

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

**MINUTES OF THE BOARD OF REGENTS
September 9-10, 2014**

The 167th meeting of the Board of Regents was convened on September 9, 2014, at 9:00 a.m. in the Board Room, Building 38, National Library of Medicine (NLM), National Institutes of Health (NIH), in Bethesda, Maryland. The meeting was open to the public from 9:00 a.m. to 3:30 p.m., followed by a closed session for consideration of grant applications until 4:00 p.m. On September 10, the meeting was reopened to the public from 9:00 a.m. until adjournment at 12:00 p.m.

MEMBERS PRESENT [Appendix A]:

Dr. David Fleming, University of Missouri School of Medicine

*Mr. Eric Dishman, Intel Corporation

Dr. Robert Greenes, Arizona State University

Dr. Henry Lewis, American University of Health Sciences

Dr. Trudy MacKay [Chair], North Carolina State University

*Ms. Sandra Martin, Wayne State University

*Dr. Esther Sternberg, The University of Arizona

Ms. Gail Yokote, University of California, Davis

MEMBERS NOT PRESENT:

Dr. Ralph Roskies, University of Pittsburgh

EX OFFICIO AND ALTERNATE MEMBERS PRESENT:

Mr. Christopher Cole, National Agricultural Library

Col. Michael Cunningham, United States Air Force

RADM Scott Giberson, Office of the Surgeon General, PHS

Ms. Caryl Kazen, Veterans Health Administration

LTC Christine Lettieri, United States Army

Ms. Kathryn Mendenhall, Library of Congress

Dr. Dale Smith, Uniformed Services University of the Health Sciences

CONSULTANTS TO THE BOR PRESENT:

Dr. Marion Ball, Johns Hopkins School of Nursing

Dr. Holly Buchanan, University of New Mexico

Dr. H. Kenneth Walker, Emory University School of Medicine

***New Members Attended as Consultants for September Meeting**

SPEAKERS AND INVITED GUESTS PRESENT:

Mr. Shomir Chaudhuri, University of Washington
Dr. Darryl Hurt, National Institute of Allergy and Infectious Diseases, NIH
Dr. Roger Kurlander, Clinical Center, NIH
Dr. Elaine Martin, University of Massachusetts Medical School
Dr. Larry Tabak, Deputy Director, National Institutes of Health

MEMBERS OF THE PUBLIC PRESENT:

Ms. Patricia Bradley, University of New Mexico
Dr. Gayle Dine Chacon, Pueblo of Saudia
Ms. Julia Szilard Chaudhuri, University of Washington
Mary Lindberg
Dr. Barbara Redman, Friends of the National Library of Medicine
Dr. Elliot Siegel, Consultant

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, Lister Hill Center, NLM
Ms. Anne Altemus, Lister Hill Center, NLM
Dr. Sameer Antani, Lister Hill Center, NLM
Ms. Stacey Arnesen, Division of Specialized Information Services, NLM
Ms. Dianne Babski, Division of Library Operations, NLM
Ms. Joyce Backus, Division of Library Operations, NLM
Dr. Dennis Benson, National Center for Biotechnology Information, NLM
Dr. Oliver Bodenreider, Lister Hill Center, NLM
Ms. Kathleen Cravedi, Office of Communications and Public Liaison, NLM
Ms. Francesca Crawford, Division of Extramural Programs, NLM
Mr. Todd Danielson, Office of the Director, NLM
Ms. Ariel Deardorff, Office of the Director, NLM
Mr. Ivor D'Souza, Office of Computer and Communications Systems, NLM
Dr. Kathel Dunn, Office of the Director, NLM
Ms. Gale Dutcher, Division of Specialized Information Services, NLM
Ms. Kristina Elliott, Office of the Director, NLM
Dr. Jessica Faruque, Lister Hill Center, NLM
Dr. Valerie Florance, Division of Extramural Programs, NLM
Ms. Erin Foster, Office of the Director, NLM
Dr. Dan Gerendasy, Office of Health Information Programs Development, NLM
Mr. John Harrington, Lister Hill Center, NLM
Ms. Lori E. Harris, Office of the Director, NLM
Dr. Michael Huerta, Office of Health Information Programs Development, NLM
Ms. Christine Ireland, Division of Extramural Programs, NLM
Dr. Stefan Jaegar, Lister Hill Center, NLM
Mr. Ken Koyle, Division of Library Operations, NLM
Dr. Dar-Ning Kung, Office of Computer and Communications Systems, NLM
Dr. Fabrico Kury, Lister Hill Center, NLM

Dr. Robert Logan, Office of Communications and Public Liaison, NLM
Ms. Lisa Lang, Division of Library Operations, NLM
Dr. Clement McDonald, Lister Hill Center, NLM
Ms. Elizabeth Mullen, Division of Library Operations, NLM
Dr. Steven Phillips, Division of Specialized Information Services, NLM
Dr. Barbara Rapp, Office of Health Information Programs Development, NLM
Dr. Jeffrey Reznick, Division of Library Operations, NLM
Dr. George Riley, National Center for Biotechnology Information, NLM
Mr. Jerry Sheehan, Office of the Director, NLM
Dr. Hua-Chuan Sim, Division of Extramural Programs, NLM
Dr. George Thoma, Lister Hill Center, NLM
Dr. Alan VanBiervliet, Division of Extramural Programs, NLM
Dr. Fred Wood, Office of Health Information Programs Development, NLM
Dr. Terry Yoo, Lister Hill Center, NLM
Dr. Deborah Zarin, Lister Hill Center, NLM

I. OPENING REMARKS

Dr. Trudy MacKay, NLM Board of Regents Chair, welcomed the Regents, new Regents, alternates, and guests to the 167th meeting of the Board. She then introduced RADM Scott Giberson, Acting Deputy Surgeon General of the Office of the Surgeon General (OSG).

