The 178th meeting of the Board of Regents (BOR) was convened on May 8, 2018, at 9:00 a.m. in the Donald A.B. Lindberg 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 4:00 p.m., followed by a closed session for consideration of grant applications until 4:30 p.m. On May 9, 2018, the meeting reopened from 9:00 a.m. to 10:00 a.m. and closed from 10:20 a.m. to 12:00 p.m. The meeting adjourned at 12:00 p.m.

MEMBERS PRESENT [Appendix A]
Dr. Alessandro Acquisti, Carnegie Mellon University
Ms. Jane Blumenthal, University of Michigan [participated by phone on May 9]
Dr. Eric Horvitz, Microsoft Research
Dr. Carlos Jaen, University of Texas Health Science Center at San Antonio
Ms. Sandra Martin, Wayne State University
Dr. Daniel Masys, University of Washington
Dr. Gary Puckrein, National Minority Quality Forum
Dr. Esther Sternberg, University of Arizona [Chair]
Dr. Jill Taylor, New York Department of Health [participated by phone on May 9]

MEMBER NOT PRESENT
Dr. Jill Taylor, Wadsworth Center, New York Department of Health

CONSULTANTS TO NLM PRESENT
Dr. Robert Greenes, Arizona State University

EX OFFICIO AND ALTERNATE MEMBERS PRESENT
VADM Jerome Adams, Office of the Surgeon General, PHS
Dr. Wayman Cheatham, United States Navy Bureau of Medicine and Surgery
Dr. James Deshler, National Science Foundation
Col. Kent DeZee, United States Army [In attendance on May 8]
Mr. Stan Kosecki, National Agricultural Library
Dr. Mary Mazanec, Library of Congress [In attendance on May 9]
Lt. Col. Thomas Mahoney, United States Air Force
Dr. Dale Smith, Uniformed Services University of the Health Sciences

SPEAKERS AND INVITED GUESTS PRESENT
Dr. Karina Davidson, Columbia University
Dr. Eliseo Perez-Stable, National Institute on Minority Health and Health Disparities, NIH
Dr. William Stead, (via teleconference) Vanderbilt University
MEMBERS OF THE PUBLIC PRESENT
Mr. Glen Campbell, BMJ Americas/FNLM
Dr. Lynne Holden, Mentoring in Medicine/FNLM
Dr. Barbara Redman, New York University/FNLM
Mr. Selby Bateman, Consultant and Note-Taker
Dr. Elliot Siegel, Consultant
Mr. Thomas West, Krasnow Institute

FEDERAL EMPLOYEES PRESENT
Dr. Patricia Flatley Brennan, Director, NLM
Mr. Jerry Sheehan, Deputy Director, NLM
Dr. Milton Corn, Deputy Director, Research and Education, NLM
LCDR Christine Renee Adams, Office of the Surgeon General, PHS
Ms. Mitzi Allen, Office of the Director, NLM
Ms. Anne Altemus, Office of Computer and Communications Systems, NLM
Dr. Sameer Antani, Lister Hill Center, NLM
Ms. Dianne Babski, Division of Library Operations, NLM
Ms. Joyce Backus, Division of Library Operations, NLM
Ms. Hua Florence Chang, Division of Specialized Information Services, NLM
Ms. Amber Channer, Office of the Surgeon General, PHS
Mr. Ivor D’Souza, Office of Computer and Communications Systems, NLM
Mr. Todd Danielson, Office of the Director, NLM
Dr. Kathel Dunn, Division of Library Operations, NLM
Dr. Valerie Florance, Division of Extramural Programs, NLM
Dr. Dan Gerendasy, Office of Health Information Program Development, NLM
Dr. Michael Huerta, Office of Health Information Program Development, NLM
Ms. Christine Ireland, Division of Extramural Programs, NLM
Ms. Janice Kelly, Division of Specialized Information Services, NLM
Ms. Elizabeth Kittrie, Office of Health Information Program Development, NLM
Ms. Michelle Krever, Division of Extramural Programs, NLM
Ms. Lisa Lang, Division of Library Operations, NLM
Dr. Robert Logan, Office of Communications and Public Liaison, NLM
Ms. Linda Lord, Office of the Director, NLM
Dr. Clement McDonald, Lister Hill Center, NLM
Ms. Christie Moffatt, Office of Library Operations, NLM
Mr. David Nash, Office of the Director, NLM
Dr. James Ostell, National Center for Biotechnology Information, NLM
Dr. Dina Palttoo, Office of the Director, NLM
Dr. Hua-Chuan Sim, Division of Extramural Programs, NLM
Dr. George Thoma, Lister Hill Center, NLM
Ms. Rebecca Warlow, Division of Library Operations, NLM
Dr. Fred Wood, Office of Health Information Program Development, NLM
Dr. Jane Ye, Division of Extramural Programs, NLM
I. OPENING REMARKS

NLM BoR Chair, Dr. Esther Sternberg, welcomed members, alternates, and guests to the 178th meeting of the Board of Regents. She called for a moment of silence for former BOR member Dr. Ken Walker who passed away recently. Dr. Sternberg said that former Board member Eric Dishman, director of NIH’s All of Us Research Program will be delivering the 2018 Joseph Leiter NLM/MLA Lecture following the Board meeting on Wednesday, May 9, 2018.

