National Institute of
Arthritis and Musculoskeletal
and Skin Diseases

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

September 17, 2024

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

MINUTES OF THE 115th MEETING

I. CALL TO ORDER

The 115th meeting of the National Arthritis and Musculoskeletal and Skin Diseases Advisory Council (NAMSAC) was held on September 17, 2024, in a hybrid format with the in-person meeting in Building 31, National Institutes of Health, Bethesda, Maryland, and virtually 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
Ms. Ann Elderkin, Consultant, American Society for Bone and Mineral Research (ASBMR)
Dr. Stuart Goodman, Robert L. and Mary Ellenburg Professor of Surgery, Department of Orthopaedic Surgery, Stanford Medicine
Dr. Valentina Greco, Carolyn Walch Slayman Professor of Genetics, Yale University
Dr. Karl Jepsen, Associate Dean for Research, Professor of Orthopaedic Surgery, Professor of Biomedical Engineering, University of Michigan
Dr. Douglas Kiel, Professor of Medicine, Harvard Medical School and Beth Israel Deaconess Medical Center
Dr. Xiaojuan Li, Director, Program for Advanced Musculoskeletal Imaging, Cleveland Clinic
Dr. Elizabeth McNally, Elizabeth J. Ward Professor of Genetic Medicine, and Director, Center for Genetic Medicine, Northwestern University Feinberg School of Medicine
Dr. Melissa Spencer, Professor, Neurology, University of California Los Angeles
Dr. Rebecca Minnillo, Chief Program and Development Officer, Society for Investigative Dermatology
Dr. Aimee Payne, Chair of the Department of Dermatology, Columbia University Vagelos College of Physicians and Surgeons
Ms. Sharon Smith-Terry, Chief Executive Officer, Orthopaedic Research Society
Dr. Teodora Staeva, Chief Scientific Officer, Lupus Research Alliance
Mr. Steven Taylor, President and Chief Executive Officer, Arthritis Foundation
Dr. Louise Thoma, Assistant Professor, Division of Physical Therapy, Department of Health Sciences, University of North Carolina at Chapel Hill, *Ad Hoc Member*
Dr. Emily Wakefield, Pediatric Psychologist, Division of Pain and Palliative Medicine, Connecticut Children's Medical Center, *Ad Hoc Member*
Dr. Jinoos Yazdany, Chief, Division of Rheumatology, Zuckerberg San Francisco General Hospital

A total of 156 NIH staff and members of the public watched via NIH Videocast.

Staff and Guests

The following NIAMS staff and guests attended:

Staff

Dr. Lindsey Criswell
Dr. Robert Carter
Dr. Robert Colbert
Dr. Gayle Lester
Dr. Susana Serrate-Sztein
Dr. Darren Sledjeski
Dr. Robert Walker
Dr. Deepti Bajpai
Dr. Kamil Barbour
Dr. Alexey Belkin
Mr. Simao Bengui
Mr. Mark Brown
Ms. Tanisha Brown-Caines
Dr. Stephanie Burrows
Ms. Justine Buschman
Dr. Emily Carifi
Dr. Faye Chen
Dr. Dillon Chung
Dr. Ricardo Cibotti
Mr. Jon Davis
Dr. Rachel Desai
Ms. Teresa Do
Dr. Jonelle Drugan
Mr. Erik Edgerton
Ms. Jana Eisenstein
Dr. Chiguang Feng
Dr. Yasuko Furumoto
Ms. Helen Girma
Ms. Stephanie Herndon
Ms. Shameeka Hunt
Mr. David Johnson
Dr. Peter Koch
Ms. Stephanie Kreider
Ms. Medha Krishnagiri
Ms. Colleen Labbe
Dr. Rebecca Lenzi
Dr. Marjorie Lindhurst
Ms. Ryan Lombardi
Dr. Kan Ma