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

RADM Scott Giberson briefed the Board about the confirmation of the new Secretary of the DHHS, Sylvia Burwell. Previously she was the Director of the White House Office of Management and Budget from 2013 to 2014. The Surgeon General nominee will probably be given consideration after the mid-term elections.

RADM Giberson said the OSG is moving forward with their Calls for Action. The 50th Anniversary of the OSG's report on smoking occurred earlier this year. In 1964, then Surgeon General Luther Terry issued a groundbreaking report on smoking which identified smoking as a causal factor in lung cancer.

A skin cancer Call to Action took place this spring. Skin cancer is the most commonly diagnosed cancer in the United States and costs more than \$8 billion annually. The OSG believes that skin cancer is an almost 100% preventable disease and education will play a big role in reducing rates nationally. He also mentioned a Call for Action to prevent prescription drug abuse among youth. In 2011, about 20% of adolescents between the years of 12 and 25 reported abusing a prescription. Lastly, a Call to Action to promote and support walking and walk-able communities is on the OSG agenda.

The OSG had several deployments in recent months, one to the Unaccompanied Children Mission in Nogales, Arizona. The OSG deployed 351 members of the Commissioned Corps of the U.S. Public Health Service to provide public health and medical coordination, medical

screening, basic medical care, vaccinations, and mental health screening for unaccompanied children at the Nogales facility.

With respect to the Ebola crisis in Africa, the OSG is preparing for the Commissioned Corps to be deployed there, along with the Department of Defense. Sixty-five members of the Commissioned Corps, with diverse clinical and public health backgrounds, will travel to Liberia to provide direct patient care to health care workers.

Board member Dr. Robert Greenes asked the RADM if the OSG had a position on e-cigarettes. Giberson said that the OSG believes that there needs to be more research on e-cigarettes. We know that they contain addictive substances and we are not able, at this point, to say we approve of this product.

Consultant Dr. Kenneth Walker asked RADM Giberson to describe the unaccompanied youth that are coming across the border. Giberson said he could not speak to that.

Board member Dr. Esther Sternberg asked about the timing of the Call to Action on Walking and Walkable Communities. Uncertain about its timetable, RADM Giberson said the first will be preventable prescription drug abuse and then walking. Dr. Sternberg asked what efforts are underway to partner with park designers. RADM Giberson noted that such partnerships will be essential.

Board member Dr. David Fleming asked whether the PHS has programs that emphasize getting health care to populations in need. RADM Giberson said that eligibility for care needs to translate into access to care. The OSG does not have a project like that now, but they are working with other agencies on such issues, monitoring how much access people have to needed care.

III. MAY 2014 MINUTES AND FUTURE MEETINGS

The Regents approved without change the minutes from the May 13, 2014 meeting. The 2015 fall meeting will take place on September 29-30, 2015.

IV. REPORT FROM THE NLM DIRECTOR

Dr. Lindberg began his report with the budget. NLM's FY2014 Operating Budget is \$336.6 million. Since the Board of Regents last convened, an additional \$1.077 million was transferred to NLM from the NIH National Children's Study allocation. The FY2015 President's Budget does recommend a small increase for NLM—\$381.1 million (\$372.9 million in appropriated funds plus \$8.2 million provided by legislation to carry out the purposes of the National Information Center on Health Services Research and Health Care Technology, NICHSR). It is expected that FY2015 will begin under a Continuing Resolution that will last until after the November elections.

Dr. Lindberg noted that Dr. Dar-Ning Kung was recently appointed Associate Director for Information Assurance. Dr. Kung joined NLM in October 2001, and has served as NLM's Information Systems Security Officer (ISSO) since 2002.

Dr. Lindberg asked LHC Director Dr. Clem McDonald to introduce new appointments to the LHC. Dr. McDonald introduced Dr. Stefan Jaeger who was appointed as a research fellow with the Communications Engineering Branch in April 2014. He will be working with Dr. Sameer Antani and Dr. George Thoma on algorithms for automated classification of chest x-rays as normal or exhibiting pathology such as tuberculosis. Dr. McDonald said that Jessica Faruque, PhD, joined the LHC in April, 2014 to develop an understanding of human perceptual similarity between images in Open-i, and to train and validate content-based image retrieval systems. Lastly, Dr. McDonald introduced Fabricio Kury, MD, who joined the LHC in April 2014 to focus on clinical research informatics and discovery in clinical databases.

Dr. Lindberg called upon Dr. Kathel Dunn to introduce NLM's Associate Fellows. They include: Ariel Deardorff, who received her MLIS in 2014 from the University of British Columbia in Vancouver, Canada; Kristina Elliott, who received her MLS from the University of Maryland in 2014; Erin Foster, who received her MSLS degree in 2014 from the University of North Carolina, Chapel Hill; and Lori Harris, who also received her MSLS from the University of North Carolina at Chapel Hill.

With respect to legislation, Dr. Lindberg noted that there is a special appropriation that relates to NLM's health services research funded by a transfer of about \$8 million from the Secretary's evaluation fund. It may get eliminated as a transfer item and added to NLM's direct appropriation. A similar situation exists for NCBI, wherein NIH Institutes contribute to NCBI's budget. While the Senate Labor-HHS Appropriations Subcommittee draft language would have provided an increase in funding for NLM to support the NCBI, it was well below the amount needed to fully support the NCBI and eliminate the needed contributions from the NIH ICs.

