DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH
NATIONAL LIBRARY OF MEDICINE

MINUTES OF THE BOARD OF REGENTS
February 11-12, 2014

The 165th meeting of the Board of Regents was convened on February 11, 2014, at 9:00 a.m. in the Board Room, Building 38, National Library of Medicine (NLM), National Institutes of Health (NIH), in Bethesda, Maryland. The meeting was open to the public from 9:00 a.m. to 3:30 p.m., followed by a closed session for consideration of grant applications until 4:00 p.m. On February 12, the meeting was reopened to the public from 9:00 a.m. until adjournment at 12:00 p.m.

MEMBERS PRESENT [Appendix A]:
Dr. Ronald Evens [Chair], Washington University School of Medicine
Dr. David Fleming, University of Missouri School of Medicine
Dr. Katherine Gottlieb, Southcentral Foundation
Dr. Robert Greenes, Arizona State University
Dr. Henry Lewis, American University of Health Sciences
Dr. Trudy MacKay, North Carolina State University
Dr. Ralph Roskies, University of Pittsburgh
Ms. Mary Ryan, University of Arkansas for Medical Sciences Library
Ms. Gail Yokote, University of California, Davis

MEMBERS NOT PRESENT:
Dr. F. Douglas Scutchfield, University of Kentucky College of Public Health

EX OFFICIO AND ALTERNATE MEMBERS PRESENT:
Mr. Christopher Cole, National Agricultural Library
Capt. Robert DeMartino, Office of the Surgeon General, PHS
Dr. Joseph Francis, Veterans Health Administration
MGEN Dorothy Hogg, United States Air Force
Ms. Kathryn Mendenhall, Library of Congress
Col. Cathy Nace, United States Army
Dr. Dale Smith, Uniformed Services University of the Health Sciences
Mr. Howard Wactlar, National Science Foundation

CONSULTANTS TO THE BOR PRESENT:
Dr. Tenley Albright, Massachusetts Institute of Technology
Dr. Marion Ball, Johns Hopkins School of Nursing
Dr. Holly Buchanan, University of New Mexico
Dr. H. Kenneth Walker, Emory University School of Medicine

SPEAKERS AND INVITED GUESTS PRESENT:
Ms. Theodora Bakker, New York University
Ms. Karen Hanson, New York University
Ms. Jacqueline Lee, KY Cabinet for Health & Family Services
Dr. Jon Lorsch, National Institute of General Medical Sciences, NIH
Dr. Kenneth Mandl, Harvard University

MEMBERS OF THE PUBLIC PRESENT:
Mr. Glen Campbell, Friends of the National Library of Medicine
Dr. Dennis Cryer, Friends of the National Library of Medicine
Mary Lindberg
Dr. Barbara Redman, Friends of the National Library of Medicine
Dr. Elliot Siegel, Consultant
Mr. Stephen Weitzman, MedData Foundation

FEDERAL EMPLOYEES PRESENT:
Dr. Donald A.B. Lindberg, Director, NLM
Ms. Betsy Humphreys, Deputy Director, NLM
Dr. Milton Corn, Deputy Director for Research and Education, NLM
Dr. Swapna Abhyankar, Lister Hill Center, NLM
Dr. Michael Ackerman, Lister Hill Center, NLM
Dr. Sameer Antani, Lister Hill Center, NLM
Ms. Stacey Arnesen, Division of Specialized Information Services, NLM
Ms. Dianne Babski, Division of Library Operations, NLM
Ms. Joyce Backus, Division of Library Operations, NLM
Dr. Dennis Benson, National Center for Biotechnology Information, NLM
Dr. Amos Cahan, Lister Hill Center, NLM
Ms. Kathleen Cravedi, Office of Communications and Public Liaison, NLM
Ms. Francesca Crawford, Division of Extramural Programs, NLM
Dr. Dina Demner-Fushman, Lister Hill Center, NLM
Mr. Ivor D'Souza, Office of Computer and Communications Systems, NLM
Ms. Gale Dutcher, Division of Specialized Information Services, NLM
Ms. Lisa Federer, Office of the Director, NIH
Dr. Valerie Florance, Division of Extramural Programs, NLM
Dr. Michael Huerta, Office of Health Information Programs Development, NLM
Ms. Christine Ireland, Division of Extramural Programs, NLM
Mr. Paul Kiehl, Office of the Director, NLM
Mr. Kenneth Koyle, Division of Library Operations, NLM
Dr. David Landsman, National Center for Biotechnology Information, NLM
Ms. Lisa Lang, Lister Hill Center, NLM
Dr. Clement McDonald, Lister Hill Center, NLM
Mr. Dwight Mowery, Division of Extramural Programs, NLM
Dr. Mallika Mundkur, Lister Hill Center, NLM
Mr. David Nash, Office of the Director, NLM
Dr. Steven Phillips, Division of Specialized Information Services, NLM
Dr. Jeffrey Reznick, Division of Library Operations, NLM
Dr. Kirk Roberts, Lister Hill Center, NLM
Dr. Wendy Rubinstein, National Center for Biotechnology Information, NLM
Mr. Jerry Sheehan, Office of the Director, NLM
Dr. Hua-Chuan Sim, Division of Extramural Programs, NLM
Dr. George Thoma, Lister Hill Center, NLM
Ms. Holly Thompson, Office of the Director, NLM
Ms. Sara Tybaert, Division of Library Operations, NLM
Dr. Alan VanBiervliet, Division of Extramural Programs, NLM
Ms. Rebecca Warlow, Division of Library Operations, NLM
Ms. Terrie Wheeler, Office of the Director, NIH
Dr. Fred Wood, Office of Health Information Programs Development, NLM
Dr. Jane Ye, Division of Extramural Programs, NLM

Dr. Deborah Zarin, Lister Hill Center, NLM

I. OPENING REMARKS

Dr. Ronald Evens, NLM Board of Regents Chair, welcomed the Regents, alternates, and guests to the 165th meeting of the Board. He then welcomed a new member of the Board, Dr. Robert Greenes, Professor of Biomedical Informatics at Arizona State University, and alternate ex-officio member Major General Dorothy Hogg, U.S. Air Force Assistant Surgeon General, representing the USAF Surgeon General Tom Travis.

