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

MINUTES OF THE BOARD OF REGENTS September 16-17, 2008

The 149th meeting of the Board of Regents was convened on September 16-17, 2008, 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 4:15 p.m., followed by a closed session for consideration of grant applications until 4:30 p.m. On September 17, the meeting was reopened to the public from 9:00 a.m. until adjournment at 12:00 p.m.

MEMBERS PRESENT [Appendix A]:

- Dr. Cynthia Morton [Chair], Brigham and Women's Hospital
- Dr. John Connolly, University of California, Irvine
- Dr. Carol Friedman, Columbia University
- Dr. C. Martin Harris, The Cleveland Clinic Foundation
- Dr. O. Wayne Isom, New York Presbyterian-Weill Cornell Medical Center
- Mr. Bruce James, Nevada New-Tech, Inc.
- Dr. Louis Rossiter, The College of William and Mary
- Ms. Eileen Stanley, Ecolab Inc.
- Ms. Virginia Tanji, University of Hawaii at Manoa

EX OFFICIO AND ALTERNATE MEMBERS PRESENT:

- Dr. Michael Corriere, U.S, Department of the Navy
- Ms. Eleanor Frierson, U.S. Department of Agriculture
- Ms. Gail Graham, Veterans Health Administration
- Dr. Caryl Krazer, Veterans Health Administration
- RADM Carol Romano, Office of the Surgeon General, Public Health Service
- Col. David Louder, U.S. Department of the Air Force
- Dr. Deanna Marcum, Library of Congress
- Col. John Powers, U.S. Department of the Army
- Dr. Charles Rice, Uniformed Services University of the Health Sciences
- Dr. Dale Smith, Uniformed Services University of the Health Sciences

CONSULTANTS TO THE BOR PRESENT:

- Dr. Marion Ball, Johns Hopkins School of Nursing/IBM Research
- Dr. Holly Buchanan, University of New Mexico
- Dr. H. Kenneth Walker, Emory University School of Medicine

SPEAKERS AND INVITED GUESTS PRESENT:

- Dr. Lisa Cannon-Albright, University of Utah
- Dr. Alan Guttmacher, Acting Director, NHGRI
- Dr. Gaylord Nordine, NetINS

MEMBERS OF THE PUBLIC PRESENT:

Dr. Sandeep Bhardwaj, Minister of the State, India

Ms. Mary Lindberg

Ms. Sara Mbaga, Makerere University

Mr. Archil Undilashvili, Emory University

Mr. Tom West, The Krasnow Institute

FEDERAL EMPLOYEES PRESENT:

Dr. Donald A.B. Lindberg, Director, NLM

Ms. Betsy Humphreys, Deputy Director, NLM

Dr. Donald King, Deputy Director for Research and Education, NLM

Dr. Michael Ackerman, High Performance Computing & Communications, NLM

Ms. Kathleen Amos, Associate Program, NLM

Ms. Stacey Arnesen, Division of Specialized Information Services, NLM

Ms. Joyce Backus, Division of Library Operations, NLM

Capt. Mary Chaffee, Division of Specialized Information Services, NLM

Ms. Kathy Cravedi, Office of Communications & Public Liaison, NLM

Dr. Milton Corn, Division of Extramural Programs, NLM

Ms. Celeste Dade-Vinson, Office of the Director, NLM

Mr. Todd Danielson, Executive Office, NLM

Ms. Donnetta Demyers, Office of the Director, NLM

Ms. Darlene Dodson, Office of Financial Management, NLM

Ms. Amy Donahue, Associate Program, NLM

Ms. Gale Dutcher, Division of Specialized Information Services, NLM

Ms. Kathel Dunn, Division of Library Operations, NLM

Dr. Valerie Florance, Division of Extramural Programs, NLM

Dr. Zoe Huang, Division of Extramural Programs, NLM

Ms. Christine Ireland, Division of Extramural Programs, NLM

Dr. Lawrence Kingsland, Lister Hill Center, NLM

Ms. Paula Kitendaugh, Division of Library Operations, NLM

Mr. Sheldon Kotzin, Division of Library Operations, NLM

Ms. Lisa Lang, Division of Library Operations, NLM

Dr. David Lipman, National Center for Biotechnology Information, NLM

Dr. Simon Liu, Office of Computer and Communications Systems, NLM

Dr. Robert Logan, Office of Communications & Public Liaison, NLM

Ms. Becky Lyon, Division of Library Operations, NLM

Ms. Paula Maez, Associate Program, NLM

Mr. Patrick McLaughlin, Associate Program, NLM

Dr. Clement McDonald, Lister Hill Center, NLM

Ms. Melanie Modlin, Office of Communications & Public Liaison, NLM

Mr. Dwight Mowery, Division of Extramural Programs, NLM

- Mr. David Nash, Office of the Director, NLM
- Dr. Aaron Navarro, Lister Hill Center, NLM
- Dr. James Ostell, National Center for Biotechnology Information, NLM
- Dr. Arthur Petrosian, Division of Extramural Programs, NLM
- Dr. Steven Phillips, Division of Specialized Information Services, NLM
- Ms. Shana Potash, Office of Communications & Public Liaison, NLM
- Dr. Barbara Rapp, Office of Health Information Program Development, NLM
- Ms. Julia Royall, Office of Health Information Program Development, NLM
- Dr. Angela Ruffin, Division of Library Operations, NLM
- Mr. John Scott, Consultant, NLM
- Mr. Jerry Sheehan, Office of the Director, NLM
- Mr. Mark Siegal, Division of Extramural Programs, NLM
- Dr. Elliot Siegel, Office of Health Information Program Development, NLM
- Dr. Hua-Chuan Sim, Division of Extramural Programs, NLM
- Dr. Charles Sneiderman, Lister Hill Center, NLM
- Dr. George Thoma, Lister Hill Center, NLM
- Ms. Patricia Tuohy, Division of Library Operations, NLM
- Dr. Rebecca Williams, Lister Hill Center, NLM
- Dr. Frederick Wood, Office of Health Information Program Development, NLM
- Dr. Jane Ye, Division of Extramural Programs, NLM

I. OPENING REMARKS

Dr. Cynthia Morton, Chair, welcomed the Regents, alternates, consultants and guests to the 149th meeting of the Board. She introduced Ms. Virginia Tanji, Director of the Health Services Library, John A. Burns School of Medicine, University of Hawaii, Manoa, who was attending her first meeting as a Board Member, and Michael Corriere, PhD, Dean of Academics, Naval Medical Manpower, Training and Education Command. He is the new ex-officio member from the Department of the Navy. Dr. Morton noted that RADM Carol Romano, Acting Chief of Staff, Office of the Surgeon General, would be speaking with the Board later in the proceedings. She welcomed the first presenter, Dr. Alan Guttmacher.