Dr. Lindberg also mentioned Senator Harkin's proposed legislation designed to accelerate biomedical research. The bill would restore the purchasing power the NIH has lost since the end of the doubling in 2003, by giving appropriators authority to raise NIH funding to \$46.2 billion by the end of the seven-year period ending in FY 2021

Other legislation pending in the Congress includes 21st Century CURES introduced by Reps. Fred Upton (R-MI) and Diana DeGette (D-CO) to accelerate the pace of cures in the US. The House Energy and Commerce Committee approved a bill on July 30 that would require the Secretary of HHS to develop recommendations for the development and use of clinical data registries that are integrated with clinical practice guidelines and the best practices or standards of care. This bill has not yet been scheduled for floor debate. Lastly, several libraries and library associations submitted comments in response to the FCC's Notice of Proposed Rulemaking on Net Neutrality. Comments note the importance of an open Internet to the library community and the significant use that health science libraries make of NLM resources in support of health care.

Dr. Lindberg discussed the HHS Public Access Plan. HHS is actively engaged in coordinating development of policies across its operating divisions to increase public access to peer-reviewed scientific publications and digital data resulting from funded research – both intramural and extramural. Agencies with “more than \$100 million in research and development expenditures”

must develop plans to make the results available free of charge within 12 months after original publication.

As part of its coordination activities, HHS developed a set of guiding principles and has promoted common approaches, where feasible. NLM has participated actively in HHS-wide discussions of public access. It has offered to assist other agencies within HHS in using PMC to support policies for providing public access to publication. To date, NLM has established agreements with two other HHS operating divisions—AHRQ and CDC—to support their public access policies by using PubMed Central.

It is time, once again, for the NLM to formulate a long-range plan as was done in 1984-85—very successfully. A long range plan should state the goals of NLM. NCBI and The Visible Human Project both arose from the long-range planning process. Dr. Lindberg suggested that in February, 2015, the Board should establish a Subcommittee to begin planning for the next long range plan. Consultant Dr. Marion Ball agreed, noting that she was part of the planning group which worked on the previous 10-year long-range plan.

Dr. Lindberg reported on the *Native Voices* travelling exhibition program that opened at the Dena'ina Center, Anchorage Convention Center on June 9, 2014 at a ceremony co-hosted by the Southcentral Foundation, the Alaska Native Heritage Center, and the National Congress of American Indians. Following the Alaskan opening, another copy of the traveling exhibition opened in the Queen's Historical Room at the Queen's Medical Center in Hawaii on July 18, 2014. Lastly, on August 26, 2014, the traveling exhibition opened in the Chickasaw Nation's ARTesian Gallery & Studios in Sulphur, Oklahoma. The opening program featured remarks from the Chickasaw Nation's Governor, the Honorable Bill Anatubby, and cultural artifacts from the Chickasaw Nation. The Honorable Tom Cole, the Chickasaw Nation's congressman, praised the NLM for developing the exhibition in July 10, 2014 *Congressional Record* remarks. A video documenting the openings was shown.

Dr. Lindberg reported that the NLM has launched *Pictures of Nursing: The Zwerdling Postcard Collection*. *Pictures of Nursing* a new traveling banner exhibition. which presents a selection of historic postcards from a collection of about 2,500 items, spanning a century of nursing imagery. The exhibition will be displayed at NLM until August 21, 2015 and is online at: www.nlm.nih.gov/picturesofnursing.

Dr. Lindberg reported that the Annual NLM Informatics Training Conference was held at the University of Pittsburgh, June 17-18, 2014. Approximately 248 trainees presented their research projects.

Dr. MacKay asked the Board to consider Dr. Lindberg's suggestion that a long-range planning session should begin in 2015. A motion to approve Dr. Lindberg's proposal was offered and approved by all. A second proposal offered by Dr. Lindberg involved the selection of a Long-Range Plan Subcommittee. Dr. MacKay said this portion of Dr. Lindberg's proposal could be discussed offline and brought to the Subcommittee for final approval at the February 2015 meeting. All agreed.

V. CLINICAL TRIALS UPDATE

Dr. Deborah Zarin, director of NLM's ClinicalTrials.gov Web site, provided an update. She explained recent work to redesign the public site to improve navigation. More challenging, Dr. Zarin said, were improvements made to the data entry system. The updates were informed by experience, expert evaluation, and usability studies. Another round of improvements scheduled for completion at the end of 2014 will focus on improving portfolio management tools.

A list of current articles authored by the ClinicalTrials.gov team was presented along with some findings reported in these publications, including: (1) In 2012 alone, between 1,300-3,700 U.S. trials were not subject to federal human subjects protections regulations, and (2) a third of NIH-funded trials remained unpublished after a median of 51 months.

Dr. Zarin noted that her group's ongoing research focuses on characterizing terminated trials, examining certain agreements between sponsors and investigators, and assessing various methods for improving trial reporting. Dr. Zarin said that the initial goals of trial registration were to help potential participants find trials and to improve scientific integrity of trial reporting. A system in which sponsors/investigators choose whether, when, and how to publish their studies can result in selective publication and missing trials, selective outcome measures and unacknowledged protocol deviations.

People are registering many trials, but it is hard to know what percentage of trials are registered. We suspect that late registrations may provide a window into this. The Food and Drug Amendments Act of 2007 (FDAAA) requires registration of a trial of an FDA regulated drug or device within 21 days of enrollment of the first participant. Of about 17,000 trials registered in 2013-2014, about 19%, or over 3,000, were late.

There are mixed but overall low rates of results reporting. About 50% of all trials report results. For those that do report, there is poor quality reporting. Will the culture change? Will FDAAA be a law that leads to culture change?

Jerry Sheehan, NLM's Assistant Director for Policy Development, discussed the Notice of Proposed Rulemaking (NPRM) for clinical trial registration that is expected to be released for comment in the Federal Register soon. [NOTE: It became available for public inspection on November 19, 2014] An NPRM is essentially a draft rule book. Although summary results for more than 14,000 trials have been submitted since FDAAA was enacted, results submission has been hampered by uncertainty about the meaning of some of the law's provisions and about how compliance will be determined.