Dr. Evens announced that NLM Director Dr. Donald Lindberg has been named the 2014 recipient of the Paul Evan Peters Award. The award recognizes notable, lasting achievements in the creation and innovative use of network-based information resources and services that advance scholarship and intellectual productivity. He then introduced Capt. Robert DeMartino, Chief of Staff, to give the report from the Office of the Surgeon General, PHS.

II. REPORT FROM THE OFFICE OF THE SURGEON GENERAL, PHS

Capt. Robert DeMartino noted that 2013 was a busy year for the Office of the Surgeon General (OSG). Dr. Benjamin left the OSG in mid-year. The OSG spent the latter part of 2013 preparing the 50th year report of the Surgeon General on tobacco use. The report, released on January 2014, highlights the fifty years of activities by the Office relating to smoking cessation and tobacco use. It details initiatives to curb the incidence of tobacco use in the US. Tobacco use remains the number one cause of preventable death in the US. There have been 32 Surgeon General Reports on smoking and tobacco use.

The OSG continues work on the National Prevention Strategy, with the National Prevention Council created by the Affordable Care Act. Comprised of 20 Federal departments, agencies and offices, the Council is committed to prevention and wellness in the U.S. health care system. There has been good progress in implementing prevention policies. In January, 2014, the Commissioned Corps of the US Public Health Service, headed by the Surgeon General, became the first Uniformed Service to prohibit the use of tobacco while in uniform.

One of initiatives undertaken by Dr. Benjamin and the current Acting Surgeon General involves walking. Capt. DeMartino said that the OSG encouraged walking as an activity everyone can do. It is free and does not require additional resources.

The OSG is also promoting the use of its family health history tool. It is helpful for the public to use and to make available through electronic health records. Suicide prevention is an initiative of particular importance to the OSG and the office continues to monitor its activities in this regard. There are also numerous calls to action that have been initiated by the OSG to reinforce actions undertaken to promote good health care, including medication adherence, skin cancer, and alcohol misuse.

Capt. DeMartino noted that the Senate has begun consideration of Surgeon General nominee Dr. Vivek Murthy, a Boston-based physician and instructor at Harvard Medical School.

Board Member Dr. Gottlieb said the OSG is using the same effective strategies to curb tobacco use as have been used to address alcohol abuse in Alaska. Dr. Ronald Evens recalled that 50 years ago, when he was in medical school, Surgeon General Luther Terry released the first report on smoking and health. He said that it was quite sensational at the time. Several board members asked if there was a Surgeon General report on marijuana and electronic cigarette use. Capt. DeMartino said there was not a report on marijuana and/or electronic cigarette use and health.

Board Member Dr. Fleming also noted that most prevention efforts by the OSG have been directed at younger populations. Yet, older Americans are an increasing portion of the population. He recommended that the OSG look at shared decision-making and end of life issues as well.

Dr. Lindberg reminded the Board that the NLM has enjoyed a long and welcome relationship with the OSG and Deputy Director Betsy Humphreys pointed out that the Board Room was the same room in which the Committee that drafted the Luther Terry report met several times. Access to the literature at the time made NLM a suitable place to meet.

III. SEPTEMBER 2013 MINUTES AND FUTURE MEETINGS

The Regents approved without change the minutes from the September 10-11, 2013 meeting. The 2015 winter meeting will take place on February 10-11, 2015. Deputy Director Betsy Humphreys said that the Board would be meeting for full days on May 13 and 14, 2014. In addition to its regular Board meeting, the NLM will host a symposium on May 14, 2014 that would look at accomplishments over the past 30 years in preparation and background for the development of the next NLM long range plan.

IV. REPORT FROM THE NLM DIRECTOR

Dr. Lindberg began his report with the budget. The 2014 budget for NLM is $340 million with a 1% pay raise for employees. The 2014 Omnibus Appropriations Act did not include, even though requested by the President, a specific increase in the NLM base budget for the NCBI. So, the new budget means that $39 million will once again have to come from the Institutes.

Dr. Lindberg asked Joyce Backus to introduce new employees within Library Operations. She announced that Sara Tybaert began as the head of the MEDLARS Management Section on October 6, 2013. She was previously a Unit Head in that Section. Rebecca Warlow began serving as head of the Images and Archives and Records Section in HMD in January 26, 2014, coming to NLM from the National Archives and Records Administration.

Dr. Clem McDonald, Director of the Lister Hill National Center for Biomedical Communications (LHC) introduced the new LHC fellows, including Dr. Amos Chan, who joined the Office of the Director and the Communication Engineering Branch at the LHC in September 2013, Dr. Mallika Mandkar, who will be working on large data assets, and Dr. Kirk Roberts, who is working with Dr. Dina Demner-Fushman on Natural Language Processing projects.

Dr. Lindberg announced that Dr. Dennis Benson is the new Deputy Director for NCBI, and noted that Dr. Angela Ruffin will be retiring from the NLM where she has served as the Head of the National Network of Libraries of Medicine (NN/LM) Office.

Dr. Lindberg asked the Board to review the section of the BOR book on legislation. In summary, however, he noted that the Appropriations bill continued funding for STEM initiatives, including the Science Education and Partnership Awards and the NIH Office of Science Education. Efforts to implement public access policies in other Federal science agencies are ongoing. Lindberg noted that NLM has offered to assist other agencies interested in using PubMed Central (PMC) to support their public access policies and several agencies have expressed interest in this offer. Lastly, Dr. Lindberg said that since the public access policy became mandatory in 2008, NIH funding is estimated to have helped generate about 473,000 peer-reviewed articles, more than 81 percent of which have been deposited in PMC.

Dr. Lindberg said that the NLM is the DHHS central coordinating body for clinical terminology standards. The Library's involvement in this arena is an outgrowth of its development, beginning in the late 1980s, of the Unified Medical Language System (UMLS). Today, NLM develops and/or provides significant financial support for the ongoing maintenance and free US-wide use of the three major clinical terminologies (RxNorm, SNOMED CT and LOINC) in certified EHRs that can be used to achieve meaningful use. Late in FY 2013, NLM entered into an interagency agreement with the Department of Veterans Affairs that will support more rapid improvements to standard vocabularies in areas of particular interest to veterans' health. Also, NLM is working with ONC on establishing standards for the structure of common data elements that can be imported for use within EHRs to support structured data capture for quality improvement, research, and public health.

