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

MINUTES OF THE BOARD OF REGENTS
September 15-16, 2009

The 152nd meeting of the Board of Regents was convened on September 15-16, 2009, 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 4:30 p.m., followed by a closed session for consideration of grant applications until 5:00 p.m. On September 16, the meeting was reopened to the public from 9:00 a.m. until adjournment at 12:00 p.m.

MEMBERS PRESENT [Appendix A]**:**
Dr. C. Martin Harris [Chair], The Cleveland Clinic Foundation
Dr. Jordan Cohen, George Washington University
Dr. John Connolly, University of California, Irvine
Dr. Carol Friedman, Columbia University
Mr. Bruce James, Nevada New-Tech, Inc.
Dr. Joyce Mitchell, University of Utah
Dr. Louis Rossiter, The College of William and Mary
Ms. Eileen Stanley
Ms. Virginia Tanji, University of Hawaii at Manoa

EX OFFICIO AND ALTERNATE MEMBERS PRESENT:
Mr. Christopher Cole, National Agricultural Library
Dr. Michael Corriere, U.S. Department of the Navy
Ms. Gail Graham, Veterans Health Administration
BGEN Byron Hepburn, United States Air Force
Dr. Haym Hirsh, National Science Foundation
Ms. Kathryn Mendenhall, Library of Congress
Dr. Charles Rice, Uniformed Services University of the Health Sciences
RADM Carol Romano, Office of the Surgeon General, PHS

CONSULTANTS TO THE BOR PRESENT:
Dr. Tenley Albright, Massachusetts Institute of Technology
Dr. Marion Ball, Johns Hopkins School of Nursing/IBM Research
Dr. Thomas Detre, University of Pittsburgh
Dr. H. Kenneth Walker, Emory University School of Medicine

SPEAKERS AND INVITED GUESTS PRESENT:
Dr. Norma Allewell, University of Maryland
Dr. Joan Ash, Oregon Health and Science University
Dr. Ross Fletcher, VA Medical Center
Dr. John Glaser, Office of the Secretary
Dr. Stephanie Guerlain, University of Virginia
Dr. Lawrence Hunter, University of Colorado

MEMBERS OF THE PUBLIC PRESENT:
Mary Lindberg, Public
Katie McCarthy, Biotechnology Industry Organization

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. Michael Ackerman, High Performance Computing & Communications, NLM
Ms. Joyce Backus, Division of Library Operations, NLM
Mr. Michael Barboza, Lister Hill Center, NLM
Ms. Rebecca Brown, Lister Hill Center, NLM
Ms. Ada Cornell, Office of the Director, NLM
Ms. Kathy Cravedi, Office of Communications & Public Liaison, NLM
Ms. Celeste Dade-Vinson, Office of the Director, NLM
Mr. Todd Danielson, Executive Office, NLM
Ms. Mashana Davis, Office of the Director, NLM
Dr. Heather Dobbins, Cognitive Sciences Branch, NLM
Ms. Darlene Dodson, Office of the Director, NLM
Ms. Kathel Dunn, Division of Library Operations, NLM
Ms. Gale Dutcher, Division of Specialized Information Services, NLM
Dr. Valerie Florance, Division of Extramural Programs, NLM
Dr. Zoe Huang, Division of Extramural Programs, NLM
Mr. Nicholas Ide, Lister Hill Center, NLM
Ms. Christine Ireland, Division of Extramural Programs, NLM
Ms. Lou Knecht, Lister Hill Center, NLM
Mr. Sheldon Kotzin, Division of Library Operations, NLM
Dr. David Landsman, National Center for Biotechnology Information, 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
Ms. Becky Lyon, Division of Library Operations, NLM
Dr. Clement McDonald, Lister Hill Center, NLM
Ms. Melanie Modlin, Office of Communications & Public Liaison, NLM
Mr. David Nash, Office of the Director, 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
Dr. Thomas Rindflesch, Lister Hill Center, NLM
Ms. Julia Royall, Office of International Programs, NLM
Mr. Ronald Shaw, Division of Extramural Programs, NLM
Mr. Jerry Sheehan, Office of the Director, NLM
Dr. Elliot Siegel, Office of Health Information Program Development, NLM
Ms. Meredith Wessels, Office of the Director, NLM
Ms. Sarah Westphal, Office of the Director, NLM
Dr. Rebecca Williams, Lister Hill Center, NLM
Dr. Fred Wood, Office of Health Information Program Development, NLM

Ms. Yani Yancey, Office of the Director, NLM
Dr. Jane Ye, Division of Extramural Programs, NLM
Dr. Deborah Zarin, Lister Hill Center, NLM
Ms. Holly Zerbe, Office of the Director, NLM

I. OPENING REMARKS

Dr. C. Martin Harris, Chair, welcomed the Regents, alternates and guests to the 152nd meeting of the Board. He called the meeting to order and introduced the first speaker, the representative from the Office of the Surgeon General (OSG).

II. REPORT FROM THE OFFICE OF THE SURGEON GENERAL

Rear Admiral Carol Romano, Acting Chief of Staff for the Surgeon General, represented Acting Surgeon General, Rear Admiral Steven Galson, MD.

RADM Romano announced that RADM Galson will retire from the US Public Health Service Commission Corps effective October 1, 2009. RADM Romano said RADM Galson's tenure advanced prevention initiatives across the country, and she cited a number of his accomplishments: he launched the first Healthy Youth for a Healthy Future Initiative, which brought national attention to childhood obesity; he advanced the effort to prevent underage drinking; and he produced two Surgeon General's Calls to Action (one on deep vein thrombosis and the other on healthy homes). RADM Romano also said the nation's preparedness and response capabilities grew under RADM Galson's leadership.

Other assignment updates: the Senate appointed Dr. Howard Koh as Assistant Secretary for Health and President Barak Obama announced his intention to nominate Dr. Regina Benjamin as the next Surgeon General of the United States. Dr. Benjamin is a family physician and founder of the Bayou Clinic in Bayou La Batre, Alabama.

RADM Romano also provided an update on OSG outreach activities. The Healthy Homes Call to Action was launched in 2009. Efforts are underway to enhance the Family Health History Tool. A Surgeon General report on tobacco is scheduled to be released in the fall. The report is called "How Tobacco Causes Disease: The Biology and Behavioral Basis for Tobacco-Attributable Disease."

