National Institute of
Arthritis and Musculoskeletal
and Skin Diseases

Minutes of the National Arthritis and Musculoskeletal and Skin Diseases Advisory Council Meeting

January 30, 2024

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
NATIONAL ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES ADVISORY COUNCIL

MINUTES OF THE 113th MEETING

I. CALL TO ORDER

The 113th meeting of the National Arthritis and Musculoskeletal and Skin Diseases Advisory Council (NAMSAC) was held on January 30, 2024, via videoconference. The meeting was chaired by Dr. Lindsey A. Criswell, Director, National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS).

Attendance

Council members present:
Dr. Edward Botchwey, Professor of Medicine, Wallace H. Coulter Department of Biomedical Engineering, Georgia Institute of Technology
Dr. Mary L. Bouxsein, Professor, Department of Orthopedic Surgery, Harvard Medical School; Center for Advanced Orthopedic Studies, Beth Israel Deaconess Medical Center
Dr. Leigh F. Callahan, Associate Director, University of North Carolina Thurston Arthritis Research Center; Mary Link Briggs Distinguished Professor of Medicine; Professor, Departments of Social Medicine and Orthopedics; Director, Osteoarthritis Action Alliance; University of North Carolina School of Medicine
Ms. Ann Elderkin, P.A., Consultant, American Society for Bone and Mineral Research (ASBMR)
Dr. Luis A. Garza, Associate Professor of Dermatology, Johns Hopkins School of Medicine
Dr. Stuart B. Goodman, Robert L. and Mary Ellenburg Professor of Surgery, Department of Orthopaedic Surgery, Stanford Medical Center Outpatient Clinic
Dr. Ellen M. Gravallese, Chief, Division of Rheumatology, Inflammation, and Immunity, Theodore Bevier Bayles Professor of Medicine, Brigham and Women's Hospital
Dr. Valentina Greco, Carolyn Walch Slayman Professor of Genetics, Yale University
Dr. Elizabeth McNally, Elizabeth J. Ward Professor of Genetic Medicine, and Director, Center for Genetic Medicine, Northwestern University Feinberg School of Medicine
Ms. Suzanne M. Schrandt, Founder, CEO, and Patient Advocate, ExPPect, LLC
Dr. Maria E. Suarez-Almazor, Barnts Family Distinguished Professor, Department of Health Services Research, Cancer Prevention and Population Sciences, and Section of Rheumatology and Clinical Immunology, Department of General Internal Medicine, Division of Internal Medicine, The University of Texas MD Anderson Cancer Center
Dr. Jinoos Yazdany, Chief, Division of Rheumatology, Zuckerberg San Francisco General Hospital

Staff and Guests

The following NIAMS staff and guests attended:

Staff

Dr. Lindsey Criswell
Dr. Robert Carter
Dr. Robert Colbert
Dr. Gayle Lester
Dr. John O'Shea
Dr. Darren Sledjeski
Mr. Steve Austin
Dr. Deepti Bajpai
Ms. Pamela Beheler
Dr. Alexey Belkin
Mr. Mark Brown
Ms. Tanisha Brown-Caines
Dr. Stephanie Burrows
Ms. Justine Buschman
Dr. Emily Carifi
Dr. Faye Chen
Dr. Ricardo Cibotti
Mr. Jon Davis
Ms. Robin DiLiello
Ms. Teresa Do
Dr. Jonelle Drugan
Mr. Erik Edgerton
Ms. Jana Eisenstein
Dr. Yasuko Furumoto
Dr. Mary Garcia-Cazarin
Dr. Stephanie George
Ms. Shappelle Ivey
Dr. Shyamalagauri Jadhav
Dr. Archana Jha
Mr. David Johnson
Dr. Peter Koch
Ms. Sarisa Kowl
Ms. Stephanie Kreider
Ms. Medha Krishnagiri
Dr. Rebecca Lenzi
Dr. Marjorie Lindhurst
Ms. Ryan Lombardi
Dr. Kan Ma
Dr. Marie Mancini
Dr. Su-Yau Mao
Dr. Aron Marquitz
Ms. Katrina Matthews
Ms. Jennifer Morgan Gray
Ms. Sara Myers
Mr. Christopher Nee
Ms. Melinda Nelson
Dr. Van Nguyen
Dr. Kristy Nicks
Dr. Heiyoung Park
Dr. Sushmita Purkayastha
Dr. Saumyadipta Pyne
Ms. Sahar Rais-Danai
Ms. Rebecca Ricklis
Dr. Kathy Salaita
Dr. Susana Serrate-Sztein
Dr. Kriti Sharma
Ms. Anamika Singh
Dr. Raj Srinath
Ms. Yen Thach
Ms. Dandre Thornhill
Mr. Herman Utama
Dr. Aneliya Velkova
Dr. Robert Walker, Jr.
Dr. Xibin Wang
Dr. Yan Wang
Dr. Chuck Washabaugh
Ms. Shalanda Wellington
Dr. Xincheng (Ted) Zheng

A total of 264 NIH staff and members of the public watched via NIH Videocast.