Dr. Lindberg asked Dr. Steven Phillips, Director of NLM's Specialized Information Services Division, to discuss NLM's recent activities related to 4-methylcyclohexane methanol, a colorless chemical compound used to rinse coal. The substance spilled into a West Virginia river, resulting in a tap water ban for up to 300,000 people. Dr. Phillips said little is known about the compound and other agencies turned to NLM to find out about it. SIS met with subject matter experts to summarize all available evidence about the effects of this chemical and rapidly release information about it in the NLM Hazardous Substances DataBank in order to assist US and West Virginia officials in managing this disaster.

Dr. Lindberg then discussed how in September 2010, the HMD initiated the HMD Aids Consortium, an online aggregation and discovery service for archival resources in the health sciences held by various institutions throughout North America. The service crawls external Web sites and harvests HTML, PDF, and XML content for indexing—no files are actually ingested. Users can perform basic keyword searches across the content and link back to the owning repository's Web site. The service currently indexes 3,700 finding aids from 35 repositories.

Increasing awareness and use of results in ClinicalTrials.gov is an important priority for NLM, said Dr. Lindberg. The NN/LM is assisting by teaching librarians, researchers, grant administrators, and grant officers about clinical trials results submission and use through an online course, presentations, and exhibits at conferences and tradeshows.

While the NLM has extensive experience in traveling exhibitions via its library network, it is unknown how the exhibition might travel through Indian Country. Dr. Lindberg described the initial pilot program which recently traveled *Native Voices* to Spirit Lake Dakota nation in Ft. Totten, North Dakota. Cynthia Lindquist, who was an advisor on the *Native Voices* project said, "It showcases role models—trial leaders, tribal elders, spiritual people and medicine people from across the country." She was extremely helpful in piloting the launch of this exhibition in North Dakota. A short video documenting the opening event at the Spirit Lake Dakota nation and the naming of a resource room at the tribal college in honor of NLM's Director was shown.

Following the Director's report, a Board Member asked if NLM had any programs targeting young people and smoking. Dr. Lindberg said that it would be appropriate for NLM to make information about the effects of smoking readily available to the public, including young people. [NOTE: MedlinePlus has a relevant topic page directed at teens: http://www.nlm.nih.gov/medlineplus/smokingandyouth.html].

Board Member Ms. Ryan, referring back to the Surgeon General's report, asked if efforts to link health histories to electronic health records were underway. Ms. Humphreys said that there were efforts both to collect the information in a standardized way and to allow them to be submitted or connected to electronic health records.

Board member Katherine Gottlieb acknowledged that NLM does a great job of collecting, organizing and disseminating the world's medical information, as outlined by Dr. Lindberg. She said that she hopes that NLM will make sure that the information from *Native Voices* reaches the consumer level. Dr. Lindberg agreed that reaching consumers was NLM's goal. Referring back to the Surgeon General, he noted that until NLM put the reports of the Surgeon General online, consumers did not have access to their recommendations. Now they do.

Board member Dr. Ralph Roskies commented that it had been some time since the Board had been shown how NLM allocates its budget internally and asked that this information be presented at the next meeting. Dr. Lindberg agreed to include a budget breakdown at the May meeting.

V. A U.S. GOVERNMENT TRUSTED INTERNET CONNECTION ACCESS PROVIDER (TICAP)

Ivor D'Souza, Director of NLM's Office of Computers and Communications Systems (OCCS), reported that on November 20, 2007, the Office of Management and Budget (OMB) issued a memo (M-08-05) to executive departments and agencies in the U.S. Government (USG) to consolidate Internet connections and replace them with newly defined Internet points-of-presence, known as Trusted Internet Connections (TIC).

The TIC objectives are to: 1) reduce the number of Internet connections across the USG by consolidating them within Departments and Agencies; 2) standardize security platforms and processes that protect the Internet and external connections across the USG; and 3) implement TIC functions only at sites that meet TIC compliance criteria set forth by the Department of Homeland Security. In January 2008, OMB issued a series of memos providing more definition to the TIC initiative. Through the memos, OMB directed agencies to implement the TIC program by selecting one of the following tracks: 1) be a Single Service Provider by providing Internet services only to one's own agency; 2) be a Multi Service Provider by providing Internet services to one's own agency AND to at least one other agency; 3) choose to Receive Service from: a) a DHS-approved commercial vendor known as a Managed Trusted Internet Protocol Service (MTIPS) provider, OR b) a Multi Service Provider agency.

In January 2008, HHS chose to be a Single Service Provider by consolidating all Internet and Internet 2 connections. The early design of the HHS TIC required all Operating Divisions and Staff Divisions within HHS to be interconnected to three TIC locations: National Capital Region, Atlanta, and Albuquerque. This design meant that NLM would have to give up its own connections to the Internet and Internet2.

But, given NLM's continually growing needs for network bandwidth, it did not seem very cost-effective to move NLM's Internet traffic to the new TIC. So, in 2010, NLM began discussions with HHS about creating separate TICs for "restricted" and "unrestricted" traffic, with the intent that NLM would manage the unrestricted TIC. The "unrestricted TIC" would handle "unrestricted" data that met the following criteria: 1) Public read-only data—this includes Web sites. FTP sites etc., that do not require a login; 2) public read-only data that allow personalization —which require a login, but mainly for reasons of personalization, e.g., PubMed; and 3) content that is licensed to a user, requiring a login to meet review requests, e.g., UMLS.

All other HHS data would be considered "restricted" and would be required to pass through the HHS-managed "restricted" TIC. On January 17, 2012, after successfully passing an on-site audit by DHS, NLM was approved to be an HHS TIC access provider for "unrestricted" data. The HHS "restrict" TIC went live on November 21, 2013.

Board member Dr. Ralph Roskies applauded NLM's decision to go with a separate unrestricted TIC – and Mr. D'Souza's success in negotiating this unique arrangement. An Ex-Officio member also commended the Library's decision to go independent, but expressed concern about any possible reduction of protections, e.g., against denial of service attacks, with this strategy. Mr. D'Souza commented that the current monitoring product used in restricted TICs has pluses, but is not yet capable of handling the full load of NLM. Also NLM is one of few federal agencies that have a distributed denial-of-service feature in the Cloud.

VI. REPORT FROM THE NATIONAL INSTITUTE FOR GENERAL MEDICAL SCIENCES

NIGMS Director Dr. Jon Lorsch gave an overview of NIGMS and its mission: to promote fundamental research on living systems to lay the foundation for advances in disease diagnosis, treatment and prevention; and to enable the development of the best trained, most innovative and productive biomedical workforce possible.