II. REPORT FROM THE NATIONAL HUMAN GENOME RESEARCH INSTITUTE

Dr. Alan Guttmacher, Acting Director, NHGRI, discussed the great relationship that the NHGRI has had with the NLM, and said that the work on the Human Genome Project (HGP) and the knowledge gained from it would not have been possible without NCBI.

Dr. Guttmacher noted that the end of the HGP (on April 14, 2003, when the final sequence was completed) capped a remarkable 50-year arc that began with Watson and Crick's description of the DNA double helix. Among other advances, the HGP spawned the field of genomics and several new technologies, including a swifter, more accurate method of sequencing. Although

the Project was not itself hypothesis-driven, it yielded a new tool to make hypothesis-driven research better and richer in the future. The HGP also demonstrated the value of public release instead of data hoarding. A hundred years from now, the immediate release of sequence data on publicly downloadable Web sites will stand as the project's crowning achievement.

The findings and new technologies emanating from the HGP have already had an impact, and much more will be seen in the mid- to long-term. When the 2003 article on the Project was published, there were a small number of human Mendelian traits (essentially single-disease disorders, like cystic fibrosis) for which the gene involved had been identified. However, because more than one gene is typically involved in cancer, heart disease and stroke, researchers started using the "candidate gene" approach. This led to the birth of genome wide association studies (GWAS), which look at multiple genes that have been found to be associated with different diseases or the same disease, in 2005. The first GWAS identified two genes involved in 50% of cases of age-related macular degeneration (AMD). This was a landmark discovery; previously, researchers had thought it was a degenerative disease, but the genes actually cause inflammation. The finding greatly altered methods of prevention and treatment, and GWAS overall are unlocking the secrets of the biology of disease at a brisk pace. By the end of 2008, scientists will have identified hundreds of genes involved in common diseases. A critical part of that achievement is the NCBI product that archives and distributes data from GWA studies, dbGaP (database of Genotype and Phenotype).

While many NCBI databases are "open access," with information available to everyone, some, like dbGaP, contain sensitive data and are classified as "controlled access;" researchers must document their bona fide intentions for a data access committee before viewing the data. A paper, published August 29th by the Translational Genomics Research Institute in Phoenix, combined multiple GWA scans to determine whether the same individuals were found in both samples. This research has important implications for forensic science, but also showed that people with access to an individual's genomic data could in fact determine with a reasonable degree of accuracy whether that individual was part of a population for which summary genomic data are available. Some claims of the power of the genome are more dubious: one company will review your DNA and that of your potential partner, and decide whether you're a good match. For \$399, another company will list all polymorphisms in your genome, but won't tell you what that information means. NLM and NHGRI need to educate health professionals and the public about these scams.

Where is genomics headed? Dr. Guttmacher discussed two projects. NHGRI organized EMERGE (Electronic Medical Records in Genomics), a five-member consortium. EMERGE will develop, disseminate and apply approaches to research that combine DNA biorepositories with electronic medical record systems for large-scale, high-throughput genetic research. Each member organization has proposed studying the relationship between genome wide genetic variation and a common human trait, testing hundreds of thousands of single nucleotide polymorphisms (SNPs) throughout the genome in people with and without the trait. He also

discussed NIH's award of \$20M to fund new sequencing technologies. The goal is to sequence an individual's DNA for \$1,000 by 2014. Undoubtedly, that will change how we practice health care and manage health information. The bigger challenge: How will we *analyze* all of that information?

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

RADM Carol Romano, Acting Chief of Staff, Office of the Surgeon General, presented the report on behalf of RADM Steven Galson, MD, the Acting Surgeon General. She noted with regret the passing of the former Surgeon General (1977-81) Julius Richmond.

The Office of the Surgeon General continues the Childhood Overweight and Obesity Prevention Initiative, which promotes the importance of healthy eating and physical activity. RADM Galson has visited over 35 states to foster partnerships and share best practices. A link from the Surgeon General's home page reflects the available resources from all HHS agencies on the topic, and they hope libraries will help to promote this resource to the public. On September 15, 2008 the Surgeon General released his *Call to Action to Prevent Deep Vein Thrombosis and Pulmonary Embolism*. This prevention-oriented report urges all Americans to understand risk factors, triggers and symptoms of these conditions, which claim the lives of over 100,000 Americans each year.

In this busy hurricane season, the Surgeon General has activated the Commissioned Corps of the US Public Health Service, deploying over 900 officers for response and recovery missions in the Gulf Coast. Field medical stations are using electronic health records, and libraries take the lead in disaster information management and informatics.

Every Thanksgiving, Family Health History Day provides an opportunity to talk about disease and health conditions that run in the family. This year, the Surgeon General's *My Family Health Portrait Tool* will be unveiled in an interoperable, harmonized form. (It is being tested by Federal and private health systems.) The new Tool, a collaborative effort with NCI, NHGRI and the Office of the National Coordinator for Health Information Technology, HHS, will be available on the Surgeon General's Web site.

IV. CONSIDERATION OF MINUTES FROM PREVIOUS MEETING

The Regents approved without change the minutes from the May 13-14, 2008 meeting.

V. DATES FOR FUTURE BOARD OF REGENTS MEETINGS

The Board of Regents will meet next on February 10-11, 2009. The Spring Board meeting is May 5-6, 2009. The dates of September 15-16, 2009 were approved for the following meeting.