II. MINUTES AND FUTURE MEETINGS

The Regents approved without change the February 2018 minutes. The next meeting will be held on September 25-26, 2018, and the winter meeting on February 12-13, 2019. Also confirmed are May 14-15, and September 10-11, 2019, and February 4-5, and May 12-13, 2020.

III. REPORT FROM THE NLM DIRECTOR

Dr. Brennan pointed out upgrades to the Lindberg Room, including new wall coverings, a new projection system, and large plasma screens. She next discussed key accomplishments since February.

Implementation of the Strategic Plan, approved by the Board in February, has begun and public feedback about the plan has been enthusiastic. The medical informatics community is pleased about NLM’s new investment in data science, training, and enhanced resources. The plan is aligned with the traditional role of libraries: a data-driven future cannot be created without the foundational work of acquiring, curating, and providing in perpetuity for the storage of the important science and health content.

NLM will be a more responsive 21st century library. Access to toxicology resources will be enhanced via a partnership between the SIS and the NCBI. A new project, “MEDLINE 2022,” is underway, to ensure that NLM’s high-quality journals are acquired, indexed, and made accessible to the public quickly and efficiently. NLM will use automated indexing tools first and apply human-curated resources as needed.

The Library responded to the NIH HEAL (Helping to End Addiction Long-term) Initiative, which uses a community-driven approach to educate the public about all forms of substance abuse. EP Director Dr. Valerie Florance identified existing research grants that could be enhanced to discover potentially dangerous opioid patterns in electronic health records.

The Library expanded uses of deep learning and neural networks, improving image interpretation and efficient algorithm deployment. And, NIH and NLM are partnering to identify ways of moving data to commercial clouds for more efficient, cost-effective storage.

Brennan introduced a new video, “A Platform for Biomedical Discovery and Data-Powered Health,” produced by Lister Hill Center, which gives an inspirational vision of the Library’s future. Brennan emphasized that the most important aspect of the NLM is the trustability of our resources.

Brennan provided additional details on MEDLINE 2022, a project led by LO Director Joyce Backus and NCBI Director Dr. Jim Ostell. NLM indexes 1 million citations annually to keep pace with publishers. A citation is indexed within 24 hours, and automated indexing and human curation is applied to ensure efficient processing. NLM is working to expand metadata to optimize access to ClinicalTrials.gov and other trial registries. Comprehensive genetic metadata and improved chemical metadata are
priorities. NLM will increase NLM funding of metadata to support research portfolio analysis. For greater efficiency, NLM will form partnerships with publishers, making sure our vocabularies are robust (including MeSH terminology), and linking to datasets to support NLM and NIH data science goals.

The Director reported that through the National Network of Libraries of Medicine (NNLM), NLM played a key role in the launch of the NIH *All of Us* initiative in precision medicine. This program will recruit 1 million people in a partnership to advance health care through data-driven research.

Brennan gave an update on NLM’s Extramural Programs. With 2018 funding, EP saw its funding base increase by $5 million. This will fund more research grants, increase training for data science research careers, and fund more outreach to students at high schools and Historically Black Colleges and Universities. NLM has a new funding opportunity that will be available in about six weeks for digital curation at scale. The Library is investing in a core curriculum for biomedical data science. And, as of June 2018, NLM will have a 15 percent increase in the number of applications received for grants and fellowships. With its increased funding, the Library will be able to fund more of these applications.

Brennan reported on the plan to modernize and optimize NLM digital resources. Led by OCCS Director Ivor D’Souza, LHC Director Dr. Clem McDonald, NCBI Director Dr. Jim Ostell, and SIS Acting Director Florence Chang, this is a complex activity of looking at all NLM systems. Do we have the right level of IT services and are we in compliance with federal IT initiatives and standards?

Another initiative is looking at who uses NLM services. Last fall, 18F, a government digital services company that studies human use and computer interaction, did an evaluation of ClinicalTrials.gov. They found that more patients, clinicians, and caregivers were using this website than researchers. NLM also took a look at who is using PubMed Central and who uses NCBI’s sequence databases.

NLM is improving its space so that it’s more accessible and functional. More changes are coming.

Brennan provided a budget snapshot. In FY17, NLM finished the year with $406 million. In FY18, it has a base budget of over $428 million, a $22 million increase. The Director challenged her team to come up with creative and innovative ways to use these funds, including investing in deep learning, increasing training, and providing supplements for opioid risks. The President’s budget for FY19 takes the Library back to $395 million. Congress approves the final budget which is still in process.

Brennan announced personnel changes. LHC’s Dr. Dina Demner-Fushman was promoted and is now an investigator. Dina Paltoo has been named the new Interim Assistant Director for Policy. Troy Pfister is the Interim Operations Manager and Lee Mewshaw is Operations Support in the Office of the Director.

NLM can now hire for 48 new positions. Sixteen will be in OD, including an Assistant Director for Policy Development, Data Science and Open Science Librarians, an Open Science Officer, a Deputy Executive Office, a Budget Officer, an Engineer, an Ethics Specialist, and nine Contract Specialists.