III. IMPLEMENTING THE HEALTH IT PROVISIONS OF ARRA

John Glaser, PhD, spoke to the board about the health information technology provisions in the American Recovery and Reinvestment Act (ARRA). Dr. Glaser, who was an NLM trainee, is the chief information officer of the Partners Healthcare System in Boston and is also currently a senior advisor to the Office of the National Coordinator for Health Information Technology (ONC) in the Office of the Secretary of Health and Human Services (HHS).

Dr. Glaser noted that a good portion of ARRA centers on accelerating the adoption and meaningful use of interoperable electronic health records. It falls under the HITECH Act, which stands for Health Information Technology Economic and Clinical Health. There are two major components. One is the provision for financial incentives — currently $44 billion in federal funds is available to hospitals and

eligible providers if they adopt a meaningful use of the technology. The second component is the action the government will take to make sure it works well. The core idea is meaningful use. Examples of meaningful use would be a physician using technology to write prescriptions, or document a problem, or exchange data with another provider — activities that facilitate improved outcomes.

Dr. Glaser detailed what has and is being done in terms of structure and implementation in advance of 2011, which is the first year of incentives. One of the first activities was to define meaningful use for 2011 and to signal what it might look like for 2013 and 2015. A second activity addressed the requirement that the technology be certified. The certification criteria were narrowed to electronic health records capabilities necessary to support meaningful use and the responsibility for developing certification criteria was placed with the federal government. A third activity was to develop standards to facilitate interoperability. Standards supported or developed by NLM — SNOMED CT, LOINC and RX Norm — are among the vocabularies recommended. A fourth activity centered on mechanisms to ensure privacy and security. Recommendations for encryption, authentication and maintaining data integrity were put forward.

With regard to implementation, extension centers will be created across the country — non-profits that will help smaller hospitals and physician practices select, implement, and make the workflow changes for electronic health records. States are expected to play a leadership role in developing the apparatus for exchanging health information within communities — the technology that would enable a discharge summary to be sent from one provider to another in the state. Efforts also are underway to develop a workforce able to make all this happen.

Dr. Glaser said the rulemaking process is taking place now. Three rules likely will be issued in mid-December. One will outline the certification criteria and the standards for electronic health records; another will define meaningful use and describes how one gets paid; the third will outline the HER certification process.

In the question and answer that followed, Dr. Kenneth Walker asked what 2011 might look like in a terms of a smaller, community provider. Dr. Glaser said that by 2011 there will be some forms of exchange, but progress will be uneven and he predicted a tumultuous couple of years.

NLM Deputy Director for Research and Education Dr. Milton Corn repeated concerns of systems engineers who say the systems are what could cause problems and should be certified rather than the components. Dr. Glaser said they are trying to anticipate consequences. Lister Hill Center Director Dr. Clement McDonald asked about the role of HITSP (the Health Information Technology Standards Panel). Dr. Glaser said it's had an enormous influence and will be here for a long period of time. Ms. Eileen Stanley inquired about plans for evening out differences in regions. Dr. Glaser said the first thing to do is to make good funding decisions so that the initial funding goes to people who have the best chance of doing well.

Dr. Jordan Cohen inquired about finding a workforce trained to do this kind of work. Dr. Glaser says he anticipates a bottleneck. Dr. Louis Rossiter asked about evaluation plans and whether NLM can play a role in that. Dr. Glaser said there will be a programmatic evaluation and there are efforts to evaluate whether meaningful use is growing. Dr. Walker asked how things will look in 10 or 15 years. Dr. Glaser predicted 80-90% adoption rates and exchange will be a routine. Dr. Carol Friedman asked what public

relations are being done to help the public understand there may be problems along the line. Dr. Glaser said there is a need to showcase organizations that have done a good job. Dr. Walker closed with the point that there is a real sense of personal responsibility with personal health records.

IV. CONSIDERATION OF MAY 2009 MINUTES AND FUTURE MEETINGS

The Regents approved without change the minutes from the May 5-6, 2009 meeting. The winter meeting is scheduled for February 2-3, 2010, the Spring Board meeting is scheduled for May 11-12, 2010, and a Fall Board meeting was approved for September 14-15, 2010.

V. REPORT FROM THE NLM DIRECTOR

Budget and personnel were the first topics addressed. Dr. Donald A.B. Lindberg noted that, in addition to the budget information found in Tab A of the Board meeting book, NLM received about $80 million dollars in ARRA money.

New personnel were introduced. There are five new Associate Fellows: MaShana Davis, Sarah Westphal, Yani Yancey, Ada Cornell and Holly Zerbe. Ronald Shaw is the new administrative officer for Extramural Programs (EP). Two new visiting scientists have joined the Lister Hill Center staff: Lei He, PhD, and Han Zhang, MD.

Dr. Lindberg updated the Board on legislative issues other than Health IT, which was previously addressed by Dr. Glaser. The Federal Research Public Access Act (S.1373) was reintroduced in June 2009 but has not passed yet. Dr. Lindberg said the bill in effect says we like what NIH has done by requiring grantees to make their reports available, we think it should be done across the government in agencies that have an annual extramural research budget of $100 million or more. The bill is a counter-balance to the Fair Copyright Research Works Act that effectively would nullify the NIH Public Access Policy. The Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs were temporarily extended.

ClinicalTrials.gov now has the impetus of another FDA modernization act that requires NLM to produce a system in which the results of the clinical trials are recorded and displayed. The law points NLM in the direction of narrative summaries — to see if NLM can produce them without problems. Dr. Lindberg expressed concerns about NLM taking on that function. He noted that trials typically have more than one interpretation and it would be better to report and argue results in scholarly, peer-reviewed journals than to leave it to a federal agency. Dr. Lindberg turned to Dr. David Lipman, director of NLM's National Center for Biotechnology Information (NCBI), for an update on the NIH Public Access Policy. Dr. Lipman said there's been a dramatic increase in manuscript submissions to PubMed Central now that the public access policy is mandatory, not voluntary. PubMed Central is being used more and more — the more comprehensive the site becomes, the more that people use it.