VI. REPORT FROM THE NLM DIRECTOR

Dr. Donald Lindberg noted that the Supplemental Appropriation Act of 2008 provided an additional \$150M to NIH. NLM received \$1.705M, which was used to restore resources to training grants. In June 2008, NIH Director Elias Zerhouni, MD, approved a special assessment of NIH Institutes and Centers, which provided \$6.4M to support NCBI's increased costs for the Molecular Core, dbGaP, and Next Generation Sequencing. In a separate NIH Management and Budget Working Group process, NCBI received \$2.6M in FY2008 funds for costs related to the mandatory NIH Public Access Policy. The FY2009 budget numbers are detailed in the Members' book. NIH expects to be funded through a continuing resolution until after the election, or the new President takes office.

Dr. Lindberg mentioned the appointment of new Budget Officer **Darlene Dodson**. (She replaced **Sue Levine** who preformed wonderfully for NLM for many years.) Most recently, Ms. Dodson served as the Deputy Associate Administrator for the Office of Federal Assistance Management at the Health Resources and Services Administration (HRSA). **Gale Dutcher** is the new Deputy Associate Director for the Division of Specialized Information Services. She had previously been doing a terrific job as the Chief of SIS's Outreach and Special Populations office.

SIS Director Dr. Steven Phillips introduced **Capt. Mary Chaffee, MD**, who has been detailed from the United States Navy to be the Research Coordinator for NLM's Disaster Information Management Research Center. He also introduced **Dr. Bert Hakkinen**, Senior Toxicologist in the Office of the Director, SIS. He will also serve as NLM Toxicology and Environmental Health Science Advisor.

Dr. Lindberg introduced **Kathel Dunn**, the new Associate Fellowship Program Coordinator. She comes from the New York University Medical Center, where she was Associate Director of the National Network of Libraries of Medicine, Middle Atlantic Region. Ms. Dunn introduced the four new Associate Fellows for FY2008-2009: **Kathleen Amos** received her MLIS from Dalhousie University in Halifax, Nova Scotia and also holds a BA in sociology and social anthropology; **Amy Donahue** received her MLIS from the University of Washington and has a dual BA in mathematics and .Russian language and literature; **Paula Maez** received her MLS from the University of Arizona, Tucson, and holds a BA degree in education and a BS in speech and health sciences; and **Patrick McLaughlin** received his MLIS from the University of South Carolina and holds an undergraduate degree in biological sciences.

Lister Hill Center Director Dr. Clement McDonald introduced **Dr. Haiying Guan**, a doctoral fellow in the Communications Engineering Branch working on machine learning methods for image retrieval from biomedical image databases and the biomedical literature. He also recognized **Dr. Krystl Haerian**, a clinical postdoctoral fellow working on a project to improve the NIH Clinical Center's electronic health record system.

Dr. Lindberg mentioned that legislation of interest to NLM is not expected to go very far. Tab C describes a bill to reauthorize the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs, both of which will expire at the end of FY2008. Federal law requires that each of the NIH Institutes set aside some grant money toward the programs; for NLM, it's a fairly modest sum. NLM gets interesting proposals in the area of information systems, and generally selects Phase One awards. Another bill of interest to NLM is H.R. 6845 about copyright. NCBI Director Dr. David Lipman attended a House Judiciary Committee hearing on the bill and will discuss it in his presentation tomorrow.

Dr. Lindberg discussed NIH's role in grantee conflict of interest. (An update on the NIH position will be presented during the Extramural Programs report.) The question before the Board is, "Should we do something?" Board members suggested that more transparency is necessary. If grantees are required to declare all of their industry-sponsored relationships on a public Web site, it will go a long way toward preventing conflicts. The American Association of Medical Colleges and other organizations have asked whether NLM could establish such a Web site.

Turning to Tab E, Dr. Lindberg noted that the Association of Research Libraries has selected NLM and four academic libraries to provide internships to 45 library science graduate students from underrepresented racial and ethnic groups. The program, funded by the Institute of Museum and Library Services, seeks to address recruitment and retention of minority librarians by providing them with a close network of peers, while providing the students with practical learning experiences to complement their academic work. Board members hailed the program.

Tab F describes Urban Indian Consultation. Dr. Lindberg explained that this is part of NLM's effort to develop an exhibition on Native American concepts of health and disease. There are more Indians in cities than on reservations. To learn whether the attitudes of urban Indians were the same as those living on reservations, a consultation was held in Seattle with Urban Indian health leaders, advocates, researchers, and providers from around the country. The Seattle Indian Health Board and the Urban Indian Health Institute hosted. We learned that the absence of gathering places for Native Americans in urban settings is a major problem. The lack of a meeting place led groups to meet in bars, creating other problems, including alcohol abuse. Other health problems for Native Americans discussed in the consultation included spousal abuse, alcoholism, drug abuse, and child abuse and neglect.

Dr. Lindberg provided an update on the *NIH Medline*Plus magazine. He expressed thanks to Dr. Donald King, Kathy Cravedi and the Friends of the NLM for their excellent work on the publication. Language in the Senate Appropriations report thanks NLM for pressing ahead on distribution of the *NIHMedline*Plus magazine to doctors and their patients nationwide. The only thing preventing the magazine from going to every doctor in the country is money. A Board book table (Tab G) shows how the distribution is increasing — up to 500,000 copies an issue.

Next, Dr. Lindberg discussed NLM's work on interactive publications. Tab H summarizes NLM's experiment with Elsevier and the Student National Medical Association. Dr. Elliot Siegel has led this, and it is going very well. NLM also has an ongoing project with the Optical Society of America. The aim is to develop and evaluate a prototype biomedical interactive archive, which will allow viewing and analysis of curated, supplemental biomedical source data, published in conjunction with a peer-reviewed manuscript.

Dr. Lindberg described the Bethesda Hospitals' Emergency Preparedness Partnership (BHEPP), at Tab I. BHEPP's main goals include developing a response in the case of a disaster. SIS Director Dr. Steve Phillips and Director of the Office of Computer and Communications Systems Dr. Simon Liu have been involved in this project and its annual disaster simulations.

Tab J discusses the 2008 NLM Informatics Training Conference. There are training grants awarded by NLM to 18 institutions with about 300 slots. Meetings alternate between Bethesda and out in the field. The next Training Conference will take place at the Oregon Health and Science University, Portland, Oregon, in June 2009. The presentations this year, at NIH's Natcher Conference Center, were amazingly good. There were 354 attendees from 18 current NLM training programs.

