DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH (NIH)
NATIONAL LIBRARY OF MEDICINE (NLM)
MINUTES OF THE BOARD OF REGENTS MEETING
September 10-11, 2024

The 197th meeting of the Board of Regents (BOR) was convened on September 10, 2024, at 9:00 a.m. in Building 38A (Visitors Center), Lister Hill National Center for Biomedical Communications (LHNCBC), 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 that lasted until 4:00 p.m. On September 11, 2024, the meeting reopened from 9:00 a.m. to 11:45 a.m. The meeting adjourned at 11:45 a.m.

MEMBERS PRESENT (Appendix A)
Dr. James Cimino, University of Alabama at Birmingham
Dr. Christopher Forrest, University of Pennsylvania School of Medicine
Dr. Mitchell Katz, New York City Health + Hospitals
Dr. Anne Kwitek, Medical College of Wisconsin
Dr. Maichou Lor, University of Wisconsin-Madison
Dr. Rasmus Nielsen, University of California, Berkeley
Dr. Omolola Ogunyemi, Charles R. Drew University of Medicine and Science [Chair]
Dr. Carmen Portillo, Yale University School of Nursing (Retired)
Mr. Christopher Shaffer, University of California, San Francisco
Mr. Philip Walker, Vanderbilt University

EX OFFICIO AND ALTERNATE MEMBERS PRESENT:
MGEN John Bartrum, United States Air Force
Dr. Michelle Elekonich, National Science Foundation
Mr. Scott Hanscom, National Agricultural Library, U.S. Department of Agriculture
Dr. Susan Kirsh, Veterans Health Administration
Dr. Mary Mazanec, Library of Congress
Dr. Niels Olson, United States Navy
Col. Joseph Sterbis, United States Army
Dr. Binbin Zheng, Uniformed Services University of the Health Sciences

SPEAKERS AND INVITED GUESTS PRESENT:
Dr. Susan Gregurick, Office of Data Science Strategy, NIH
Dr. Gabriel Ibarra-Mejia, University of Texas, El Paso
Dr. Sean Mooney, Center for Information Technology, NIH
Dr. Lawrence Tabak, Principal Deputy Director, NIH

MEMBERS OF THE PUBLIC PRESENT:
Mr. Glen Campbell, Friends of the NLM
Dr. Kristi Holmes, Northwestern University
Ms. Loretta Jurnak, Technical Resources International, Inc.
Dr. Barbara Redman, Friends of the NLM
Ms. Angela Ryder, 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. Stacey Arnesen, User Services and Collection Division, NLM
Ms. Dianne Babski, User Services and Collection Division, NLM
Mr. Raja Cholan, User Services and Collection Division, NLM
Mr. Todd Danielson, Office of the Director, NLM
Dr. Lisa Federer, Office of Strategic Initiatives, NLM
Dr. Anna Fine, National Center for Biotechnology Information, NLM
Dr. Kin Wah Fung, Lister Hill National Center for Biomedical Communications, NLM
Ms. Jeane Garcia Davis, Office of the Assistant Secretary for Health, HHS
Dr. John Greene, National Cancer Institute, NIH
Ms. Christine Ireland, Division of Extramural Programs, NLM
Ms. Michelle Krever, Division of Extramural Programs, NLM
Dr. David Landsman, National Center for Biotechnology Information, NLM
Dr. Zhiyong Lu, Division of Intramural Research, NLM
Ms. Wei Ma, Office of Computer and Communications Systems, NLM
Dr. Richard Palmer, Division of Extramural Programs, NLM
Dr. Kim Pruitt, National Center for Biotechnology Information, NLM
Dr. Richard Scheuermann, Office of the Director, NLM
Dr. Valerie Schneider, National Center for Biotechnology Information, NLM
Mr. Peter Siebert, User Services and Collection Division, NLM
Dr. Heidi Sofia, National Center for Biotechnology Information, NLM
Dr. Teresa Zayas Cabán, Office of the Director, NLM

I. CALL TO ORDER AND INTRODUCTORY REMARKS

Omolola Ogunyemi, PhD, Chair, BOR

Dr. Lola Ogunyemi called the meeting to order, welcoming attendees to the meeting. Dr. Ogunyemi welcomed two new *ex-officio* board members:

- Mr. Scott Hanscom, Acting Director, National Agricultural Library, U.S. Department of Agriculture
- Dr. Binbin Zheng, Associate Professor, Center for Health Professions Education, Uniformed Services University of the Health Sciences

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 Noelle Harada, MPH, Science and Policy Fellow, Office of the Surgeon General

Ms. Jeane Garcia Davis provided an update on the Office of the Surgeon General's (OSG's) continuing efforts aimed at supporting social connection, workplace well-being, and youth mental health. She noted the OSG's continued support of over 6,000 officers of the

Commissioned Corps of the U.S. Public Health Services and highlighted two recent OSG Advisories—one on the mental health and well-being of parents and the other on firearm violence and prevention. Vice Admiral (VADM) Vivek Murthy has been engaging with U.S. and global partners, including the World Health Organization (WHO) Commission on Social Connection (2024-2026), and traveled to Japan to meet with the Minister of Loneliness and discuss the harmful effects of loneliness and social isolation. The OSG continues to conduct briefings with U.S. intra- and interagency partners on the 2022 Surgeon General's Framework for Workplace Mental Health and Well-Being and is working with the HHS Office of Minority Health to address health care worker well-being.

In August 2024, the latest Surgeon General's Advisory on the Mental Health and Well-Being of Parents was launched to identify the stressors that impact the mental health of parents and caregivers, highlight the critical link between parental mental health and children's long-term well-being, and underscore the urgent need to better support parents, caregivers and families. Ms. Davis noted that over the past decade, parents have consistently reported high levels of stress and financial concerns. In 2023, 48% of parents said their stress is completely overwhelming most days, compared to 26% of other adults. Financial worries were the top stressor, with 1 in 4 U.S. parents reporting multiple times in the past year that they lacked the resources to meet basic needs. The Surgeon General's Advisory provides recommendations to better support the well-being and mental health of parents and caregivers through policy changes, community programs, and individual actions. The advisory calls for improving early childhood education and childcare programs, increased access to paid family leave, and historical investments to improve the access and quality of mental health care.