Brennan asked NLM Deputy Director Jerry Sheehan and Dina Paltoo to present a legislative update. Sheehan said the report accompanying the 2018 appropriations bill contained two important items for NLM and NIH. The first commends NLM for its good work on increasing access to clinical trials information through the ClinicalTrials.gov website and results reporting. At the same time, there are concerns about the definition of a clinical trial, particularly as it relates to behavioral and social sciences research. The report asks NIH to consult with affected stakeholders in those areas. The other issue had to do with data science. A report on data science was to be submitted to the Congress this week. The NIH Data Council, which includes the NLM Director, issued a report for public comment a month ago. In line with NLM’s strategic plan, it detailed what it would take to bring a data science enterprise to the NIH.
Sheehan also mentioned a bill regarding the Federal Depository Libraries Modernization Act. This effort, in which NLM is a participant, will be a national collection of dissemination projects. Paltoo said that the European Union (EU) General Data Protection Regulation goes into effect on May 25. It was created to protect European citizens from privacy and data breaches. NLM seeks to better understand how this policy will affect future research collaborations in the US and in the EU.

Brennan noted that NLM will be partnering with the National Academies to do a study on modeling, to get better tools in place and better decisions about investments. This work can be paid for by FY18 funds.

Brennan reminded the group of its charge: they are a federally appointed body selected to guide the NLM and the HHS Secretary on aspects related to the BoR. Last fall, asked to reflect on the role and responsibilities of the Board of Regents, members submitted many interesting ideas. The group wants to maintain its membership structure -- 10 appointed and nine ex officio members -- and continue meeting three times a year. They requested new functions to increase Board engagement in key NLM issues earlier in the planning process. They asked to serve as ambassadors for the NLM goals. Lastly, members requested that NLM retain a narrative record of the meetings.

IV. RESTRUCTURING THE BOR

The Board said they would like to help in decision-making. Because the Board was instrumental in creating the Strategic Plan, they wanted a greater role in implementation. Dr. Sternberg suggested every member serve on a subgroup. The Board would determine if subgroups would be subcommittees or working groups, based on federal rules.

Dr. Sternberg asked Board members to select one subgroup. She thanked Jane Blumenthal, Dan Masys, Eric Horvitz, and Stan Kosecki for helping determine the categories: 1) Extramural Programs, which oversees grant programs. Valerie Florance is the NLM staff contact; 2) Strategic Plan Implementation. Mike Huerta is the staff contact; 3) Research Frontiers, which would provide thematic guidance for intramural and extramural research. Milt Corn is the staff contact; 4) Public Services, which would monitor the quality, integrity, and appropriateness of public services. Ivor D’Souza is the staff contact; and 5) Literature and Collections, which would operationalize board authority for collections management. The staff contact is Joyce Backus.

Members discussed the structure and time of meetings. It was proposed that subgroups meet at every Board meeting and if needed, in between. There will be 2-2.5 hours for them to meet. Every member would participate in one group. All groups would report to the entire Board at each meeting. Board members discussed options for future meetings: one-day; two-day, late start; and the current two-day. Members voted to keep the current two-day schedule.

Dr. Sternberg opened the meeting for discussion. Bob Greenes asked if the outreach subgroup was under the umbrella of the Strategic Plan Implementation. He said Board members could help develop partnerships with outside groups. Dr. Sternberg agreed. Dr. Brennan said that NLM defines outreach as increasing access to its products and services. Although that connotes a human-to-human interaction, increasingly outreach efforts are through the web. She asked members to think broadly about public services recognizing that the strategic plan speaks to outreach as does collection management and extramural programs. She suggested as broad a definition as possible. Dr. Greenes agreed and asked how NLM engages with other
partners in areas such as standards adoption and how NLM would leverage itself, within NIH and the broader community. Many members belong to groups that could add dimension to NLM. He asked if the Board should create a separate subcommittee or incorporate it into the groups.

Dr. Sternberg said outreach seems to cut across all the categories. Dr. Horvitz supported outreach being discussed in all the groups if addressed properly. Dr. Puckrein said NLM needs to engage in outreach by transferring information about its services to the public. Dr. Brennan said NLM makes tools available to the public to better access resources, holds hackathons to engage the public, and builds better data management systems. Dr. Ostell said NLM has applications packaged for redistribution, services that people use through APIs, and that with the advent of commercial clouds, NLM is repackaging some internal pipelines and holding hackathons. NLM is partnering with sequencer manufacturers who want to use the Library’s analysis pipeline at the end of their product cycle. Dr. Masys said that the planning panels recommended that NLM, because of its institutional prestige and natural technical competence, serve as a convener of things that don’t currently exist. He said whether outreach is discussed across subcommittees or on its own, the idea of NLM convening others to create something that does not yet exist ought to be included. Dr. Deshler said that the NSF just released its strategic plan and one of its priorities is building partnerships. He is on a working group trying to increase them by 5% by 2019, relative to 2017. Lt. Col. Mahoney said they primarily formalize interagency partnerships via memoranda of understanding (MOUs). Col. DeZee said they work with Air Force and Navy colleagues to develop training for new health care delivery systems, and, there will be more partnerships with the VA for services they do not have. They also have educational partnerships. Dr. Dale Smith said that the military has more partnerships in research than in clinical care and many of those require MOUs. The challenge with partnerships is ensuring that appropriate rules are followed. Dr. Sternberg said because there are so many types of partnerships, outreach needs to be a separate mandate that should be considered within each group. Dr. Jaen agreed that it is a crosscutting issue. Dr. Greenes said it would be important to give partnerships careful consideration. Dr. Sternberg noted that everyone agreed that within each of the working groups, we should review existing partnerships, their purposes, and their effectiveness.

Dr. Brennan asked the Board to consider NLM’s role with industry. Industry partnerships are important when sharing research investments. There are things that industry does that NLM should not do and vice versa. Dr. Sternberg asked about a separate category for industry. Dr. Brennan did not see a need for a separate group for industry as it is a crosscutting issue.