Dr. Lindberg concluded with an informal report on the change that is likely to occur in the NIH research grant proposals process. He showed a PowerPoint presentation, developed by Dr. Zerhouni, describing the new process. The consequence of flat funding is not a decrease in the number of applications; in fact, there is an increase. At the same time, you have to go through numerous revisions to get funding. In the future, they are going to allow one revision and that will be it. Cohorts of submissions will be ranked separately so that, in first submissions, you will be ranked along with others in first submissions, and first *revisions* will be ranked with other first revisions. The other change, which everyone was enthusiastic about, is the desire to shorten applications. The overarching goal is to streamline the grants process.

VII. EYEWITNESS REPORT: REPUBLIC OF GEORGIA

Next, the Board of Regents welcomed its consultant, H. Kenneth Walker, MD, Professor of Medicine at Emory University School of Medicine, and his colleague, Archil Undilashvili, MD, MPH, Director of International Programs at the School of Medicine. They receive funding from the US Agency for International Development (AID) to train emergency medicine physicians in the Republic of Georgia. This program took on significance during recent altercations between Georgian and Russian forces in the South Ossetia region. The Emory-trained team of Georgians set up field hospitals there. Dr. Walker was in Georgia when the flare-up with Russia began on August 7th.

Georgia has a population of 4.5 million. It lies in the Caucuses and is close to the Caspian Sea, with its vast oil reserves. After the Soviet Union imploded in 1991, a violent conflict erupted

between people living in the South Ossetia region, which borders Russia, and the Republic of Georgia. In its wake, 100,000 internally displaced Ossetians migrated to Russia and 23,000 Georgians fanned out into other parts of Georgia. The next year, Georgia accepted a ceasefire, to avoid a war with Russia. Georgia rattled Russia's cage in 2002, by applying to join the North Atlantic Treaty Organization (NATO) and agreeing to host oil and gas pipelines running from the Caspian Sea to Turkey, thus skirting around Russia. President Bush took an interest in Georgia and the nation receives some \$100M annually in US foreign aid. Georgia has turned toward the West, to Russia's chagrin. With the Rose Revolution of 2003, Mikheil Saakashvili took the reins of government and pledged to reunite Georgia.

What precipitated the 2008 clash between Georgia and Russia? With support from the US and European Union, and despite intense Russian objections, Kosovo declared its independence from Serbia in February. Emboldened by that act, South Ossetia asked the world to recognize its independence from Georgia. Georgia recommended a power-sharing arrangement, to ensure national unity, but South Ossetia rebuffed that proposal and President Putin concurred. In July, Russian moved its air corps near the region and conducted military exercises. On August 1st, two roadside bombs set by South Ossetians wounded five Georgian policemen. That night, Georgia initiated a firefight that left six Ossetians dead. Military action from both sides was ratcheted up for a week.

While Dr. Walker was in the Georgian capital in August, he could see the Russian bombs, which were being dropped about four miles away. The recent conflict brought the number of Georgians wounded to 2,231. Many were treated in the Hospital in Tbilisi, with which the Emory program is affiliated.

Dr. Lindberg asked what impact the conflict was having on Emory's projects in Georgia. They were already helping the nation establish an emergency medical network throughout the country, he said, but obviously the need became more urgent with the August war. Dr. Walker said he was planning to set up a learning center in Georgia, similar to the ones at US medical schools, with distance learning capabilities and the chance to practice skills virtually. With such a facility, dramatic progress can be made.

VIII. HEALTH DATA STANDARDS UPDATE

Betsy Humphreys explained that NLM has long played a significant role in the Federal health IT agenda. NLM activities have focused on semantic interoperability, which requires content standardization. NLM's role is noted in its Long Range Plan, which recommends that the Library continue to enhance its standards efforts in response to US government priorities and to feedback from those attempting to implement standards in current electronic health records, personal health records, regional health information exchanges, clinical research systems and public health applications. The Plan also calls for continued NLM support for research, development and policy studies that will help define and develop the "next generation of

electronic health records" and advanced decision support capabilities to assist the public, clinicians and the public health workforce. Another recommendation directly related to standardization is to expand the informatics research workforce. NLM's training grants have prepared many of today's experts in the development and application of health data standards. Others were trained by involvement in our Unified Medical Language System (UMLS) project.

NLM and many other government agencies have been collaborating for two decades on a basic strategy, recommended in numerous reports over the years, to promote adoption and use of standards in electronic health records. The steps of the strategy are: 1) establish a mechanism for designating U.S. national standards that would be binding across US federal and state agencies and the private sector; 2) pick the best available system as a starting point; 3) broaden participation in standards development to ensure that all affected stakeholders are involved; 4) support the development, ongoing maintenance, and low or no cost distribution of selected standards – since fees and restrictive licensing agreements have been shown to discourage use; 5) promote use and improvement via several means including early federal adoption, conformance and production testing, demonstration projects, incentives; and 6) coordinate selected standards to achieve an effective interlocking set. A list of the many reports that outlined all or parts of this standards strategy appears as an appendix in the 2005 report of the Commission on Systemic Interoperability. Dr. Harris was a member of the Commission, as was former Board chair Dr. Bill Stead. The Commission agreed with the strategy, Ms. Humphreys said, and added additional elements to it, like engaging the public in understanding the value of standards to them, and more targeted steps for removing certain barriers to standards adoption.

What has been achieved in implementing this strategy? Multiple mechanisms for selecting national standards are in place. Some of the mechanisms involve Federal regulations, and we have proven that this is not a very responsive way to establish standards and keep them updated. However, there are some stakeholders who benefit from delays, and some key players cannot be compelled to follow standards without regulation due to the legal framework within which they operate. Many standards have indeed been designated as national standards. NLM, in collaboration with other agencies, has removed barrier of cost and cumbersome licensing from key terminology standards. NLM has made key vocabularies freely available by supporting them, licensing them for US-wide use, or developing them in collaboration with other federal agencies, such as the VA and the FDA. NLM also distributes the FDA's structured product labels, linked to related standards and additional information sources. NLM's NCBI has developed RefSeqGene, which is the standard reference for recording and interpreting clinically significant genetic test results.