The NIGMS has five divisions: Cell Biology and Biophysics; Genetics and Developmental Biology; Pharmacology, Physiology and Biological Chemistry; Biomedical Technology, Bioinformatics, Computational Biology; and Training Workforce Development and Diversity.

Upon his arrival at NIGMS, the Institute began development of a strategic plan. We wanted to find optimal models for future investments to promote a thriving and sustainable biomedical research enterprise. One goal is to promote agility to adapt to changes in society and science. This planning process is highly data driven, and we need to analyze those data in a way to drive the decisions we make. Finally, we want close communication with the biomedical community and other stakeholders.

Every strategic plan has some watchwords. In the NIGMS strategic plan they are efficacy, efficiency, and adaptability. NIGMS wants to renew its commitment to investigator-initiated (single PI- and team-based) research. They don't know where the next great discovery will come from so there is a need to diversify their portfolio to let investigators determine the most interesting areas of research.

NIGMS invested in specific areas of research during the budget doubling. With the shift away from doubling, it was necessary for NIGMS to take a new look at how it invests its research dollars. In the 1990s, a portion of the NIGMS grant dollars were investigator-initiated —99% initially and now only 80% are investigator-initiated. So, it went from 1% targeted to over 20% targeted over this period of time.

NIGMS is also exploring the development of more stable, flexible and efficient funding mechanisms. Right now, PIs spend a great deal of their time writing grants. The grant system constrains people. Some of the greatest discoveries have been through serendipity, which the grant system does not support. One model NIGMS is considering would support a PI's overall research program instead of individual projects. NIGMS is also looking at how to support research resources and technology development. Science drives technology development, but it is also true that technology drives science.

NIGMS is also promoting the development of the best trained, most innovative and productive biomedical workforce possible. NIGMS is funding more than half of all NIH pre-docs. One of the big issues in training is diversity. Diversity at all levels strengthens the research enterprise. How can NIGMS promote diversity? It is critical to do so. NIGMS will be working with its stakeholders to determine how to best support diversity and how to promote innovation and experimentation in education and training. Dr. Lorsch said that small, efficient, investigator-initiated science and research saves lives.

Board consultant Dr. Kenneth Walker asked about NIGMS's continuation of long-range planning. Dr. Lorsch said that a long-range planning committee should have a life span that keeps coming back and continues to reevaluate the strategic plan to make sure it is moving forward correctly. The long range plan has three levels: the high level long range plan that goes to HHS, the implementation plan, and the plan that incorporates all the other ideas that people come up with along the way. We have to get everyone invested in the plan. It is not just as a one-time thing. Things change day to day, and the long-range plan should change accordingly.

Dr. Evens said that he thought NIGMS dealt with general medicine and not specialties. Dr. Lorsch said that NIGMS does not support primary care research. But, he said, the NIGMS recently picked up the Office of Emergency Care Research because NIGMS does have a clinical portfolio of research in the area of trauma and burns. So, NIGMS is now the coordinating center for emergency care.

VII. NEWBORN SCREENING DATA STANDARDS

Swapna Abhyankar, MD, a pediatrician in the Lister Hill National Center for Biomedical Communications (LHNCBC), addressed NLM's role in newborn screening data standards. She was followed by Ms. Jacquelyn Lee, who provided an example of how the Kentucky Department for Public Health used those standards.

Dr. Abhyankar gave an overview and history of newborn screening (NBS). It's a public health program to identify newborns that appear healthy but have serious conditions. The goal is to intervene early to prevent serious disability and death, and also reduce the burden of disease. Newborn screening started in the 1960s when Massachusetts mandated that all newborns be screened for phenylketonuria (PKU). Over the next few decades, more states mandated screening and more screening tests became available. In 1999, recognizing a need for uniformity between the states, the American Academy of Pediatrics recommended that the Health Resources and Services Administration (HRSA) develop national standards for NBS. Criteria were developed to determine which diseases should be included in the screening (i.e. benefit vs. risk; the sensitivity of the screening test; the availability and affordability of treatment). Today, screening guidelines include 31 primary and 26 secondary conditions.

Dr. Abhyankar said NBS data standards are needed because there are many differences in the way states report results. That makes it hard to capture results and exchange them meaningfully between clinical electronic health records and public health records and registries. Standardization enables individual results to be communicated more quickly and enables aggregate results to provide more data for research--all of which could ultimately improve patient outcomes.

NLM has collaborated with multiple agencies to standardize the variables used in NBS and create guidance for electronic reporting of NBS results. This was done using federally-endorsed data and information exchange standards. NLM created a Newborn Screening Coding and Terminology Guide Web site that contains codes and terminology for newborn screening tests and conditions. The site also provides an HL7 template that programs can use as they implement electronic messaging of their NBS orders and results between labs, hospitals, and health information exchanges.

NLM is working with many states implementing electronic messaging, including Kentucky which is on the forefront of NBS data standards adoption. Jacquelyn Lee, the IT Manager for the Kentucky Department for Public Health, described Kentucky's experience implementing a health information exchange for NBS.

The Kentucky Division of Laboratory Services provides 3.5 million tests per year to providers and environmentalists throughout Kentucky. The Kentucky Health Information Exchange (KHIE) has 659 live connections, including hospitals, labs and physicians. It serves about 1,700 providers, hospitals, and practices. As the state moved from paper to electronic messaging, NLM helped with the mapping and by securing new mapping codes that were not previously in existence. To date, thousands of newborn screening reports have been validated and Kentucky goes live in 2014. Ms. Lee gave a demonstration of the KHIE portal and the NBS report. She said the benefits to KHIE are numerous and include 24/7 availability of reports; retrieval by providers at any location; and intrastate and interstate availability of reports to meet emergency needs.

VIII. INFORMATIONIST SERVICES FOR DEAFNESS RESEARCH: A CASE STUDY

In 2012, NLM awarded its first informationist supplement grants. Eight NIH-funded researchers received awards to add informationists to their teams and to measure the value .added to the research. The Board heard a case study from two informationists who worked on one of those projects.