In June, the OSG released a landmark Surgeon General's Advisory on Firearm Violence, declaring firearm violence in America a public health crisis. Ms. Noelle Harada gave an overview of the advisory, providing data and describing a public health approach to preventing firearm violence. She also noted that the advisory is the first OSG publication dedicated to firearm violence and its consequence for the health and well-being of the American public.

Firearm violence is a long-standing and pervasive issue in the United States. Based on a recent nationally representative survey, 54% of U.S. adults report that either they or a family member has experienced a firearm-related incident. Firearm violence has particularly devastating impacts on children and adolescents. In 2020, firearm-related injuries have surpassed car accidents as the leading cause of death of U.S. children and adolescents. Fears and worries about firearm violence, especially regarding school shootings, are highly prevalent among youth. A national survey found that half (51%) of 14–17-year-olds worry about school shootings and nearly six in ten recently thought about what would happen if a person with a gun entered their school or one nearby. While firearm violence can affect anyone, it disproportionately impacts certain communities. In 2022, Black individuals had the highest firearm homicide rates across all age groups. For those 45 and older, the firearm suicide rates were highest among White individuals, while for those under age 45, the firearm suicide rate was highest among American Indian or Alaska Native (AI/AN) individuals. Ms. Harada emphasized that the impact of firearm violence extends beyond those who experience direct and immediate harm; there is cascading harm across witnesses, family and friends, and the broader community. Research indicates that families and friends of victims of firearm violence face an increased risk of mental health challenges, including depression, anxiety, and post-traumatic stress disorder. Additionally, high levels of exposure to firearm violence in communities can negatively impact the public's perception of

safety. More than three-quarters of U.S. adults (79%) report experiencing stress from the possibility of a mass shooting and one in three adults (33%) say that fear prevents them from going to certain places or attending certain events.

Ms. Harada presented the four-step evidence-based public health approach to addressing the firearm violence crisis outlined in the advisory. The advisory calls for advancing research on the causes and solution for firearm violence; implementing community risk reduction and education prevention strategies and firearm risk reduction strategies; and increasing mental health access and support for those exposed to firearm violence.

BOR members discussed potential methods for evaluating the impact of the OSG advisories. They noted the interconnection among the advisories addressing loneliness, social connection, worker burnout, parental health and well-being, and discussed the impact of childcare costs on parents' mental health and well-being.

III. MAY 2024 MINUTES AND FUTURE MEETINGS

Lola Ogunyemi, PhD, Chair, BOR

Dr. Ogunyemi noted the listed dates for future BOR meetings, including the Winter BOR Meeting which will be held virtually on February 4, 2025, and the addition of the Fall BOR Meeting on September 15-16, 2026. There were no objections or conflicts noted.

Motion: The BOR approved the motion to accept the Fall BOR Meeting date of September 15-16, 2026.

Motion: The BOR approved the motion to accept the minutes from the May 2024 meeting, with one minor correction.

IV. REPORT FROM THE NLM DIRECTOR

Stephen Sherry, PhD, Acting Director, NLM

Dr. Stephen Sherry welcomed and thanked the BOR members, NLM senior leadership, and guests for their attendance. He introduced Dr. Kin Wah Fung as the new Director and Mr. Jim Mork as the Deputy Director of the Lister Hill National Center for Biomedical Communications (LHNCBC). Dr. Sherry also shared a video on the principles of Open Science, featuring Dr. Lisa Federer, Acting Director of NLM's Office of Strategic Initiatives (OSI), and Dr. Maryam Zaringhalam, Data Science and Open Science Officer. The video defined Open Science as the principal and practice of making research processes and products accessible to all while respecting cultural diversity, maintaining security and privacy, and promoting collaboration, reproducibility, and equity, and highlighted its benefits for researchers and broader communities.

NLM plays a pivotal role in Open Science by providing access to research products through platforms like PubMed Central (PMC) and the National Center for Biotechnology Information (NCBI). These resources support researchers and individuals interested in contributing to Open Science by offering repositories to share data for broader access. Open Science also requires rethinking how research products are shared, including new methods like preprints and engaging diverse communities to participate in the scientific process.

Dr. Sherry highlighted NLM's commitment to fostering innovation and shared updates on the progress of NLM's Innovation Program. He announced that all workstreams have met their targets, with the program's official launch set for September 26, 2024. This initiative encourages staff to propose innovative solutions and showcase them across NLM, advancing the organization's mission to support biomedical research.

The Innovation Program reflects NLM's commitment to transformative initiatives that align with the NIH Director's vision and address the evolving needs of the biomedical community. It promotes inclusivity, consistency, and collaboration across NLM divisions, supporting staff in brainstorming, collaborating with subject matter experts (SMEs), and turning innovative ideas into actionable projects. The process begins with an Innovation Owner submitting an idea, outlining key details such as stakeholders, vision, scope, and expected outcomes. An Innovation Facilitator, in a part-time role for 12 months, guides the Owner through the workflow, collaborating with stakeholders and preparing the idea for evaluation by the Innovation Program Board.

NLM's first cohort of 19 Innovation Facilitators is currently training in innovation principles, creativity, and project management. The six-member Innovation Program Board will evaluate ideas, allocate resources, and oversee project development. The program will continue evolving in fiscal year 2025 (FY25) as new ideas are gathered and refined.

Dr. Sherry anticipates NLM's FY25 budget to receive a continuing appropriation of $526.8 million, a $29.2 million increase from the previous year. The FY25 Congressional Justification for the President's request is available online. While budget formulation for the President's request is underway, specific figures are not yet public, with further updates expected during the legislative process in Fall 2024.

Dr. Sherry shared updates on the FISMA Moderate Environment for Health-Related Data about Individuals (FEHRDI), a secure NLM environment launched in September 2023, which now hosts 11 datasets and supports various NLM projects.