There has considerable Federal activity to promote use, including recent requirements for U.S. government agencies to implement certain standards. There are emerging mechanisms for doing validation and some conformance or certification testing. Significant demonstration projects are being funded by various HHS components. There is major health data exchange activity between the Department of Defense (DOD) and VA which is leading to useful implementations

and valuable feedback. NIH, including NLM, funds work in this area, too. NLM also has significant intramural research efforts within the Lister Hill Center. There are many bills pending in Congress to provide financial incentives of various kinds for implementing standards-based electronic health records. It remains to be seen whether any of them will pass.

Overall, progress has been made. Some significant barriers have been removed. Nonetheless we are not yet close to widespread adoption of electronic health records – let alone standards-based records. Implementing standards is hard. And as significant implementations occur, they will inevitably generate considerable feedback on how existing standards should be modified to meet real-world needs. Many standards organizations are not equipped to respond to significant feedback. They rely on a largely volunteer workforce. They are overstretched in trying to keep up with current Federal initiatives and mandates. Some policy makers do not recognize the need for continuous stable support for ongoing maintenance and dissemination of standards.

Despite the obstacles, interest in promoting use of health data standards is unlikely to wane. Ms. Humphreys asked the Board to assist NLM in reviewing its current standards-related activities, identifying opportunities for progress toward the goal of standards-based electronic health records, recommending appropriate priorities, and estimating the resources necessary to achieve them. Specifically, she hoped the Board would appoint a working group on standards, to serve for about six months, to generate a report and recommendations. Because the Board is advisory to the Secretary of HHS, the report will also be useful in educating the new Administration on standards issues and NLM's role in this arena.

Ms. Graham noted that the issues are more complex than just adopting the standards, but certainly the general effort will prove helpful to the VA, too. Board members discussed the need to gain clarity on the issues involved, identify where the next opportunities are and to engage consumers. A Board working group would be essential, Dr. Harris concurred. Dr. Rossiter commented that CMS can obviously play an influential role in promoting use of standards. Dr. Lindberg said that the desired result from the group would be a roadmap for moving forward. He commented that NLM's successful collaboration with the VA and FDA on RxNorm could be a useful model for other efforts.

IX. PRESENTATION OF REGENTS AWARD

Dr. Morton presented the Regents Award for scholarship and technical achievement to Dr. Michael J. Ackerman, Assistant Director for High Performance Computing and Communications. The citation reads, "In recognition of his energetic and visionary leadership during the development and implementation of the Visible Human Project." Begun in 1989, the Visible Human male and female have proved a tremendous boon to research and development in clinical imaging and anatomy. More at:

http://www.nlm.nih.gov/research/visible/visible_human.html

X. WISER ALGORITHMS FOR NONEXPERT RECOGNITION OF POST TRUMATIC STRESS DISORDER AND TRAUMATIC BRAIN INJURY

Steven J. Phillips, MD, Associate Director, SIS, gave an overview of the Wireless Information System for Emergency Responders (WISER). SIS is expanding it to test a screening tool for early warning signs of PTSD/TBI. The Working Group for this effort is chaired by neuropsychiatrist Dr. Gaylord Nordine of netINS, West Des Moines, Iowa.

Dr. Nordine observed that returning veterans have intense feelings of stress and, when they "act out," tragedies can occur. Often, they're unable to talk about their problems, and they may also drift away from DOD or VA care. The new WISER system uses 20 questions to explore behaviors, feelings, thoughts and engagement with others. If a subject's score is in the top 20%, follow-up instructions to the screener say that he or she is to stay with this person and find appropriate care. Dr. Nordine described three phrases of the project: (1) developing a good screening tool for PTSD/TBI; (2) collecting, organizing and disseminating information gained from use of this device and refining the problem-defining process; and (3) stabilizing the patient and finding solutions. Asked about testing, Dr. Nordine said that the Working Group is coordinating with Cong. John Murtha's Pennsylvania district, and that Iowa would likely serve as a test site, as Sens. Grassley and Harkin are interested in PTSD/TBI. Ms. Graham asked that the VA be closely involved, too, and said she'd be happy to identify appropriate VA participants. Dr. Nordine responded that the VA is a primary asset in the treatment of PTSD/TBI. Dr. Rice commented that one of the challenges of PTSD/TBI is the lack of a clear, well-understood phenotype. A screening tool is an appropriate first step, but veterans give different responses at different time intervals, post-event. He said there is credible research, with proven screening questions, on substance abuse, depression and threat of suicide among veterans. He recommended that the Group ensure that questions are culturally sensitive (particularly for PTSD) and that there is training for those asking the questions. He noted that a daunting challenge will be getting approval from the NIH internal review board (IRB). Also, he suggested NLM consider applications of this technology for the civilian survivors of natural disasters. Dr. Nordine responded positively to these suggestions. Dr. Lindberg complimented the Working Group and commended to them the research of Dr. Warner Slack at the University of Wisconsin. Betsy Humphreys added that Dr. Slack discovered that patients answer selfadministered computer-based questionnaires more honestly than questions asked by a doctor or other human being. Dr. Nordine said that WISER would probably move in that direction, with subjects clicking in the answers themselves. Asked how test subjects would be selected, Dr. Nordine replied that he is working with the American College of Physicians and other medical organizations, to encourage use of this system at the primary care level. Dr. Lindberg suggested that family members ask the questions, or be asked the questions themselves. Dr. Nordine concurred that often "collaterals" like family and friends are deeply affected by the behavior of the person in their lives with PTSD/TBI and may spot symptoms before professionals do. Dr. Rice said that USUHS already conducts a six-month assessment screening for returning veterans and could test the new tool, to see whether it is a more accurate detector of problems. Ms.

Graham added that the VA does similar post-deployment assessments, and that they could probably do testing, too. Col. Louder suggested that the testing focus on members of the National Guard and Reserves, who have left active duty. Dr. Nordine concurred, saying that all members of the military, past and present, deserve to be screened.

XI. MUZUNGU IN THE MIST: NLM FILINGS FROM THE FRONTLINE IN UGANDA

Chief of NLM's Office of International Programs, Julia Royall, gave a multimedia report on her August 2007-June 2008 experience as a Fulbright Scholar and NLM/NIH representative in Uganda. She began by explaining the meaning of "muzungu," a common word in east Africa for a foreigner, usually a white person.

