DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH (NIH)
NATIONAL LIBRARY OF MEDICINE (NLM)
MINUTES OF THE BOARD OF REGENTS MEETING
(VIRTUAL)
May 14, 2024

The 196th meeting of the Board of Regents (BOR) was convened virtually on May 14, 2024, at 10:00 a.m. The meeting was open to the public from 10:00 a.m. to 3:45 p.m., followed by a closed session that lasted until 4:15 p.m.

MEMBERS PRESENT (Appendix A)
Dr. James Cimino, University of Alabama at Birmingham Dr.
Dr. Kristi Holmes, Northwestern University [Chair]
Dr. Mitchell Katz, New York City Health + Hospitals
Ms. Jennie Lucca, The NIH Children's Inn
Dr. Omolola Ogunyemi, Charles R. Drew University of Medicine and Science
Dr. Nancy Smider, Epic Systems Corporation
Mr. Philip Walker, Vanderbilt University

CONSULTANTS PRESENT:
Dr. Christopher Forrest, University of Pennsylvania School of Medicine
Dr. Anne Kwitek, Medical College of Wisconsin
Dr. Maichou Lor, University of Wisconsin-Madison
Dr. Carmen Portillo, Yale University School of Nursing
Dr. Rasmus Nielsen, University of California, Berkeley
Mr. Christopher Shaffer, University of California, San Francisco

EX OFFICIO AND ALTERNATE MEMBERS PRESENT:
MGEN John Bartrum, United States Air Force
Dr. Michelle Elekonich, National Science Foundation
Dr. Susan Kirsh, Veterans Health Administration
Dr. Mary Mazanec, Library of Congress
Dr. Holly Meyer, Uniformed Services University of the Health Sciences
Dr. Niels Olson, United States Navy
Mr. Paul Wester, National Agricultural Library, U.S. Department of Agriculture

SPEAKERS AND INVITED GUESTS PRESENT:
Dr. Janine Clayton, Office of Research on Women's Health, NIH

MEMBERS OF THE PUBLIC PRESENT:
Mr. Glen Campbell, Friends of the NLM
Ms. Loretta Jurnak, Technical Resources International, Inc.
Dr. Barbara Redman, Friends of the NLM
Mr. Philip Spencer, Technical Resources International, Inc.

FEDERAL EMPLOYEES PRESENT:
Dr. Stephen Sherry, Acting Director, NLM
Dr. Michael Huerta, Acting Deputy Director for Operations and Innovation, NLM
Dr. Dina Paltoo, Acting Deputy Director for Policy and External Affairs, NLM
Ms. Dianne Babski, User Services and Collection Division, NLM
Mr. Todd Danielson, Office of the Director, NLM
Dr. Catherine Farrell, National Center for Biotechnology Information, NLM
Dr. Lisa Federer, Office of Strategic Initiatives, NLM
Dr. Anna Fine, National Center for Biotechnology Information, NLM
Ms. Kathryn Funk, National Center for Biotechnology Information, NLM
Ms. Jeane Garcia Davis, Office of the Assistant Secretary for Health, HHS
Mr. Ian Henderson, Division of Extramural Programs, NLM
Dr. Zoe Huang, Division of Extramural Programs, NLM
Ms. Christine Ireland, Division of Extramural Programs, NLM
Ms. Amy Keener, Division of Extramural Programs, NLM
Ms. Michelle Krever, Division of Extramural Programs, NLM
Dr. David Landsman, National Center for Biotechnology Information, NLM
Mr. Howard Lu, Lister Hill National Center for Biomedical Communications, NLM
Ms. Madeline Ludwig, Division of Extramural Programs, NLM
Ms. Wei Ma, Office of Computer and Communications Systems, NLM
Ms. Margaret McGhee, User Services and Collection Division, NLM
Mr. Patrick McLaughlin, User Services and Collection Division, NLM
Dr. Kaushiki Mazumdar, Division of Extramural Programs, NLM
Dr. Virginia Meyer, Lister Hill National Center for Biomedical Communications, NLM
Dr. Ilene Mizrachi, National Center for Biotechnology Information, NLM
Ms. Rebbecca Moen, Division of Extramural Programs, NLM
Mr. James Mork, Lister Hill National Center for Biomedical Communications, NLM
Ms. Jody Nurik, Office of Communications and Public Liaison, NLM
Dr. Richard Palmer, Division of Extramural Programs, NLM
Dr. Goutham Reddy, Division of Extramural Programs, NLM
Dr. Jeffrey Reznick, Office of the Director, NLM
Dr. Caitlin Ruppel, Office of the Surgeon General, U.S. Public Health Service
Ms. Leigh Samsel, Office of Strategic Initiatives, NLM
Dr. Richard Scheuermann, Office of the Director, NLM
Dr. Valerie Schneider, National Center for Biotechnology Information, NLM
Dr. Ali Sharma, Division of Extramural Programs, NLM
Dr. Cristan Smith, Division of Extramural Programs, NLM
Dr. Heidi Sofia, National Center for Biotechnology Information, NLM
Dr. Meryl Sufian, Division of Extramural Programs, NLM
Ms. Kimberly Thomas, Office of Strategic Initiatives, NLM
Dr. Tony Tse, National Center for Biotechnology Information, NLM
Ms. Amanda J. Wilson, User Services and Collection Division, NLM
Dr. Teresa Zayas Cabán, Office of the Director, NLM