Following the May 2009 Board meeting, the final report of the working group on health data standards was sent to HHS Secretary Kathleen Sebelius. Dr. Lindberg said NLM currently is the only obvious federal agency supporting health information standards — spending about $10-15 million dollars a year — and it ought to be supported by the Department. NLM Deputy Director Betsy Humphreys said she thinks it's possible there will be some level of support.

The Friends of the National Library of Medicine and NLM co-sponsored a Personal Health Records Conference in May 2009. The annual NLM Informatics Training Conference was held in June 2009. NLM hosted and participated in the VistA Community Conference in June 2009. VistA is an open source electronic medical record system, originally developed by the VA. NLM collaborated with other NIH Institutes and Centers to convene a national conference on the future of telehealth, held at NIH in June 2009. Representative David Obey recognized the 20th anniversary of NCBI in the *Congressional Record*. NLM Communications Research Scientist Dr. Rob Logan instituted a fellowship program for journalists to spend time at NLM and NIH. NCBI developed a new resource called Rapid Research Notes, which is a more rapid way to publish results. H1N1 provided increased impetus for the project. The Public Library of Science (PLoS) is the publisher. Researchers submit their contributions via the Web and they are screened by experts in the field as quickly as possible. Those deemed suitable for publication are then immediately posted to the "PLoS Currents: Influenza" Web site.

VI. REPORT FROM THE NCBI BOARD OF SCIENTFIC COUNSELORS

Dr. Norma Allewell, a professor and dean at the University of Maryland, College Park, provided a report from the NCBI Board of Scientific Counselors (BOSC). Dr. Allewell summarized NCBI's history and mission and detailed the role of the Board of Scientific Counselors. The BOSC provides advice and assessment in four board areas: database and software development; NCBI research programs; dissemination of biomedical information; organizational and resource issues. Dr. Allewell said five databases under development have occupied most of the attention of the BOSC during her time as an adviser. Those databases are: the Short Read Archive (SRA), which is receiving data from next generation of high throughput sequencers; dbGaP, which relates genotype to phenotype; Gene Expression Omnibus (GEO), which compiles data from high throughput gene expression studies; PubChem, which compiles structures and biological activities of small organic molecules; BioSystems, which is a new effort to integrate information about interactions of all the molecules within a single cell. Other BOSC discussion topics include: public access and PubMed Central; the Discovery Initiative to improve ease of access and integration of NCBI resources; and My NCBI.

Dr. Allewell concluded with an example of the opportunities and challenges that NCBI faces. The opportunity is the huge capacity of next generation sequencing technology. The challenge is managing, integrating, and presenting unprecedented amounts of genomic information. The 1,000 Genome Project epitomizes this. The project will enable investigators at five centers around the world to sequence genes of 1,000 individuals, building the most detailed map of human genetic variation to date. NCBI is working to develop a data management framework, which is a multi-national, multi-institutional collaboration.

VII. REPORT OF THE LISTER HILL BOARD OF SCIENTIFIC COUNSELORS

Dr. Joan Ash, a professor at the Oregon Health and Science University and chair of the Lister Hill Center Board of Scientific Counselors (BOSC) presented highlights from the past two years of BOSC meetings. The BOSC meets twice a year, focuses on specific projects and makes recommendations. In September 2007, the BOSC addressed 3D Informatics — what's next after the Visible Human and how to use Web 2.0. The BOSC recommended continued involvement of users in planning and evaluation using Web 2.0 methods. In April 2008, the BOSC reviewed some projects to enhance the efficiency of MEDLINE indexing and go into new areas. The BOSC recommended looking at enhancements that would be useful at the point of care. In September 2008, the BOSC reviewed point of care knowledge sources to help

clinicians use NLM resources at point of care — such as PubMed for handhelds. The BOSC recommended further evaluation of user needs, and maybe moving into other areas such as building NLM resources right into electronic health records. In April 2009, the BOSC reviewed applied medical terminology research. The recommendations include establishing metrics for success. Dr. Ash noted there were several consistent themes in all the reports. They include: planning to articulate a clear vision, goals and steps; focus on usability and the end users; collaborate inside and outside LHC to augment staffing; and publish results more broadly to let people know what LHC is doing.

VIII. ANNOUNCEMENT OF REGENTS AWARD AND PRESENTATION OF NLM DIRECTORS AWARD

The Regents Award went to James Marcetich, who recently retired after 30 years of service to NLM, most recently as the head of the Index Section. He was recognized for his significant contributions in the ongoing effort to automate and enhance the indexing of the biomedical journal literature for the MEDLINE database. Mr. Marcetich was not present, but was able to view and hear the proceedings remotely. Dr. Lindberg presented the NLM Director's Award to Dr. Deborah Zarin. She was recognized for her inventiveness, vision and continuous enthusiasm in leading clinicaltrials.gov through a period of extraordinary growth, volume and expansion of scope.

IX. LISTER HILL CENTER UPDATE

Director Dr. Clement McDonald said that his report would focus on Recommendation 3.2 of the NLM Long Range Plan: projects designed "to promote the development of Next-Generation electronic health records to facilitate patient-centric care, clinical research, and public health" and the recommendation in the final report of the Board Working Group on Health Data Standards "to provide additional tools and services that help vendors and user sites to incorporate standards where they will have a positive impact."

Personal health records (PHRs) allow patients to maintain a personal profile of drugs, health problems, surgeries and other key data. PHRs also remind patients about preventive care measures. Recent technical enhancements, such as major improvements in reminder rules and instant form expansion (when needed to capture arbitrary data sets as structured data) make NLM PHR system more usable in a variety of environments. Dr. McDonald demonstrated the "fetch rules" function, which fetches data from the browser database so that it can be used in different calculations. The fetch rules can then be embedded in more complex rules, like the Framingham risk equation, to provide patients with a snapshot of their cardiovascular health and suggest appropriate interventions. Another improvement is tighter control over user changes to previously stored data. Progress on deploying the NLM PHR has slowed because NIH leadership has requested an NIH-wide review of policy issues related to the provision of tailored advice based on patient health data. Meanwhile, LHC is working with Suburban Hospital in Bethesda, Maryland to deploy the NLM software as *their* PHR, and developing software linking it to their existing Hospital Information System. In addition, the Indian Health Service wants to use the NLM PHR as the front-end patient interface for their PHR project. These efforts will enable LHC to adapt the PHR to two diverse settings and demographics, studying its use and impact in both.