Dr. Su-Yau Mao
Dr. Marie Mancini
Dr. Aron Marquitz
Ms. Katrina Matthews
Dr. Stephanie Matthews
Dr. Anna Mazzucco
Ms. Leslie McIntire
Ms. Jennifer Morgan Gray
Ms. Sara Myers
Ms. Melinda Nelson
Dr. Kristy Nicks
Dr. Van Nguyen
Ms. Nikki Ostrenga
Mr. Rick Phillips
Dr. Giuseppe Pintucci
Dr. Sushmita Purkayastha
Ms. Sahar Rais-Danai
Ms. Christa Reynolds
Ms. Trish Reynolds
Dr. Kathy Salaita
Dr. Kriti Sharma
Dr. Raj Srinath
Ms. Yen Thach
Ms. Jamie Thompson
Dr. Dandre Thornhill
Mr. Herman Utama
Dr. Aneliya Velkova
Dr. Isaah Vincent
Ms. Robin Wolz
Dr. Xibin Wang
Dr. Yan Wang
Dr. Chuck Washabaugh
Ms. Elisa Weiss
Ms. Shalanda Wellington
Dr. Justin Wilson
Dr. Xincheng (Ted) Zheng

Guests:

Dr. Monica Bertagnolli, Director, National Institutes of Health (NIH)
Dr. Victoria Shanmugam, Director, Office of Autoimmune Disease Research, Office of Research on Women's Health, Office of the Director, NIH
Dr. Karriem Watson, Chief Engagement Officer, NIH *All of Us* Research Program
Dr. Monica Webb Hooper, Deputy Director, National Institute on Minority Health and Health Disparities (NIMHD)
Dr. Shannon Zenk, Director, National Institute of Nursing Research (NINR)

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

Dr. Lindsey Criswell, NIAMS Director, called to order the 115th meeting of the NIAMS Advisory Council at 9:30 a.m. and led Council members and other attendees in a round of introductions. Dr. Darren Sledjeski, NAMSAC Executive Secretary, reviewed the logistics for the hybrid meeting. He 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 reminded the Council of the upcoming conflict of interest reporting deadline in October.

Dr. Sledjeski asked Council members if there were any comments or corrections to the minutes of the 114th NAMSAC meeting, which took place on May 29, 2024. There were no comments or corrections, and Dr. Sledjeski moved to approve the minutes. The motion was seconded and passed unanimously.

The dates of the next two Council meetings are January 28, 2025, and June 3, 2025. The date for the September 2025 meeting will be finalized in the coming weeks. The January meeting will be fully virtual, while the June and September dates will be hybrid meetings.

III. NIAMS DIRECTOR'S REPORT AND DISCUSSION

Dr. Criswell began her remarks and announced that this will be the last meeting for four Council members: Dr. Stuart Goodman, Dr. Valentina Greco, Dr. Teodora Staeva, and Dr. Maria Suarez-Almazor. She thanked the departing members for their service to NIAMS and valuable guidance during their four-year terms, which coincided with Dr. Criswell's arrival as Director. She then introduced and welcomed five new Council members representing diverse research and advocacy backgrounds: Dr. Douglas Kiel, Dr. Xiaojuan Li, Dr. Rebecca Minnillo, Dr. Aimee Payne, Ms. Sharon Smith-Terry, and Mr. Steven Taylor. NIAMS has continued its practice of inviting investigators from the pool of NIAMS mentored career development award grantees to serve as ad hoc Council members to familiarize them with the work of the Council and so that NIAMS can receive input from researchers at an earlier stage in their career than the typical Council member. Dr. Criswell welcomed the two ad hoc Council members for this meeting: Dr. Louise Thoma from UNC-Chapel Hill and Dr. Emily Wakefield from Connecticut Children's Medical Center.

NIH and NIAMS Budget

Dr. Criswell updated the Council on the current status of the NIH and NIAMS budgets. The final fiscal year (FY) 2024 NIAMS funding plan sets the R01 payline at the 8th percentile, and that decision gives the institute more flexibility to look critically at the grants it funds. Dr. Criswell was pleased to be able to report that NIAMS has funded the same number of R01 awards in FY24 as in FY23 despite the constrained budget climate. FY 2025 is fast approaching, and Dr.