I. CALL TO ORDER AND INTRODUCTORY REMARKS

Kristi Holmes, PhD, Chair, BOR

Dr. Kristi Holmes called the meeting to order, welcoming attendees to the meeting. The

meeting was broadcast to the public via streaming video at https://videocast.nih.gov/.

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

Jeane Garcia Davis, MSN/MPH, RN, Public Health Advisor, Office of the Assistant Secretary for Health and Caitlin Ruppel, MPH, Public Health Advisor, Office of the Surgeon General

Ms. Jeane Garcia Davis provided an update on the Office of the Surgeon General's (OSG) continuing efforts aimed at supporting workplace well-being, social connection, and youth mental health. Vice Admiral (VADM) Vivek Murthy continues to serve as Co-Chair on the National Academy of Medicine Clinical Well-Being Collaborative, engaging with health care workers and leadership around the country to address health care worker well-being and resilience. The OSG recently collaborated with the National Institute for Occupational Safety and Health (NIOSH) and the Centers for Disease Control and Prevention (CDC) on their impact campaign to support leadership across health care settings impacted by health care worker burnout and mental health challenges. Additionally, Ms. Davis highlighted recent work examining artificial intelligence (AI) in the health care setting, engaging with partners through seminars on workforce well-being—including with NIH and the Office of Personnel Management (OPM)—and the upcoming Surgeon General's report on addressing disparities around eliminating tobacco-related disease and death.

Regarding social connection and isolation, Ms. Garcia described existing measures and surveys. These include the Census Household Panel and Pulse surveys, which now contain questions on social support, loneliness, and isolation and the Behavior Risk Factor Surveillance System (BRFSS), which now has an optional state module on social support and subjective isolation, which 42 states are opting to use. Furthermore, San Mateo County, California, became the first county in the U.S. to recognize loneliness as a public health emergency through a unanimous vote by its Board of Supervisors.

Ms. Caitlin Ruppel provided an update on OSG's effort around social isolation and protecting youth mental health. She noted that OSG continues to prioritize youth mental health following the publication of the 2023 OSG Advisory on social connections and the 2021 OSG Advisory on protecting youth mental health. In 2022, one in five, or about 4.8 million, adolescents aged 12 to 17 had experienced a major depressive episode in the past year.