NLM has worked with NIH, FDA, and the Office of the General Council (OGC) to prepare a NPRM to implement the provisions of the FDAAA that require registration and submission of summary results information about certain clinical trials of drugs (including biological products) and devices at ClinicalTrials.gov. The NPRM clarifies the Department's interpretation of statutory requirements and describes its proposed approaches for addressing issues that the law requires to be considered via rulemaking, including whether to require the submission of: (1) results information for clinical trials of drugs (including biological products) and devices that are not approved, licensed, or cleared for marketing by FDA; (2) the clinical trial protocol and/or

other information on the protocol to assist in understanding result information; and (3) narrative summaries (technical and lay) of a clinical trial and its results. As of September 9, the draft NPRM was undergoing regulatory review by the White House Office of Management and Budget (OMB). This is the final step in the approval process before the NPRM may be published in the *Federal Register* for public comment. A public announcement will be made when the NPRM is published so all affected stakeholders will have an opportunity to review and provide comment.

A Board member asked if mobile devices were covered by the NPRM. NLM Deputy Director Betsy Humphreys and Mr. Sheehan said that they could be covered if they belonged to a category of device subject to FDA Regulation.

Dr. Fleming said that there seems to be a high rate of noncompliance, or submission of bad data. He asked whether there are any tools that can be made available through the website to provide guidance and mentoring on how to use the site. Dr. Fleming also asked to what extent should the NLM act as a monitoring agency to ensure the integrity of the information submitted in terms of human subjects protections? He queried, “What do we do about that?” With respect to Dr. Fleming’s first question, Mr. Sheehan noted that NLM has done quite a bit to educate scientists about the submission process. When the NPRM goes out, the Department’s view of what constitutes complete and correct submissions will become clearer. On the data integrity side, NLM can check that the data submitted are internally consistent and notify the submitter if is not. We cannot verify that the information submitted is valid.

Dr. Fleming asked Dr. Zarin if NLM will report instances of inconsistencies corrected. Dr. Zarin said that we have had received inquiries questioning the validity of the data about several studies. We refer them to the FDA. NLM is not a regulatory body but we can point people in the right place.

VI. PRESENTATION OF REGENTS’ AWARD

The Regents’ Award for scholarship or technical achievement was presented by Dr. Trudy MacKay to Olivier Bodenreider, MD, PhD, senior scientist and chief of the Cognitive Science Branch, Lister Hill Center. Dr. Bodenreider received the award in recognition of his exceptional leadership in the dissemination of NLM drug information sources through graphical and programming interfaces. His work has greatly enhanced the use of standard drug terminology in both informatics research and electronic health record systems.

VII. NIH 3-D PRINT EXCHANGE

Dr. Terry Yoo, head of NLM’s 3D Informatics Program, presented each Board member, consultant and staff member at the table with a blue box containing products of the NIH 3D Print Exchange. Two of the models were based on data from NLM’s Visible Human Project, and the third was taken from pyruvate dehydrogenate, an enzyme found in bacteria and prokaryotes, whose shape was uncovered by the National Cancer Institute. Dr. Yoo is one of the research investigators associated with the NIH 3D Print Exchange, a fast-moving project which has received considerable recognition in the course of its short lifespan.

In fall of 2013, staff from NLM and the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development joined with the National Institute of Allergy and Infectious Diseases to examine and enable the public use of emerging 3D-print technologies for biomedical research and education. Bryan Sivak, Chief Technology Officer at the Department of Health and Human Services (HHS), was given the charge to spark innovation within the Department. Among other initiatives, he launched HHS Ignite, an incubation program. The NIH 3D Print Exchange was one of 13 projects selected from the 65 proposals in the inaugural class of HHS Ignite. The team then was asked to appear before an Ignite “Shark Tank” in February 2014; its presentation made it one of two from the original class to be awarded HHS Ventures funding, which allowed the project to continue to fulfill its promise. Dr. Yoo introduced Dr. Darrell Hurt, the NIH 3D Print Exchange principal investigator.

Dr. Hurt noted that HHS funding, although modest, has meant a lot, coming as it has from the very highest levels of HHS. In fact, support has come from even higher—the White House—and this, plus HHS’s vote of confidence, has been instrumental in pushing this project forward.

The NIH 3D Print Exchange is a combination Web site, portal and database, and a source of accurate, high quality biomedical models. We offer everything from medical anatomical models to molecular models and even things like lab gadgets that save time and money in the lab and in the clinic. The framework used by the NIH 3D Print Exchange is all open source, as is related software. Dr. Hurt then demonstrated the Web site, showing how users can preview an item in 3D and read its description, then click “Download” and get the parts that they need to put into their printer or send off to a printing service.

The other thing that the Web site portal delivers is a place for community engagement. The site offers tutorials, forums and e-mail addresses so that people can talk to each other, compare notes and understand better what’s going on with 3D printing. There are also sections for news and blogs.

Dr. Yoo returned, pointing out that Dr. Hurt invited NLM into this partnership because of its interest and expertise in bringing together open source software tools. The 3D Print Exchange not only looks at medical imaging but also at molecular models, protein models from data that is already in existence in terms of the structure, plus image stacks in microscopy and other forms.

One question often heard about 3D printing is, “Why do it?” Biomedical data natively exists in three dimensions—molecules have three dimensions certainly, and gross anatomy has three dimensions, for example. Also, the protein and electron microscopy databanks are also a rich source of pre-existing information. Dr. Yoo then briefly discussed how the raw data is converted to data used in 3D printing. Another great resource is NLM’s Insight Toolkit (ITK), a 16-year NLM enterprise which has become the standard, for how to do medical image analysis. 3D printing has provided another outlet for ITK, extending the reach of NLM in education and discovery into high schools and universities through open-source software pipelines and workflows.