Criswell reviewed the various budget proposals released by the President and the two chambers of Congress. The proposals from the White House and the Senate Appropriations Committee call for three percent and four percent increases to the NIH budget, respectively, while the House has proposed a flat NIH budget. The President's plan calls for a one percent increase for NIAMS, but the Senate's proposal would set NIAMS' budget at FY24 levels. Dr. Criswell noted that the House budget includes a proposal to restructure NIH. Since the budget negotiations are likely to continue into the start of the fiscal year, the federal government will begin FY25 operating under a continuing resolution that would set federal spending at approximately FY24 levels.

Personnel Changes

NIAMS has begun the process for hiring the next NIAMS Deputy Director following Dr. Robert Carter's retirement announcement this spring. Dr. Criswell was pleased to report that Dr. Carter will continue to serve as an advisor to the institute beyond his retirement date. Applications for the Deputy Director position will be accepted through September 30th. NIAMS also continues its efforts to recruit a new Scientific Director, and Dr. Criswell hopes to be able to announce that the position has been filled by the next Council meeting. Dr. Criswell informed the Council that Dr. Susana Serrate-Sztein, NIAMS Associate Director for Strategic Initiatives, has announced that she will be retiring in October, after which she will continue to serve as an advisor. Dr. Criswell thanked Dr. Serrate-Sztein for her many years of dedicated service to NIAMS. In order to assist the institute during Drs. Carter and Serrate-Sztein's transition to retirement, Dr. Anna Mazzucco has joined the Office of the Director on a temporary detail through October. Dr. Mazzucco comes to NIAMS from the NIH Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI) and has served as the NIH Acting Associate Deputy Director.

Dr. Criswell also updated the Council on personnel changes in the NIAMS Division of Extramural Research (DER). Dr. Ricardo Cibotti has announced his retirement. Dr. Cibotti most recently served as program director of the Skin Immunology and Diseases, Skin Microbiome Program. Dr. Kamil Barbour has joined DER as a new program director. Dr. Barbour joins NIAMS from the Centers for Disease Control and Prevention (CDC) where he worked in the Chronic Disease Epidemiology Program. Dr. Barbour also serves as Commander in the U.S. Public Health Service.

At the NIH level, Dr. Geri Donenberg was recently named NIH Associate Director for AIDS Research and Director of the Office of AIDS Research (OAR). NIAMS works closely with OAR and regularly receives funding to support research on HIV/AIDS in the context of NIAMS mission areas.

NIH and NIAMS Activities

Dr. Criswell updated the Council on the White House Women's Health Research Initiative. NIH has committed to investing $200M in new interdisciplinary women's health research for FY 2025, most of which will be issued via the Women's Health Research Notice of Special Interest (NOSI) that was released this spring. NIAMS participates in this NOSI and other related programs originating from other NIH Institutes and Centers (ICs).

NIH will be releasing an updated Grants & Funding webpage (https://grants.nih.gov/) that has been redesigned to incorporate user feedback. The update will also include a streamlining of the NIH Guide for Grants and Contracts and the "How to Apply – Application Guide" page.

At the May Council meeting, Dr. Criswell informed the Council of a NIH Common Fund initiative called the Complement Animal Research in Experimentation (Complement-ARIE) program, which aims to accelerate the development, validation, and standardization of human-based, non-animal approaches to study biological functions and human disease, also known as new approach methodologies (NAMs). NIH recently announced its intention to issue a new Notice of Funding Opportunity that will support NAMs Technology Development Centers to help stimulate the development of combinatorial NAMs supporting the areas of greatest need.

NIH has released a Request for Information (RFI) to solicit feedback on recommendations on re-envisioning U.S. postdoctoral research training and career progression. These recommendations were developed by the NIH Advisory Committee to the Director's Working Group on Re-envisioning NIH-Supported Postdoctoral Training, and the deadline for submitting comments to the RFI is October 23, 2024.