The NLM Center for Clinical Observation Investigations (CCOI) is focused on improving access to large clinical datasets. Its new website, launched in May 2024, provides public access to Dataset Profiles on the metadata of a dataset, featuring overviews and statistics. Currently, four datasets are available on the site.

Recent advancements include the NLM Malaria Screener Project, a desktop app which uses image processing and machine learning (ML) to evaluate antimalarial drug efficacy and vaccines. The Intelligent Unified Medical Language System (UMLS) Editing Assistance Project applies deep learning (DL) to expedite term curation, aiding in the management of 100,000 new terms added biannually. In June 2024, NCBI hosted a workshop in Ethiopia on genomic data curation, training participants from 20 African countries on preparing data for public repositories such as GenBank and the Sequence Read Archive (SRA) using NLM/NCBI tools. NCBI also held the BioEd Summit 2024, where science educators developed innovative curricula and interactive materials, which are shared on GitHub for broader use.

PMC has reached a milestone of 10 million articles, advancing open access and artificial intelligence (AI) training. The updated PMC website, set to launch in October 2024, will feature

a new interface, improved navigation, and enhanced bulk download capabilities. This update, aimed at improving user experience and sustainability, was previewed for feedback earlier this year.

The Comparative Genomics Resource (CGR) has been enhanced with optimized Basic Local Alignment Search Tool (BLAST) databases and NCBI Datasets. BLAST now uses the more efficient core nucleotide database (core_nt), reducing redundancy while maintaining search accuracy. NCBI Datasets provides updated access to genomic data through modernized web, command line, and Application Programming Interfaces (APIs), replacing outdated resources.

In June 2024, OSI hosted a workshop on advancing equitable Open Science, leading to the development of new resources and strategies for community access and engagement. The NLM Division of Extramural Programs (EP) also held a workshop on using AI to improve health equity, which will inform future funding opportunities. An EP webinar on September 18, 2024, will explore collaborative strategies for high-quality dataset development and community engagement, featuring presentations on AI applications in health research.

Dr. Naa Oyo A. Kwate received a NLM Grant for Scholarly Works in Biomedicine (G13) and the 2024 Best Book in Urban Affairs Award for her book, *White Burgers, Black Cash: Fast Food from Black Exclusion to Exploitation*, which examines the intersection of race, food environments, and health disparities.

NLM has completed a system realignment project to enhance information security and comply with FISMA requirements. The project established three new information technology (IT) authorization boundaries based on budget, data type, and operating environment, replacing the previous single boundary. This change, supported by Office of Computer and Communication Systems (OCCS), NCBI, and LHNCBC, transitioned the NLM Data Center to a moderate-impact system, ensuring compliance with National Institute of Standards and Technology (NIST) standards and NIH's Risk Management Framework. Over a dozen security documents and hundreds of security controls were updated or created, with effectiveness reviewed by an independent assessment team.

In January 2024, NLM launched the beta version of its Dataset Catalog, featuring the Dataset Metadata Model (DATMM) to standardize biomedical dataset descriptions. Feedback from BOR members on the catalog will guide future refinements and contribute to NLM's strategic plans for federated data access.

NLM's Digital Collections have expanded with five new digitized archival collections, including two Civil War-era collections and over 26,000 pages from Dr. Stanhope Bayne-Jones's archives. Additionally, NLM acquired the interactive exhibit, *"Where It All Began,"* previously at the Smithsonian National Museum of Natural History, showcasing the Human Genome Project and featuring Dr. Marshall Nirenberg's Nobel Prize-winning RNA codon chart.

The NLM virtual exhibit, *"This Lead is Killing Us: A History of Citizens Fighting Lead Poisoning in Their Communities,"* received the Health and Safety Virtual Exhibit of the Year Award from the American Industrial Hygiene Association (AIHA). This award recognizes the exhibit's compelling narrative on lead exposure prevention in workplaces and aims to inspire further development of health and safety-related virtual exhibits.

Dr. Sherry announced several new NLM funding opportunities. A recent solicitation seeks grant applications to improve health information accessibility for populations experiencing health disparities and their providers, with a focus on creating or enhancing resources to promote health equity. In response to the White House's Women's Health Research (WHR) initiative, NIH issued a Notice of Special Interest for applications targeting diseases affecting women, especially those using AI and data science for early detection and personalized risk assessment. NLM will also publish a funding announcement by the end of 2024 for computational approaches to scale curation processes for biomedical data, with the first receipt date in February 2025.

NLM is also collaborating with NIH's Office of Research on Women's Health (ORWH) to develop a minimum viable product (MVP) of a novel discovery portal for WHR. This portal will provide patients, caregivers, researchers, and the public with comprehensive access to research data and literature on health issues primarily affecting women as well as common conditions that present differently in women. The initial phase is expected to launch soon, focusing on a few key topics with plans for further expansion.

Dr. Sherry shared personnel updates, including retirements, departures, and new arrivals. He also shared that Dr. Paulito Fontelo received a 2024 NHLBI Director's Award for his contributions to the COVID-19 Response through the Researching COVID to Enhance Recovery (RECOVER) initiative.

Dr. Teresa Zayas Cabán outlined recent policy and legislative updates. On June 19, 2024, NIH released a draft Public Access Policy proposing the removal of the embargo period for NIH-funded publications, with a final policy expected by the end of 2024. The Department of Health and Human Services (HHS) reorganized, renaming the Office of the National Coordinator for Health Information Technology (ONC) to the Assistant Secretary for Technology Policy (ASTP), which now oversees technology, data, and AI policy. ASTP/ONC released USCD Version 5 and is accepting submissions for Version 6, while the Health Data Technology and Interoperability (HTI-2) Proposed Rule, which updates API certification and data interoperability, is open for public comments until October 4, 2024.

She mentioned that Congress has introduced 30 AI-related bills, including a notable proposal to make NLM a hub for federated data sharing in biomedical research. Three other AI bills are awaiting Senate consideration. NLM is also monitoring the FY25 Appropriations Process. The Senate's FY25 Appropriations Bill proposes $50.2 billion for NIH, with $589 million for NLM, including $100 million for a new AI data initiative. The House bill maintains FY24 levels and proposes $4.4 billion for a proposed consolidated institute merging NLM with other research centers. Finally, five non-AI-related bills were introduced, including the Long COVID Research Moonshot Act, which mandates NIH to establish a long COVID research program, managed by NLM.