Ms. Blumenthal said we have a good set of subgroups. As the process moves forward, they will determine whether additional groups or fewer groups are needed.

Dr. Sternberg asked that the Board receive more feedback about issues. Dr. Brennan will work with the chair to identify issues that need addressing. Dr. Masys recommended that the structure be agile, so when an issue needs to be addressed, the working group could meet. He suggested laying out the framework for the working groups.

Dr. Smith suggested that the strategic plan implementation group be a working group because it requires input from consultants. Others agreed. Dr. Sternberg said it is harder to establish a subcommittee and harder to disband it. Dr. Masys said subcommittees have more FACA
entanglements. Dr. Sternberg said it might be best to start as working groups.

The Board of Regents also discussed the importance of consultants for the strategic plan. They discussed having one person from the Board and one person from staff represented in each subgroup. In addition, they talked about how subgroups could provide a way for the Board to achieve a greater role in providing help with decision making and guidance.

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

US Surgeon General Jerome Adams highlighted his interest in health and economic prosperity. His office would be releasing a report examining existing data and suggesting solutions. He said seven out of 10 young people in the nation aren’t qualified for military service because they can’t pass the physical or meet the educational requirements, or are incarcerated. He hoped to work with the DoD to address these medical challenges.

VADM Adams noted the connections between infant mortality, smoking, and cardiovascular disease, where there is much room for improvement and education. He shared the theme of his tenure at the Office of the Surgeon General (OSG), “Better health through better partnerships.”

VADM Adams described the scope of the opioid epidemic, termed “a crisis” because of the dramatic loss of life. He said 2.1 million people in the US struggle with an opioid use disorder; every 12.5 minutes somebody is dying from an opioid overdose; 77 percent of opioid overdose deaths occur outside of a medical setting; 56 percent occur in a home setting; this is more than half of all cases and usually 911 can’t help; 21 percent occur in another non-medical setting; and 23 percent in a medical setting.

VADM Adams discussed his Surgeon General’s Advisory on Naloxone and Opioid Overdose, released April 5, 2018. The report urges more Americans to have and know how to use the narcotic blocker Naloxone. Naloxone is at most pharmacies and is a covered insurance benefit. The impact of the Surgeon General’s Advisory has been dramatic: 2,139 news articles made more than three quarters of a billion impressions, and data furnished by industry indicates a 25 percent increase in the number of retail-dispensed prescriptions for Naloxone. Naloxone is an important part in the battle against the opioid crisis. It’s essential to disrupt the addiction, turn off the opioid supply spigot, and improve public health efforts to prevent addiction before it begins.

VADM Adams urged BoR members to help by spreading the word, helping to educate the public, and encouraging clinicians, pharmacists, and other health professionals to learn more about the opioid crisis and get around any stigmas attached to its victims.

In closing, the Surgeon General discussed upcoming deliverables, including the addition of a section, Spotlight on Opioids, to augment his predecessor Vivek Murthy’s Status Report: Facing Addiction in America. VADM Adams will also issue Surgeon General’s Prescription for America, with a “CliffsNotes” postcard covering the basics of opioid addiction, much like the one on HIV mailed nationally by former Surgeon General C. Everett Koop in the 1980s. VADM Adams will also issue Surgeon General’s Perspective on Improving Access to Opioid Treatment.
A couple of questions centered on cuts to the Medicaid program for addiction treatment. The Surgeon General said that this Administration likes the states to determine their own funding needs and then make the case for federal dollars. He also said that healthy people can create prosperity for themselves and their communities, which can be driver of good health.

VI. PRESENTATION OF AWARDS AND CERTIFICATES

Dr. Brennan presented awards to several staff members. HMD’s Christie Moffat received the Frank B. Rogers Award, that recognizes employees who have made significant contributions to the Library’s fundamental operational programs and services. She was recognized for significant contributions and leadership in web collecting and archiving, resulting in an important new program at NLM. EO’s Linda Lord received the NLM Director’s Award for her skilled and sustained, excellent performance in the daily administration of NLM’s ethics program.

In addition, an NLM/NIH Center for Information Technology (CIT) Special Recognition Award was given to: NLM/NCBI Staff: Igor Lozitskiy, Stephen Sherry, Eugene Yaschenko, Georgy Godynskiy (contractor), Carl Leubsdorf (contractor), Thomas Murphy (contractor); CIT Staff: Jeffrey Erickson, Sravan Chintaluri (contractor), Sumit Nando (contractor), Gregory Posteraro (contractor), Satya Vipparty (contractor); and OD/OER/eRA Staff: Dmitriy Kokiyelov (contractor). It was presented in recognition of foundational efforts unifying NCBI and Era identity data under the CIT Virtual Directory Service.

Dr. Brennan presented certificates of appreciation and writings of John Shaw Billings to outgoing Board chair Dr. Esther Sternberg and outgoing board member Sandra Martin. Dr. Brennan also presented Dr Sternberg with a commemorative gavel for her service as chair.

VII. REPORT FROM THE NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES

Dr. Eliseo J. Pérez-Stable, Director of the National Institute on Minority Health and Health Disparities (NIMHD) gave an overview of the history of NIMHD. reporting that NIMDH is the newest NIH Institute. It began as an Office under the NIH Director through HHS Secretary Louis W. Sullivan LM.D. in 1990, and transitioned to a Center by legislation offered by Rep. Louis Stokes in 2000. It became an Institute in 2010.