Dr. McDonald next described a project to ensure access to electronic prescription information in disasters. The goal is to provide the Bethesda Hospitals Emergency Preparedness Partnership (BHEPP) with access to electronic records of prescriptions filled using SureScripts/Rx Hub, which currently handles about 65%

of all US prescriptions. If a disaster were to occur, the hospitals in the partnership would see an increase in the number of patients. Medication histories are very important in emergency care, but they take time. LHC is comparing the accuracy of manually-collected patient medication history information with the data obtained from SureScripts reports of those same patients' prescriptions. At present, neither source is complete. LHC researchers will next explore ways to combine the data, resulting in the best of both sources.

Dr. McDonald then discussed a project on the statistical analysis of laboratory orders. HITSP (the Health Information Technology Standards Panel) would like an empirically-determined set of common test orders. They would then require that standard codes for them be used in laboratory test orders messages, Dr. McDonald explained, mapping key research variables to LOINC (Logical Observation Identifiers Names and Codes) codes for delivery in HL7 messages. This would be a good first step and could be adopted quickly. After that, coverage could expand with demand. As a test, LHC used datasets of 10 million lab orders and 30 million lab test results; 26% of tests were Complete Blood Count (CBC) tests of various types. Overall, the two datasets provided balance. LHC will present their findings to HITSP, for use in their implementation proposals.

LHC is involved with the National Human Genome Research Institute (NHGRI) in an ambitious collaboration called PhenX. NHGRI is developing protocols for phenotypic measurements across genome-wide association studies. LHC and LOINC fully analyzed one set of measures, and found some gaps and inconsistencies in PhenX definitions. PhenX plans to load LOINC in their database, and LOINC will link to their text explanations. PhenX doesn't code all variables, Dr. McDonald observed, but LOINC does. There are many benefits to this collaboration. There will be a common approach to PhenX conceptualization of measures across subject matter, which is not the case now. Also, there will be greater uniformity, as in the coding of null answers. The merging of PhenX and LOINC will also bring about a single approach to variables used in research and clinical care, with sharing in both directions.

LHC accepted responsibility for maintaining and deploying a database of codes and standard vocabularies for electronic reporting of newborn screening (NBS) test results. Why standardize? Current reporting patterns are non-standard to the extreme, said the LHC Director. Also, the many quantitative measurements taken in NBS labs are rarely reported. Unfortunately, current NBS procedures have high rates of false positives, obviously very painful for parents. In addition, regional and national NBS centers need the original numbers for public health monitoring and quality assurance. This system uses a prescribed template of LOINC and SNOMED CT (Systematized Nomenclature of Medicine — Clinical Terms) codes, to define standard content for sending laboratory orders and results to birth institutions, responsible providers and to national and regional NBS centers. A collaborative effort with the Office of the Secretary of HHS, the Office of the National Coordinator for Health Information Technology and other federal entities, the new Web site will provide interactive views, user-customized reports and database downloads of codes for conditions and newborn screening measurements, plus other related content. In addition, the site links to NLM's Genetics Home Reference, to provide more information about newborn screening and the conditions screened for.

Dr. Lindberg asked about the variation in the number of newborn screening tests performed by the states. Dr. McDonald replied that the range is from about 39-100, but that there is a core set of about 30 tests. New Board member Dr. Joyce Mitchell added that the number used to vary as widely as 3-100, but the

law changed 2-3 years ago and now most states require 20-30. Dr. Lindberg asked what is done with the NBS data. Dr. McDonald replied that public health departments receive it, and other interested organizations. Dr. Friedman asked whether, in PHRs, all fields were coded or were some left open for additional data? Many of the fields accept standard codes and do autocompleting of answers but some are left open, Dr. McDonald replied. Board consultant Dr. Thomas Detre noted that, in the case of a disaster, no matter how quickly you can data-mine, it is not fast enough. Could there be a simple, portable scale measuring a patient's functional capacity, along with medication history, etc.? That might prove very helpful in helping medical facilities treats multiple casualties. Dr. McDonald said that the NLM PHR does have pop-up panels that ask about exercise, pulmonary function and other aspects of physical function. Dr. Detre suggested that, as this instrument evolves, genetic and pharmacogenetic information be added to it, too. Board consultant Dr. Tenley Albright suggested that, if an electronic health record is to be adopted nationwide, there must be a clear, simplified way of explaining it to the public. Dr. McDonald said that his staff will test that (once permissions to use it are granted). Dr. Albright said she hoped it would be appealing to use and written so that most Americans could understand it. Ms. Stanley asked whether the PHR was ready for testing at Suburban Hospital. Yes, Dr. McDonald replied, but they're awaiting authorization from NIH. Dr. Lindberg said he thought that would come through before the next NLM Board meeting. Dr. McDonald noted that he and his staff theorize that the main PHR user groups will be younger and middle-aged adults, caring for children and aging parents, probably with some degree of higher education. The Indian Health Service may present a different demographic. Ms. Stanley asked whether there was a place in the PHR for noting traumatic events in a patient's life, such as the Minneapolis bridge collapse. That might add an important dimension to the patient's profile and help if retroactive studies were done on the survivors. Dr. McDonald said he would consider that. (Dr. Phillips thought that Twitter and other social media could help with that function.) Dr. Friedman commended Dr. McDonald for all the good work and asked how many people were assisting him. He said that it was a small but talented and dedicated group.

X. DOD-VA VIRTUAL LIFETIME ELECTRONIC HEALTH RECORD FOR MILITARY PERSONNEL/VETERANS

Dr. Ross Fletcher, chief of staff of the Washington, DC Veterans Administration Medical Center, presented next. The Department of Veterans Affairs and the Department of Defense have both been early adopters of health information technology, and the implementation of EHR systems has facilitated sharing of health information between the two. He said he hoped lessons from the DoD-VA collaboration would benefit the US as a whole, as it moves toward an EHR system.