Ms. Ruppel mentioned that the OSG's work in this area includes tracking federal-, state-, tribal-, and local-level investments in school and community-based programs that address youth mental health. She also noted recent work on social and emotional learning, highlighting literature supporting this area as an effective strategy for addressing youth mental health and social connection in educational settings from Pre-Kindergarten (Pre-K) through Grade 12.

Ms. Ruppel provided an overview of federal investments in school-based mental health services, including social and emotional learning, and state policies supporting learning competencies in these areas in early childhood/Pre-K through Grade 12. She noted that last month, VADM Murthy visited Ross Elementary School, a District of Columbia Public School (DCPS), and met with leadership and students to better understand their experiences in implementing social and emotional learning programs at the school. DCPS is finalizing city-wide social and emotional learning standards for the K-12 curriculum that will be implemented in the next academic year,

along with biannual surveys to measure student belonging and mental health outcomes.

BOR members discussed OSG's efforts on workplace well-being and their impact on industries and academic institutions outside of the health care sector. They also deliberated on the impact on local communities of recognizing loneliness as a public health emergency. Additionally, members discussed the importance of including teachers and parents in social and emotional learning programs and surveys.

III. FEBRUARY 2024 MINUTES AND FUTURE MEETINGS

Kristi Holmes, PhD, Chair, BOR

Dr. Holmes noted the listed dates for future BOR meetings, including the addition of the Spring BOR Meeting date of May 12, 2026. There were no objections or conflicts noted.

Motion: The BOR approved the motion to accept the Spring BOR meeting date of May 12, 2026.

Motion: The BOR approved the motion to accept the minutes from the February 6, 2024 meeting.

IV. REPORT FROM THE NLM DIRECTOR

Stephen Sherry, PhD, Acting Director, NLM

Dr. Stephen Sherry welcomed and thanked the BOR, NLM senior leadership, and guests for their attendance. He highlighted transitions in NLM leadership and in BOR membership, introducing new BOR members and *ex officio* members. He shared that the recruitment window for the next NLM Director opened on May 1, 2024, and will close on July 1, 2024, and noted NLM personnel updates, including retirements, departures, and new appointments since February 2024. Dr. Sherry also presented a video about an NLM grantee at Vanderbilt University who used explainable AI to provide better clinical decision support and potential workflow improvements for health care providers.

In alignment with the NLM Strategic Plan, NLM's current priorities to support NIH through data collections and services include the following: engaging with the public directly (for instance, study participation through electronic health records (EHRs)); sustaining and enlarging biomedical research data; integrating data from diverse biomedical research fields; employing a federated architecture for data sharing and use; and disseminating data and enabling low-cost access.

Dr. Sherry provided an update on the NLM and NIH budgets for fiscal year 2024 (FY24), noting the appropriation of $497.5 million to NLM, the same amount as in FY23. The NIH budget for FY24 is $47.4 billion. The President's budget request for FY25 includes $526.7 million for NLM, which is an increase of $29.2 million from FY24.

Dr. Sherry next shared recent updates to NLM's services and products. The beta version of the Dataset Catalog discovery tool, launched on January 23, 2024, currently includes four repositories, with an additional eight targeted to be added. BOR members were asked to try the tool and provide their feedback. In addition, the NLM Center for Clinical Observational

Investigations (CCOI), which aims to reduce barriers to finding and using large clinical datasets, has launched new dataset profiles through the Lister Hill National Center for Biomedical Communications (Lister Hill). Compared to the Dataset Catalog, the CCOI dataset profiles provide in-depth characterization of datasets to help users answer specific clinical questions. Dr. Sherry noted that data from the *All of Us* research program, which include more than 32,000 variants in 61 genes, has been added to ClinVar. Regarding the Comparative Genomics Resource (CGR) project, an Alpha version of the Eukaryotic Genome Annotation Pipeline (EGAPx) has been made available to select users for testing. The GenBank database has also reduced its processing backlog for new submissions from 17 months to 1 to 3 days, with new data being released shortly after submission. PubMed indexing has also transitioned from the Medical Text Indexer-Automated (MTIA) to the Medical Text Indexer-NeXt Generation (MTIX) machine learning (ML) model. The MTIX provides significantly increased performance compared to MTIA and can also better recognize abstract ideas and avoid contextual errors. NLM adopted Google Analytics 4 (GA4) in April 2024, which provides further insights on the use of its sites and services and improvements to data privacy impact footprints.