Located in east Africa, Uganda has a population of roughly 32 million. Malaria is a major disease burden and kills up to 110,000 people annually. AIDS is the second largest killer, taking the lives of about 78,000 Ugandans each year. Ms. Royall's home base was the Faculty of Medicine at Makerere University in Kampala. Connected to the medical school is the Albert Cook Medical Library.

Among the many activities undertaken by Ms. Royall were:

- **Development of MedlinePlus African tutorials.** She, and an NLM team, created a series of tutorials on malaria and other topics for use in 40 rural districts. Although these print and electronic items are quite simple, their development was complex, because they had to communicate messages to those who can't read.
- Creation of NLM database training programs with staff of Cook Library. University librarians collaborated with Ms. Royall on a module to teach the community about NLM's PubMed, MedlinePlus, ClinicalTrials.gov and others. Training was also conducted at Gulu Medical School in northern Uganda.
- Training for the Ugandan Health Communication Alliance. Ms. Royall and Cook Library colleagues conducted three workshops for print and electronic journalists, on how to use search NLM databases. Now, reporters regularly cite MedlinePlus in their articles and have praised the site's rich, reliable content.
- Collaboration with the Faculty of Medicine at Makerere University to develop an E-pathology project (e-PATH). This simple but effective telemedicine project created an electronic pathology archive for training health professionals and assisting in clinical decision making at a distance.
- Consultation with Kabale University in western Uganda. At this new university, Ms. Royall assembled a team of librarians, IT personnel and others, to provide information on counseling and addiction, and to form local partnerships.
- Collaboration with Tororo Hospital on electronic health management and information system (eHMIS). This Uganda town is the site of the first such electronic

system to be adopted by a Ugandan hospital. NLM has contributed seed money to this effort, which has dramatically eliminated paper record keeping.

• Working with Gulu Faculty of Medicine students and faculty, to develop a tutorial on mental health. This northern city has seen widespread violence. Alcoholism and depression are rampant. Ms. Royall has teamed with medical students and faculty to produce a MedlinePlus tutorial on mental health.

Her recommendations for future NLM activities in Africa include continuing:

- The Library's commitment to training and building human infrastructure. An important element is selecting NLM Associate Fellows from Africa and supporting those librarians and their networks.
- Engagement of African medical university librarians and deans in incorporating training in medical database searching in their curricula.
- The MedlinePlus tutorial program, with a concerted effort to engage medical students in the countries of east Africa.
- Support of projects in medical informatics, such as e-PATH and eHMIS.

Ms. Royall mentioned that, in 1994, she had worked with staff at Albert Cook Medical Library in Kampala, to establish the first satellite Internet connection in the nation. A teenager on staff then operated the satellite ground station. That young girl now works as a medical librarian at Cook. Ms. Royall then introduced Ms. Sara Mbaga to the Board.

Dr. Connolly asked whether the Gates Foundation was on the ground in Uganda, and Ms. Royall replied that they are primarily focused on malaria vaccines and drugs. Ms. Tanji stressed the importance of librarians providing training to medical students, so that they can find reliable information for themselves and their patients. Ms. Royall assured her that Ms. Mbaga and others are traversing Uganda, sometimes at great peril, to get out the word about NLM. Dr. Walker asked what Ms. Royall would recommend for the next 15 years in Uganda, if she had unlimited funds. She observed that Ugandan medical students often have promising ideas on how to serve the health needs of people in their districts, but lack mentors and funds. With such support, they'd stay in Africa, instead of leaving for other countries. Col. Louder asked whether Google Scholar might be a helpful portal for African researchers trying to access NLM resources. Ms. Royall said that Google is intent on wiring Africa for Internet, but that searching Google is no substitute for a focused search of the NLM Web site. She said she tells her Ugandan contacts that, if they want to be part of the international scientific and medical community, they must know how to do effective Internet searching.

XII. CLINICALTRIALS.GOV UPDATE

Rebecca J. Williams, PharmD, Deputy Director of ClinicalTrials.gov, reviewed the enactment of the Food and Drug Administration Amendments Act (FDAAA) of 2007 and its implications for

NLM's registry of human subject studies. Basically, FDAAA extends the CT.gov registry to include a broader range of trials and a broader range of data elements. It also added a results database component. The deadline for having that component up and running is September 27, 2008. Testing is complete and the final version will be launched on schedule. Currently, there are over 61,000 records in CT.gov, with about 300 trial registrations added each week. This represents a 50% increase over the weekly registration rate prior to FDAAA.

In designing the results database, CT.gov staff tried to solicit comments from as many stakeholders as possible. They sought input from the public through a May 21, 2008 *Federal Register* notice and posted test systems and draft data elements upon which anyone could comment. They sent notices about the rulemaking to listservs and to past CT.gov contributors. NIH established a Subcommittee on Clinical Trials, which first met in August 2008 and has endorsed the proposed basic results data element requirements. On September 15, staff received feedback from the BOR's Working Group on Clinical Trials, which had helpful suggestions and generally supported the basic results database implementation.

The basic results database will include only "applicable clinical trials" of FDA-approved or – cleared medical products. Participants must submit results within 12 months of completion of the trial or face penalties. If the blind on a study has not yet been broken, investigators may request in writing a delay in the submission of results. The law mandates four data categories: (1) demographic and baselines characteristics, such as one would see in "Table 1" in a journal article (age, gender, etc., along with information on how many subjects dropped out or were excluded from analysis); (2) primary and secondary outcomes, including scientifically appropriate tests of statistical significance; (3) a point of contact for scientific information; and (4) whether there were any restrictions on the principal investigator (PI) to discuss or publish the results after the trial completion date. The law has staged implementation phases. Information on adverse events in a trial, for example, is not required until September 2009. However, many who commented on implementation of the first phase of implementation of results database expressed concern that *benefits* would be listed, but not health risks. Obviously, that would be misleading. In response, the September 2008 results page includes a field in which trial sponsors can voluntarily list adverse events.

Dr. Williams then demonstrated the public interface of the results display. CT.gov Quality Assurance and Quality Control staff are being trained to process records and provide technical support to users. As required by law, staff will post results no later than 30 days after submission. Staff is also completing an NIH Communications Plan, for outreach to the intramural and extramural community. In March 2009, there will be a public meeting to evaluate the work to date and plan future steps. September 27, 2009 is the deadline for "adverse effects" and an expanded registry and results database is due September 27, 2010.