Paper medical records are hard to share, contain no images and pose problems when information contained in them is needed for reports. Conversely, CPRS (Computerized Patient Record System) information is easy to share, has diagnostic images built in and allows easy data retrieval for reports. This huge store of data —776 million medications administered, for example — can be viewed remotely anywhere, with an authorized code. Dr. Fletcher demonstrated the system with the case study of a patient who was exposed to 11 blasts while serving in Bosnia, Iraq and Afghanistan, now a dual user of VA and DoD services. Clinicians as well as programmers created the interface for the Virtual Lifetime EHR, and made it easy to navigate. The remote site, VistAWeb, is a portal accessible through CPRS. Dr. Fletcher said that a physician walking down the hall with a patient could query the system using the patient's name, pull up his recent angiogram and show him why an angioplasty is warranted. He showed another example of a patient who was losing weight rapidly but responded well and gained weight while taking

Lasix. A graph showed a history of the patient's weight from VA and DoD records but also from the patient's home, where a special scale measured his daily weight and sent that data to CPRS. Another strength of this system is that is captures all pharmacy records: from Landstuhl, Germany, Walter Reed and even CVS. The system features many safeguards: if a patient is allergic to penicillin and that antibiotic is prescribed, a flag will appear on the screen.

When a health care system can view and analyze data system-wide, there can be dramatic health benefits. Dr. Fletcher showed how hypertensive patients at his VA hospital have gone from 30% having their disease under control (1998) to 80% under control (2007). Clinical reminders are a key element. An added benefit is that, after viewing graphs of treatment outcomes across age groups, the VA strives to provide all treatments necessary, to help young and old alike achieve the same health status as much as possible. It can perform similar analysis for gender, ethnicity, etc., to ensure that equal treatment is provided.

Dr. Fletcher next demonstrated MyHealtheVet, the patient portal. This personal electronic health record contains information on medications, test results, surgeries, etc., and can be accessed via the World Wide Web, anywhere.

Dr. Walker asked what the biggest obstacle was to acceptance of this system by the DoD-VA. Dr. Fletcher replied that it's probably doctors who don't type fast or well. They were frustrated at first but VA staff often paired them with expert computer users. The non-typing docs saw how things worked and became frustrated that their own notes weren't included in the records. Mr. Bruce James asked why this system hasn't been adopted nationwide. Was there a large license fee? No, Dr. Fletcher replied, this system has been implemented in European and US health facilities, and no fee was involved. The software, on a CD, costs about $50 and can be customized to different organizations. Dr. Harris said that this system would not suit the Cleveland Clinic, which is intertwined with private insurance companies and other commercial systems, with special considerations of scheduling, registration and billing. Dr. Lindberg hailed the VA system as the best one today and expressed regret that the NIH Clinical Center had turned down a similar system, believing it to be too "one size fits all." Dr. Fletcher noted that the CPRS is interoperable and can import many software programs.

Dr. Charles Rice noted that this is a federally run system and still has great ability to innovate. He attributed some of its success to the buy-in of clinicians, who helped design it, and its reliability. There are challenges in expanding it to other branches of the military; the Air Force, for example has firewalls that prevent sharing of data. Dr. Fletcher is working on a VA-Navy collaboration, the Great Lakes Hospital, with an eye toward that kind of partnership. Ms. Gail Graham described the VA's partnership with Kaiser Permanente. There's actually more of a need for the DoD and VA to share information with the private sector than with each other, she said. Responding to a question from earlier in the day, she remarked that it would be helpful if the US adopted a system of patient identifiers but, for now, the system is functioning fine without it.

Dr. Lindberg asked whether the VA could give patients their medical records on a thumb drive. Dr. Fletcher replied that, instead, he'd recommend they view that information online at My HealtheVet. It's still a work in progress but can already allow patients to view their medications, reminders and so on. Dr. Ball asked whether the MyHealtheVet portal and the CPRS were different. They contain the same information, Dr. Fletcher said, but the patient version is much more personalized, and organized

differently for ease of use. Dr. Haym Hirsh of the National Science Foundation suggested that it's not so much that we want our information on thumb drives – which may not even exist even only a few years from now, but rather that they allow personal control of data. We want any solution where we can trust that we have control over the data. The VA-DoD site has many safeguards, Dr. Fletcher said. Its data is encrypted and it allows secure messaging between health professionals. Dr. Hirsh added that data security regulations may be needed for the private sector. If a firm goes bankrupt or is bought out by another company, who gains control of its data?

Dr. C. Martin Harris, Chair of the NLM Board of Regents, welcomed the Regents to the second day of their meeting. He welcomed Joyce Mitchell, PhD, to the Board. She mentioned that she has been at University of Utah for the past five years, serving as chair of the Department of Biomedical Informatics and university associate vice president for information technology services. Before that, she was on the faculty of the University of Missouri, School of Medicine. Her training is in medical genetics.

XI. NLM UNIVERSITY-BASED TRAINING IN BIOMEDICAL INFORMATICS

For more than 20 years, NLM has supported training for careers in biomedical informatics. These university-based training programs provide graduate degrees and in-depth research experience across the spectrum of bioinformatics topics. In November 2006, NLM announced the results of its most recent competition for training programs and among those universities selected for the five-year awards. The directors of the two newest programs, which began in July 2007, gave the Board progress reports.

Dr. Lawrence Hunter is director of the training program at the School of Medicine, University of Colorado, where he is professor of pharmacology. He said that their program is unique, providing no training in medical informatics but focusing instead on computational molecular biology (CMB). The program supports basic and translational research in genomics and next-generation high throughput molecular biology. After earning his PhD, Dr. Hunter came to NLM and worked to bridge the divide between the computer science/artificial intelligence side of the house and the molecular biology/genomics side. (The Human Genome Project was just getting underway.) He found a dramatic disconnect. To bridge the chasm, he spent a lot of time encouraging one group to pay attention to the methods and findings of the other, and vice versa. Armed with this new knowledge of two different worlds, he accepted the offer at Colorado. Without a computer science department at the medical school, he and his colleagues designing the training program decided to bring in candidates already trained in computer science, with an MS degree or equivalent experience. They also committed to building brideges between computer science and CMB, with frequent exchange of information and honest dialogue. How, then, could they award a PhD in both computer science and CMB without requiring eight years of study? They shaved some time by bringing in trained computer people. The medical school also developed a series of core courses for all first years, on microbiology, molecular biology, etc. It's a rigorous experience, with two hours of classroom instruction daily and an exam each week, and the computer scientist students must take and pass it, as well. So far, all of them have and, when they leave it, they feel like biologists. They're confident and can ask hard questions about methodology, data and so forth. Dr. Hunter distributed the program's mission statement to the Board. In addition to knowledge goals regarding biology, the experimental method, etc., there is also "hidden curricula" training, about how to plan scientific work, apply for grants, report on one's research and communicate about your research to different audiences.