Guests:

Dr. Michael Chiang, Director, National Eye Institute

II. INTRODUCTIONS/CONSIDERATION OF MINUTES/FUTURE COUNCIL MEETING DATES

Dr. Lindsey Criswell, NIAMS Director, called to order the 113th meeting of the NIAMS Advisory Council and led Council members and Institute leadership in a round of introductions. Dr. Darren Sledjeski, NAMSAC Executive Secretary, reviewed the logistics for the meeting and reminded members of the public that they may submit written comments at the email address NIAMScouncilmail@niams.nih.gov up to 15 days following the meeting. Dr. Sledjeski reminded Council members of their conflict of interest obligations under federal law and notified the Council of upcoming conflict of interest reporting dates.

Dr. Sledjeski asked the Council if there were any comments or corrections on the minutes of the 112th NAMSAC meeting, which took place on August 29, 2023. There were no comments, and Dr. Sledjeski moved to approve the minutes. The motion was seconded and approved unanimously.

Dr. Sledjeski noted that the dates of the next three Council meetings are scheduled for May 29, 2024; September 17, 2024; and January 28, 2025. The May 29 meeting will be an in-person meeting, the September 17 meeting will be held in a hybrid format, and the meeting next January will be conducted virtually.

III. NIAMS DIRECTOR'S REPORT AND DISCUSSION

Dr. Criswell began her remarks by announcing that this will be the last meeting for Drs. Mary Bouxsein, Leigh Callahan, and Luis Garza and Ms. Suzanne Schrandt as members of the Council. Dr. Criswell thanked them for agreeing last year to continue to serve an additional 180 days on the Council under an administrative extension and for having devoted their valuable time in support of NIAMS over the recent years.

Budget

Dr. Criswell updated the Council on the status of the NIH and NIAMS budgets. NIH is currently operating under a continuing resolution that expires on March 8 as Congress works to pass a formal budget for fiscal year () 2024. The draft budgets from both the Senate and House of Representatives have proposed a flat budget for NIAMS for the coming year. In a climate of anticipated cuts to federal spending, Dr. Criswell is grateful to members of Congress and the American public for keeping NIH and NIAMS mission areas a priority. Nevertheless, even a flat budget will have negative consequences on NIAMS' ability to support important science. Dr. Criswell also warned that last year's Fiscal Responsibility Act included language that would trigger automatic cuts to discretionary spending if Congress is unable to reach agreement on the federal budget by April 30. If these cuts were to take place, NIH is particularly concerned about the effect it would have on trainees and early-stage investigators (ESIs), based on experiences from the last budget sequestration in 2013.

Despite the uncertain budget outlook, NIAMS continues to fund the best-scoring applications. As Dr. Criswell discussed at the previous Council meeting, while NIAMS' 10th percentile payline figure from last year is lower than in previous years, NIAMS expanded its use of "select pay," which are funds made available for meritorious research applications identified as being of the highest priority that score beyond the published payline. This change has not affected the overall number of R01 grants that NIAMS has been able to fund compared to recent years. However, the prospect of a budget that does not keep up with inflation will complicate the Institute's ability to make a consistent number of awards without changing its funding policies. As one might expect, how to minimize the negative impacts of a constrained budget climate is a top priority for NIAMS and NIH as a whole. Dr. Criswell mentioned some examples of funding policy changes that might be made, such as decreasing the number of new and/or competing awards and limiting the number of grants an individual investigator can receive. NIH and NIAMS remain committed to supporting a robust research workforce capable of sustaining scientific momentum and weathering this difficult period.

Personnel Changes

Before updating the Council on new arrivals and departures at NIH and NIAMS, Dr. Criswell announced the recent passing of Dr. Paul Plotz, long-time NIAMS intramural investigator and scientist emeritus. Dr. Criswell described Dr. Plotz's career as a research rheumatologist and his four decades of service to NIAMS, including time as Acting Scientific Director and Acting Deputy Director.

At the NIH level, Dr. Monica Bertagnolli was confirmed by the Senate as the new Director of the NIH last fall, and she began her tenure on November 9. Dr. Bertagnolli's priorities as Director are to ensure clinical trials yield the best results by increasing the diversity of participants, to embrace the potential of advanced data science analytic tools while ensuring their use improves care for all people, and to restore trust in science by making it accessible to all communities and inspiring the next generation of doctors and scientists. She also aims to prioritize increased collaboration between NIH Institutes and Centers (ICs). To replace Dr. Bertagnolli as Director of the National Cancer Institute (NCI), President Joseph Biden selected Dr. Kimryn Rathmell to serve as the 17th NCI Director.

Elsewhere at NIH, Dr. Patricia Brennan retired as the Director of the National Library of Medicine in September following an influential tenure, and Dr. Stephen Sherry is serving as Acting Director while NIH conducts a national search to fill the position. Dr. Criswell also announced several new additions to roles within the Office of the NIH Director. Dr. Tara Schwetz has been appointed NIH Deputy Director for Program Coordination, Planning, and Strategic Initiatives, Dr. Lyric Jorgenson has been named NIH Associate Director for Science Policy, and Ms. Kate Klimczak is now the Associate Director for Legislative Policy and Analysis. Dr. Criswell also informed the Council of new members of the leadership team at the Office of Research on Women's Health (ORWH) and its newly-established Office of Autoimmune Disease Research (OADR-ORWH). Dr. Vivian Ota Wang has been named the new ORWH Deputy Director, and Dr. Victoria Shanmugam has been appointed the inaugural Director of OADR-ORWH.