Karen Hanson and Theodora Bakker are librarians in the NYU Health Sciences Library System and work at NYU's Langone Medical Center. They partnered with two NYU researchers funded by NIH's National Institute on Deafness and Other Communications Disorders. The Director of NYU's Health Sciences Library system, Neil Rambo, MLibr, appeared via video and said the library took a systematic approach to identify researchers with whom to partner for the awards. Two research projects were identified and both received funding. Mr. Rambo said the effort was a success not just because the projects were chosen but because the effort made the researcher community more aware of the information and data management role the library can play.

Ms. Hanson and Ms. Bakker worked with NYU researchers Mario Svirsky, PhD and Arlene C. Neuman, on their research project, "Clinical Management of Cochlear Implant Patients with Contralateral Hearing Aids." Drs. Svirsky and Neuman also appeared via video to describe their research and data management needs. Dr. Svirsky explained the difference between cochlear implants, which replace the sense of sound, and hearing aids, which amplify sound. He said some people have an implant in one ear and a hearing aid in the other, meaning they are bimodal. Dr. Svirsky, an expert in implants, and Dr. Neuman, an expert in hearing aids, joined forces to study bimodal patients. Dr. Neuman said they used retrospective data from their clinic to see how patients performed with the cochlear implant alone, the hearing aid alone, and the two devices together. They found that in about a third of patients, there was a decrease in performance in the hearing aid ear over time while there was an increase in performance with the cochlear implant over time. They did not expect that. So, they wanted to explore how performance changed in the un-implanted ear over time and how bimodal performance changed over time. To give their analysis more power, they reached out to colleagues at cochlear implant centers around the world to pool their data. That increased the complexity of obtaining and analyzing data. They expected the informationists added to their team would provide knowledge about handling large and complex data sets so that the database would meet their current needs and could be expandable when those needs change.

Ms. Hanson and Bakker said their specific aims were to evaluate and restructure the data model, database and data entry tool to allow for the more comprehensive collection of disparate data sets; to reevaluate the reporting queries; and to create a tool for the research team to search and run queries themselves instead of relying on developers. Ms. Bakker said she and Ms. Hanson spent many hours with the PIs and the lab manager to develop an understanding of their data and their workflow and processes.

The NYU researchers had site specific data in database as well as data in Excel spreadsheets, plus de-identified patient data from the international consortium participants. Ms. Hanson and Bakker used the guiding principles of electronic health records to build a cohesive single data model that they hoped

would be future proof. They also needed to find a better tool for the researchers. After assessing existing tools, they decided to build a custom tool that included extra validation; autocomplete features; a special a page to import data from the consortium; and a built-in and custom reporting feature.

The challenges in the project were gaining the knowledge of the tests and devices used in the research and the lack of an existing tool. But, they had the opportunity to create an infrastructure for a new area of research; to promote data sharing; and to promote the value of complex data management and a new role for librarians.

In questions after the talk, the presenters were asked about prospects and lessons learned. Ms. Hanson and Bakker said the effort has led to new partnerships and sparked a lot of interest. Board member Ms. Gail Yokote said that other libraries could learn from NYU's experiences. NLM Deputy Director Betsy Humphreys noted there has been an active effort, including webinars, to get the word out to other health sciences libraries. Ms. Yokote suggested that, beyond the scientific community, this could be of interest to other communities that have data problems.

Dr. David Fleming noted the research that Ms. Hanson and Bakker did flipped the paradigm—their research subject was not the patient but the PI. Ms. Bakker noted that second-year NLM Associate Fellow Kevin Read is now working with them on a project in which they are interviewing PIs about their data needs. Dr. Ken Walker asked how librarians gain the experience to do this work and whether it can be taught in library schools. Dr. Lindberg noted that NLM is providing expertise--- three of the people in the NYU department were NLM Associate Fellows, and Ms. Humphreys added library and information schools are getting into this area.

IX. EXTRAMURAL PROGRAMS REPORT

Valerie Florance, PhD, Director of Extramural Programs asked the Board for its annual approval of NLM's operating procedures for grants adjustments. The Board gave unanimous approval.

Dr. Florance then provided an overview of the FY2013 grant year for NIH and NLM, noting the impact of sequestration. Compared to 2012, both NIH and NLM saw a decrease in the overall success rate for competing research project grants (RPG); the total amount of funding that went to RPGs; and the total number of research grant applications received. One difference between NIH and NLM—the average size of RPGs decreased for NIH and increased for NLM.

In FY2013, NLM had about $41 million to spend on grants and made 133 awards (27 new grants and 106 continuing grants). NLM's largest investment continues to be in clinical and public health informatics grants. NLM also has trans-NIH grants that are paid for by NIH and managed by NLM. They include two NIH Pioneer awards, a New Innovator award, and an OppNet award, which was solicited via the NIH social and behavioral sciences network initiative.

NLM's active portfolio includes 160 active projects. In 2013, 325 articles acknowledged NLM grants (up from 200 in 2012). The articles were published in 137 different journals. *The Journal of the American Medical Informatics Association*, *PLoS ONE* and *Nucleic Acids Research* were the top three titles.

Dr. Florance called attention to some widely-published NLM grantees. Dr. George Hripcsak has published 70 articles since NLM awarded his grant, "Discovering and Applying Knowledge in Clinical Databases," in 2001. Dr. Jason Moore's grant, "Bioinformatics Strategies for Genome-Wide Association Studies," has produced 49 papers since 2009. Moore's other grant "Machine Learning Prediction of Cancer Susceptibility" has produced 61 publications since 2006. Dr. Florance also noted the honors

grantees have received and the impact of their work. For example, Dr. Joan Ash, who has been funded for work on the unintended consequences of physician order entry, is the lead author of the new *SAFER Guides* for the Office of the National Coordinator.

X. REPORT FROM THE LHC BOARD OF SCIENTIFIC COUNSELORS

Dr. Evens introduced Dr. Kenneth Mandl, a professor at Harvard Medical School and chair of the Lister Hill Center Board of Scientific Counselors (LHC BSC).