The Council heard from a panel of patient engagement experts at its May meeting and will hear from a panel of community engagement experts later in this meeting. Dr. Criswell presented examples of ways NIAMS is engaging with the broader community, including partnering with the National Scleroderma Foundation to incorporate a scleroderma pilot into the Accelerating Medicines Partnership® Autoimmune and Immune-Mediated Diseases (AMP® AIM) program; developing lesson plans and classroom materials on bones, joints, muscles, and skin for 4th through 6th grade science teachers; and Dr. Criswell's participation in a series of events involving patients, their families, and organizations that support them, such as the celebration of 30 years of lupus research at the NIH Clinical Center sponsored by the D.C. Lupus Consortium and the patient conference organized by the National Alopecia Areata Foundation.

Finally, Dr. Criswell provided an update on the development of the NIAMS' Strategic Plan for FYs 2025-2029. NIAMS issued an RFI this summer to solicit feedback on the draft Strategic Plan and has presented the final version to Council members. The institute hopes to release the Strategic Plan to the public by the end of the calendar year and will publish updates on the progress on the Plan's priorities on its website at the end of each fiscal year. Dr. Criswell summarized the Plan’s four goals and ten priorities; the ten priorities include six research priorities, three capacity-building priorities, and one operational priority. In brief, the four goals are to identify and test interventions; develop resources; support infrastructure, team science, and a diverse workforce; and communicate advances. The six research priorities are mechanisms in human health and disease; regenerative medicine; data science, artificial intelligence/machine learning (AI/ML), and computational biology; behaviors and environmental exposures; interventions; and health disparities and health equity. The capacity-building and operational priorities are research infrastructure, interdisciplinary research, training and workforce, and communication and engagement.

Discussion

Dr. Criswell opened the floor to the Council to provide additional comments on the Strategic Plan or any other topics of interest. She noted that Council members have until September 24th to submit written comments on the Strategic Plan to the institute.

Dr. Elizabeth McNally expressed excitement about the Strategic Plan, particularly the emphasis on interdisciplinary research and team science. She advised NIAMS to ensure that its funding strategies are well-aligned with the strategic goals; for example, limiting the number of NIAMS grants to individual investigators without providing exceptions for multi-PI studies may end up conflicting with the team science priority. Dr. Criswell acknowledged the difficult balancing act of encouraging a broad and diverse pool of funded researchers in a constrained budget climate. She expressed the hope that the biomedical research community can find more ways to properly highlight the contributions of co-investigators. One example of how this can be done is the National Cancer Institute's grant program for co-investigators.

Dr. Aimee Payne raised the topic of postdoctoral training. She cautioned that limiting postdoctoral fellowship training to five years might cause problems for the class of postdocs who were affected by the research restrictions and other impacts of the COVID-19 pandemic. She asked what NIH's plan is for supporting postdoc fellows in the context of limited faculty positions in academia and stagnant pay for staff scientists. Dr. Criswell said that these are profound problems that will take many years to address. In the current budget climate, raising staff scientist pay would necessitate lowering the number of positions. NIH is exploring the creation of new pathways for career progression, but this is also difficult to achieve with limited funding. Another important factor is the decision of the NIH fellows to unionize, which means that many of these topics will ultimately be determined via the collective bargaining process.

Dr. Karl Jepsen praised the report's emphasis on inclusivity and health equity, which he thinks will be of particular importance as the use of AI tools in medicine and research expands rapidly.