NIMHD has a dual mission – to lead scientific research to improve minority health and reduce health disparities.

Dr. Pérez-Stable said that minority health focuses on health determinants that lead to specific outcomes within a minority group and, in comparison, to others. Race and ethnic minorities share a social disadvantage and/or are subject to discrimination as a common theme. Ethnic classifications, according to OMB, include African American or Black, Asian, American Indian and Alaska Native, Native Hawaiian and other Pacific Islander, Latino or Hispanic, and White.
Mechanisms leading to health disparities include individual behaviors and social determinants, biological processes and genetics, physical and cultural environment, and clinical events and health care.

NIMHD has been reorganized into three functional divisions of research: Integrative Biological and Behavioral Science; Community Health and Population Science; and Clinical and Health Services Research.

Dr. Pérez-Stable said that future directions of research will require multi-level interventions to address health disparities and improve minority health. NIMHD needs to identify mechanisms that lead to disparities: biological pathways, social determinants, behavior, system, assess specific communication strategies between patients-clinicians to maximize trust, and implement structural change to modify behavior.

NIMHD research funding opportunity announcements in FY 2018 included immigrant populations, disparities in surgical care and outcomes, social epigenomics, Caribbean initiatives, sleep disparities, liver cancer and chronic liver disease, opioid use disorders, simulation modeling and systems science, lung cancer etiology, and health information technologies.

Pérez-Stable said that inclusion of diverse participants in research is critical. They are historically underrepresented in research. Inclusion of minorities in clinical studies is an important domain of science. In NIH clinical studies, only 28% are minorities. The All of Us initiative intends to recruit 50% minorities.

Achieving diversity in the biomedical workforce is critical to the full realization of NIMHD’s national research goals. NIMHD offers career development awards, diversity supplements and individual fellowship grants, and it funds about 10 percent of all loan repayment programs. He said that the NIMHD will sponsor a 2018 Health Disparities Research Institute in July – a one-week interactive, intensive course on the NIH campus covering emerging research addressing minority health and health disparities.

Dr. Pérez-Stable said he recruited a Scientific Director, Anna Maria Napoles, PhD, in November 2017 and she is busy building their Intramural Research portfolio.

Dr. Pérez-Stable said the following big data science factors are needed to improve minority health and reduce health disparities: the addition of social determinants information in EHRs; the improvement of public health surveillance; understanding of etiology to guide interventions to reduce disparities leveraging big data.

Dr. Dan Masys asked Dr. Pérez-Stable where he thought the Library could be catalytic in accelerating progress at the NIMHD. Dr. Pérez-Stable said that the data science workforce issue is a big one. There is little diversity in both the industry and academic side of the data science workforce. We need to promote the training and diversity of the workforce.

Dr. Valerie Florance said NLM expects to reach out to make connections with HBCUs and diversity-serving institutions for faculty to work together with our training faculty to start to
build collaboration and curriculum sharing. Summer programs for high school students and early college students have been set up with an emphasis on this community. We know our programs try to recruit a more diverse population in training.

Dr. Pérez-Stable said that the resource centers for minority institutions, the RCMI, would be good template to apply this to -- not just HBCU’s. NIMHD is in the process of renewing those grants, but the current institutions would be terrific receptor sites for partnerships. A lot of the data science here is about genomics and phenotypes and the big biological data. There is less skill development in mining health science data and electronic health records? How do we get at this large set of health data? Leveraging big data with current statistical analytical tools can provide answers to most of clinical questions. But people with the skill set to do it are needed.

Dr. Pérez-Stable said that the National Academy of Medicine report was heavily influenced by psychologists and has more questions on depression and anxiety. It is a good document to start with. He said he is referring not just to the demographic social determinants. Socioeconomic determinants are extremely important -- they predict mortality in a very robust way. Clinicians do not take that into account most of the time. If you are poor in the US, you are three times more likely to die from anything than if your household makes more than $115,000 a year. We think of blood pressure, cholesterol. Yet this is more powerful than either of those. Food and housing security is important. Gender identity, and sexual orientation is important. Culture and national origin is important.

VIII. PLANNING AND NEXT STEPS FOR THE BOR

At the suggestion of Jane Blumenthal and Eric Horvitz, Esther Sternberg announced that Board members would separate into the following subgroups for discussion: strategic planning, research frontiers, collections management, and public services.

Board members self-selected which group they’d like to join and met for about 15 minutes. A group for extramural programs did not meet because the group was already established.

Board members divided into subgroups as follows: Strategic Planning: Ms. Jane Blumenthal, Ms. Sandra Martin, and Dr. Dan Masys, Dr. Michael Huerta (staff); Research Frontiers: Dr. Eric Horvitz, Dr. James Deshler, Dr. Robert Greenes, Dr. Milton Corn (staff); Collections: Dr. Carlos Roberto Jaén, Dr. Dale Smith, Lt. Col. Mahoney, Ms. Joyce Backus, Dr. Dina Paltoo, Rebecca Goodwin, Esq. (staff); Public Service: Dr. Alessandro Acquisti, Dr. Gary Puckrein, Col. Kent DeZee, Mr. Stan Kosecki, Mr. Jerry Sheehan (staff). Esther Sternberg, Board Chair, rotated between subgroups.

Reporting for the strategic planning subgroup, Dan Masys said that that the group was actually a strategic plan implementation group as the implementing was already underway. Software will be tracking progress.