In the first year, students are assigned a major research project, the findings of which they're required to present orally and in writing. They perform peer review on each other's project plans, too. They have the chance to review submissions to the *Journal of Biomedical Informatics*, which is a great education. The program has already graduated six students and they are doing well. In fact, one has a position now at NCBI. The Colorado program is avidly recruiting computer science students from underrepresented populations, too, attending schools in or around Colorado. Dr. Hunter hopes to prove empirically how well this program works and see it take off at other institutions. Dr. Connolly asked whether this model could be implemented at other NLM training program sites, too, and Dr. Hunter replied that Colorado's requirement for a computer science master's degree might not fit at other places. Dr. Mitchell remarked that she's often asked by schools wanting to apply for training program grants, what are the keys to success? Her stock answer is that a school needs a track record *before* they apply. She asked Dr. Hunter how Colorado established a track record and had institutional buy-in for their grant proposal; he replied "sweat equity," and said that they were able to launch this program by riding two existing PhD programs at Colorado, in biomedical science and analytic health science. By setting up this new training program under the umbrella of the health sciences, they did not have to go to the state for clearance to set up a new PhD track. In many ways, the Colorado program was student-driven; students were already producing strong projects and needed a program for them. Dr. Hunter said that his research grants were funded by an NLM R01 grant. He also said that many students in his program were already doing computer analysis for the other basic sciences departments at the school. He got signed letters in support of the training program from chairs of all of those departments. It cost nothing but probably lifted up their application. Dr. Friedman inquired about the kind of outreach efforts Dr. Hunter's program has made, for recruitment. He said that he and his colleagues travel into the field, to tribal colleges, schools with high percentages of Hispanic students, etc. They could use the time and money to do much more. He summarized by saying that the best recruiting tool is the message that students in this program can help improve human health and gain an understanding of the living world.

Dr. Stephanie Guerlain, associate professor in the Department of Systems & Information Engineering (SIE), directs the Medical Informatics/Systems Engineering Training Program (MINDSET) at the University of Virginia. It, too, is unique, Dr. Guerlain said, because its full-time trainees earn a degree in SIE, with research and mentorship focused on healthcare information topics. This is in line with the Institute of Medicine/National Academy of Medicine recommendation for building a better healthcare system by creating a multidisciplinary environment in which systems engineers and healthcare researchers collaboratively mentor trainees in medical informatics. The program has rigorous prerequisites, particularly in math. Some of the students have MDs while some of the PhDs coming in have degrees in economics, engineering and other fields, but no medical training. The latter group looks to the MDs in the program for information and clinical guidance. The executive committee for the training program includes faculty from the Department of Public Health Sciences and the director of the Claude Moore Health Sciences Library, Gretchen Arnold. Dr. Don Detmer, CEO of the American Medical Informatics Association (AMIA), chairs the program's Advisory Board. There are 100 graduate students in the department at any time, 60 MDs and 40 PhDs. The department now offers a new track in medical informatics. The curriculum centers on systems engineering methods and research/application.

She gave examples of research in progress at the department: new methods for visualizing Clinical Data Repository (CDR) data; basic research into the neural basis of touch, for example, and how to restore it when it's lost; haptic simulations of physical exams, featuring virtual tumors; and improving resident sign-out and medication administration.

The training program's overarching goal is to train top-notch researchers who are able to apply the techniques of systems and information engineering and medical informatics to address major open problems in biomedical information technology, devices, processes, safety, biomedicine and healthcare delivery. As is evident, it is very interdisciplinary.

How can the program's progress be measured? They apply metrics to eight program goals, including recruiting high-quality students, developing and maintaining a curriculum that supports careers in biomedical and clinical informatics from a Systems Engineering perspective and placing trainees in academic and research positions around the country. The program also aims to increase collaboration between engineers and medical researchers in biomedical informatics.

Dr. Connolly asked what had been learned, in developing an improved sign-out system for residents. Dr. Guerlain said that they were developing new modules, so that a busy resident wouldn't have to repeat information already in the patient's record but could focus instead on contingency planning, health status evaluation and other things that would constitute a better use of busy residents' time. Dr. Corn asked how collaborations formed between medical students and system engineers. Dr. Guerlain said that it was basically word of mouth, but that the students in the program are all very close and worthy projects just keep coming. Dr. Harris noted that a lot of work in the program was devoted to optimizing existing workflow into computer-based tools. He asked whether UVA ever approached the challenge the other way, asking clinicians, "Why do you do it that way?" She answered in the affirmative, explaining that this was the underpinning of their work in human factors. They first do ethnographic research: What are you doing? Why are you doing it that way? Who are you talking to? Dr. Harris asked whether that approach has resulted in any change. Rarely, Dr. Guerlain replied because, in the hospital setting, all data systems are interconnected and there are many forces that want to keep the status quo. Dr. Harris observed that, with evidence-based medicine, experts have just looked at results. The next step would be to develop a well-designed, well-engineered approach to the system management of acute and chronic disease. Taking stroke as an example, he said that our treatment methods are rather haphazard. Those should instead be by design. Working toward that goal is where all the promise of higher quality care, with lower costs, resides. Ms. Stanley agreed, saying that it's good to turn it around and think about knowledge-based evidence.

XII. EXTRAMURAL PROGRAMS REPORT

Acting Director Dr. Valerie Florance presented EP's grants budget for FY2009, almost $50 million, out of which 190 grants were awarded. She showed a chart of the various grant types and their funding levels, including $26 million for research grants, and said that, usually, that'd be all she had to report. This year, however, NLM received $82 million in ARRA funds, to be spent over two years. To date, the Library has given summer research awards that will benefit 67 individual trainees, 45 two-year training slot awards across 8 of its 18 training programs and 59 supplement awards, to speed up work in existing grants or, in some cases, to add new goals to grants. So far, NLM has committed nearly 50% of its ARRA funds.