Work continues at NLM to create a culture of continuous innovation by establishing and implementing a forward-looking model of innovation. The model includes the following four components: Governance and Management, Idea Lifecycle, Deployment and Measurement, and Organizational Readiness. Planned next steps include developing, testing, and implementing key components of the innovation model. NLM will also continue to develop and evaluate use cases for generative AI using a risk management-based approach.

Per a March 2024 Executive Order and in partnership with the NIH Office of Research on Women's Health (ORWH), NLM will develop and launch a system to find information on women's health research. The first phase of implementation is anticipated to link existing NLM resources and NIH funding information.

Dr. Sherry noted recent awards and honors presented to NLM Intramural Research Program (IRP) investigators. Dr. Eugene Koonin was elected to serve as a Fellow of the International Society for Computational Biology (ISCB). Dr. Dina Demner-Fushman received the 2023 NIH Director's Award and the UNITE Co-Chairs Certificate of Service on the Anti-Racism Steering Committee (ARSC). Dr. Teresa M. Przytycka received the Rosalind Franklin Society Special Award in Science. Dr. Sherry also recognized IRP investigators for 95 publications since September 2023. The NLM IRP Training Office is continuing outreach and recruitment efforts. The IRP will welcome a record-high 32 summer interns in 2024 and continues to recruit and train researchers through a variety of programs.

Dr. Teresa Zayas Cabán outlined recent policy and legislative updates. The National Academies of Sciences, Engineering, and Medicine published proceedings from workshops on enhanced public access to United States Department of Health and Human Services (HHS) research. Dr. Zayas Cabán also outlined recent legislative and policy activity concerning AI. Regarding FY25 appropriations, HHS appropriations hearings were held in March and April 2024. NLM's contributions to NIH priorities were highlighted in the NIH Budget Request, released in mid-March 2024. The NLM Congressional Justification was highlighted as a summary of NLM's progress and priorities for FY25.

BOR members discussed the future datasets funding roadmap for the CCOI, and Dr. Sherry noted discussions with other NIH institutes and centers regarding potential agreements for holding CCOI datasets. Members also discussed developing guidance for data use and AI; Dr. Sherry noted NLM's work in monitoring industry trends and collaborating with diverse stakeholders to determine opportunities for generating relevant content. BOR members also discussed NLM's model for orienting its workforce toward continuous innovation, with Dr. Sherry remarking on progress in establishing operational procedures. NLM is targeting an open call for NLM staff for the submission of new ideas for innovation by the September 2024 BOR meeting. The BOR also discussed focusing on competency and literacy in the use of AI and other new technologies.

V. FUTURE OF BOARD WORKING GROUPS

Dina N. Paltoo, PhD, MPH, Deputy Director, Policy and External Affairs (Acting), Office of the Director, NLM

Dr. Dina Paltoo provided an overview of the types of subcommittees and ad hoc working groups which the BOR may establish to support its mandate to advise, consult, and make recommendations on NLM activities and policies. Subcommittees, consisting of select BOR members, may be established to provide group advice or recommendations on specific issues. Depending on the need, subcommittees can be either standing or established on an ad hoc basis. Temporary or ad hoc working groups, consisting of both BOR members and non-members, may be established to gather, analyze, and present information and report findings from its members. Discussion or breakout groups, consisting of BOR members and NLM staff, may be established for ongoing, topic-focused discussion; these groups would report directly to the BOR.