BOR members discussed leveraging NIH IT Help Desk data to support the Innovation Program and explore public products and services to enhance it. NLM's product development teams actively engage with communities for direct feedback, suggestions for improvements, and ideas for new products. They aim to create a framework to align new initiatives with the ongoing work under the Innovation Program's governance.

The BOR also discussed the BioEd Summit 2024, which currently targets college-level users of NLM and NCBI molecular biology services. They considered expanding the program to middle school students to inspire early interest in molecular biology and support their progression into related college programs.

V. REPORT FROM THE NIH OFFICE OF THE DIRECTOR

Lawrence Tabak, DDS, PhD, Principal Deputy Director, NIH

Dr. Lawrence Tabak thanked Dr. Sherry for his leadership as Acting NLM Director and the NLM staff for their efforts during this transitional period. He provided updates on NIH leadership, including departures and new appointments, and noted that recruitment for the next NLM Director is progressing.

Dr. Tabak provided an update on the NIH budget for fiscal year 2024 (FY24), noting that the appropriation of $48.85 billion reflects a slight decrease from the FY23 budget of $49.18 billion. The President's budget request for FY25 of $51.62 billion is an increase of $2.77 billion from FY24.

Next, Dr. Tabak shared the guiding principles articulated by the NIH Director, Dr. Monica Bertagnolli, emphasizing her vision that the NIH's work is not finished until all people are living long, healthy lives. He also highlighted that NIH research goes beyond the laboratory and clinic, requiring community engagement, and noted that progress is accelerated when new discoveries are rapidly and equitably adopted in clinical care.

He underscored that the lack of access to biomedical research is a major barrier to research participation for rural and medically underserved communities, emphasizing the need for a sustained research infrastructure to expand research participation to these areas. To address this, he introduced the Communities Advancing Research Equity for Health (CARE for Health™) initiative as a means of integrating biomedical research into community-based primary care practices nationwide. CARE for Health™ aims to build trust in science by addressing each community's individual needs as, increase adherence to evidence-based care, and collect longitudinal data to address health issues across the lifespan. It also aims to reduce the burden on health care providers by using innovative data collection methods.

Dr. Tabak also outlined the challenges of expanding biomedical research, and NLM's role in addressing them. He described NLM as the epicenter for NIH-funded research, providing a hub for clinical data and educational programs to help equitably expand the biomedical informatics and data science capabilities of the research workforce. He also emphasized the importance of NLM maintaining an open, scalable, federated digital ecosystem for accessing biomedical data and analytics, and providing a "front door" where anyone can access data and analytic tools to explore novel research questions.

BOR members discussed NLM's training programs for biomedical informatics researchers and incorporating other NIH institutes and agencies in biomedical workforce training. They discussed ways to provide a sustained infrastructure to support local health care providers involved in biomedical research in their communities and ways to engage middle school students in biomedical research through the CARE for Health™ program. Dr. Tabak also described the Science Education Partnership Award (SEPA) program, an NIH-wide initiative

that funds grants for innovative educational programs for pre-K through Grade 12. The discussion also covered incorporating incentives into institutional data management and sharing policies to promote data sharing, addressing the costs associated with data submission, and the challenges of creating novel data sets that are inclusive of underrepresented populations.

VI. BOARD OF REGENTS WORKING GROUP FOLLOW-UP

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

Dr. Dina Paltoo recapped the discussion on BOR Working Groups from the May 2024 BOR Meeting, including providing an overview of the types of subcommittees and ad hoc working groups that 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 advice or recommendations on specific issues. Depending on the need, they can either be 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.

Dr. Paltoo gave a brief history of the BOR Working Groups. In 2016, the Public Services, Literature Collections, Research Frontiers, and Strategic Planning BOR Working Groups were created to support the development and implementation of the NLM 2017-2027 Strategic Plan. In 2022, the Office of Strategic Initiatives evaluated the BOR Working Groups and found that, while they created meaningful interactions and contributed to NLM's work, there was a need for additional clarification on their purpose, clearer objectives for the sessions, and a stronger link between topics and NLM priorities. Further, the Public Services and Literature Collection Working Group were combined in 2023 due to overlapping topics.

In her summary of the May 2024 discussion on the future of BOR Working Groups, Dr. Paltoo mentioned that BOR members supported the idea of time-limited Working Groups focused on specific topics; recommended sharing discussion topics ahead of BOR meetings to guide discussions; and emphasized the need for NLM to identify discussion topics for the BOR's input to facilitate strategic thinking from all board members on topics relevant to NLM. This summary was taken to NLM Leadership for review. Leadership proposed forming group discussions on specific topics at BOR meetings; creating time-limited Working Groups on specific topics with clear objectives, and reporting findings to the BOR; and using subcommittees as needed.

Dr. Paltoo presented the initial BOR discussion topic, "NLM of the Future and Research Enterprise Service at NIH," for further discussion on day 2 of the BOR meeting. She also proposed an initial BOR Working Group for the BOR's consideration: Sequential Read Archive (SRA) Sustainability Working Group. The SRA, the largest publicly available repository of high-throughput sequencing data, was originally released in 2008 and currently holds approximately 31 million sequence read archive data records. A multi-year strategic transformation sustainability effort is currently underway to engage stakeholders and users to reimagine the SRA data model, modernize its architecture, and build an integrated cloud environment for data processing, management, and dissemination. The proposed Working Group would focus on maximizing the SRA's value to the scientific community, identifying stakeholder engagement strategies, and coordinating with enterprise NIH activities to

demonstrate accountability to the SRA modernization process.