Dr. Hurt recognized important partners in the project, listed in the Board Book, which include Capt. Gerald Grant at the Walter Reed National Military Medical Center. The NIH 3D Print

Exchange has been featured at numerous outreach events, including the USA Science and Engineering Festival in downtown DC, where there were over 400,000 visitors. After beta testing, the NIH 3D Print Exchange officially launched its site, <http://3dprint.nih.gov/>, at a White House event June 19, 2014. The group has been talking with NASA, NIST and the US Army, and all three have expressed serious interest in adopting this framework and using it for their own digital collections. He credited many people at NLM for the project's success, including the head of High Performance and Communications, Dr. Michael Ackerman, as well as others from NIH and HHS.

Board member Ms. Yokote asked for more details about how the information for 3D printing is shared. The data are inherently sharable, said Dr. Hurt, because these 3D shapes, even if from different datasets and disciplines, share the same file type, which allows the 3D printer to then take that as input and manufacture it in the same way that everyone uses a PDF files and laser printers. When asked by Ms. Yokote how the NIH Exchange stores data, the group has an enterprise storage system back-up, with pretty large servers. Space for these large files is not unlimited. However, they are prepared—the framework is open and can be moved to the cloud if necessary.

Ms. Yokote asked about the rule for citing 3D printing files. In the model page, replied Dr. Hurt, they cite the original work, where it came from, and the name of the person who uploaded. They also assign each item a unique identifier so that people who have already used that identifier to refer to their 3D prints. Dr. Yoo added that, regarding the archiving question, one of the essential reasons to build software pipelines or workflows is because NIH doesn't have to archive that much.

Board consultant Dr. Kenneth Walker asked the presenters whether they could foresee a time when patients could have access to their images and models of their organs and other body parts. Dr. Yoo replied that we are going to see it right away. You can go to Staples and buy a good quality 3D printer for \$1,100. Also, the ABS plastic used in these printers is recyclable.

Dr. Lindberg requested more details about a scientist who looked at the protein model and saw something in the model that he hadn't seen by looking at the screens. In response, Dr. Yoo reminded the Board that Watson and Crick's original model of the DNA structure was fashioned out of cardboard and paper. With their models, they were able to make the intuitive leap eventually got them the Nobel Prize. When it comes to that "Eureka!" visualization moment, there is something intuitive about building things with your hands and putting your hands on them, to gain a greater understanding. Being able to pick up something engages a great deal more of our mental faculties than the entertainment moment of seeing it on a screen. We do not yet have a double-blind study, explaining how this kind of modeling can enhance the learning of students and researchers, we only have anecdotes. He continued, unlike cadavers used in the study of gross anatomy or training simulators costing many thousands of dollars, these 3D models can be printed very inexpensively by people with modest training—and if it breaks, it is easy and cost effective to print a replacement.

VIII. OLDER ADULTS' ATTITUDES TOWARDS FALL DETECTION DEVICES

Dr. MacKay then introduced Mr. Shomir Chaudhuri, a research associate at the University of Washington. He is part of HEALTH-E, an interdisciplinary group of researchers committed to exploring systems that support older adults and promote independent aging using innovative technology tools. Environmental sensors, placed in the homes of older adults to monitor them over a long period of time, are frequently used to measure various things, like water consumption in a particular home. Once data has been gathered from the sensors, researchers figure out different ways to visualize and present the information to the older adult in a meaningful way. This information can also be shared with caregivers or healthcare providers.

His objectives are to describe the current state of fall detection devices, to capture the perceived user needs of these devices for their intended population (persons age 65 and over) and to understand the usability and feasibility for their intended population. This is especially important, given the fact that the older adult population is rapidly increasing, with the aging of Baby Boomers. In 2010, there were about 48 million older adults, a figure predicted to rise to about 92 million by 2060.

Falls are a big problem in older adults, with one in three adults over age 65 falling at least once annually. This number increases as you grow older, with one in every two adults over the age of 80 falling at least once annually. When he discusses falls, Mr. Chaudhuri is referring to this definition by Fedder: unintentionally coming to the ground, not as a consequence of being pushed or being hit but more because of a trip or an inherent balance issue.

Falls can have a tremendous impact on the health and independence of older people, as they usually result in physical injury - anything from lacerations to head trauma to fractures. Falls can also be deadly especially if the person requires hospitalization. A recent study showed that, in 2011 in the United States alone, around 23,000 older adults died from fall-related injuries. Along with the health impact, there is also a huge economic impact. The US spends about \$30 million a year on fall-related injuries. This number is predicted to increase dramatically in coming decades. Putting these figures in perspective, the total hospital cost for a person who has fallen is up to \$32,000 more than for a person who has not. Finally, falls can have a huge emotional impact on the person who has fallen, as well as his or her caregivers. People who have fallen become afraid to perform normal activities because they never know when they are going to fall again. Their family, friends and caregivers have similar fears.

All of these factors and risks are amplified in the event of a “long lie”—involuntarily remaining on the ground for more than an hour following a fall. The faster a person is discovered after a fall, the better chance they he or she has of survival and recovery. A recent study shows that half of those who suffered a long lie will die within a year of the fall.

The news isn't all bad, however. There are ways to prevent falls, including regular strength and balance exercises. Tai chi has proved very effective, and there are also various supplements you can take, too. Older adults can remove trip hazards such as throw rugs, and also employ assistive devices such as canes or walkers, to prevent falls.

