planning for the future and maintaining core values and missions of the ICs. Dr. Richard Kronick has been appointed Director of the Agency for Healthcare Research and Quality (AHRQ). HHS released the National Plan to Address Alzheimer's Disease: 2013 Update. The 2013 Update includes a new timeline for achieving its first goal—prevent and effectively treat Alzheimer's disease by 2025. It also reviewed progress over the past year.
**NIH News**—Dr. Jeremy Brown has been named Director of the new NIH Office of Emergency Care Research (OECR). The Office is housed within the National Institute of General Medical Sciences (NIGMS). Dr. Brown will work with the NIH Emergency Care Research Working Group Steering Committee, which includes representatives from NINR; National Institute of General Medical Sciences; National Heart, Lung, and Blood Institute (NHLBI); National Institute of Neurological Disorders and Stroke (NINDS); and National Institute of Child Health and Human Development (NICHD).

The National Institute on Alcohol Abuse and Alcoholism (NIAAA) has produced a new online training course to help health care professionals conduct fast, evidence-based alcohol screening and brief interventions with youth. The NIH Office of Dietary Supplements has launched a dietary supplement label database that contains ingredients and product information and is searchable by ingredient, label text, and supplement manufacturer or distributor. The My Dietary Supplements (MyDS) application is available at [http://www.dsid.nlm.nih.gov/](http://www.dsid.nlm.nih.gov/).

The NIH Initiative to Enhance Reproducibility and Transparency of Research Findings seeks to address the issue that many investigators cannot repeat the experiments of others. Unsuccessful clinical trials based on preclinical work have led to questions about the reliability of preclinical data. An ad hoc group developed guiding principles to address these issues:

- Raise community awareness.
- Enhance formal training (integrate modules on experimental design into required training and award terms and conditions).
- Improve evaluation of applications (standardized checklist for review).
- Protect the integrity of science by adopting more systematic review processes.
- Increase stability for investigators (adapt a standardized NIH biosketch to allow investigators to place their work into a functional context).

**NINR News**—

The Institute’s 30th anniversary is approaching, and NINR is moving forward based on its strategic plan. The main focus areas that have emerged from the strategic plan are:

- Symptoms science—personalized health strategies
- Wellness—preventing disease and promoting health
- Self-management—improving quality of life for individuals with chronic illness
- End-of-Life and palliative care—the science of compassion.
- Technology and Training
The extramural program has been aligned according to these science themes and team leads have been identified for each of the areas: Dr. Martha Matocha -- Symptom Science; Dr. Lynda Hardy – Wellness; Dr. Donna Jo McCloskey -- Self-Management and End of Life / Palliative Care; and Dr. Paul Cotton -- Technology and Training.

NINR released *Building Momentum: The Science of End-of-Life and Palliative Care. A Review of Research Trends and Funding, 1997-2010*. The report summarizes trends in end-of-life and palliative care research over the past 14 years, including information on federal research awards, funding patterns and the contributions of public and private investments in this area of science.

A recent NINR workshop on identifying research opportunities in genetics piloted a meeting approach to identify potentially innovative research questions. This pilot forms the basis for the new Innovative Questions (IQ) initiative to implement NINR’s strategic plan. A video detailing this approach will be posted on the NINR website.

The following NINR staff news was noted:

- Dr. Suzanne Wingate joined NINR as Clinical Director and Senior Clinician in NINR’s Division of Intramural Research (DIR).
- Dr. Donna Jo McCloskey was elected to the American Academy of Nursing.
  NINR Deputy Director Dr. Ann Knebel was profiled in “The Nurse Scientist” in the University of California, San Francisco alumni magazine.

**Training Opportunities –**

- This year’s Summer Genetics Institute (SGI) included 25 participants from across the country, including students, postdoctoral fellows, and faculty. The SGI has over 270 alumni since its inception. The application for SGI 2014 opens November 2013.
- NINR collaborates with the Fogarty International Center Global Health Fellowship Program, which would like to have more nurses involved in this Program. The Program provides mentorship, research opportunities and a collaborative research environment for early stage investigators to enhance their global health research expertise and their careers.
- The NINR Symptom Management Research Methodologies Boot Camp was focused on fatigue and sleep this year. Seventy-five people from over 50 organizations across the country participated in the one-week intensive research training course. Next year, the focus will be on the use of big data in
symptom management and measurement. The applications for the 2014 Symptom Research Methodologies Series will open in early 2014.

IV. OVERVIEW OF THE INTRAMURAL RESEARCH PROGRAM—Dr. Ann Cashion, Acting Scientific Director, NINR

The NINR Division of Intramural Research (DIR) focuses on symptom science—the molecular and behavioral mechanisms underlying a single symptom and clusters of symptoms, environmental influences, individual variability, and clinical interventions. The DIR has three branches.