BOR members discussed the recommendation to establish a BOR SRA Sustainability Working Group, including its composition, scope, the types of challenges or gaps it would address, and the group's life cycle. The Working Group would be time-limited, and address issues such as sustainability, accessibility, connectivity, management, and data sharing. Members expressed support for the establishment of the SRA Sustainability Working Group with the understanding its scope would be clearly defined. The BOR recommended that NLM move forward with this Working Group, and Dr. Paltoo agreed to present this recommendation to NLM leadership for its decision and report back to the BOR.

VII. ENVIRONMENTAL HEALTH INFORMATION PARTNERSHIP (EnHIP)

Stacey Arnesen, MS, Chief, Engagement Branch, User Services and Collection Division, NLM
Gabriel Ibarra-Mejia, MD, PhD, Associate Professor, Public Health Sciences, University of Texas, El Paso

Ms. Stacey Arnesen presented a brief history of the Environmental Health Information Partnership (EnHIP), noting that this initiative addressed a 1988 Senate mandate that expanded NLM's mission to ensure all health care professions are able to access NLM information services, regardless of location. Established in 1991 as the Toxicology Information Outreach Project (TIOP), it was a collaboration between NLM and nine Historically Black Colleges and Universities (HCBUs), all members of the Association of Minority Health Profession Schools (AMHPS). The partnership aimed to provide assessable toxicology and environmental health information to health professionals serving those communities. Over time, the partnership expanded to include additional institutions and began providing environmental health information directly to the communities served by those institutions. To reflect this change, the name was changed to Environmental Health Information Outreach Program in 2004. In 2009, it became the EnHIP, reflecting the true partnership between NLM, the member institutions, and their communities. Today, EnHIP's mission is to enhance HCBUs, tribal colleges and universities, Hispanic-serving universities, and lower-resourced academic institutions by helping them acquire and disseminate environmental health information, expand data-driven science, and promote health equity. Ms. Arnesen noted that in 2019, NLM consolidated its toxicology resources and databases, while expanding its focus in open science, health equity, and health and science literacy.

Ms. Arnesen shared a video, produced by NLM, detailing EnHIP's evolution and its role in the environmental justice movement. She noted that EnHIP has expanded to include 23 participating member institutions across 17 states. She provided examples of funding awards and introduced Dr. Gabriel Ibarra-Mejia, a recipient of several such awards.

Dr. Ibarra-Mejia discussed the importance of EnHIP's partnership with member institutions, particularly his own at the University of Texas, El Paso (UTEP). Through EnHIP's funding and support, UTEP has been able to strengthen its academic and research capacity and output; expand health information and science curricula; impact student development through internship opportunities, workshops and hands-on training; and promote cross-disciplinary collaboration. This partnership has also impacted the El Paso community by improving community engagement, increasing access to health information, and improving health outcomes. UTEP has

also amplified EnHIP's community impact through partnerships with local health organizations, hospitals, and non-profits.

Dr. Ibarra-Mejia gave a brief history of UTEP-EnHIP partnership. He noted 12 seed-funding grants since 2007, covering such topics as disaster preparedness, environmental health, climate science, and health literacy. He also highlighted the current funding project, "Empowering Rural Youth: A Holistic Approach to Climate Science, Health Literacy, and Community Engagement in El Paso County." This project, in partnership with community health workers (promotoras), science teachers, librarians, and community members, has enabled the development of environmental health literacy curricula for middle and high school students in four rural communities in El Paso County. He highlighted the project's success as an example of the importance of the continued relationship between UTEP and EnHIP in achieving long-term health equity by expanding digital health literacy, integrating emerging technologies, focusing on local health, increasing community engagement, and bridging disparities in underserved communities.

Ms. Arnesen concluded by emphasizing that institutions serving underrepresented communities are key to advancing NLM and NIH goals and objectives. She highlighted NLM's continued support of the Network of the NLM (NNLM) to improve equitable access to reliable health information. She also mentioned the NIH Environmental Justice Initiative, which addresses environmental factors contributing to health disparities through community engagement, training opportunities, and increased research capacity. NIH is also focused on increasing diversity in both the workforce and among its grantees. Through the Engagement and Access for Research-Active Institutions (ERA) Program, NIH continues outreach to institutions that serve historically underrepresented populations, offering funding opportunities in biomedical and behavioral research.

BOR members suggested enhancing the EnHIP website to include success stories, tool kits, and lessons learned from member institutions. They also discussed possible funding sources, different funding mechanisms, ways to promote funding opportunities within local communities, and expanding EnHIP's membership.

VIII. NLM LISTER HILL NATIONAL CENTER FOR BIOMEDICAL COMMUNICATONS VISION AND UPDATE

Kin Wah Fung, MD, Director, LHNCBC, NLM

Dr. Kin Wah Fung provided an update on LHNCBC, reviewing its history since its establishment by Congress in 1968 to advance biomedicine through innovations in computer technology, data science, and medical informatics. In response to the 2018 Blue Ribbon Panel Review, LHNCBC reorganized into four branches: three—Applied Clinical Informatics, Scientific Computing, and the Office of the Director—remained within LHNCBC, while the Computational Health Research moved to the NLM Intramural Research Program. This restructuring marked a shift from a research-centric model to one emphasizing the translation of research into operational health care solutions and the use of clinical data to support biomedical research.

Dr. Fung highlighted three key influences shaping LHNCBC's strategy: (1) Dr. Bertagnolli's vision for NLM, which stresses improving health outcomes, integrating NIH research, and applying advanced data analytics equitably in clinical care; (2) the NIH Strategic Plan for Data

Science, which focuses on infrastructure, data management, workforce development, and sustainability; and (3) NLM's strategic goals of accelerating data-driven research, expanding engagement, and building a data-centric workforce.
Dr. Fung discussed several translational projects, including the Intelligent UMLS Editing Assistance, which uses deep learning and AI for semantic normalization to improve synonym prediction and editing tools. Testing for new methods will begin in the next three months, in collaboration with LHNCBC, USCD, and OCCS. Dr. Fung also presented the Malaria Screener, an Android app that uses AI to automate parasite detection in blood smears, which met WHO Level 3 requirements. Future development will include a desktop version for rodent malaria research. A mobile app for early detection of retinal diseases is also in development, using deep learning to classify fundus images for glaucoma diagnosis, with plans to expand to other retinal conditions.