She discussed the NIH ARRA Challenge Grant program. More than 20,000 applications came in to NIH for these two-year grants, totaling no more than $500,000 per year. NLM was assigned 336 Challenge Grant applications, because of their subject matter. This is more applications than NLM receives for all grant programs in a typical year. The reviews were performed by an editorial board convened by the NIH

Center for Scientific Review (CSR), in a style modeled on the usual process for journal review. Of the group assigned to NLM, 36 were scored and 16 funded.

Dr. Florance announced that the NIH CRISP system, documenting new NIH grants, has been retired, replaced by the much more versatile NIH Research Portfolio Online Reporting Tool (RePORT). She gave a quick demonstration of the system, and how it shows amounts of awards and provides project abstracts, lists of project terms, research results, related publications, and much more. The system, at report.nih.gov, can also be searched by PI name.

Dr. Corn hailed the new grants reporting system as much more rich than its predecessor. He then presented a program for concept approval. Anytime NLM adds a new program or direction in grantmaking, it requests approval of the concept by the Board. Dr. Corn talked about artificial intelligence, the notion that tasks could be done by computers that were previously performed only by humans. Optimally, of course, it's best to find a blend of what humans do best and machines to best. Computers never forget. They can move information around the world and read speedily. Computers enhance creativity and expand possibilities for clinicians and biologists, without question. Mindful of that, NLM proposes to use $2-3 million of its stimulus funds to explore the use of AI software in medicine. These would be short-term projects but, if they prove successful, NLM would likely use its own appropriated funds to continue the effort. Dr. Mitchell urged that public health be a part of the initiative, as well as medicine and science, and Dr. Corn assured her it would be. Dr. Hirsh expressed disappointment that despite its pervasive successes, perceptions from the 1980's that AI is unsuccessful still persist to this day. He was hopeful that this program might be able to change that perception to match its current reality. Ms. Stanley asked whether AI was a category in research supported by other NIH ICs. Ms. Humphreys answered that it is a Challenge Grant category because NLM wrote it in. Dr. Cohen asked whether the proposed sum was large enough, and Dr. Corn said the Library wanted to start small. The motion was made to adopt the Concept Review, seconded and unanimously adopted.

XIII. VIDEO FROM NIH ALL-HANDS MEETING WITH DR. FRANCIS COLLINS, NEW NIH DIRECTOR ON AUGUST 17, 2009

Dr. Harris introduced a video statement by NIH's newly appointed Director, Dr. Francis Collins. It was an excerpt from his remarks to NIH staff on August 17, 2009, his first day on the job.

Following the video, Dr. Lindberg mentioned that there is a lot of enthusiasm for Dr. Collins, who was previously the Director of the National Human Genome Research Institute. Ms. Humphreys noted that he was unanimously confirmed by the Senate without a hearing. Mr. James commented that Nevada gave him the Nevada medal for his contributions to science this year. Dr. Lindberg reported that Dr. Collins has been very supportive of NLM work, in general, and that he chaired a Committee that sought special funding for NCBI. A discussion about Dr. Collins' interest in global health followed.

XIV. CLINICALTRIAL.GOV POLICY UPDATE - REPORT FROM THE BOR WORKING GROUP ON CLINICAL TRIALS

Dr. Zarin provided an update on ClinicalTrials.gov (CT.gov). The site has been receiving about 350 new trial registrations per week, for a total of nearly 80,000 trials. There are 4,600 device trials in the registry,

compared to 47,000 drug studies. About 35% of the studies registered have no US sites. CT.gov gets about 40 million page views per month.

About a year ago, CT.gov launched the results database; to date about 1,500 sets of results have been submitted, most by industry. The rate of submission of results continues to increase. Currently, about 50 new results records are added each week. Most are drug studies. Dr. Zarin showed what a typical results record looks like, with text, outcome measures, adverse event tables, etc.

On September 27, 2009, adverse events reporting within the results database will become mandatory, in accordance with the FDA Amendments Act of 2007 (FDAAA). Prior to this time, data submitters had the option to use the Adverse Events module that was launched as part of the "Basic Results Database" in September 2008. The next milestone relates to expansion of results requirements via rulemaking and is due next September.

With a few exceptions, the Basic Results requirement is that results are due within one year of the primary completion date of the trial., if the drug or device under study has FDA approval at the time of the due date. Otherwise, the results are not due until 30 days after approval, which means if the drug or device is not approved, those results are not legally required to be posted.

The biggest problem Dr. Zarin discussed at the May meeting was quality assurance (QA) of results data; there has been significant improvement in this area. NLM continues to refine its QA processes to ensure that posted results records are meaningful, logical, and internally consistent and have apparent validity. The CT.gov staff has been working closely with data providers and has held numerous outreach and educational activities, including developing and revising materials to assist data submitters in preparing their results records and avoiding common mistakes. CT.gov has expanded its QA staff, and is also working with experts at the Tufts Medical Center. Overall the quality of submissions has improved and many organizations now have a high percentage of their submissions posted without revision. CT.gov now has a written list of quality standards. A year ago, nothing got posted without revision but, in the last two months, 44% of results records were launched without revision.

Next, Dr. Zarin discussed adverse events reporting. It will become mandatory on September 27, 2009. Previously, data submitters had the option to use the Adverse Events (AE) module that was launched as part of the "Basic Results" database in September 2008. There will be a few modifications made to the AE module to comply with the "default" provisions in the law and to allow for the voluntary provision of more complete information. Dr. Zarin was asked by a Board member which controlled vocabulary they were using for AE. She responded that we can't require that a controlled vocabulary be used. The law is clear, however, that an adverse event is an "adverse change in health status that occurred during the trial's course."