The Public Services, Literature Collections, Research Frontiers, and Strategic Planning BOR Working Groups were originally established in 2016 to support the NLM 2017-2027 Strategic Plan. Dr. Paltoo proposed that these Working Groups now be phased out and new groups formed, as appropriate, to support NLM's ongoing work. Per the 2022 BOR Working Group Process Assessment, BOR members shared, via polling and survey, that while the BOR Working Groups created meaningful interactions and contributed to the work of NLM, additional clarification on the roles of individual BOR members and the purpose of specific Working Group meetings was needed. BOR members recommended that the purpose of Working Groups be better clarified and clear objectives for individual meetings be established. Per Dr. Paltoo, NLM proposed establishing the following three new Working Groups (to replace the existing groups): Strategic Planning, Operational Excellence, and Innovative Initiatives.

BOR members discussed whether NLM should consider additional or different groups and how important topics should be discussed, reported, and advised on. BOR members expressed support for forming specific, time-limited breakout/discussion groups on an as-needed basis, rather than standing working groups. In addition, members requested that the BOR and NLM provide specific requests for recommendations or information ahead of group meetings to guide discussions. Members recommended that, in addition to convening during in-person BOR meetings, groups should also explore ways to collaborate asynchronously. Members requested that NLM notify the BOR of areas of concern or issues on which the BOR's advice, expertise, or collaboration may be helpful. Dr. Sherry noted the BOR's importance in

supporting NLM as a thought leader in the rapidly evolving data management landscape. He also noted the NIH Director's vision for NLM as a data federation working with diverse stakeholders.

VI. CONCEPT CLEARANCE: COMPUTATIONAL APPROACHES TO CURATION AT SCALE OF BIOMEDICAL RESEARCH ASSETS

Catherine Farrell, PhD, Division of Extramural Programs, NLM

Dr. Catherine Farrell presented on the proposed reissue of NLM's grant, "Computational Approaches to Curation at Scale for Biomedical Research Assets," which supports the cataloging of diverse biomedical data and enhancing accessibility. Initially issued in May 2018 as an R01 funding opportunity, reissued in September 2020 as PAR-20-304, and expired on May 8, 2024, the grant aimed to develop open-source computational tools for automating data curation. It aligns with the NLM Strategic Plan 2017-2027, Goal 1 objectives to accelerate discovery and advance health through data-driven research by developing large-scale curation strategies, enhancing operational efficiency, and fostering open science. Continued efforts are necessary to manage the growing data volume and develop new approaches for data mining and knowledge discovery.

A portfolio analysis of the two curation Notice of Funding Opportunities (NOFOs), conducted on March 12, 2024, indicated 118 submissions since 2018, reflecting steady interest from the biomedical research community. Fifteen grants totaling $14.4 million were awarded, producing at least 74 publications with over 1,100 citations. These projects cover a range of curation subjects, including biomedical imaging, electronic health records, biomedical metadata, and literature curation. Notably, 87% of the projects utilize machine learning (ML) or AI methods, reflecting current computational trends. However, there were few applications for curating molecular biology data, including genomic, proteomic, and genetic variation, as well as for metabolomic, public health, and epidemiology data. Given the massive data production in these areas and their importance to health research, attracting more applications for scalable curation in these fields is highly desirable.

The NLM Curation at Scale Workshop, held in March 2022, brought together approximately 800 registrants from academia, government, industry, and publishing, including biocurators, curation system developers, and other stakeholders. It showcased various data types and research areas benefiting from innovations in at-scale curation, with a focus on future needs for managing large volumes of data to ensure they are findable, accessible, interoperable, and reusable (FAIR). Dr. Farrell emphasized the importance of FAIR data principles and the Four S's: Speed, Scale, Sharing, and Standards. While manual curation ensures high data quality, it is too slow for current research needs, necessitating increased speed and scale through automation. The importance of data standards, particularly metadata standards, was emphasized for successful sharing and archiving.