Reporting for the research frontiers subgroup, Eric Horvitz said that they may be interested in input into the extramural research process, the flow of ideas between NLM and NIH, internal communication, collaborations, and portfolio concepts.
Reporting for public services, Stan Kosecki talked about increasing NLM’s impact and balancing outcomes, economics, and societal forces. Esther Sternberg also mentioned the importance of strengthening the bonds between the Surgeon General and NLM.

Reporting for collections management, Dale Smith said that the subgroup would actually be concentrating on literature and collections management and looking at modifications to the policies on collection because of budgetary constraints.

The Board then discussed the pros and cons of these subgroups being subcommittees or working groups and they concluded that working groups would better serve NLM at this time.

At the end of the session, the Board talked about changing the meeting structure but after considering a single day meeting or a day and a half meeting, they voted in favor of maintaining the two-day meeting structure.

IX. RE-ENGINEERING PRECISION THERAPEUTICS THROUGH N-OF-1 TRIALS

Karina W Davidson, PhD, MASc, said that the grant she is talking about really took a village of people with different health professional backgrounds. She said that in conventional clinical practice, clinicians use ‘trial and error’ medicine to identify the best treatments for individuals.

Dr. Davidson discussed the heterogeneity of treatment effect associated with positive randomized controlled trials. The majority of patients have some benefit from the trial treatment, a smaller portion have a neutral response. And, a small percentage are harmed by the treatment.

Personalized trials customize medical decisions according to the unique properties and response of the individual. Essentially, it is a single patient, often randomized trial. The information from the patient will be the best predictor of a positive response. A personalized trial has balanced or randomized trial periods from which you get repeated outcome measurements to which you apply a statistical analysis. This leads to feedback for decision-making.

Davidson presented a case study of a 62-year-old male with new onset hypertension. There was concern about treatment side effects and a desire to be on the least amount of medication to control his blood pressure. To determine which drug would be best, he was put through a randomized trial during which he got three active medications. A medication was found.

N-of-1 personalized trials, said Davidson, started in psychology in the 1880s. It was popularized by Dr. Gordon Guyatt in 1986. It is amazing that the evidence-based pyramid that was published in that 1986 article had N of 1 randomized trials at the top of the evidence-based pyramid.

Davidson did market research engaging 54 patients with 2+ conditions in focus groups with 24 primary care providers. She ran two national polls with 500 patients with 2+ conditions and 250 patients conjoint analysis. The key questions asked were: **What are the perceived benefits and barriers to personalized trials?** Which conditions, diseases, symptoms and/or treatments are
amenable to personalized trials? What design decisions must be made to increase the acceptability and sustainability of personalized trials?

Concerns about personalized trials included the time burden, the need for continuous monitoring, the potential for negative health outcomes, disruption of clinical management, concern about being experimented on, that the results will not generalize to the population, and the cost.

The deliverables from this transformative RO1 include pilot studies for three conditions that clinicians agreed would benefit from personalized trials: blood pressure, insomnia, and fatigue.

Davidson said the long-term vision is for a clinician, with a patient, to choose a symptom or problem that patient is having, like fatigue or blood pressure. The clinician then orders the randomization, the order of treatments, and a kit is mailed to measure whatever needs to be measured. The patient goes through the testing, statistical analysis is performed, followed by feedback. The clinician sees the patient to decide the patient’s preferred treatment.

Davidson hopes to build a deep data phenotyping archive. Patients need to be randomized and exposed to multiple treatments. Data must be collected objectively, continuously, and for a sufficient time period to determine whether the therapy, compared to a placebo or other active therapy, is optimal for a particular patient. A patient-facing website has been developed so patients can find out what personalized trials are, clinicians can find out how to order this for their patients, and researchers can find out how to help build up their database.

Both Dr. Jaen and Ms. Martin expressed an interest in the patient-facing website, noting that the website explains personalized trials to the patient in plain language.

Davidson said that the website should be added to an EHR. Jaen added that in the context of personalizing, is there a way to integrate N-of-1 studies? Davidson said they envision something like a data repository. Jaen suggested that they do not limit their work to only biometrics.

Dr. Masys said that if the patient is included in the data collection process, their confidence will increase. He asked Davidson if she was measuring their level of satisfaction? Davidson said they are trying to collect information about whether the data informed their decision. Col. DeZee said the Army is really interested in sleep. But soldiers don’t want anything in their medical record. Is this a problem? Davidson said this privacy of data did not come up for them. She said this is going to be primarily for treatment-seeking patients.

Dr. Greenes asked if there were instances where one could develop a tolerance for the drug? Davidson said she is certain that they are going to run into those problems.

Dr. Brennan asked Davidson how you convey risk to someone in this kind of study? And, to what extent do our formal vocabularies help to characterize the end points traced? How do we encourage our own investigators to use the vocabulary tools that NLM is building?
X. EXTRAMURAL PROGRAMS REPORT

EP Director Dr. Valerie Florance discussed individual Fellowship and Career Transition grant programs NLM has supported from 1990 to 2017, highlighting some traditional indicators of successful outcomes, summarizing the current program state and costs as compared to university-based training, and providing insights about evaluating the return on workforce investment.