At the NIAMS level, Dr. Criswell provided an update on the search for the next NIAMS Scientific Director following Dr. John O'Shea's decision to step down from that role. NIAMS began receiving applications in late October and has received a robust response thus far. The Institute is considering a number of highly qualified candidates, and Dr. Criswell hopes to have the position filled by this summer. She thanked Dr. O'Shea for staying on in the role during the search process. Elsewhere at the Institute, Ms. Dandre Thornhill was recently hired as the Chief of the Clinical Research Operations and Management Branch. NIAMS has also brought on two Scientific Review Officers: Drs. Archana Jha and Sushmita Purkavastha. Dr. Criswell announced two notable staff departures since the last Council meeting. Dr. Helen Lin has retired after 20 years of federal service, and Mr. Neil Roberts has moved on to an opportunity at another NIH IC.

NIH and NIAMS Activities of Interest

Dr. Criswell announced that President Biden recently established the White House Initiative on Women's Health Research. The initiative will be managed by the Office of the First Lady, and it aims to foster trans-agency collaboration to deliver recommendations to advance women's health research. Dr. Criswell highlighted that training and career development will be a priority area for this program. NIAMS has provided information on research opportunities at NIAMS and NIH in support of the program.

As Dr. Criswell briefly noted earlier in the Director's Report, upon taking up the role as NIH Director, Dr. Bertagnolli quickly articulated her guiding principles that will inform her tenure. In addition to the priorities mentioned above, Dr. Bertagnolli believes that NIH's work is not finished until all people are living long and healthy lives. NIH research should include the community and patients as partners in discovery and strive to eliminate barriers to participation across all sociodemographic categories. Dr. Bertagnolli also is stressing NIH's commitment to harnessing the power of artificial intelligence and machine learning (AI and ML) to advance research and emphasized that progress is accelerated when these advanced methods are applied to inclusive data and when discoveries are rapidly and equitably translated to the clinic. Dr. Criswell highlighted two existing NIH Notices of Funding Opportunity (NOFOs) that are in alignment with these principles: Health and Health Care Disparities Among Persons Living with Disabilities (R01) and Transformative Research to Address Health Disparities and Advance Health Equity (U01). These NOFOs are managed by the National Institute on Minority Health and Health Disparities and the National Institute of Nursing Research, respectively.

Following Dr. Criswell's Director's Report, the Council will hear from Dr. Michael Chiang, the Director of the National Eye Institute (NEI). NEI is a partner with NIAMS on a number of trans-NIH initiatives, such as the Accelerating Medicines Partnership® (AMP®) Autoimmune and Immune-Mediated Diseases (AIM) Program. Dr. Criswell reminded the Council that one of her goals as Director is to forge partnerships with every NIH IC, and NIAMS' work with NEI is an important part of achieving that goal. The two Institutes are also partnering on a proposed AMP initiative called the AMP Cell-Based Therapy Consortium (CBTC), which aims to confront issues related to translational biology, manufacturing, and clinical trial design for cell therapies that can be applied to a range of diseases and conditions.

Dr. Criswell also made the Council aware of two important NIH Requests for Information (RFIs), the NIH Strategic Plan for Data Science 2023-2028 and NIH-Wide Strategic Plan for Autoimmune Disease Research. The latter RFI is designed to inform the work of the OADR-ORWH office mentioned earlier. Responses to the RFIs are due March 15 and March 1, respectively.

A NIAMS-led NIH Common Fund concept was recently presented to the NIH Council of Councils, which serves as NIH's external review panel for Common Fund concept proposals. The proposed concept, called SysBio, would be a pilot program for the Common Fund's Venture Space initiative, which is designed to support transformative, catalytic, and cross-cutting programs that are smaller and shorter than conventional Common Fund programs. SysBio aims to develop a systems biology data portal that leverages AMP achievements to enable a new paradigm for understanding the causal biology of chronic diseases and accelerate the development of precision medicines.

In December, the NIH Advisory Committee to the Director Working Group on Re-envisioning NIH-Supported Postdoctoral Training released its recommendations, which called for the NIH to increase pay and benefits for all NIH-supported postdoctoral scholars, expand K award funding mechanisms, promote training and professional development, and develop improved metrics for assessing career progression, among other recommendations. Dr. Criswell noted that the Working Group acknowledged the broad scope of their recommendations and the need for the extramural community to support these efforts. NIH is currently reviewing the recommendations, and more information will be released regarding next steps in the coming months. In other NIH workforce news, the NIH Fellows United union received a majority of votes in favor of its establishment and has affiliated itself with the United Automobile, Aerospace and Agricultural Implement Workers of America, also known as UAW. The National Labor Relations Board certified the election on December 15, 2023. NIH Fellows United unit represents approximately 5,000 fellows, and NIH looks forward to partnering with the UAW to negotiate a historic collective bargaining agreement for both parties.