In the event that a person does fall, there are personal emergency response systems which usually involve a button a person can press to call for help. Fast response equals better care, so these buttons can be of great help. However, if the person is unconscious, unable to reach the device or too embarrassed to use it, that poses challenges. A study showed that 80% of adults who had these devices did not use them to call for help after experiencing a fall. A more practical solution would be a device that automatically understands the fact that the person has fallen and places a call without the user having to press the button.

Mr. Chaudhuri conducted a literature review to figure out what sort of devices are currently on the market, and published the results in *The Journal of Geriatric Therapy*. He identified articles on a range of technologies and their accuracy. Most evaluated wearable systems, while a smaller portion dealt with environmental systems.

Wearable devices are always with the person, of course, and experience the same in acceleration or impact as their user, making them very accurate for indicating a fall. However, many of these devices are also battery powered and must be charged regularly. Environmental systems—including cameras, acoustic sensors, pressure sensors—are placed in the user's normal environment. They are usually plugged into a sustainable power source so, after installation, the user doesn't have to worry about them. However, some people do not want to be videotaped at all times. There can be problems with occlusion—for example, a chair may be blocking the camera and there's no way to know if the person has fallen. Mr. Chaudhuri then showed a graph representing the median accuracy and specificity for the various devices that he found from the papers. Most of the median figures for accuracy and effectiveness are in the mid-90s, which is impressive, but device detection is continuing to rapidly improve. (He found one study that used a wearable device that could detect falls from activities of daily living 100% of the time.) Unfortunately, the way in which these studies were conducted is a little concerning. The majority of the studies for the environmental devices were done without older adults, this usually involved fall-dummies or simulated data or young volunteers. Some studies looked at older adults in a laboratory setting, doing a prescribed set of falls. In fact, real world falls have been shown to be much more difficult to detect than laboratory falls—if you imagine a person falling in the real world, often he or she grasps onto something, trying to stabilize themselves, which makes the fall much more difficult to detect. Why are there so few real world studies? Because they are much more difficult to implement and gather quick data from, you have to give a person a device and then hope that they fall at some point in time.

Mr. Chaudhuri's research also evaluated user feedback. Many people did find that the devices gave them a greater sense of security and enabled them to remain at home. Others found the devices very annoying, with false alarms being a problem. To gain greater clarity, he convened focus groups in the Seattle area, to gauge participants' experiences with falls and fall detection devices. Many people reported an unpleasant feeling of dependence when they used these devices. To some, the devices came with a stigma about looking old. A desired feature was automatic fall detection, in case someone lost consciousness following a fall. Someone suggested monitoring when people get off balance using technology that would beep to say, "Please regain your balance." This all led to suggestions of customization, like adding a GPS device to the monitor of an Alzheimer's patient who wanders. Cost was another concern; many, regardless of socioeconomic level, thought the devices were very expensive.

He closed by describing the pilot study he is conducting, featuring real-world testing of a particular device. It has the ability to detect automatically when a person has fallen, has GPS capabilities and can be worn as a lanyard or a belt clip. These studies are being conducted at three communities, and for the purpose of this study they have the device calling the front desk of their housing communities, which are staffed 24/7. Participants are wearing the device for four months, with interviews at baseline, two months and four months. Mr. Chaudhuri also has an online interface, letting him keep track of conditions and activities in subjects' homes. The overall conclusion of his research to date is that this technology is improving but more work needs to be done to document effectiveness. There should also be efforts to encourage people to use the devices. The overarching goal is to find a foolproof way to prevent and monitor falls.

Board member Eric Dishman mentioned the growing number of demented aging individuals. Of course, one of the principles of geriatrics is to optimize independence, preferably in the home, even for those in a demented state, ensuring that there is adequate caregiving process for them in a safe environment. Remote monitoring and response mechanism like this is very challenging simply because the patient can't trigger it and it has to be an automated process. Perhaps another pilot study could look at the impact on this kind of monitoring and this kind of response mechanism on the caregiver.

Ex-officio member Dr. Joseph Francis of the Veterans Health Administration said he's been interested in this topic for over 20 years. The VHA has a 300-household cohort of about five years of data collected about actual falls that I think we could help you with from the Oregon Center for Aging and Technology. We had the same problem in the early studies a decade ago when we were trying to do this and we were struggling with compliance because the devices were ugly, larger and creating more false positives. But what you are getting at is something that we have seen for 20 years where across the whole class of assistive devices were two problems: (1) people don't get a device until they're in an emergency situation and they don't want to be perceived as old; and (2) once they do need one, it is the stigma that their own perception of their abilities and everything now is overestimated. Do you have thoughts or strategies where you can overcome these challenges?

Changing the perception of the devices is key, said Mr. Chaudhuri—call them balance builders instead of fall detection technology. Also, involve the users in the technology in some way—sending data back to them would be easy to do but it would need to be done in a meaningful way, perhaps helping them to change the way they live their life or to show them, with other users' data, that they're not the only ones challenged by falls.

A Board member asked about sports devices like the FitBit, targeted at athletes and fitness people. Might these take the stigma off, moving the focus from high-performance activity to preventing falls? Mr. Chaudhuri said that one of their study participants suggested that hikers might need to wear fall detection devices with GPS, in case they lose their footing. Something like that could be greatly helpful in removing the stigma some feel with fall detectors.

IX. EXTRAMURAL PROGRAMS REPORT

Dr. MacKay introduced Dr. Valerie Florance, to give the Extramural Programs report. She began her review of FY2014, which technically ends September 30. She started by saying how proud NLM is of its grantees and trainees. She then displayed a chart of the success rates of those applying for funding. “Awards Made” is the numerator and the “Number of Applications Received” is the denominator. Trying to preserve the success rate, given the financial climate of the past few years, has been challenging. NLM has done a good job keeping up with the rest of NIH and did a little bit better this year than we did last year.