Dr. Fung then discussed two clinical data science projects: the FISMA-moderate Environment for Health-Related Data about Individuals (FEHRDI) and Center for Clinical Observational Investigations (CCOI). FEHRDI is a centralized, secure storage system for patient-level data, currently housing 11 datasets totaling 2 terabytes. Expansion to other cloud platforms, such as Microsoft Azure and Google Cloud Platform (GCP), is under consideration, with Craig Mayer as the Data Custodian. The CCOI, launched in mid-2024, aims to reduce barriers for researchers by providing a "one-stop shop" for accessing large clinical datasets like AllofUs and the UK Biobank. Future plans include acquiring new datasets, such as the National Emergency Medical Services Information System (NEMSIS) and the Health care Cost and Utilization Project (HCUP), as well as adding advanced search and query functions to improve accessibility.

Lastly, Dr. Fung outlined LHNCBC's alignment with NIH's vision for health care data transformation, emphasizing patient control over data ownership to foster a shared, secure, and interoperable health ecosystem. Dr. Fung concluded by introducing the LHNCBC team.

BOR members discussed LHNCBC's role in intramural research and potential collaborations, including with the NIH Clinical Center. Dr. Fung explained that each dataset has its own analysis platform, with CCOI acting as a hub to provide access and guidance for using data from various sources. The discussion also covered CCOI's strategy for selecting datasets, which includes needs assessments with researchers and evaluating popular datasets, as well as plans to develop tools that allow users to query datasets directly, generate data summaries, and retrieve relevant information from external data sources.

IX. NLM INTRAMURAL RESEARCH PROGRAM AND BOARD OF SCIENTIFIC COUNSELORS UPDATE

Richard Scheuermann, PhD, Scientific Director, NLM

Dr. Richard Scheuermann provided an update on the recent accomplishments of the NLM Intramural Research Program (IRP). He acknowledged NLM IRP investigators for publishing 189 primary scientific papers and review articles within the past 12 months, and highlighted three examples of types of recently-published research: the identification of a novel bilirubin reductase enzyme produced by the gut microbiome, which demonstrates the important symbiotic relationship between humans and our microbiomes; an investigation into generative large language models (LLMs) and their capacity to achieve expert-level performance in various real-world medical tasks, while also highlighting the need to address hidden flaws and safety issues

when implementing medical AI in clinical workflows; and the development of an AI-based system which could serve as a model for inferior vena cava (IVC) analysis and support cardiac diagnostic applications.

Dr. Scheuermann noted recent awards and honors presented to NLM IRP investigators. Among the distinctions: Dr. Eugene Koonin was elected to serve as a Fellow of the International Society for Computational Biology; 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; and Dr. Sameer Antani was elected Fellow of the Institute of Electric and Electronics Engineer (IEEE). In addition to core support from congressional appropriations to NLM, IRP investigators secured additional funding from sources such as the NIH Director's Challenge Awards, the Office of Data Science Strategy (ODSS), and the Office of Autoimmune Disease Research (OADR). Dr. Scheuermann also described the Board of Scientific Counselors Evaluation of IRP investigators and the continuing IRP outreach and strategic and opportunistic recruitment efforts to identify tenure-track investigators. The IRP welcomed a record 32 summer interns from 28 institutions across the United States to the 2024 Data Science and Informatics (DSI) Scholars Summer Internship Program.

In August 2024, per the 2018 Blue Ribbon Panel Review recommendation to unify the IRP under a single Scientific Director, NIH approved the IRP re-organization, establishing a new Division of Intramural Research (DIR). The DIR will also absorb the Computational Biology Branch from NCBI and the Computational Health Research Branch from the LHNCBC.

Dr. Scheuermann presented the Strategic Plan for the DIR, and identified six key goals to help the DIR fulfill its mission to push the frontiers of computational biology and health informatics: (1) foster and grow a broad a broad portfolio of independent and collaborative research; (2) recognize and advance innovative projects that promote NLM's mission; (3) train the next generation of computational researchers; (4) raise the visibility of the NLM DIR's research; (5) enable a robust and supportive Diversity, Equity, Inclusion, and Accessibility (DEIA) environment for research; and (6) advance modern approaches for the administration of the DIR. Each goal includes relevant sub-objectives. For example, the first goal—to grow a broad portfolio of collaborative research—includes defining new areas of research, fostering research in related fields, identifying ways to promote collaboration, conducting targeted recruitment, and identifying one or more high-risk, high-reward projects for the DIR. He also presented a draft infographic of the DIR Strategic Plan and outlined the next steps, including providing an initial draft by December 2024, gathering feedback from NLM Leadership, BOR, Board of Scientific Counselors, and other stakeholders, and developing an implementation plan. The Strategic Plan document is expected to be finalized by March 2025, with implementation beginning in April 2025.

BOR members discussed the challenge of evaluating the overall IRP beyond individual investigator success, the rubric used to evaluate candidates and the recruitment process, and the importance of integrating computational research and health informatics and collaborating with the NIH Clinical Center and other institutes, centers, and agencies.

X. CLOSED PORTION

The closed portion of the meeting took place from 3:30 p.m. to 4:00 p.m. on September 10, 2024. The Board reviewed and approved for further consideration during *en bloc* concurrence, a total of 545 applications with the requested direct cost amount of $232,795,374.

XI. NLM OF THE FUTURE AND RESEARCH ENTERPRISE SERVICES AT NIH

Susan Gregurick, PhD, Associate Director for Data Science, Director, Office of Data Science Strategy, NIH
Sean Mooney, PhD, Director, Center for Information Technology, NIH
Stephen Sherry, PhD, Acting Director, NLM

Dr. Susan Gregurick provided a comprehensive update on the Office of Data Science Strategy (ODSS), highlighting its role in modernizing NIH's data resource ecosystem. She shared progress on the NIH Strategic Plan for Data Science, noting that the responses to the Request for Information (RFI) are currently under analysis, with a public synopsis and the finalized plan expected by the end of 2024. Key goals of the plan include the sustainability of the NIH policy for data management and sharing, enhancing human-derived data for research, exploring new opportunities in software, computation, and AI, and supporting federated data infrastructure.