Dr. Criswell was excited to announce that NIAMS will be supporting a second round of awards for the Team Science Leadership Program in Women's Health, Autoimmune and Immune-Mediated Diseases, under the auspices of AMP AIM. Applications will be accepted through April 1, 2024.

In December 2023, NIAMS held its annual forum for clinical mentored K awardees in their third year. The forum brings together scholars and others across NIAMS' mission areas to discuss the challenges of pursuing independent research careers.

Dr. Criswell updated the Council on NIAMS' fiscal year 2025-2029 strategic plan development activities. NIAMS held a three-day idea generation meeting in September and issued an RFI in November to solicit input on cross-cutting themes identified at those sessions. The Institute has begun the drafting process and plans to present the draft strategic plan to the NAMSAC prior to its May meeting. After receiving Council input, the draft plan will be released to the public for further feedback. NIAMS intends to submit the final plan to the Council for its consideration at the fall NAMSAC meeting.

To conclude the Director's Report, Dr. Criswell discussed the biennial NIAMS Coalition Outreach and Education Meeting that was held in September. The gathering provides an opportunity for Coalition members to share best practices on connecting science to the public and to offer Coalition members insight into how NIAMS functions. The meeting was attended by over 50 representatives from over 40 Coalition member organizations and included presentations by Dr. Julie Gerberding, the CEO of the Foundation for the NIH (FNIH), and Dr. Renee Wegrzyn, Director of the Advanced Research Projects Agency for Health (ARPA-H).

Discussion

Dr. Mary Bouxsein asked Dr. Criswell to elaborate on NIAMS' involvement with the White House Initiative on Women's Health Research and the program's objectives. Dr. Criswell said that NIH ICs were asked to identify opportunities to advance women's health research, and NIH leadership has also worked to respond to the White House's request for policy recommendations in this arena. NIAMS has not heard back yet following these action items, but Dr. Criswell anticipates NIAMS will continue to play a prominent role in NIH's future interactions with the Initiative. Ms. Ann Elderkin briefly discussed the ASBMR's activities to provide policy recommendations to the Initiative regarding osteoporosis and fracture liaison services.

Dr. Bouxsein also asked if any assessment has been made on the impact implementing the Working Group on Re-envisioning NIH-Supported Postdoctoral Training's recommendation for an across-the-board postdoc pay increase would have on the budget. Dr. Criswell said that NIH is strongly in favor of providing additional support to postdoc scholars, and discussions are underway on how to make this happen given the realities of the budget. Dr. Criswell hopes this conversation will help stimulate further efforts to find efficiencies in the biomedical research enterprise.

Dr. Luis Garza asked Dr. Criswell to expand on NIAMS' efforts to maintain a generous payline and how NIAMS and NIH can navigate the constrained budget climate without discouraging the next generation of researchers. Dr. Criswell acknowledged the funding challenges that NIAMS is facing, both in terms of the political climate and NIAMS' status as one of the smaller ICs. Because the Institute's budget is set by Congress, NIAMS has limited flexibility in redirecting how that money is spent. This makes the outreach efforts all the more important in order to positively affect future funding cycles. In the meantime, NIAMS is striving to maximally leverage its own resources and to take advantage of collaborative opportunities and trans-NIH programs. The decision to increase select pay funding is an important part of this effort.

Dr. Valentina Greco said she was excited to hear about the K awardee forum and suggested that future meetings include the entire K awardee community. She also asked if it would be possible for NIAMS to attempt to renegotiate grants so that universities cover more of the indirect costs, since their budgets are less impacted by political climate in Congress. Dr. Robert Carter, NIAMS Deputy Director, said that renegotiation of federal contracts takes place above the level of NIH, at the Office of Management and Budget, and the process is outside of the control of individual ICs.

The Council continued to discuss with NIAMS staff the potential impacts of raising postdoc scholar salaries. Providing across-the-board raises will have to be paid for by a reduction in the number of postdocs that can be supported by NIH. Dr. Criswell acknowledged the importance of this issue and the future of the biomedical research career pathway, and she suggested that this would be a good topic for a future Council meeting.

IV. NATIONAL EYE INSTITUTE: WHAT WE DO, AND WHAT WE COULD DO WITH NIAMS

Dr. Criswell introduced Dr. Michael Chiang, Director, NEI, to present on the work of his Institute and opportunities for collaboration between NEI and NIAMS. Before being named NEI Director in 2020, Dr. Chiang held several appointments at the Oregon Health and Sciences University.

Dr. Chiang began his presentation by briefly describing his research background and career trajectory. He noted that he originally studied engineering before going on to medical school and an ophthalmology residency, and early on became interested in biomedical informatics, telehealth, and, as his career progressed, biomedical applications of AI and data science.

NEI was established in 1968 and two years ago revised its mission statement for the first time since its founding. After conducting fulsome outreach, the Institute published its new mission statement, "to eliminate vision loss and improve quality of life through vision research," which it aims to achieve by driving innovative research, fostering collaboration in vision research and clinical care, recruiting and training a talented and diverse workforce, and educating people about advances in vision research and how they affect their lives. Dr. Chiang also provided a high-level overview of NEI's current strategic plan that is in effect until 2026. The plan has seven areas of emphasis: genetics, neuroscience, immunology, regenerative medicine, data science, quality of life, and public health and disparities research. These areas of emphasis are designed to be cross-cutting across NEI's research portfolios that are organized by disease and anatomical structure. During his presentation, Dr. Chiang focused on three of NEI's areas of emphasis that are particularly ripe for collaboration with NIAMS: regenerative medicine, data science, and immunology.