Not every type of grant has the same success rate. We protect, to the extent that we can, the success rate for research project grants and we’ve fared pretty well, saving those—the research grants and the career transition awards for informatics trainees who are just launching their careers. Some programs like the Resource Project Grants to help reduce health disparities are offered every other year.

In FY2014, the amount we had to spend was \$42,317,138, a 2.75% increase over last year. We made 126 awards, 39 of them new and 87 of them continuing. Last year, 83% of our budget was in the Continuing Grants; this year, it is only 68%, because some ended. She showed a chart with new grants that were awarded, the general subject Clinical, health care-related informatics is the area that NLM funds most heavily, but we have a good spread of topics including public health, bioinformatics and translation.. NLM also supports special scholarly works, related to the history of medicine and science. There are some very exciting new directions—mass casualty research and protection of health care data in the cloud for example.

In the area of Bioinformatics and Translation, we are funding more complex biological modeling We also made New Career Awards, and these cover the landscape of different areas. Dr. Florance then discussed NLM’s Informationist supplement. A couple of years ago , the Library started a program of giving competitive supplements to research grants from other Institutes to put librarians into the research teams to help them organize and manage their research data and information.. With some co-funding from other Institutes, NLM awarded eight of them in the first round and 10 more this year. We are encouraged that other Institutes like this idea and that it gives librarians an opportunity to contribute to research data management.

Dr. Florance reminded the Board that NLM also manages a couple of NIH Common Fund grants, including a Pioneer Award. When we see such grants addressing informatics, we try to have them managed by us so we can fold them into our community.

Dr. Florance then shared a list of NLM’s top 10 grant getting institutions. The Library did 126 new awards this year but active grants in total that have NLM’s name on them consist of 157 projects that are currently active. She also presented data on publications and citations emanating from NLM grants.

Dr. Florance concluded her report by saying she was happy to report that NLM was doing better than it did last year, in terms of the number of grants and dollars it was able to award. Dr. MacKay then announced the start of the closed session.

X. REPORT FROM THE NIH DEPUTY DIRECTOR

Dr. Lawrence A. Tabak, DDS, PhD, NIH Principal Deputy Director, discussed NIH efforts to enhance the reproducibility of research results. He told Board members NIH will need their help, not just as Board members, but as members of their home institutions and as individuals who might serve as reviewers or editors.

He said one of the challenges to ensure rigor and transparency in reporting science is that science is often viewed as “self-correcting.” While there’s some truth to that over the long term, he noted, the checks and balances for reproducibility in the short- and medium-term are hobbled by some interrelated factors. Those factors compromise the ability to reproduce findings, particularly in preclinical research studies involving animal models of disease. One of the most significant challenges is poor experimental design. Dr. Tabak said the underlying issues are: poor training; poor evaluation; difficulty in publishing negative findings; and perverse reward incentives. He said NIH is addressing them by: raising community awareness; enhancing training; adopting more systematic review processes and increasing stability for investigators to ameliorate some of the hyper-competitiveness. NIH has had meetings with stakeholders including a June 2014 workshop with journal editors. Attendees agreed on a set of principles and guidelines that journals can adopt to improve transparency and reproducibility of published work. The guidelines are being reviewed by journal boards for final approval. Dr. Tabak noted that NIH purposely focused on pre-clinical research, and left out clinical journals which he said are a bit ahead in their thinking on this. NIH also is developing training materials on experimental design and a number of pilot projects are being implemented.

Dr. Tabak noted NLM has contributed tremendously to ensuring reproducibility and rigor in science. NLM began indexing published retractions, errata and comments back in the 1980s. He also noted PubMed Commons, which allows researchers to share scholarly opinion on publications indexed in PubMed. He said he thinks it has tremendous promise.

In discussion following the presentation, Dr. Sternberg commented that people who design pre-clinical studies think about things very differently than clinicians, so there’s a divide. Dr. Tabak agreed and said that’s the sort of thing the training modules will address.

XI. ADAPTING OSIRIS FOR CLINICAL APPLICATIONS

Dr. Stephen Sherry of NLM’s National Center for Biotechnology Information, and Dr. Roger Kurlander of NIH’s Clinical Center, discussed new clinical applications for an NCBI software tool that was originally developed for forensic identification.

After the 9/11 attack on the World Trade Center, NLM collaborated with the National Institute of Justice (a research branch of the Justice Department) to create a framework for identifying the remains of victims. There was a need for a freely-available software tool that would automate the review of DNA profiles, which was a time-consuming task being done manually. The resulting software, called the Open Source Independent Review and Interpretation System (OSIRIS), computationally assesses the quality of DNA profile data and returns a report noting the profile components that don’t meet quality standards. Dr. Sherry said that in the 11 years since OSIRIS

was developed, it has become useful in a number of applications. For example, the FBI tested it and accepted it for case work in all federal labs in the US, and it was used by the Hurricane Katrina Victim Identification Response team.

OSIRIS also is being used in clinical applications where DNA profiles are regularly reviewed as part of patient care. Bone marrow transplants require that kind of monitoring to determine that the patient's original immune system is completely suppressed and does not compete with newly transplanted cells. OSIRIS has proved extremely sensitive to monitoring patients' white blood cell DNA profiles so that any changes can be reliably detected and treatment begun to prevent life-threatening complications in the transplant procedure.

Dr. Kurlander, who runs the NIH Clinical Center molecular hematology lab, explained how his team is using OSIRIS to monitor patients after allogeneic hematopoietic stem cell transplantation (HSTC). HSTC is the transfer of immature cells from the bone marrow or blood of a donor into another individual. It's used to treat several conditions including aplastic anemia and sickle cell anemia; and certain types of cancer such as leukemia, pre-leukemia, and malignant lymphomas. Dr. Kurlander and the OSIRIS team have been using OSIRIS for chimerism monitoring, which means measuring the percent of donor cells within various tissue pools at various times after the transplant. He said the analytic innovations that were engineered into OSIRIS to improve forensic identification are equally important in measuring chimerism. He showed a few examples of OSIRIS analysis; noted several advantages of the software; and said it has simplified workflow.