Dr. Gregurick elaborated on efforts to sustain the NIH Policy for Data Management and Sharing through the data lifecycle. She highlighted several ODSS partnerships, including with the Federation of American Societies for Experimental Biology (FASEB), ELIXIR Core Data Resource, NLM, and the Data Curation Network. She also noted the establishment of a Data Management Center of Excellence (DMCOE), which aims to provide guidance and resources for NIH staff regarding data management sharing plans and the Findable, Accessible, Interoperable, Reusable (FAIR) principles.

The ODSS is supporting key biomedical data assets through two funding announcements aimed at enhancing data repositories and knowledge bases by filling scientific gaps, promoting good data management practices, and ensuring proper governance of the data lifecycle.

Dr. Gregurick introduced the Generalist Repository Ecosystem Initiative (GREI), which aims to improve data sharing effectiveness and promote secondary data use across generalist repositories by fostering "co-opetition"—collaboration among competitors to standardize capabilities and best practices. She also outlined plans to enhance Strategic Biomedical Data Assets (SBDAs), which are dynamic data repositories and harmonized collections that are vital for NIH's mission, by creating sustainability plans, establishing best practices, adopting standardized metrics, and ensuring stakeholder feedback.

The ODSS is supporting an NIH membership in DataCite that will enable NIH funded data resources to mint digital object identifiers (DOIs) for their digital holdings. This effort promotes the FAIR principles and encourages researchers to link their data with their ORCID IDs. Collaboration with FASEB support a Challenge Competition to incentivize secondary data analyses.

Dr. Gregurick highlighted efforts to enhance human-derived data, focusing on improving health outcomes, reducing redundancies, increasing data quality, and facilitating access to diverse datasets for AI applications. She gave an example of the dbGaP Controlled Data Access Process

Modernization Project that aims to streamline the user experience and improve access times, enhancing overall user satisfaction.

ODSS is also collaborating with NLM on the NIH Common Data Element (CDE) Repository, which hosts over 24,000 CDEs. This partnership aims to automate processes and improve user experience by increasing capacity and reducing manual review times. The ODSS also provides training on Fast Health care Interoperability Resources (FHIR) and has initiated the NIH Cloud Platform Interoperability (NCPI) Program, which connects various NIH data systems to enable a federated ecosystem.

Additionally, Dr. Gregurick described the NIH Data and Technology Advancement (DATA) National Service Scholar Program, launched in 2020, which recruits advanced data experts to lead impactful projects, and the new NIH DataPath, which is a program focused on developing early-career data science talent.

Dr. Sean Mooney then presented the new vision for the Center for Information Technology (CIT), highlighting its historical origins as a central processing facility within the NIH Office of the Director. He introduced the Digital NIH Framework, which encompasses extramural and intramural research along with NIH administration, leading to five key recommendations: (1) a common architecture for integration; (2) an innovative storage and analytics infrastructure; (3) a technically competent workforce; (4) technology for a flexible workplace; and (5) embedded cybersecurity protections.

To guide these efforts, the Information Technology, Cyberinfrastructure, and Cybersecurity (ITCC) Working Group of the Advisory Council to the Director (ACD) was established in 2024. This group includes both internal and external members and will meet quarterly or biannually, with an interim report due in 12 months and a final report in 18-24 months. Dr. Mooney emphasized the vital role of the NIH Network, which supports 45,000 staff and 700,000 visitors across 200 buildings, featuring 65,000 devices over 4,300 miles of infrastructure and a 100 Gbps connection. This network handles significant daily internet traffic while facing rising costs in IT and data.

Dr. Mooney also discussed key initiatives, including the NIH Science and Technology Research Infrastructure for Discovery, Experimentation, and Sustainability (STRIDES) Initiative, which promotes modern, secure technology and cost efficiencies through usage-based discounts. The initiative currently supports over 334 million gigabytes of data for approximately 2,500 research programs. He introduced the NIH Cloud Lab, which provides NIH-associated researchers with $500 in credits for cloud access and tailored training.

He highlighted the importance of cyberinfrastructure in managing clinical research data, addressing challenges such as improving integration across workspaces and scaling solutions. Future goals include enhanced data management, exemplified by initiatives like the Researching COVID to Enhance Recovery (RECOVER) platform for Long COVID research. Finally, Dr. Mooney outlined CIT's strategy to support NIH institutes and centers in data management and analysis, emphasizing ongoing collaborations with NLM, including the Researcher Authentication Service (RAS) and advancements in AI services. To keep the NIH community informed, a newsletter for CIT will be forthcoming.

Dr. Stephen Sherry discussed NLM's collaborative IT priorities, highlighting three main themes: AI, sustainability, and the enterprise information landscape. He emphasized NLM's role in AI research, noting its trusted reputation for providing biomedical standards and computational research, which are essential for driving national competitiveness. NLM is leveraging its curated repository of information for secure generative AI applications, underscoring the importance of human oversight in maintaining workforce capabilities. Current pilot projects focused on ten use cases aim to develop best practices for large language models (LLMs) within Azure's "playground."

Dr. Sherry highlighted NLM's initiative to transform big data into computable knowledge, specifically through the creation of a knowledge graph centered on cellular information, which involves integrating pre-computed data with insights from PMC literature. To address responsible AI practices, NLM is implementing risk-mitigating frameworks such as the NIST AI Management Framework. NLM is also fostering a culture of responsible AI oversight by identifying key projects, documenting challenges, and recommending standards aligned with best practices.

Sustainability is a priority, with efforts focused on management tools for biomedical data assets and promoting standardized metrics. NLM aims to assess the maturity and interoperability of SBDAs. Collaboration among ODSS, CIT, NLM, and OCIO is vital in shaping the data science landscape at NIH. NLM's governance roles position it to influence policy development and the implementation of AI initiatives across NIH.