On the topic of regenerative medicine, Dr. Chiang talked about how the first FDA-approved gene therapy for an inherited disease was for Leber congenital amaurosis, and the therapy was based on a gene initially cloned in the NEI IRP. The eye is a prominent organ for work in this area because it is uniquely accessible for non-invasive observation and surgical techniques, and for this reason many early advances in gene editing and gene therapy were conducted in the eye. Dr. Chiang discussed NEI's involvement in the AMP Bespoke Gene Therapy Consortium (BGTC), which is a public-private partnership that aims to develop gene therapy platforms and standards for ultra-rare diseases. NEI was keen to partner in this program because there are many rare genetic eye conditions. Another example of NEI's work in regenerative medicine dates back to its 2013 Audacious Goals Initiative, which set the goal of regenerating neurons and connections in the visual system (i.e., photoreceptors and retinal ganglion cells). This program has supported approximately $80 million in grants for research on functional imaging, regenerative factor

discovery, and translational modeling. Dr. Chiang also described two NEI-supported studies that are exploring the frontiers of cell therapy. The first, out of Dr. Kapil Bharti's lab in the NEI IRP, uses induced pluripotent stem-cell-derived retinal pigment epithelium scaffolding to treat dry age-related macular degeneration. The second, from Dr. Ula Jurkunas at Harvard, involves limbal stem cell replacement to treat severe corneal injuries via a process that regenerates corneal epithelial cells. These research efforts have highlighted the need for the development of good manufacturing practices for cell replacement tissues and means of assessing transplant survival and tissue integration. Dr. Chiang also described the NIH Regenerative Medicine Innovation Project (RMIP), which is a recently-concluded trans-NIH project to accelerate the field by supporting clinical research on adult stem cells. The program emerged from the 21st Century Cures Act and was provided a budget of $30M, ultimately funding 20 projects from 2017-2020. NEI recently partnered with NIAMS to create a working group to determine the level of interest in another iteration of RMIP focused on cell-based therapies, potentially as an AMP program.

Dr. Chiang next described NEI's work on the data science area of emphasis. Modern science is coming to be defined by the unprecedented access to large-scale data methodologies across the biomedical research spectrum from molecules to tissues to people and to populations. One of the most influential avenues of innovation in vision research in recent years has been the development of greatly improved imaging technologies, which has enabled the rapid integration of AI and ML applications into vision research and the emergence of the field of oculomics. Dr. Chiang highlighted the need for the biomedical research enterprise to be wary of the ways AI and ML can produce or perpetuate biases, and this concern is at the forefront of NIH's myriad data science initiatives. One of the important trans-NIH data science programs that NEI helps manage is Bridge2AI, which aims to accelerate the use of AI by generating flagship datasets from multiple sources and developing standards for data collection, data management, and bias reduction. The program is funded for up to $130 million in grants over four years, and Dr. Chiang said the ultimate goal is to use AI to recognize diseases and help understand chronic disease progression and recovery. As the field of data science expands and becomes more central to the research enterprise, the need for data sharing standards and data harmonization strategies becomes ever more vital. Dr. Chiang strongly believes that there needs to be incentives for data sharing to complement the recent federal policy announcements. One such example could be academic and research journals establishing a new publication type for articles about datasets or software libraries. NEI has also been working with the American Academy of Ophthalmology (AAO) to develop a common data model. The concept of a federated data network is emerging as the more feasible path forward, as opposed to a centralized model, and NEI selected the Observational Health Data Sciences and Informatics Observational Medical Outcomes Partnership Common Data Model for a proof-of-concept pilot study. The pilot was conducted by Dr. Cindy Cai of the Johns Hopkins School of Medicine who developed a cohort of 6.1 million patients from a larger collection of datasets representing 485 million individuals and answered her research question within nine weeks. Dr. Chiang also described NEI's efforts to overcome the hurdle of proprietary imaging formats, which culminated in a joint statement by the AAO and the Association for Research in Vision and Ophthalmology calling for the adoption of standard formats for digital imaging. For its part, NEI plans to include language in future NOFOs that will strongly encourage standards conformance. Dr. Chiang also informed the Council about the NEI Data Commons, which is a central resource for indexing vision research data, tools, software, and policy resources.

Finally, Dr. Chiang discussed NEI's work on the immune system and eye health. In recent years, the role of the immune system has become increasingly important in understanding eye health. Dr. Chiang briefly described several NEI-funded uveitis-related studies and the ocular surface microbiome. Dr. Chiang noted that one of the awardees in the Team Science Leadership Scholars Program in Women's Health, Autoimmune and Immune-Mediated Diseases that Dr. Criswell mentioned in her report is a vision researcher. Dr. Chiang also briefly touched on NEI's involvement in the AMP-AIM program. There are a number of immunological conditions where NEI and NIAMS can collaborate, most notably Sjögren's syndrome.