DIR Branches-

- The Biobehavioral Branch conducts research into the interplay of behavioral, biological, and environmental determinants of health and wellness across populations. Two focus areas are mechanisms of symptom distress in digestive disorders, and biobehavioral relationships between inflammation and patient symptoms. The long-term goal of this research program is to identify genetic or other biologic/physiologic factors to improve diagnosis and predict patient-related clinical outcomes. Recent biobehavioral research advances will be presented later today.

- The Symptom Management Branch performs research on the underlying biological mechanisms of a range of symptoms, their effect on patients, and the bases for patient responses to interventions. The purpose of this research is to identify genes and pathways for potential therapeutic intervention, as well as opportunities for lifestyle changes. Focus areas of this research are the nature and causes of fatigue in a variety of specific conditions, including prostate cancer, and pain associated with fibromyalgia.

- The Tissue Injury Branch researches mechanisms of tissue injury and identifies molecular targets and pathways for interventions. The two focus areas are traumatic brain injury and comorbidity risks, and biomarkers for post-traumatic stress disorder (PTSD). The goal is to design screening methods to approximate psychological and neurological risks following TBI and design interventions to mitigate risks and treat early symptoms.

DIR Training Opportunities-

- The Summer Genetics Institute has been offered since 2000. Alumni are building research programs, disseminating findings, and integrating genetics content into nursing school curricula and practice.

- Symptom Research Methodologies Boot Camps have focused on pain (2010/2011) and fatigue/sleep (2012/2013), and will focus on big data in symptom research in 2014.
The Minority Faculty-Student Partnership in Biotechnology was developed to address the underrepresentation of minorities in research science. NINR supported 6 of 24 participants in 2013 to participate in a week long training on the latest principles/techniques in biotechnology. Participants are from minority serving universities.

Graduate Partnerships Program is a doctoral fellowship training program that coordinates training and funding for Ph.D. students attending any school of nursing. GPP fellows focus their dissertation research primarily in pathophysiological mechanisms related to symptoms and symptom management, health promotion, disease prevention, tissue injury, and genetics. The 2014 GPP application period is now open; applications are due on Monday, December 2, 2013.

Career development opportunities offered by the intramural program include:
1) Postbaccalaureate fellows who are mentored for one to two years by an NINR investigator.
2) Postdoctoral fellows are mentored by an NINR investigator for two to three years. The emphasis is determined by the applicant, but usually is focused on molecular-genetics.
3) Assistant clinical investigators work for two to three years following their postdoctoral fellowships and can transition to tenure track for outstanding trainees. They receive independent resources for personnel and supplies.
4) Tenure track investigators are supported for six to eight years to develop independent research programs. They are provided increased independent resources for personnel and supplies to support their IRB-approved studies.
5) The NIH Pathways to Independence Award (K99/R00) provides up to five years of support consisting of two phases. The initial phase provides one to two years of mentored support for highly promising postdoctoral research scientists. This phase is followed by up to three years of research support contingent on securing an independent research position.
6) NIH-Lasker Clinical Research Scholarship supports a small number of exceptional clinical researchers in the early stages of their careers to promote their development to fully independent positions. The program combines a period of independent research as a Principal Investigator in the NIH Intramural Research Program for five to seven years, with the opportunity for additional years of independent financial support at either NIH or an extramural research institution.

V. IMMUNO-GENETIC MECHANISMS IN GASTROINTESTINAL SYMPTOM DISTRESS
—Dr. Wendy A. Henderson, Chief, Digestive Disorders Unit, NINR

Research conducted within NINR’s Biobehavioral Branch focuses on the relationship of gut barrier function, genetics and gastrointestinal (GI) symptoms. Pilot studies investigate factors of inflammation, barrier function, genetics, and stress, to identify underlying subclinical inflammatory mechanisms in
pediatric patients with GI symptoms. The future directions of this research will involve patient-reported outcomes, genetic patterns and pathways, identification of etiologies, targeted treatment and point-of-care diagnostics.

VI. **TRAUMATIC BRAIN INJURY**—Dr. Jessica Gill, Lasker Clinical Research Scholar, NINR

Research conducted within NINR’s Tissue Injury Branch examines biological mechanisms underlying clinical outcomes following trauma, which includes traumatic brain injuries (TBI) in civilians and military service members. These projects examine the mechanisms underlying the risk for sleep disorders, post-traumatic stress disorder, depression, and postconcussive syndrome. Future research will examine mechanisms of psychological compromise and biological mechanisms underlying TBI and comorbid conditions.

VII. **ADVANCING FATIGUE RESEARCH THROUGH CLINICAL AND BIOLOGICAL INVESTIGATIONS**—Dr. Leorey Saligan, Chief, Symptoms Biology Unit, NINR

Research conducted within the Symptom Management Branch seeks to understand the mechanisms of fatigue intensification during cancer therapy. The opportunity to conduct this type of research is only available at NIH, which provides the unique ability to do clinical and basic research in one building with the input of multidisciplinary experts. Future research plans include development and testing of interventions in this patient population, as well as confirmation of findings in other patient populations.