Based on insights from the NLM Curation at Scale Workshop, portfolio analysis, other research into the current state of the biocuration field, and program staff brainstorming, Dr. Farrell proposed a reissue of the NOFO to address current gaps in the project portfolio. The new NOFO will emphasize interest in diverse data types, including molecular biology, metabolomics, and public health/epidemiology, while balancing and augmenting the existing focus. Emphasis will be placed on data credibility, provenance, and the importance of curated

datasets or tools that inform and advance research. Applicants will need to describe their strategy for evaluating computational approaches, including plans for product accuracy, maintenance, and ethical considerations. The goals of reissuing the NOFO include advancing human health through data-driven research, and utilizing innovative computational approaches to curate, integrate, and harmonize vast quantities of data. The reissued NOFO will align with the NLM Strategic Plan and NIH Data Management and Sharing (DMS) policies, support the development of novel computational approaches for scale and curation, and foster the production of reliable, high-value datasets to advance research. Projected grant costs for NLM include a total of $250,000 awarded annually to approximately five or six submitters for up to four years.

BOR members discussed methods for increasing applications in interdisciplinary areas such as molecular biology, metabolomics, and public health/epidemiology. They emphasized the need to curate vast datasets into usable and shareable formats that are accessible to the public. Dr. Farrell highlighted the diverse nature of the biocuration community, stressing the importance of a community-driven approach to improving computational curation methods. Members proposed using automation tools to engage biocuration experts and suggested leveraging previous research examples to resonate with other communities.

Members also considered using promotional videos, example use cases, or an NLM blog to raise awareness. Dr. Richard Palmer noted that the historically greater need for computational approaches to analyze large volumes of molecular data may have contributed to lower application numbers from other fields, such as public health, in the past.

Motion: The BOR approved the motion to proceed with the above recommendation.

VII. TEAMWORK FOR THE GREATER GOOD: NLM, NIH, AND PUBLIC AVAILABILITY OF THE DIGITIZED DOCUMENT COLLECTION FROM THE USPHS UNTREATED SYPHILIS STUDY AT TUSKAGEE AND MACON COUNTY, ALABAMA

Jeffrey Reznick, PhD, Senior Historian, User Services and Collection Division, NLM

Dr. Reznick explained the significance of NLM, in October 2023, releasing a digital collection of reproduced documents from the 1932 study by the U.S. Public Health Service (USPHS) on the effects of untreated syphilis in Black men at Tuskegee and Macon County, Alabama. The documents, now available in digital form via NLM Digital Collections, were previously only accessible in their physical form to researchers visiting the NLM reading room. The goal of the project was to make these important documents more broadly available, both to ensure this chapter in history is never repeated, and to build greater trust in current biomedical research through transparency. Staff had previously begun preparing this collection for digital release, however this work was interrupted by the COVID-19 pandemic.

Dr. Reznick presented a video produced by NLM, detailing the history of the study and highlighting the ethical issues with its conduct. The video also outlined NLM's role in acquiring and preserving the historical documents related to the study. In 1972, an ad hoc federal panel was formed to investigate the study, ultimately concluding that it was ethically unjustified. Participants were not informed about the nature of the disease and were denied treatment even after the discovery of a highly effective treatment. The investigation and its findings led to

compensation for the victims of the research and to significant changes in research practices, including enhanced protection of study participants.

Dr. Reznick further explained that in September 2023, NIH leadership welcomed representatives of Leaders from the Voices for Our Fathers Legacy Foundation to the NIH campus. These representatives, descendants of the men who were treated unethically in the USPHS Untreated Syphilis Study at Tuskegee and Macon County, Alabama, visited the NIH campus to study NLM's collection of reproduced documents from the study.