Ms. Stanley asked whether they were expecting a flood of data after September 27th. Dr. Williams wasn't sure, but said that some trials will come due on their reporting near the time of

the launch of the results database and will have to get their findings in right away. Dr. Rossiter, a Member of the Board Clinical Trials Working Group, noted that eight of the 14 members of that body had participated in yesterday's discussion and unanimously supported the staff's recommendations. (A six-page summary is available.) Questions and comments included: (1) if researchers aren't in compliance, will Cong. Henry Waxman send the Justice Department after Dr. Lindberg or the Board?; (2) could there be a field for information on the baseline characteristics about the history of a disease?; (3) in some complex studies, data are frequently collected *after* the formal completion of a study. Can the CT.gov results database accommodate several sets of findings?; (Dr. Rossiter said that he'd been assured that this was possible in the new system.); (4) if a member of Congress or anyone else would like to know when data on the results page have been changed, can he or she do so? (Again, Dr. Rossiter said yes, because an archive capability has been built into the system.)

Dr. Rossiter asked whether NLM has ever issued a rule before. Dr. Lindberg and Ms. Humphreys said that the Library had played a role in the issuance of HHS-wide rules but that this was a first, performed at the insistence of lawyers. This draft rule will be thoroughly reviewed by NIH and, afterwards, submitted to the Office of Management and Budget, the representative of the executive branch. Dr. Lindberg mentioned that many nations (157, according to Dr. Williams) that are not under FDA authority submit trials to the database. They may post results voluntarily. Interestingly, Dr. Lindberg continued, before there were any requirements to register medical *device* trials in CT.gov, 1,200-1,400 such trials were submitted so NLM began to include them on the site. Mr. James asked whether there was language to prohibit investigators from using results data in CT.gov for commercial interests. Dr. Lindberg clarified that there would be no personally identifiable data in CT.gov and no interpretation of results. Dr. Rossiter asked whether the Working Group would continue and Ms. Humphreys said that its work has just begun.

XIII. EXTRAMURAL PROGRAMS REPORT

Extramural Programs Director Dr. Milton Corn presented graphs and tables on FY2008 resource, research and training grants in the Board briefing book. More extended discussion was held on the issue of grantee conflict of interest (COI). Such conflicts occur in all sciences, but they're especially pernicious in health research because, in addition to affecting the quality of the science, publicity about the conflicts impacts negatively on public willingness to participate in clinical trials, or to trust the results of such trials.

Dr. Corn showed several news reports about psychiatrists at Harvard, Stanford, and Emory who had been named by Senator Grassley as having undeclared conflicts of interest on projects funded by NIH because of fees or ownership issues. Despite the public disclosure, the reactions of the parent Universities has been muted, ranging from denial of ethical lapses to promises to investigate the matter.

In response to the problem, NIH Director Elias Zerhouni, MD, formed the Task Force to Review NIH's System of Oversight of Extramural Financial Conflict of Interest. The current NIH FCOI Policy:

- Establishes standards to ensure that research funded under Public Health Service grants awards is not biased by any conflicting financial interests of an investigator (that is, profit over \$10,000 earned by the investigator or a family member)
- Assigns responsibility to the university for developing a policy for identifying and managing investigators' FCOI. The Principal Investigator (PI) must report on any possible conflicts at the time of the award and every year thereafter.
- Assigns responsibility to NIH for overseeing compliance with requirements.

In practice, NIH delegates compliance to the grant-receiving institution. If an institution detects a problem, it sends the grant-giving Institute or Center (IC) at NIH a short letter, disclosing that a particular PI is apparently in violation of NIH policy and will be evaluated. The nature of the violation is not described. In the experience of NLM Extramural Programs, a subsequent short letter is usually sent by the institution, telling the IC that the matter has been handled, in accordance with policy. Again, the nature of the settlement is not disclosed, although the case is then considered closed.

In 2007, when Sen. Grassley began probing the area of COI and NIH grants, NIH was not able to tabulate quickly the number and disposition of such incidents. Although the NIH COI policy is well intentioned, it is neither robust nor organized for efficient administrative oversight. The task force's findings are still in draft form, but attempt to clarify and strengthen the NIH policies and university compliance. Sen. Grassley has proposed that all US pharmaceutical companies file yearly public lists of all fees paid to physicians.

Dr. Corn believes that blame for the ineffectiveness of the COI policy belongs to all parties, including NIH, the Universities, and the PIs, although for PIs, some of the violations seem to be clearly at odds with generally accepted moral standards.

COI is a flourishing weed in America's medical university communities. With funding from Pew, the American Medical Student Association (AMSA) recently completed a scrupulous review of COI policies at the nation's academic medical centers. The results, for example, give USUHS an A, Columbia a B, Missouri a C, Cornell a D and Harvard an F. George Washington's policy, like that of several other institutions, was marked "in revision." Universities that failed to reply after three requests were flunked. Results for all schools can be examined at http://AMSAscorecard.org.

In response to Dr. Corn's presentation, the board unanimously passed a motion requesting the NIH Director convey the Board's sense that the NIH task force working on conflict of interest move expeditiously. The Board also asked Dr. Corn's division to report at the next meeting on the status of the institutions NLM has made grants to and how the medical student association graded them.

XIV. NLM GRANTEE: ANALYSIS OF THE FAMILIAL COMPONENT TO DISEASE IN A BIOMEDICAL RESOURCE WITH LINKED GENEAOLOGY

Dr. Lisa Cannon Albright, professor and genetic epidemiologist at the University of Utah, discussed her NLM-funded research. She is using electronic medical data, linked to genealogy data, to analyze the familial or genetic contribution to various diseases.

Resources in Utah, with its large Mormon population, are particularly good for her studies. The Utah Population Database (UPDB) contains an extensive set of family histories and is updated annually with birth, death, and marriage certificates, cancer data, and driver's licenses. She also has access to data on 1.8 million people who visited the University of Utah hospital and clinic. Mormons have proscriptions against coffee, tea, alcohol, and tobacco, which are risk factors for many phenotypes. And, since polygamy was practiced among about 10 percent of pioneers before 1890, a single polygamist with multiple wives may have 100,000-200,000 progeny who can trace their genealogy to him.