In summary, Dr. Chiang listed a series of ideas for topics that NIAMS and NEI can consider collaborating on: cell-based therapies, incentives for data sharing, common data models, multimodal data ecosystems, and systems biology modeling for inflammatory eye disease.

Discussion

Dr. Ellen Gravallese asked Dr. Chiang if he thought any of the potential collaboration topics should be prioritized or are more likely to produce fruitful results in the near-term. Dr. Chiang said that was a tough question because the research with the greatest potential impact is often the most difficult to achieve, but he believes that regenerative medicine collaborations would have the most momentum right now. Developing improved data infrastructure could also yield wide-ranging benefits by enabling more researchers to do their work better.

Dr. Jinoos Yazdany asked how NEI handles the balancing of investments between data science infrastructure activities and traditional hypothesis-driven science. Dr. Chiang said that he sees the infrastructure efforts and traditional research as working hand-in-hand, and he particularly likes study designs that combine both in the same project.

Dr. Edward Botchwey discussed with Dr. Chiang how trans-NIH programs like AMP select the disease areas they target and the importance of developing technologies that are available to the people who need them the most.

V. NIAMS INTRAMURAL RESEARCH PROGRAM (ANNUAL IRP REPORT)

Dr. Criswell invited Dr. O'Shea and Dr. Robert Colbert, NIAMS Clinical Director, to deliver the annual report to Council on the activities of the NIAMS IRP.

The NIAMS IRP is currently comprised of approximately 270 staff members and accounts for approximately 11% of NIAMS' budget. The IRP employs 40 faculty-level staff, which includes 11 tenured senior investigators and three tenure-track investigators. 23 of these staff conduct clinical research, and 15 focus on basic research. Dr. O'Shea noted that the relatively small size of the NIAMS IRP compared to other NIH ICs requires its work to be more coordinated and focused. The IRP maintains two clinical programs: rheumatology (which includes the NIAMS Community Health Clinic) and dermatology. Dr. O'Shea noted that the Dermatology Consult Service is the busiest consult service at the NIH Clinical Center. The IRP also includes six

Research Cores, the Career Development and Training Branch, and the Administrative Management Branch. Dr. O'Shea presented a list of the IRP's faculty-level researchers and noted their research interests, which Dr. O'Shea described as fairly evenly balanced between basic science and translational clinical research. The faculty-level staff list includes NIAMS' two Independent Research Scholars. Dr. O'Shea mentioned that the future of this program is unclear given the NIH Fellows United unionization that Dr. Criswell mentioned in her report. Dr. O'Shea then described several research highlights from the 172 publications generated by the IRP in 2023, as well as a number of awards, career milestones, and other noteworthy achievements by IRP staff.

Dr. O'Shea also provided an update to the Council on the NIAMS IRP's DEIA-related activities, including the promotion of Dr. Robert Walker to the role of NIAMS Chief Diversity Officer, several workshops and training events, and participation in NIH DEIA-focused scholarship programs. Dr. O'Shea also previewed this year's IRP Scientific Retreat, which will include keynote speeches by Dr. John Mather from NASA, Dr. Jimmie Ye from UCSF, Dr. Azra Raza from Columbia University, and Dr. Jinoos Yazdany, also from UCSF and a NIAMS Council member.

Dr. Criswell then invited Dr. Colbert, NIAMS Clinical Director, to brief the Council on the IRP's Clinical Program, including NIAMS' Rheumatology Fellows and Scholars, the Community Health Clinic (CHC) and Hope Center, clinical and translational advances from IRP research, and upcoming clinical trials. Including this year's class, NIAMS has eight Rheumatology Fellows and five Scholars in Translational Research. Dr. Colbert briefly discussed their research interests and progress. The three new Rheumatology Fellows for the 2024 cohort are Drs. Casey Stein, Hannah Berrett, and Jessica Simpson, and the two new Scholars are Drs. Mariana Correia and Meghan Nelson. Last January, Dr. Paul DeMarco joined NIAMS as the new Director of the Adult Rheumatology Fellowship Program and the CHC. Dr. DeMarco's background is in musculoskeletal sonography, which Dr. Colbert looks forward to seeing incorporated into NIAMS' protocols. The CHC was established in 2001 as an extension of the Rheumatology Clinical Research Program and was designed to reduce barriers to minority participation in clinical research and to conduct health disparities research. The CHC also provides important community-based learning experiences for NIAMS' fellows. The clinic had been located in the Clinical Center on the NIH campus since 2016, but this month, in partnership with NHLBI, NIAMS opened the Hope Center, located in Ward 5 in Northeast Washington, D.C., to return the program back to the community.

In September 2023, the NIAMS IRP partnered with the Spondylitis Association of America to convene the 4th Spondyloarthritis Unmet Research Needs Conference on the NIH campus. Dr. Colbert was a conference co-chair, and agenda topics included disease endotypes, pain, imaging modalities, health disparities, and therapeutics.