The Library launched its Fellowship program in 1992. The first type was a F37 NLM Individual Fellowship in Informatics, which focused on applied informatics for health care workers to develop model information systems. Fellows received up to $50,000 annually plus $3,000 in tuition support. In 2003, we moved to National Research Service Award (NRSA) stipend and tuition levels. Thirty-nine awards before the program ended in 2005. The F38 NLM Senior Fellowship in Informatics also began in 1992 and ended in 2005. It was a program for experienced scientists and clinicians who wanted to change direction or broaden their background, and who were at least 10 years post-doctorate. NLM made 41 awards.

From 2014 to present, the Library has offered NLM NRSA Predoctoral Fellowships, F30 and F31. They can support someone for up to five years at $23,844, plus tuition and fees and a $4,200 institutional allowance. To date, six awards have been made.

The K22 NLM Early Career Development Award for Informatics was started in 2004 by former EP Director and current NLM Deputy Director for Research and Education Dr. Milton Corn. Other Institutes had career transition awards to help people move into their first research position. People could apply for this award before they found their job and then NLM would give their institution the award. It provided a salary up to $85,000 plus benefits, and a $50,000 research fund. NLM made 27 awards in this program before it was suspended, to many who would become luminaries in the field.

Today, NIH and NLM give the K99-R00 NIH Pathway to Independence Award. The two components of this award offer recipients up to 5 years of funding (one or two years mentored K99, $50,000 plus benefits, and a $20,000 research fund) and 3 years independent R00 in a permanent position approved by NLM staff ($249 total costs per year for 75 percent time, including a research fund). NLM also launched a K01 Career Development Award in 2013, which provides support and protected time for up to 3 years for doctorate-prepared junior investigators in the first 3 years of their initial position (75 percent time, up to $100,000 salary, and a $50,000 research fund). The expectation is that awardee will apply for a R01 after this.

In sum, from 1990 to 2017, NLM has made 154 awards in its two Career Awards and two Fellowship programs. Have the programs proved successful? Two indicators of success are the number awardees’ publications and the awarding of additional NIH grants. Forty-two percent of those funded by NLM Career Awards or Fellowships have come back to get subsequent funding from NIH. Recipients have issued 642 publications, with the K22s winning the award for the most publications. Eighty-two percent of our individual Fellowships and 56 percent of the senior Fellowships published at least one article, with at least one citation of it. There have been 566
peer-reviewed publications from 68 career awardees, 89 percent of K22 awardees published, 93 percent of K99 awardees published, and 72 percent of K01 awardees published.

Currently, NLM is supporting predoctoral training for 100 predocs at 16 university-based programs and for six F30 and F31 predoctoral fellowships. There are 57 postdoctoral slots at NLM’s 16 university-based training programs. In the Career Transition Awards, there are eight K01 awardees, no K99s, and seven active R00s hired into a professional position.

Florance estimated that NLM’s has invested about $28 million in Fellowships and Careers Awards since 1990, and another $330 million in university-based training. About 30 percent of funding went to workforce investment, with the balance supporting research grants.

In evaluating workforce development, one must evaluate the success of the people—are they moving the field forward? And what does a successful career path look like? In biomedical informatics/data science, the path of awardees would include sequential milestones, evidence of advancing the science and practice of biomedical informatics/data science, and training or mentoring the next generation of researchers.

Given NLM’s commitment to and level of investment in workforce development, what form(s) of evaluation make the most sense? Should each workforce grant program be evaluated separately, independent of the others? When should career trajectory be a component? Dr. Masys said one way to evaluate would be to define a case representing a failed career trajectory. What you do need to do is keep people from wasting resources invested in their career. Dr. Brennan said that workforce development is a big portion of NLM’s scarce research dollars. She is concerned about grantees’ departures to industry; if they’re not choosing a professorial pathway, NLM needs to make sure that the training of the next generation still happens in their workplace. They may not be accelerating the research, but they could be going into a field where their informatics training is used, and NLM will have succeeded in helping grow the next generation of informaticians. But we don’t know that.

Dr. Sternberg said it is important to say that going to industry is not a failure. Brennan agreed. said that awardees can get good offers from industry and take them before graduating. Dr. Jaén said they may not be getting their PhD, but they are changing the way things are done. The National Science Foundation’s Dr. Deshler said that these programs are designed to promote career paths. He was asked how NSF does it. He said he had concerns as to whether the postdoc programs in his division were having an impact on awardee career paths. Using social media and other methods to track down past awardees, he and his colleagues found evidence supporting the idea that individual awardees of the targeted postdoctoral program were more likely to have a career in academia than postdocs funded off of larger research grants in a less targeted fashion.

Sternberg suggested that the Library needs a more comprehensive set of criteria for a successful career. Brennan said she is going to be asking the Board’s working groups to take on this issue. NLM is using federal dollars for health and should be able to show some health impact. Perhaps NLM doesn’t train librarians as much it needs to. The Library will need to expand the number of data scientists at the doctoral and post-doctoral level, as well as the technical level. How do we do that? She was optimistic that more funding would coming—in fact, it may double in the next
That would be $50 million for training—not a large sum for that purpose. Dr. Brennan will look to the Board for guidance in evaluating and maximizing its training programs.

[CLOSED PORTION]

XI. OPTIMIZE NIH

NLM Deputy Director Jerry Sheehan told the Board that Optimize NIH is a program to streamline administrative processes across NIH. Its leader is NIH Principal Deputy Director Dr. Lawrence Tabak. Since 2017, HHS has been working to meet the White House’s comprehensive government-wide reform plan with an initiative called RelImagine HHS. Through a range of proposals that span the Department, the program aims to improve the efficiency, quality, and cost-effectiveness of the work HHS does for the American people. In support of this effort, NIH launched Optimize NIH in December 2017 to improve NIH’s organizational effectiveness and performance in support of its mission through a thoughtful, data-driven approach.