The law requires the Secretary of HHS to consider various ways in which results reporting requirements might be expanded to improve public access to information about clinical trials. NIH convened a public meeting on this topic in April and is still inviting public comment. Over 100 comments have been received so far, and the public can view them or submit them. The staff also received input from the Board of Regents Working Group on Clinical Trials. That group met by telephone July 1 and talked about requests for extensions to the reporting deadlines and the AE requirements. The Working Group discussed the value of keeping the number of extensions to a minimum, a view that is shared by an

internal NIH committee on clinical trials reporting. Everyone agreed to a "natural disaster" extension would be reasonable. .

Dr. Rossiter commended Dr. Zarin and her team. He asked about compliance with the program. Dr. Zarin said that most organizations know that studies need to be registered. In terms of results, the drug industry is well aware of the law, but there is still a lot of ignorance. NIH has helped to get the word out to academia. But the word still needs to get out for people to report results. Ms. Humphreys noted that NIH had expanded its outreach efforts recently. Dr. Cohen mentioned that this is a great example of how "the devil is in the details." He said that those who crafted the law had noble goals, but no one had any concept of how complicated it would be. Dr. Lindberg noted that the industry fought the bill until it was enacted and then decided that they had to comply. Universities have been a different story. Dr. Ball said that much of what she had accomplished in the past could not be done today, in the new regulatory environment. She asked whether the program was hindering the advancement of science or clinical trials. Dr. Lindberg indicated he did not believe so.

XV. REPORT FROM THE SUBCOMMITTE ON OUTREACH AND PUBLIC INFORMATION

Board member Eileen Stanley reported on the Subcommittee on Outreach and Public Information. They had a report by Joyce Backus and Sarena Burgess on the use of new technologies online between Google and MedlinePlus called "One Box." That is the name of the technology, not the actual product. It allows users, when we are searching medically-related topics, to have MedlinePlus as one of the featured reliable sources. It is also active and running. The group also heard about several Twitter applications that are now in place at NLM, including, "MedlinePlus4You" which sends out 2-7 Tweets daily. The SIS division is also Tweeting, sending news about emergency issues. A question was raised about whether there should be an addendum to the strategic plan, to consider the use of social media as we move forward. It was also suggested that this might be a way to get information directly to health professionals.

Ms. Humphreys discussed collaboration between NLM and the National Museum of American History, to extend access to the exhibitions. The talks were positive and plans in development. Mr. James helped to set up the initial meeting. The Subcommittee talked about planning for NLM's 175th anniversary in 2011. Several NLM planning groups have been organized. Mr. Jerry Sheehan gave an update on ClinicalTrials.gov. Dr. Elliot Siegel and Mr. David Nash discussed the New York high school program, the focus of which is to spark interest among young people in health science careers.

Ms. Humphreys provided an update on the *NIHMedline*Plus magazine. The Subcommittee has expressed an interest in learning more about future distribution plans. We understand that we will be getting a fuller presentation at a future meeting. We are currently distributing around 500,000 issues of the magazine. This September, a bilingual version of the magazine is expected to be released, further expanding the reach of this magazine to new and diverse populations nationwide.

XVI. SEMANTIC TWITTER

Dr. Thomas Rindflesch explained that this is collaborative research between Lister Hill Center for Biomedical Communications and SIS's Disaster Information Management Research Center to exploit the use of Twitter to keep of abreast of topics of public concern. It is important for government agencies to know what people are talking about and what they are concerned about. The goal is effective

dissemination of information but this requires that you also extract information in order to effectively disseminate. Increasingly, the public is using social information to disseminate information.

Twitter itself is like a micro-blogging service. It is a short message service gateway that allows posting from a computer, a mobile device including a cell phone, and people can respond immediately. You can keep your finger on the pulse of what is going on. There are a growing number of users on Twitter. Google and others use an analysis of the frequency of distributional patterns. What LHC staff is proposing here and is pursuing is a more advanced method for analyzing and exploiting the information on the Internet. We need to analyze Twitter posts using NLM's natural language processing tools (MetaMap which identifies medical concepts in text and SemRep which identifies relationships between concepts) and the Unified Medical Language System. Increasingly, newsworthy information spreads across Twitter and other online social media more quickly than through official channels. In the case of epidemics, such as the recent H1N1 outbreak, these media reflect widespread concerns and sentiments. As part of a strategy for syndromic and disease surveillance, disaster information providers can exploit this information to help understand fears and misconceptions that need to be addressed.

A promising method for monitoring this traffic is semantic processing used to isolate health topics. A recent experiment highlights LHC's ability to recognize "swine flu" as a major concern in selected Twitter traffic. After extracting semantic concepts and relationships using MetaMap and SemRep, we defined a schema for epidemics, which consisted of selected UMLS semantic classes, including "Disease or Syndrome," "Sign or Symptom," and "Health Care Related Organization." Such a schema can be used in conjunction with frequency of occurrence calculations to alert disaster information providers when public concern, as reflected in Twitter, is focused on health issues.

In conclusion, LHC sees several opportunities in the use of social media for surveillance potential for disaster information preparedness. CDC has expressed initial interest in the potential use of this technology for CDC.

Mr. James raised the issue of the government's use of this technology to monitor twitter traffic and wanted to know who was using it. Dr. Rindflesch responded that policy makers have to decide. Joyce Mitchell said that the issue of whether to do it or not is important. On the other hand, there are a lot of government agencies that have been doing something similar with e-mail for terrorism. Mr. James mentioned that you would need a court order and Mitchell responded that it is being done without a court order. Ms. Stanley noted that there is no privacy on Twitter. You can see every message on Twitter, so analyzing twitter traffic is not the same as monitoring private email. Ms. Humphreys pointed out that NLM has no desire to connect the substance of searches or twitter posts to the individual people involved. NLM does not retain information that links individuals to what they are doing on our systems. We look at patterns, not individual people, she explained, and certainly don't want to retain information about individuals. Mr. James agreed that NLM should be careful about monitoring individual activities.

XVII. ADJOURNMENT

The Board of Regents meeting was adjourned at 12:00 p.m. on September 16, 2009.

ACTIONS TAKEN BY THE BOARD OF REGENTS:

- Approval of the May 5-6, 2009 Regents' Minutes
- Approval of September 14-15, 2010 Meeting Dates
- Concept Review and Approval for a Research Contract on Artificial Intelligence

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.	C. Martin Harris, M.D.
Director, National Library of Medicine	Chair, NLM Board of Regents