Dr. Colbert briefly shared two research highlights from the NIAMS Clinical Program: Dr. Mike Ombrello's work on PLCG2-associated antibody deficiency and immune dysregulation (PLAID), published in the *Journal of Allergy and Clinical Immunology*, and Drs. Iago Pinal-Fernandez and Andy Mammen's article on transcriptional de-repression in patients with dermatomyositis and Mi-2 antibodies, published in *Translational Science*. Dr. Colbert also noted several upcoming

trials: "The Role of Anifrolumab in Improving Markers of Vascular Risk in Patients with Systemic Lupus Erythematosus (SLE);" "Safety and Tolerability of Gusacitinib in Subjects with SLE;" a Phase I trial of KYV-101, "Autologous Fully-Human Anti-CD19 Chimeric Antigen Receptor T-Cell (CAR T) Therapy in Subjects with Refractory Lupus Nephritis;" and a Phase II trial of "Deucravacitinib for Refractory Adult and Juvenile Dermatomyositis." NIAMS IRP also has trials in the planning phase on JAK inhibitors in Degos disease and CD 19 CAR T therapy in dermatomyositis.

Discussion

Dr. Leigh Callahan asked if patients who visit the Hope Center will be open to recruitment for NIAMS or NIH studies. Dr. Colbert said they are and noted that all Hope Center patients are automatically enrolled into NIAMS' existing minority health and rheumatic disease protocol. Given the resource constraints at the community-based clinic, Hope Center patients occasionally need to travel to the NIH campus to complete aspects of their protocols.

Drs. Garza and Botchwey encouraged NIAMS to consider how to leverage the IRP to have a wider impact; for example, through a greater focus on team science and collaborations. Dr. O'Shea agreed that the IRP should be thinking of how it can better use the unique status of its researchers, but noted that the IRP is prohibited to spend money outside the Institute, which would be the purview of the Extramural Program. Drs. O'Shea and Colbert provided examples of IRP researchers who collaborate with colleagues outside of NIAMS through research consortia and international cohorts. Dr. Colbert added that the IRP encourages its early-career investigators to stay engaged with the broader research community. Dr. O'Shea acknowledged that the IRP could do a better job of publicizing its partnerships and collaborative opportunities with the external community. As Dr. Criswell noted in her report, the constrained budget climate will only make collaborations even more important to achieving the Institute's mission.

VI. DATA SCIENCE WORKING GROUP UPDATE

Dr. Criswell invited Dr. Susana Serrate-Sztein, the NIAMS Associate Director for Strategic Initiatives, to deliver her presentation on the findings of the Council's Data Science Working Group (DSWG).

Dr. Serrate-Sztein reviewed the Working Group roster, which included current and former NAMSAC members, representatives from the scientific community whose research places a strong emphasis on data science, other NIH representatives, and NIAMS support staff.

The Working Group conducted its activities in the context of the first NIH Strategic Plan for Data Science, which prioritized the themes of data infrastructure; modernized data ecosystems; data management, analytics, and tools; and workforce development. As Dr. Criswell mentioned in her Director's Report, the NIH Strategic Plan is currently being updated for the next five-year period. An open RFI soliciting comments from the public on the draft plan will close on March 15, 2024. The DSWG also took into account the NIH Policy on Data Management and Sharing that went into effect in 2023.

Dr. Serrate-Sztein reminded the Council of the Working Group's charge of providing "general guidance to NIAMS on opportunities in data science, big data, and bioinformatics to further arthritis and musculoskeletal and skin diseases insights." The scope of the Working Group's work was to develop targeted recommendations in critical areas related to data science at NIAMS. Dr. Serrate-Sztein described the Working Group meeting process, which included assessing existing NIH resources and approaches, benchmarking best practices, hearing from guest speakers from NIH and the extramural community, and conducting a landscape analysis of existing funding opportunities, among other activities.

The Working Group presented its findings as a set of needs, challenges, and opportunities for the NIAMS Council to consider in making final recommendations to the Institute. During its work, the DSWG identified several overarching factors that touched on all of its findings: the rapidly evolving and complex nature of data science, the need for a broadly interdisciplinary approach, the importance of FAIR (Findable, Accessible, Interoperable, and Reusable) and TRUST (Transparency, Responsibility, User-focused, Sustainability, and Technology) guiding principles, the policy landscape, ethical considerations, and the budget climate.

The first set of findings was on the topic of opportunities to modernize the data science infrastructure and ecosystem in order to help researchers identify sources of data and potential locations to share their data. The Working Group recommended that NIAMS work to identify, catalogue, and leverage existing knowledgebases and repositories, including generalist repositories, and improve data findability and accessibility by establishing knowledgebases in several specific mission areas. On the topic of data sharing, the DSWG recommended that NIAMS expand and support standards for data annotation, metadata protocols, and a common data elements library; encourage the inclusion of participant-generated data into data sets and repositories; work to transfer isolated data sets into appropriate repositories, and participate in NIH-wide data science initiatives. The Working Group also identified opportunities related to identifying and sharing high value data assets (HVDAs), and recommended that NIAMS adopt a working definition for HVDAs, establish required elements to identify HVDAs, and consider developing scoring criteria and processes for sharing HVDAs. The DSWG additionally highlighted several opportunities related to data science workforce development, including for NIAMS to partner with academic departments focused on data science to integrate NIAMS-relevant data, to develop structured outreach sessions with the broader data science community, and to continue to fund data science applications in existing research activities.