The digitizing and public release of this collection in October 2023 was achieved through the experience and expertise of a team of colleagues, including NLM archival, technical, policy, and public affairs staff as well as policy and public affairs staff in the Office of the NIH Director. This work also involved collaboration with colleagues at Fisk University, Nashville, a historically Black university, whose John Hope and Aurelia E. Franklin Library holds a portion of original documents in the Special Collections Division.

The collection NLM has held since its deposit in 1973 consists of over 3,000 reproduced copies of correspondence, memoranda, meeting minutes, reports, and scientific articles. The collection forms a distinct historical record, which has, since its deposit, informed research led by historians, medical ethicists, and many others across a variety of disciplines.

Dr. Reznick displayed the landing page for the digitized collection located on the NLM Digital Collection webpage. The arrangement of the documents in the digital collection replicates the sequence of the physical collection. Finally, Dr. Reznick emphasized that the digitization of the documents in this collection supports NLM's mission to collect, preserve, and make collections publicly available to advance open access, improve transparency in research, and ensure that lessons of the past inform the present and future of biomedical research, health care, public health, and health behavior.

BOR members discussed the future of digitizing historical records and the various stakeholders interested in digital collections, as well as the cost, timeframe, and prioritization of digitizing historical records. Additionally, they addressed the need to link the NLM Digital Collections page to other webpages, explored various avenues for promoting the digital collections, and discussed ethical considerations related to digital collections.

VIII. REPORT FROM THE OFFICE OF RESEARCH ON WOMEN'S HEALTH, NIH

Dr. Janine Clayton, Director, Office of Research on Women's Health, NIH

Dr. Janine Clayton presented a brief history of women's health research, noting the establishment of the NIH ORWH in 1990. She highlighted the NIH Revitalization Act of 1993, which mandated the inclusion of women and minorities in NIH-funded clinical research, and the 2016 21st Century Cures Act, which expanded to encompass all age groups, created a pathway for inclusion of pregnant and lactating women, and required NIH-defined applicable phase III clinical trials to report results disaggregated by sex/gender, race, and ethnicity into ClincialTrials.gov.

Additionally, she described programs supported by ORWH, including Building Interdisciplinary Research Centers in Women Health (BIRCWH), established in 2000, and

Specialized Centers of Research Excellence on Sex Differences (SCORE), established in 2002. She emphasized ORWH's mission to enhance and expand women's health research, include women and minority groups in clinical research, and promote career advancement for women in biomedical careers. Dr. Clayton also presented data spanning the last 15 years, showing the increase of federally-funded clinical trials reporting outcomes by sex, race, and ethnicity and gave an overview of the NIH-supported research that plays a critical role in women's health.

She also announced the publication of the 2024-2028 NIH-Wide Strategic Plan for Research on the Health of Women, which is driven by three guiding principles: considering the complex intersection among multiple factors that affect women's health; including a diverse group of women in clinical trials; and integrating perspectives from a diverse workforce of scientists. The strategic plan provides a roadmap to guide and inform NIH-supported research on various diseases and health conditions that affect women. She emphasized the collaborative effort by NIH institutes and centers to support workshops, working groups, funding opportunities, and initiatives in support of the strategic plan.

Dr. Clayton also emphasized the importance of women's health research across the life course, highlighting over 30 years of NIH-funded research on menopause. She presented the NIH Research on Menopause & Midlife Health webpage and outlined ways it can be of use to the public.

On November 13, 2023, President Joe Biden and First Lady Dr. Jill Biden announced the first-ever White House Initiative on Women's Health Research. The initiative was followed by Executive Order (EO) 14120 to Advance Women's Health Research & Innovation. The four key points of the EO are to: prioritize investments in women's health research, integrate women's health across the federal research portfolio, galvanize new research on women's midlife health, and assess unmet needs to support women's health research.