Dividing his comments into themes, Dr. Mandl began with "Learning to Read," exploring NLM's major initiative in natural language processing (NLP), one of the most promising areas in biomedical research. With NLP, we can actually begin to make inferences from the enormous corpus of biomedical literature and electronic health information, which will accelerate discovery. Unfortunately, today's health care is more about the health of the chart than the health of the patient. What will save medicine from this is intelligence in the ability to interpret text that is not completely structured. NLM has long worked to develop standards, but there is no standards organization that will keep up with the new ways we need to express ourselves and the new kinds of data we need to be able to have a computer look at a chart and understand. An example of the work that is going on at Lister Hill is SemRep, is part of the Semantic Knowledge Representation project, which leverages UMLS resources to extract semantic predications regarding clinical medicine from the literature. There is literature and we can read it, but we certainly cannot keep up with it all. SemRep can pull out concepts and insert predication, which is very useful. (One recently discovered correlation, for example, was between hypergonadism and sleep in men—in many ways, a very exciting discovery.) Another publication is about reading the laboratory data in the literature. The ability to pull that out is quite important.

For his next theme, "Divination," Dr. Mandl discussed probabilistic models and prediction. It turns out that the future is actually largely knowable for many patients, thanks to some of the work that NLM has funded. The Lister Hill Center has really begun to exert the power of computing in this area, and one result has been a paper predicting ICU outcomes based on physiological data. He cited another LHC paper, which got good pick-up in the press; it looked at patients' body mass index (BMI) and mortality. It turned out that if you were heavier, you survived longer in the ICU.

To illustrate the theme, "Patients are just shy," Dr. Mandl showed a screen shot of the scrubber, which removes personal information about patients. If we're going to share text for research, we should never share patient identities. It's illegal and its bad practice. Technology to do this is being developed here and exciting work is also being done on the extramural side, funded by NLM. Between these two areas there is a very real possibility of increasing the amount of data that can be shared among researchers—which is a good segue into one of our BSC recommendations: that NLM is in a tremendous position to curate corpuses, texts and electronic health record data of things that are appropriately de-identified. This concept came up in a number of areas both on the intramural and the extramural side —there is the NLP community, and yet, Dr. Mandl observed, there always seems to be less annotated text in that community than he would expect. It's always a few hundred or a couple of thousand, but the community actually needs tens of thousands of notes in order to get these techniques. They have to be de-identified to be shared globally and this, in his opinion, is an area where NLM could make a tremendously enabling contribution.

His next theme, "Medicine 101," focused on getting existing medication data from large prescription databases to the point of care and actually testing what happens. Before a pharmacist fills your prescription, he or she needs to know that you're eligible to have it filled and that they'll be reimbursed. This is a real applied project in an emergency department, and it shows that you actually get improved medication and history data using these data streams— there is really nothing more important in medicine

than your care team knowing what medications you're taking. This is more than incremental. It's a really important finding.

Finally, "Keeping them honest" looked at the clinical trials initiatives at NLM. A constant challenge with clinical trials is publication bias—that is, only wanting to publish positive studies and positive results. What the NLM has done is to define the denominator of studies so we know what studies were started, finished and published.

Interestingly, a lot of studies are not published, so NLM is able to see documentation of publication bias. Another issue is cherry picking —what they said they were going to study isn't what they're reporting on; they're reporting the positives. This is because the statistical inferences no longer apply. With guidance from ClinicalTrials.gov Director Dr. Deborah Zarin, NLM is doing clinical trials matching—looking at the way the data is used and how to operate it. This was not something the original legislation had intended to support, but the Library and the LHC BSC is finding this database is useful for much more than initially envisioned.

In summary: 1) the Lister Hill Center should continue the great work; 2) where tools are being developed, there is an opportunity to engage the research community more properly; 3) we want LHC to keep producing the high-impact papers, it is a really good focus to continue to keep reaching for the stars; and 4) the LHC trainee program, not previously mentioned, is thriving, and the Board has recommended strategies for enhancing opportunities for the fellows to communicate and collaborate with each other, across LHC, and with visiting scientists.

Board member Dr. Robert Greenes requested more information about the role of the Board of Scientific Counselors. Dr. Mandl explained that in a typical meeting the BSC receives an extensive report from the Lister Hill Center on two research projects or areas. The BSC examines the research groups, deliberate on the scientific merit of the presented work, give attention to the career trajectories of the investigators and trainees involved, and make recommendations. The BSC is gratified that the investigators are quite appreciative and responsive to our comments.

Dr. Greenes asked how research priorities are identified. Dr. Mandl noted that the LHC BSC considers those carefully, looking at whether the Lister Hill Center is focusing on work that leverages NLM's unique strengths as opposed to work that might be better done in the extramural community.

Board consultant Dr. Holly Buchanan said that she was intrigued by NLM's transformative role in curating de-identified medical data, because all of our institutions struggle with making data available for our researchers. Yes, said Dr. Mandl, because NLM is a library and also an informatics research institution, it's well positioned to make available text that would be usable either publically or under a data use agreement. Our research data is very fragmented and, unfortunately, innovation can get stifled due to a lack of this type of data. There are very significant regulatory concerns but there is no substitute for real data.

Dr. Lindberg then commented on the de-identified group and the importance of it. When NLM started the UMLS program, one of the first things we did was request that the UMLS research contractors at various universities to provide us with the de-identified full text from patient records. It proved to be a daunting task, even for a human being. To this day, nobody is doing this thing right computationally, and to ask NLM to do it is fine, but funds, from NIH or some other source, need to follow.

XI. REPORT FROM THE NCBI BOARD OF SCIENTIFIC COUNSELORS

Dr. David Landsman, Chief of NCBI's Computational Biology Branch (CBB), said he would take a different approach than Dr. Mandl's. He described the NIH Intramural Research Program (IRP) and the scientists who participate in it. To become a senior investigator you have to go through a tenure process. Conversion to tenure means that your program is guaranteed support. There are about 900 IRP investigators at the NIH, and many more postdoctoral fellows than there are graduate students, unlike at universities. The NIH IRP has featured several well-known scientists, including Nobel laureates Marshall Nirenberg and Julius Axelrod, and their fields are quite varied. Likewise at NCBI, the researchers have a very broad diversity of interests.

NCBI has a director, David Lipman, and three branches: the Information Engineering Branch, the Information Resources Branch, and the Computational Biology Branch. In addition, NCBI has a Board of Scientific Counselors (BSC). Each counselor serves a four-year term and collectively they represent a variety of disciplines and talents. The NCBI BSC meets twice a year. At the spring meeting the information resources are reviewed and at the fall session the research programs are reviewed. Every NCBI Senior Investigator researcher is reviewed every four years, showing accomplishments to date and plans for the future. Projects are discussed at great lengths by the BSC, and they also have a private discussion with each principal investigator (PI). In their review, BSC members consider many factors besides research output, such as mentorship of fellows. The BSC also recommends whether tenure for a PI should be initiated.