Dr. Albright said she uses electronic medical data (disease and procedure coding) to define cases (individuals affected by a particular disease or condition). She then studies their genetic relationships to close and distant relatives, to determine whether genetics plays a role in who has a particular disease and who does not. If a disease has a genetic contribution, it will show up more often in the cases' relatives than in the population at large. One example was her analysis of 100 years of Utah death certificates, to see whether there was a genetic contribution to death from influenza. Dr. Albright said she detected excess relatedness, which is a strong sign of a genetic contribution.

Dr. Morton asked about issues of privacy and potential identification of individuals. Dr. Albright said the state has orders protecting the Utah Population Database resource.

XV. NIH PUBLIC ACCESS POLICY UPDATE

Dr. Morton introduced Dr. David Lipman, Director of the National Center for Biotechnology Information (NCBI), which runs the PubMed Central (PMC) database. She congratulated him for being a finalist for a "Service to America Medal," for developing PMC. He noted that it was an accomplishment for NCBI, Library Operations and the Office of the Director of NLM.

Launched in 2000, PMC is NIH's repository for free, full-text biomedical research articles. Submission to PMC had been voluntary, but in 2007 legislation took effect making it mandatory for NIH-funded investigators to submit, or have submitted for them, their final peer-reviewed journal manuscripts. Dr. Lipman said that, since the mandatory policy started, there has been an increase in submissions by both publishers and authors; author submissions have shown the greatest increase.

He explained there are several submission pathways: authors submit them directly; publishers upload articles in bulk for the authors or publishers join PMC and don't involve the author at all. Before the new requirement Dr. Lipman said, PMC was missing 81% of articles. They were getting about 12% from publishers participating in PMC and 7% of the total from authors depositing directly. In June of 2008, with the mandatory submission in effect, about 30% of submissions came directly from authors, 26% came from publishers participating in PMC, and about 44% were missing. He said that, while publishers are adapting to the mandatory public access policy, some still do not like it, and a bill was introduced to reverse it, which was recently the subject of a hearing of the House Judiciary Committee's Intellectual Property Subcommittee. Supporters of public access will have to be vigilant, he cautioned.

Assessing overall activity on the NCBI site, Dr. Lipman said that, in a typical day, there are about 2 million user sessions and about 10 million page views. He noted that PMC has about 400,000 users and roughly 650,000 articles are retrieved per day. The NCBI Web site sees about 4.4 terabytes of data downloaded a day.

XVI. REPORT FROM THE SUBCOMMITTEE ON OUTREACH AND PUBLIC INFORMATION

Ms. Eileen Stanley reported on the Subcommittee on Outreach and Public Information meeting. The Subcommittee discussed the imminent release of the current issue of *NIH Medline* Plus magazine. Thanks to an agreement with the Peripheral Arterial Disease (PAD) Coalition, distribution on this issue, featuring that topic, will be increased by several hundred thousand copies. Mr. James suggested investigating controlled circulation, as opposed to standard circulation of the magazine; it could reduce costs.

The Subcommittee also addressed getting out the word on the new results feature in ClinicalTrials.gov. Dr. Lindberg noted that Dr. Zerhouni wants all parts of NIH to communicate in a simple, understandable fashion, that ClinicalTrials.gov does not contain personal data or recommendations for treatment. Mr. James suggested that there should be some type of disclaimer on the database, reminding users to always consult a health professional, too.

The Subcommittee also discussed promoting NLM exhibitions to new audiences Suggestions included installations outside of the NLM building, to make the exhibitions more accessible to a wider public and collaborating with the US Postal Museum, science museums and Congressional offices, to broaden awareness.

XVII. MEDLINEPLUS: MULTIPLE LANGUAGES COLLECTION

Paula Kitendaugh, Head of the Reference and Web Services Section, introduced the new MedlinePlus multiple languages collection, which addresses the need to provide consumer health information in languages besides English and Spanish. About 52 million people in the U.S.

(19% of the population over the age of 5) speak a language other than English; 23 million people (8% of the population) have limited English proficiency; and 3 million households (3% of the population) live in homes where no adults speak English.

Most non-English speakers speak Spanish. MedlinePlus en español, available since 2002, serves that population. The new multiple languages collection is intended to help others. Ms. Kitendaugh displayed a map showing that while California, Texas, New York and Florida have the highest number of non-English speaking residents, there are many rural and urban counties across the country where tens of thousands of people do not speak English. Demographics are shifting — the South is home to more immigrants. There also has been a change in the languages spoken in the US. Western European languages are declining, while most other languages are growing.

Ms. Kitendaugh pointed out the correlation between English proficiency and health status. Those with limited proficiency are less likely to have a regular source of primary care, less likely to receive preventive care and less satisfied with the care they receive. A 2006 study of hospitals found that 80% of urban and rural hospitals are seeing patients who do not speak English. A 2006 American College of Physicians survey found that 65% of doctors were seeing non-English speaking patients. Visits with those patients tended to take 15 minutes longer than visits with English speakers. Many said they thought a clearinghouse of patient information would help.

The multiple languages collection was launched in May 2008. The site currently covers 43 languages and 250 health topics, and is expected to grow. About 500-700 people, from every state and many countries around the world, use the site each day. So far, Chinese and other Asian languages are among the most popular languages in the collection.

The foreign language information in the multiple languages collection must meet the same strict guidelines as other MedlinePlus material. In addition, it must furnish an English language translation, so that English-speaking NLM staff and users, such as health care providers and librarians, can assess the content of the information provided.

Board Members suggested the inclusion of Native American languages and electronic health record linking, figuring out how to info-button this new resource to EHRs. They also recommended providing nurses with information about the multiple languages collection, to hand out to patients when they are discharged.

XVIII. ADJOURNMENT

The Board of Regents meeting was adjourned at 12:00 p.m. on September 17, 2008.

ACTIONS TAKEN BY THE BOARD OF REGENTS:

- ➤ Approval of the May 13-14, 2008 Regents' Minutes
- > Approval of September 15-16, 2009 Meeting Dates
- > Creation of the Working Group on Health Data Standards
- ➤ Board Request for Follow-up on Grantee Institution Conflict of Interest

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

Cynthia C. Morton, Ph.D.

Chair, NLM Board of Regents