VIII. **IDENTIFICATION OF REGULATORS OF TRAIL-INDUCED APOPTOSIS IN BREAST CANCER CELLS**—Ms. Jennifer Dine, GPP Predoctoral Fellow, NINR

Research is seeking to identify the biological mechanisms that regulate sensitivity to the TRAIL protein that selectively induces death to malignant cells and determine the patient population that would most benefit from TRAIL-targeted therapies. She plans to graduate in the spring of 2015 and obtain a postdoctoral position in translational cancer research. Her goal is to assume an academic research position in nursing to continue this work to optimize therapeutic approaches in cancer.

IX. **MITOCHONDRIAL DYSFUNCTION AND FATIGUE**—Ms. Kristin Filler, Graduate Partnership Program Predoctoral Fellow, NINR

During the first year of the GPP the student attended elective classes, completed three rotations, developed laboratory skills, and defended her research proposal. During the second year, she will further develop laboratory skills and conduct her dissertation research. In the final year, she will defend her
dissertation focused on mitochondrial dysfunction and fatigue intensification during cancer therapy. Her future plans are to become an independent researcher.

The Council expressed appreciation for the GPP students’ presentations—hearing about these opportunities firsthand can excite other predoctoral students who may be interested in the program.

Dr. Grady thanked participants and attendees 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 concerned 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 133 research and training grant applications on which NINR was the primary Institute; these applications requested a total of $34,165,197 (direct costs year 01). The Council also considered 537 applications on which another Institute/Center was primary and NINR was secondary. These applications requested a total of $122,287,377 (direct costs year 01). The Council concurred with the IRG recommendations on these 670 applications.

ADJOURNMENT
The 81st meeting of the NACNR was adjourned at 1:00 p.m. on September 18, 2013.
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

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

MEMBERS PRESENT

Dr. Patricia A. Grady, Chair
Dr. Ann Knebel, Executive Secretary
Dr. Anna Alt-White, Ex Officio
Dr. Julie Anderson
Dr. Cynthia Barnes-Boyd
Dr. Glenna Dowling
Dr. Everette Freeman
Dr. Susan Gennaro
Dr. Donna Hathaway
Dr. William Holzemer
Dr. Jillian Inouye
Dr. Elaine Larson
Dr. Bernadette Mazurek Melnyk
Dr. Anne Rosenfeld
Col. Bruce Schoneboom, Ph.D., Ex Officio
Dr. Marjana Tomic-Canic
Dr. James Tulsky

MEMBERS OF THE PUBLIC PRESENT

Ms. Nikki Brandon, University of Maryland School of Nursing
Dr. Jane Lipscomb, University of Maryland School of Nursing
Ms. Sherry McAtee, University of Maryland School of Nursing
Dr. Mary Regan, University of Maryland School of Nursing
Ms. Kathy Sedgwick, NOVA Research Company
Dr. Angela Starkweather, Virginia Commonwealth University
Dr. Jamie Sturgill, Virginia Commonwealth University
Ms. Michelle Wheeler, Christiana Care Health System
Dr. Christine Zambricki, American Association of Nurse Anesthetists

FEDERAL EMPLOYEES PRESENT

Ms. Sarah Katherine Abey, NINR/NIH
Mr. Brian Albertini, NINR/NIH
Ms. Irene C. Arveson, NINR/NIH
Dr. David Banks, NINR/NIH
Ms. Melissa Barrett, NINR/NIH
Ms. Karen Bashir, NINR/NIH
Dr. Yvonne E. Bryan, NINR/NIH
Ms. Adrienne McGill Burroughs, NINR/NIH
Ms. Amber K. Cabrejos, NINR/NIH
Dr. Ann Cashion, NINR/NIH
Dr. Paul A. Cotton, NINR/NIH
Dr. Cynthia M. Danielson, OD/NIH
Ms. Jennifer L. Dine, NINR/NIH
Dr. Marguerite M. Engler, NINR/NIH
Dr. Mary B. Engler, NINR/NIH
Ms. Ana Ferreira, NINR/NIH
Ms. Kristin A. Filler, NINR/NIH
Dr. Nicolaas H. Fourie, NINR/NIH
Ms. Inka E. Ghazaleh, NINR/NIH
Dr. Jessica M. Gill, NINR/NIH
Dr. Lisa L. Gough, NINR/NIH
Dr. John Grason, NINR/NIH
Dr. Amanda L. Greene, NINR/NIH
Ms. Lydia H. Greene, OD/NIH
Dr. Brian T. Walitt, NINR/NIH
Dr. Linda S. Weglicki, NINR/NIH
Mr. Max Whitfield, NINR/NIH
Mr. Kevin G. Wilson, NINR/NIH
Dr. Suzanne J. Wingate, NINR/NIH
Ms. Natalie C. Zeigler, NINR/NIH