In questions after the presentation, Dr. Greenes asked if this was going to be offered as a service to the community. Dr. George Riley of NCBI responded that the OSIRIS team is reaching out to a large number of transplant programs in the US.

XII. ACCESS TO LITERATURE FOR THE PUBLIC HEALTH WORKFORCE

Ms. Lisa Lang and Dr. Elaine Martin presented on access to literature for the public health workforce. Ms. Lang is Head of the National Information Center on Health Services Research and Healthcare Technology. Dr. Martin is Director of Library Services at the Lamar Soutter Library at the University of Massachusetts Medical School, and Director of the New England Region (NER) of the National Network of Libraries of Medicine.

Access to quality and timely research literature has long been identified as a challenge for public health. Many public health workers have limited or no access to full-text literature. At the same time, there is an increasing emphasis on evidence-based information in order to influence practice.

In 2010, the NER began a multiyear project to improve information access for public health departments through identification and delivery of 'core' public health literature. In 2011, NICHSR joined the project, in support of its goal of helping promote evidence-based public health practice. The Public Health Information Access Project (PHIA) started in six New England States and Colorado and has since expanded to 18 sites in 17 states. Dr. Martin said its goals are to identify knowledge resources that are core, useful and evidence-based to improve

public health practice; promote seamless access to and reinforce understanding of usefulness of PubMed, e-books, other databases, resources from national agencies; integrate technology and human systems to support PH access to knowledge resources; and identify cost-effective and sustainable models for providing PH information access on ongoing basis.

Dr. Martin explained the basic model. The NER works with participating public health departments to develop digital libraries, available on an intranet, that enable states to provide access to a set of commonly-licensed e-resources that NER makes available through special pricing. Any article from literature not on the list of “core” e-resources can be accessed through the inter-library loan arrangements of the NN/LM.

Currently, 160 core journals are licensed through the PHIA, as well as four subscription literature databases that augment and complement PubMed: Cochrane Summaries, eCLIPSE, CAB-Direct and STAT!Ref. The digital libraries also highlight publicly-accessible resources from NLM, the Centers for Disease Control and Prevention and the National Agricultural Library. Dr. Martin showed examples of the digital library. She gave an overview of the licensing process, discussing how “enterprise licensing” of resources could potentially provide a cost savings to PHDs compared to paying per-retrieved item, while assuring a fair return to the publishers.

Dr. Martin also provided an overview of the importance of training, which is used to both explain the resources and to introduce concepts of evidence-based public health practice. To date, about 900 people serving in a variety of capacities in the participating public health departments have received training.

Dr. Martin briefly described the evaluation approach for the project and shared recent anecdotes from focus groups indicating how the project is being used to contribute to public health practice. Beginning in 2014, a statistician was added to the project team to help analyze utilization and cost data; in 2015, options will be identified for how to potentially extend the model into a national sustainable endeavor.

After the presentation, Dr. Henry Lewis called this a “fascinating project” and asked about the possibility of partnering with the CDC. Ms. Lang noted that the CDC has expressed interest in the project and will be one of those organizations consulted for how best to expand the project.

XIII. CIRCULATING NOW BLOG

Jeffrey S. Reznick, PhD, chief of the History of Medicine Division (HMD), and Ms. Beth Mullen, HMD’s manager of Web development and social media, presented on HMD’s relatively new blog, *Circulating Now*.

The blog offers a constantly updated collection of articles about the history of medicine based on NLM’s collections. Dr. Reznick said the blog was created to raise public awareness of and engagement with the collections, and the name was chosen to evoke the history and function of NLM. *Circulating Now* has published more than 350 posts and accumulated 230,000 followers since its launch in July 2013. Blog posts cover a wide range of topics and are written by staff, volunteers, interns, and researchers providing guest posts. Dr. Reznick said readers have

provided positive feedback. The blog is helping HMD build relationships with like-minded colleagues and institutions.

Ms. Mullen then gave an overview of the blog itself, which uses the WordPress platform. The design, like the title, was chosen to convey the vitality, currency and communicative qualities of NLM's historical collections. Comments are moderated by a member of the *Circulating Now* editorial board. No personally identifiable information is needed to read the blog or comment. Using a post about Florence Nightingale as an example, Ms. Mullen detailed the components of a post, explaining how articles usually include several images of digitized collection items as well as links to other resources that provide more information. Dr. Reznick then displayed the day's post about a rough film of FDR in October 1940 dedicating the National Cancer Institute and the National Institutes of Health. The post was timed to coincide with the PBS broadcast of the Ken Burns documentary, *The Roosevelts: An Intimate History*.

In discussion following the presentation, Board member Sandra Martin asked about reaching younger populations. Ms. Mullen said blog posts go out through NLM's Facebook and Twitter pages, and summer interns are asked to write posts that we hope will appeal to younger readers. Ms. Mullen said the blog is relatively new and the team is open to ideas. Dr. Sternberg congratulated team for taking the history of medicine into the 21st century.

XIV. ADJOURNMENT

Dr. MacKay adjourned the Board of Regents meeting at 12:00 p.m. on September 10, 2014.

ACTIONS TAKEN BY THE BOARD OF REGENTS:

- Approval of the May 13-14, 2014 Board Minutes
- Approval of the September 29-30, 2015 Future Meeting Dates
- Creation of Long Range Planning Panels

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

Trudy MacKay, Ph.D.
Chair, NLM Board of Regents