The DSWG also identified several areas for further consideration for the Institute, including AI and ML readiness and the NIAMS data science organizational structure. Dr. Serrate-Sztein added that the Working Group sees its findings as complementary to the ongoing NIAMS strategic planning process.

Dr. Serrate-Sztein invited other DSWG members to provide comments. Dr. Callahan stated that NIAMS will also have to work with partners such as the NIAMS Coalition to perform outreach about new and modernized resources as they emerge. She added that she sees particular promise in partnering with academic institutions to provide students access to NIAMS data sets as a way to spur further interest in the NIAMS mission areas and clinical research. Dr. Garza noted that

NIAMS will have to be conscious of budgetary limitations in terms of hosting large data sets, et cetera, but the Institute will have an important role to play in setting standards and providing guidance to the research community.

Discussion

Dr. Yazdany said that, in her opinion, AI and ML readiness is one of the most important opportunities and challenges for biomedical research and asked how NIAMS is incorporating AI and ML into its portfolio. Dr. Serrate-Sztein agreed and said the DSWG's recommendations were in part designed to modernize the data science ecosystem and lay the foundation for data sets that adhere to the FAIR and TRUST principles and are thus more valuable for AI and ML applications. The Working Group also wanted to provide recommendations that were feasible in the near-term, but how to further integrate AI and ML is an active topic of discussion at the NIH-wide level where Dr. Bertagnolli has made AI and ML a priority; at ARPA-H; and government-wide.

Dr. Saumyadipta Pyne, NIAMS' NIH Data Scholar, provided additional comments on criteria for determining a data set's value. Dr. Pyne identified two ways to classify the value of data sets, actualized value and potential value, and provided examples of the characteristics of both. An important factor to consider when assessing the value of a data set is assessing the value of its metadata, as well as other factors such as quality of annotation and the continued availability of the authors.

VII. CONCEPT CLEARANCE

Dr. Sledjeski reminded the Council of the process by which NIAMS extramural staff identifies critical research opportunities within NIAMS' mission areas. Concept clearance is the planning process by which NIAMS receives feedback and approval on a proposed concept from the Advisory Council. Concepts often represent broad, early-stage proposals and do not always result in formal NOFOs. Approved concepts are published on the NIAMS website, which improves transparency and makes the research community aware of potential future funding opportunities.

Dr. Gayle Lester, Director, Division of Extramural Research, presented one concept to the Council, which was the NIAMS Clinical Trials Program. The goal of the program is to support clinical trials and observational studies that are designed to "prevent or reduce symptoms and improve outcomes and function in patients with rheumatic, musculoskeletal, or skin diseases." NIAMS expects trials funded by this initiative will address highly significant clinical questions with impact potential. Dr. Carter noted that this concept emerges from the interim recommendations of the Council's Clinical Trials Working Group and is intentionally broad in scope. The Clinical Trials Working Group will deliver its final recommendations at the May Council meeting. Dr. Charles Washabaugh, a NIAMS program director, added that all future mechanisms that are to be reviewed by the NIAMS' clinical trials study section should originate from this program. Dr. Gravallese asked how the Institute plans to offer robust funding support for clinical trials given past concerns about the budget implications. Dr. Lester replied the

Institute will scrutinize each application very carefully and will also work to leverage partnerships with other ICs and organizations whenever feasible. Dr. Garza said NIAMS should bear in mind that while clinical trials are important, he believes they are not always the best mechanism for training. Dr. Criswell acknowledged the challenges about budget and impact and said she looks forward to discussing this topic further in May.

The Advisory Council voted unanimously to approve the concept.

XIII. CLOSED SESSION

This portion of the meeting was closed to the public in accordance with the determination that it concerned matters exempt from mandatory disclosure under Section 552b(c)(4), Title 5, U.S. Code and Section 10(d) of the Federal Advisory Committee Act, as amended. Members exited the meeting during the discussion and voting process on applications from their own institutions or other applications that presented a potential conflict of interest, real or apparent. Members signed a statement to this effect.

IX. REVIEW OF APPLICATIONS

The 113th National Arthritis and Musculoskeletal and Skin Diseases Advisory Council met on January 30, 2024. All Council members attended virtually. En bloc concurrence was unanimously approved for 724 primary and 244 secondary applications. The total cost requested in year -01 for all applications was $441,034,209.

IX. ADJOURNMENT

The 113th National Arthritis and Musculoskeletal and Skin Diseases Advisory Council adjourned at 3:15 p.m. Proceedings of the public portion of this meeting are recorded in this summary.

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

Darren D. Sledjeski -S
Digitally signed by Darren D. Sledjeski -S
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Darren Sledjeski, Ph.D.
Executive Secretary, National Arthritis and Musculoskeletal and Skin Diseases Advisory Council
Director, Division of Extramural Activities
National Institute of Arthritis and Musculoskeletal and Skin Diseases

Lindsey A. Criswell -S
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Lindsey A. Criswell, M.D., M.P.H., D.Sc.
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