Phase 1 of Optimize NIH focuses on the three enterprise-wide function areas that provide service to every NIH IC or Office: Committee Management, Ethics, and Freedom of Information Act (FOIA) services. One hundred and 13 volunteers from the NIH communities involved are participating in process mapping—breaking things down into steps and looking for any that can be eliminated. This work is well underway, and recommendations should be forthcoming. Phase 2 is gathering metrics and assessing workload distribution across NIH in areas of scientific review, grants, and program management to better manage resources. Phase 3, which begins in six to nine months, is a vision to harmonize select administrative functions across the NIH. The full Optimize NIH effort is expected to take place over two to three years.

Sheehan said that the NLM was in a comfortable position. NLM has been pretty good at figuring out how to argue for new positions in a variety of areas. He said that NLM is doing a lot of other work to streamline its own functions using recommendations in its strategic plan.

Dr. Mazanec asked what the measures of success would be. Sheehan said that the plan’s working groups would be asked to examine metrics to measure the improvements and efficiencies. There is not yet an established type of metric that NIH is looking for, but it expects groups to find ways to measure progress for improving efficiencies. NIH is not trying to address a perceived problem, but rather to streamline and improve administrative processes, leaving more funds for research.

Mazanec noted that the three administrative areas mentioned are essentially duplicating efforts across the Institutes. Will Optimize NIH address the administrative duplication of efforts by centralizing those functions? No, Sheehan said, the aim is to establish best practices and improve ways of carrying out administrative tasks. To improve NLM’s way of doing things, it may mean more coordination, or it may mean it would be better to centralize the function.

Dr. Puckrein asked if Optimize NIH harmonizes with the NLM strategic plan or is something separate. Sheehan replied that the two are separate motivations for improvements. NLM will try to make connections where it can with Optimize NIH, but strategic plan implementation will not be dominated by the Optimize NIH initiative.
Dr. Horvitz cautioned against false economies. Sometimes the tension between trying to make things efficient and saving money is not worth the trouble. When the focus is on finances, other areas tend to suffer. Sheehan said that, for better or worse, the streamlining of the science across NIH is not going to come out of the Optimize NIH effort.

Brennan said that Optimize NIH and Reimagine HHS are externally driven and internally embraced strategies. Reimagine HHS is the “parent” direction. As it’s practiced at NIH, it’s meant to improve the science by ensuring administrative efficiency. Our responsibility is to ensure that we improve the science. But the logistics side is focused on administrative efficiencies. Sheehan added that, within the programs’ rich set of objective functions, there is the notion of employee and job satisfaction—what will make your life easier by removing hurdles or streamlining your work?

Board consultant Dr. Greenes thought there might be a lot of core functions across the NIH, like data and sequencing cores, that could be shared. Sheehan said that those kinds of issues have not come up in the context of Optimize NIH.

Brennan said that the NLM walks a balance between serving NIH and serving society. One of the challenges accompanying the success and growth of NCBI resources is that the increasing onslaught of data has led to skyrocketing costs, the need for more servers and technological support, etc. That’s why the Library is moving its files into the cloud—where the ICs, not NLM, pay for storage. Another challenge is the fact that clinical trials require domain expertise that NLM does not have. The Library provides the methodological assistance infrastructure and the terminologies, but the quality of the trial itself it leaves to the clinical side.

Masys asked whether there were administrative processes at NIH that are just broken, and everyone knows that they are broken. Do we have any of those scenarios here? Brennan described the laborious, paper-laden process to get members of the Board appointed. So, there is a big issue of compliance at the wrong levels.

Dr. Sternberg said that NIH was quite good at addressing public health emergencies like the AIDS epidemic and the anthrax scare. Someone needs to look at the administrative issues.

Sheehan said that an open question in all this is, what is a proper degree of centralization versus distribution down to the ICs?” We could end up with the situation where there is no functionality that gets centralized. We want to coordinate our administrative processes more.

Board consultant Dr. Cheatham said that the 20th effort since 1947 is underway, to consolidate the three medical services. In each of these efforts, we have found that definitions in internal documents, buy you more problems in this kind of process. With the unique public face of NIH, words like “communication” can be loaded, with some thinking you’re referring to communication on this campus and some thinking of PubMed Central.

Discussion continued on questions of administration, organization, scientific research, and finding best practices. In this case, we are working to improve our ability to do science by improving our administrative efficiencies, said the NLM Director.
XII. REPORT FROM THE NOMINATING COMMITTEE FOR NEXT BOR CHAIR

Dr. Mary Mazanec reported that the nominating committee recommended Dr. Jill Taylor for the next Board of Regents Chair. The nomination was unanimously approved by the full Board.

[CLOSED PORTION]

XIII. ADJOURNMENT

Dr. Sternberg adjourned the Board of Regents meeting at 12:00 p.m. on May 9, 2018.

ACTIONS TAKEN BY THE BOARD OF REGENTS:
Approval of the February 13-14, 2018 Board Minutes
Approval of the May 12-13, 2020 Future Meeting Date
Nomination and Approval of New Board Chair

Appendix A - Roster - Board of Regents

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

Patricia Flatley Brennan, RN, PhD                  Esther M. Sternberg, M.D.
Director, National Library of Medicine            Chair, NLM Board of Regents