ORWH has been working with NLM, across NIH, and with other federal partners on plans to implement the EO. Dr. Clayton described the actions and efforts taken by NIH that align with the EO, including creating a front door to NIH funding opportunities on women's health, standardizing data to support research on women's health, supporting private sector innovation, creating a comprehensive research agenda on menopause, and using biomarkers to improve the health of women through early detection and treatment of conditions such as endometriosis. Additionally, NLM is partnering with ORWH to develop and launch the NIH Discovery Service for Women's Health Research (DiscoverWHR), a multi-phase project in support of EO 14120.

Dr. Clayton highlighted the newly established Office of Autoimmune Disease Research (OADR) within ORWH, directed by Congress to coordinate and foster collaborative research, identify emerging areas of innovation and research opportunities, evaluate the NIH autoimmune disease research portfolio, and develop a publicly accessible repository for autoimmune disease research. She also noted the collaboration between the BIRCWH and SCORE programs to promote the Building a Translational Workforce Innovation Network (TWIN), a public-private partnership to support BIRCWH scholars and SCORE investigators. Additionally, she described some of the SCORE-supported research on sex differences in areas such as depression, addiction and stress related disorders, effects of endocrine disruption,

aging, Alzheimer's disease, and cardiometabolic health and disease. She highlighted the newest SCORE initiative, the Rural, Obese, At-Risk (ROAR) collaborative program, and its related research areas.

Internationally, ORWH collaborated with the Bill and Melinda Gates Foundation to host the Innovation Equity Forum that produced the 2023 Women's Health Innovation Opportunity Map, laying out 50 high-return opportunities for stakeholders across the Research and Development (R&D) ecosystem to advance global innovation for women's health. ORWH has also collaborated with the Office of AIDS Research (OAR) on a signature program for women and HIV with the aim of fostering an interdisciplinary knowledge exchange, reviewing the state of the science for HIV and women, highlighting methods and challenges to advance health equity for women with or affected by HIV, and identifying research opportunities.

NIH is working to implement programs in five domains of workforce inclusion: enhancing flexibility options, demonstrating leadership support, ensuring a culture of inclusion, ensuring action-oriented accountability measures are in place, and supporting research around the intervention and best practices for addressing diversity and equity. She also discussed the ORWH Resource Library, including e-learning courses, interprofessional services, and other web-based products.

On May 15, 2024, the NIH Wide Women's Health Research Strategic Plan will be launched, along with the release of new ORWH resources and the 8th Annual Vivian W. Pinn Symposium (2024), focusing on autoimmune diseases. On May 16, 2024, a Future of Menopause Research Event roundtable will be convened, focused on menopause pathways to prevention (P2P) and optimizing the midlife health of women.

BOR members discussed the use of new data analytics to address questions on current treatments that may not have been tested on women when they were approved years ago. Additionally, they explored the multidisciplinary approach to supercharge the research effort in women's health, specifically in the university setting, and advocated for the promotion of public-private partnerships.

IX. CLOSED PORTION

The closed portion of the meeting took place from 3:45 p.m. to 4:15 p.m. The Board reviewed and approved for further consideration during *en bloc* concurrence, a total of 1406 applications with the requested direct cost amount of $3,318,267,800.

X. ADJOURNMENT

Dr. Holmes adjourned the BOR meeting at 4:15 p.m. on May 14, 2024.

Actions Taken by the Board of Regents:

- Approval of the February 6, 2024, BOR meeting minutes
- Approval of the May 12, 2026, meeting dates
- Approval of the Computational Approaches to Curation Concept Clearance
- *En Bloc* Concurrence of Grants

Appendix A.

- Roster — Board of Regents

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

Stephen T. Sherry -S

Digitally signed by Stephen T. Sherry -S
Date: 2024.07.16 14:03:26 -04'00'

Stephen Sherry, PhD
Acting Director, National Library of Medicine

Kristi Holmes

Digitally signed by Kristi Holmes
Date: 2024.07.25 06:01:47 -05'00'

Kristi L. Holmes, PhD
Chair, NLM Board of Regents