Dr. Landsman ended by very briefly discussing some of the many scientific projects managed by the investigators at the NCBI.

XII. GENETIC TESTING REGISTRY (GTR) UPDATE

GTR Director Dr. Wendy Rubinstein of NCBI said that the initial call for a genetic testing registry came from a recommendation by the HHS Secretary's Advisory Committee on Genetics, Health and Society in 2008. At that time, most of the tests used to evaluate genetics were thought to be laboratory-based and not closely regulated.

NIH Director Dr. Francis Collins led the launch of the GTR Web site on Rare Disease Day, February 29, 2012, encouraging providers to enhance transparency. There was a lot of deliberative action for stakeholders about GTR specifications and, since May 2012, we have enabled submission of detailed information about tests.

GTR staff has been fortunate to be advised by many colleagues and a wide variety of stakeholders about what the database should look like, as well as the quality of the data. All submitters must agree to a code of conduct to help ensure that the information is accurate and not misleading. GTR users are also engaged to report what may be inaccurate or misleading. A standard operating procedure is in place to evaluate any reports of inaccurate or misleading information.

The initial scope of GTR was clinical tests for heritable disorders that can be ordered by health care providers. We have also developed research test registrations and, this past December, began accepting registration of somatic tests, largely for cancer—something that no other public database provides. We also instituted a requirement for an annual review of the data. In 2014 a new phase will begin to describe a whole exome (all of the parts of the genome that encode proteins) test in fine detail, as well as whole genome tests. These are now in scope as laboratory services and, in fact, you can find labs that offer these tests. However GTR aims to enable review of details surrounding these tests. With time, we will bring in information from manufacturers about their kits into scope and tackle the direct-to-consumer issue.

For some time, NIH has supported the GeneTests Laboratory Directory. Once NIH announced plans to discontinue support for GeneTests, NCBI has been working with the laboratory staff to develop a transition plan. We communicated with the labs about this and they agreed to have their information redisplayed; also, GeneTests decided to continue their site, relying on commercial funding. NCBI funding for *GeneReviews* continues and NCBI's Bookshelf continues to host *GeneReviews,* which are integrated throughout GTR. Submitter participation in GTR—enormously important—has been very strong. There are close to 400 registered laboratories in 39 participating countries. About 60% of labs that participated in GeneTests have been actively engaged with GTR, and all of the large labs are participating.

Dr. Rubinstein showed the rapid growth in number of registered tests. From spring of 2012 to present, the number of tests has shot up to close to 14,000 registered tests and 4,000 conditions tested. The submitter burden is important to take into consideration and NCBI has worked enable multiple ways to submit data—by migrating data from GeneTests, entering data interactively, and using semi-automated submissions through spreadsheet. NLM has engaged our sister agencies, such as the Food and Drug Administration (FDA), early on, to determine whether harmonization can be done. The HHS Centers for Medicare & Medicaid Services (CMS) has created a new set of coding, Z-codes through a subcontractor. There are no apparent technical barriers to mapping the data of interest to FDA and CMS and from the standpoint of the labs, they would like one-stop shopping. However, there needs to be a groundswell of need and purpose for this to really go forward. In the meantime, the American Medical Association (AMA) has created a new set of molecular pathology CPT (Current Procedure Terminology) codes to improve the understanding of the work performed by laboratories. Through an agreement between AMA and NLM, GTR now represents the molecular pathology CPT codes.

GTR provides detailed information about tests submitted by laboratory providers, but we also do a lot of linking to the literature resources, *GeneReviews*, PubMed and PubMed Central, and the full text of relevant practice guidelines. We are very engaged in not only using standard vocabularies but helping the genetics community at large to adopt standards. We also endeavor to advance the conversation on genetic terms and diseases.

Looking at the information that laboratories provide about tests, analytical validity is a minimal requirement for participation and is available on 100% of tests. Clinical validity and clinical utility are provided at about a 9-10% rate—we wish we had more, but it was decided that the laboratories may not have this at their fingertips although clinical validity would be required if a test underwent an FDA review process. Clinical utility is a component of information needed for payment, but nonetheless the labs generally haven't been willing or able to provide it to GTR. They more commonly provide information about target populations for tests.

Dr. Evens asked about the cost of a typical genetic test and Dr. Rubinstein replied that some are in the $1,000-3,000 range. With increased competition due to the US Supreme Court ruling on gene patenting, the costs of individual tests or combinations of small numbers of tests have been reduced to the $1000 range. In terms of the method types in GTR, molecular methodology is the predominant type but there are also cytogenetic and biochemical tests. It's interesting to look at the adoption of next generation sequencing (NGS) into the clinical realm—GTR data indicated that about 10% of molecular tests already use NGS as a methodology, although there was no FDA-approved platform for NGS until November 2012. Dr. Rubinstein noted that NCBI maintains the Human Genome Assembly, without which NGS would be impossible. .NGS assays DNA without maintaining information about its location on the genome assembly. A virtual alignment using software is needed to then determine where on the genome a sequence resides.

With respect to the FDA on this topic, Dr. Rubinstein presented the first quantitative data to show that the vast majority of genetic tests are indeed laboratory-developed tests. Only eight of the 6,000 clinical tests from US labs report that they are FDA-approved/cleared. Reporting of FDA status is not required in GTR but we do have about 14% of labs saying that the FDA exercises enforcement discretion—they have authority to regulate these tests—but choose not to.

Dr. Rubinstein showed the layout of tests in the GTR such as the test name and tested conditions provided by the submitter. There are seven tabs of information such as methods, indication, how to order, test performance and interpretation. The central and left sections of the test records primarily reflect what the lab says about their test. We assign a GTR accession and version, and the last update and the version history. On the right side of the page we bring in the information on what the community says in the literature.

Dr. Evens wanted to know, with the wealth of information in GTR, how does one best put it to use—and who is actually trying to turn this into case-specific clinical recommendations? And what makes a good genetic test?

Dr. Rubinstein responded that the structure of the GTR is intended to enable information exchange with electronic medical records—we use SNOMED CT terms preferentially when available. As far as what constitutes a good test that is for the community to determine. The NCBI staff sees its role as providing the information to the community for them to decide based on the evidence. GTR ranks tests with more detailed information higher, so that information is more readily accessible to users. We have also suggested to the professional organizations that if they were willing to review tests, we would be willing to post their categorization of tests.