BOR members discussed the cost and utility of data sharing, strategies to enhance return on investment (ROI) by evaluating core repositories like the Sequence Read Archive (SRA), and opportunities for less-resourced institutions to address local research questions. They emphasized the need for better showcasing of data reuse. Dr. Gregurick highlighted that datasets are citable, allowing researchers to receive credit for both depositing and using data, and proposed collaboration between NLM and ODSS to incentivize data reuse through targeted funding opportunities.

Dr. Mooney noted that CIT is currently assessing the cost-effectiveness of tools to save money and enhance efficiency, viewing IT infrastructure as a facility rather than a grant. This perspective encourages discussions on how NIH supports IT infrastructure, and BOR members explored how NLM, ODSS, and CIT support could be adapted for small clinics and health departments. Dr. Mooney acknowledged challenges in implementing NIH tools, highlighting the need for technical skills and HIPAA-compliant personnel in clinical settings.

The discussion also emphasized the roles of electronic health record (EHR) vendors and IT standards in effective data management. Dr. Gregurick shared ODSS initiatives focused on improving clinical trial participation in small and rural communities. BOR members proposed a demonstration project at small clinical and rural sites to evaluate effective implementation in these settings. They noted the importance of addressing the unique challenges faced by diverse populations, positioning NLM as a valuable resource for identifying and tackling issues within these communities.

BOR members discussed the importance of understanding various research platforms to enhance user experiences in unfamiliar environments, with a focus on developing robust, community-

driven software to ensure sustainability and modularity. NIH's Research Software Engineer Award aims to support Principal Investigators (PIs) with funding opportunities for software development. Members also highlighted the need for consistent data identification across servers and advocated for documenting data extraction assumptions to address discrepancies in large datasets.

While products like PubMed Central (PMC) are valuable for clinicians, challenges remain in applying this information in clinical settings. NLM is exploring ways to aggregate real-world health outcome data to assess drug efficacy and track adverse events, aiming to leverage passively generated data for improved analysis and decision-making in health care.

BOR members discussed strategies for standardizing how datasets and articles are reported to promotion and tenure committees, highlighting the need for new technologies and tools to better link data management sharing plans and enhance metadata tracking. They emphasized establishing standards for dataset identification, such as using Digital Object Identifier (DOI) variants and clinical trial identifiers. The Dataset Catalog, currently in its beta stage, aims to become a PubMed-like resource for finding datasets, includes DOIs, and serves as a robust metadata model for describing datasets. Members were encouraged to test the proof-of-concept platform.

BOR members also raised promotion and tenure activities that are being addressed for academic organizations . The American Academy of Universities (AAU) and the Association of Public and Land-grant Universities (APLU) have been exploring this, along with a roundtable at National Academies of Science, Engineering, and Medicine (NASEM) focused on incentives, which includes key representatives from academic institutions.

The discussion also addressed NLM's resources, training programs, initiatives, and funding opportunities designed to help researchers and medical students leverage AI in research and clinical decision-making. The NIH AI/Machine Learning Consortium to Advance Health Equity and Researcher Diversity (AIM-AHEAD) Program was highlighted.

AIM-AHEAD is an AI/ML consortium focused on enhancing the representation of underserved populations and researchers in AI development. Utilizing a co-design approach, algorithms are created in collaboration with the communities they aim to serve, particularly those from underrepresented backgrounds, including tribal colleges and community groups. Members also discussed an opportunity for a partnership between CIT and NLM to support AI through technical office hours, where subject matter experts (SMEs) provide real-time support and consultations to intramural investigators and extramural program officers developing AI services and tools.

BOR members urged NLM to explore broader strategic directions for post-market surveillance studies for AI, beyond clinical care for underserved communities. They suggested NLM consider becoming a standard repository for validating systems and establishing future criteria. Members emphasized the importance of balancing centralized and distributed data for computational purposes and recommended that NIH engage with indigenous groups to ensure their data remains integral to the ecosystem, to empower communities in controlling data access and disclosure.

Additionally, BOR members proposed supporting underserved communities in improving health

equity through personalized information. They advocated for synthesizing publicly available clinical trial data and best practices to train generative models that interact with patients. This would require NLM to assess its budget, framework, expertise, and computational capacity to turn its rich data into actionable knowledge.

XII. PRESENTATION OF REGENTS AWARD

Lola Ogunyemi, PhD, Chair, BOR

Dr. Ogunyemi presented the Board of Regents Award for Scholarship or Technical Achievement, which recognizes scholarly and technical achievements that enrich biomedicine, to the following individuals:

- **Dr. Zhiyong Lu**, Senior Investigator in the Computational Biology Branch of the Division of Intramural Research. Dr. Lu was recognized for outstanding and scholarly achievement leading to the development of TrialGPT, a large language model framework to aid patients.
- **Mr. Jeffery Beck**, Supervisory Technical Information Specialist in the Information Engineering Branch of NCBI, **Mr. Peter Siebert**, Supervisory Technicial Information Specialist in the Health Data Standards Branch of the User Services and Collection Division, and **Mr. Alvin Stockdale** and **Ms. Nancy Fallgren**, Technical Information Specialists in the Discovery Branch of the User Services and Collection Division. Mr. Beck, Mr. Siebert, Mr. Alvin, and Ms. Fallgren were recognized for their leadership and expertise leading to the development and launch of the Dataset Catalog beta product and the Dataset Catalog Metadata Model (DATMM) that accelerates discovery and advances NLM's Strategic Plan.

XIII. ADJOURNMENT

Dr. Ogunyemi adjourned the BOR meeting at 11:45 a.m. on September 11, 2024.

Actions Taken by the Board of Regents:

- Approval of the May 14, 2024, BOR meeting minutes
- Approval of the September 15-16, 2026, meeting dates
- Review and Recommendation for Establishment of the Sequential Read Archive (SRA) Sustainability Working Group under the Board of Regents
- *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: 2024.11.14 10:26:13 -05'00'

Stephen Sherry, PhD
Acting Director, National Library of Medicine

Digitally signed by Omolola Ogunyemi
Date: 2024.11.18 18:06:17 -08'00'

Omolola Ogunyemi, PhD
Chair, NLM Board of Regents