XIII. NOMINATING COMMITTEE FOR BOR CHAIR

Dr. Evens announced that his term on the Board will end in May. He has named ex-officio member Kathryn Mendenhall of the Library of Congress to chair the nominating committee, assisted by ex-officio members Dr. Cathy Nace of the Office of the Army Surgeon General and Dr. Simon Liu of the National Agricultural Library.

XIV. REPORT FROM THE SUBCOMMITTEE ON OUTREACH AND PUBLIC INFORMATION

Subcommittee chair Mary Ryan summarized yesterday morning's meeting. Dr. Barbara Rapp of the Office of Health Information Programs Development reported on NLM's K-12 initiatives. Recently, the Library has been analyzing these programs across the board, to identify areas for collaboration and determine whether there are any duplicative efforts. The K-12 programs fall within NLM's consumer health mission; also, informing students about health and medicine early in their lives will not only benefit them but, also, their family members, with whom they'd likely share their discoveries. The K-12 programs fall into four categories: information resources; promoting health literacy; curriculum support; and promoting health careers. Some information resources, such as ToxTown and the Environmental Health Student Portal, were created specifically for the K-12 age group, whereas other NLM resources like Genetics Home Reference are meant for the general public but have been put to good use in the classroom. Health literacy has been promoted through the teen health leadership project and some after-school programs. And it should be noted that working with the K-12 age group is an important aspect of the National Network of Libraries of Medicine. The third category of activities is curriculum support, including the creation of lesson plans to be used in class and for after-school programs. Health careers are promoted though the Mentoring in Medicine program, in which NLM is an active participant. It's important to note that NLM's K-12 programs are designed to develop information resources, not to

actually teach classes. Moving forward, the plan is to increase curriculum support to cover additional resources and to promote more widespread awareness of the resources that are already available. Dr. Lindberg commented that the U.S. Office of Management and Budget has called for consolidation of such programs within the National Science Foundation and the Smithsonian Institution. Almost everything that NLM and the other NIH Institutes do related to K-12 programs is aimed at recruitment of minorities into the health professions.

NLM Associate Director for High Performance Computing and Communications (OHPCC) Dr. Michael Ackerman gave a presentation on NLM's pill images project. The purpose of this project is to help the public easily identify pills. If someone brings a pill into the ER and a child has ingested a bunch of these pills and the physician doesn't know what the pill is, there needs to be an easy way to identify it. OHPCC will soon launch a challenge to the community of developers to create a program that can help identify pills from pictures of them, say, taken and submitted via a smart phone. Whoever develops the best program to identify pills will get an award. What sounds like a simple task is actually quite difficult, Dr. Ackerman noted. He showed examples of how photographs can misrepresent the actual pill, depending on angle, color, background, etc.

The Subcommittee is recommending that both of these presentations be presented to the full Board in the future.

XV. DIGITIZING NLM HISTORY

Ken Koyle, Deputy Chief of the History of Medicine Division, began his talk on this project by describing the broader effort of which it is a part, the Digital Collections repository, NLM's online archive of biomedical books and videos. Launched in 2010, Digital Collections currently includes more than 10,000 items, and it is constantly growing. This unique resource provides preservation of and unique access to NLM's rich historical resources. The repository allows searching and retrieval of monographs and access to additional content in other format types as well. It's complementary to PubMed Central (PMC). Materials in Digital Collections are displayed as image files; users can download the entire text or copy specific pages.

Focusing next on this specific project, Mr. Koyle said that NLM recently completed the initial phase to digitize the Library's publications and productions. To date, the NLM History collection consists of over 500 items dating from the 1860s to the present day, reflecting the Library's ongoing effort for preservation, enabling future research.

What does the content consist of? There are monographic publications produced by NLM and its predecessors and selected audiovisual productions from the past six decades. There are old publications like the 1864 *Catalog of The Army Surgeon General's Library*, and newer things, like a 1963 booklet about the origin of MEDLARS. Users will also find a 1946 booklet quoting Johns Hopkins doctors describing NLM and the *Index-Catalogue* as "America's most important contributions to medical knowledge."

And how does HMD see this collection being used? The most obvious would be a future historian writing our history. Cultural historians might also find it valuable, as would historians of science and technology, military medical historians, or any number of other research areas.

The NLM History collection is open-ended, with newly-discovered material to be added in perpetuity. In short, it will continue to promote and preserve the works provided by and for the Library. The project represents an important aspect of NLM's future and accomplished three important goals: creating a

permanent storage and preservation method; improving access to these materials; and establishing a record of the past and present.

Board consultant Dr. Tenley Albright asked for more detail about how the NLM History collection was complementary to PubMed Central. From the inception of the NLM digital repository itself, Mr. Koyle explained, that was a key aspect. With PMC, we already have this digital repository of journal materials, searchable and freely accessible. We wanted to make sure we weren't replicating any of that, so we turned to things that wouldn't have been in scope for PubMed Central. Now, as we look to the future and start looking at digitizing historical serials, of course we're checking to make sure those are not already in PMC. The focus and content of the two systems, even though they are complementary, are clearly different.

Board member Dr. Henry Lewis asked whether, since these materials are digitized, they are also indexed by and therefore searchable on Google. Mr. Koyle replied that he didn't know whether the collection was indexed by Google, but a Google search will return some of our items.

Dr. Lindberg praised this addition to NLM's digital holdings as beautiful stuff, the product of admirable conservation and re-binding efforts.

XVI. ADJOURNMENT

Dr. Evens adjourned the Board of Regents meeting at 12:00 p.m. on February 12, 2014.

ACTIONS TAKEN BY THE BOARD OF REGENTS:

- Approval of the September 10-11, 2013 Board Minutes
- Approval of the February 10-11, 2015 Future Meeting Dates
- Approval of Grant Operating Procedures
- Appointment of Nominating Committee for Next BOR Chair

Appendix A - Roster - Board of Regents

I certify that, to the best of my knowledge, the foregoing minutes and attachment are accurate and complete.

Donald A.B. Lindberg, M.D.
Director, National Library of Medicine

Ronald G. Evens, M.D.
Chair, NLM Board of Regents