Mr. Steven Taylor said he was excited about the Plan's priorities related to diversifying the workforce and expanding scientific outreach initiatives into elementary and high schools and colleges. Dr. Criswell underscored NIAMS' increased focus on K-12 outreach as a vital avenue for getting future scientists interested in biomedical research in general and NIAMS' mission areas in particular. On this topic, Dr. Robert Walker, NIAMS Chief Diversity Officer, discussed NIAMS' outreach efforts to minority-serving institutions across the country, and Dr. Isaah Vincent, NIAMS Training Director, highlighted NIAMS' participation in the NIH Science Education Partnership Award (SEPA) Program. NIAMS also participates in several other NIH mechanisms related to enhancing workforce diversity, including the NIH diversity supplements, the Research With Activities Related to Diversity (ReWARD) program, the STrengthening Research Opportunities for NIH Grants (STRONG) program, the Support for Research Excellence (SuRE) Award program, and the Maximizing Opportunities for Scientific and Academic Independent Careers (MOSAIC) program. Dr. Criswell said that NIAMS is continuously assessing the impact of the programs it participates in and looking into joining other initiatives as they emerge. Dr. Walker discussed how his office has developed guides targeted towards smaller, less-resourced institutions to help them navigate the myriad NIH grant offerings. Dr. Valentina Greco stressed the importance of ensuring these programs are effective and achieving the goals they were designed to achieve over the long term.

Dr. Stuart Goodman asked if NIAMS has considered the potential repercussions of the proposed consolidation of NIH ICs that is included in the House Appropriations Committee's FY25 budget proposal. Dr. Criswell said that proposal should be viewed as a policy statement, but is unlikely to move forward at the current time. Dr. Monica Bertagnolli, NIH Director, joined the meeting during the conversation on this topic and offered her thoughts. One of the ways NIH could respond to the congressional appropriations committees' recommendations would be to reinvigorate the Scientific Management Review Board to explore ways to better coordinate and innovate on the administrative and operational sides of NIH. The House Appropriations Committee's recommendation to consolidate the 27 ICs down to 15 was surprising but has spurred NIH leadership to think harder about how its ICs can better collaborate and coordinate. Dr. Bertagnolli believes that the current ICs provide unique value by being able to respond to the patient groups they serve, and to disrupt that would be harmful. NIH must constantly work to prevent ICs from becoming silos, and Dr. Bertagnolli believes it has done so through the interdisciplinary spirits of its leaders and staff and via the many trans-NIH initiatives and the work of the NIH Common Fund.

IV. NIH DIRECTOR'S INTRODUCTION: TOWARD EVIDENCE-BASED HEALTHCARE

Dr. Criswell formally welcomed Dr. Bertagnolli and highlighted NIAMS' efforts to align with NIH priorities related to community engagement, enhancing research participant diversity, data science and computational biology, and regenerative medicine and gene therapies.

Dr. Bertagnolli thanked the Council and NIAMS for the invitation and noted that she has maintained a career-long interest in immunology, which led to a three-year tumor immunology research fellowship at the Dana-Farber Cancer Institute. One of her life experiences that has profoundly informed her worldview is her childhood in Wyoming where her family lived 100 miles from the nearest doctor's office and hospital. Many rural areas around the country remain medically underserved and underrepresented in clinical research. At the national level, the U.S. has seen a disturbing deterioration in a number of important health metrics, and health disparities remain an intractable problem. NIH has a vital role to play in correcting these issues by engaging underserved and underrepresented communities and vulnerable populations in research. She strongly believes that research drives better health, both through discovery of new treatments and interventions, but also by engaging more people in healthcare through their participation in research.

Dr. Bertagnolli reiterated that NIH believes that research does not stop in the lab or in the clinic but must extend into the community. This is the principle underpinning a new trans-NIH initiative called Communities Advancing Research Equity for Health (CARE for Health) which focuses on community-based primary care practices. This program will take a unique approach to community engagement by tailoring the research based on specific community needs, rather than bringing a predetermined research plan to a community for its approval. The program will involve the integration of research into the clinical care environment, foster trust in science by addressing community needs, collect longitudinal clinical data to improve health across the

lifespan, and increase adherence to evidence-based care. CARE for Health recently began its two-year pilot phase, which will include the funding of network research hubs in year one and program evaluation in year two.

Another exciting project is the National Library of Medicine's (NLM) efforts to establish a trans-NIH data science platform that provides a federated data and data analytics ecosystem, including data science and bioinformatics educational programs, that will advance the NIH research community from data sharing to data use.

Dr. Bertagnolli emphasized that fundamental science remains at the core of NIH's mission. The COVID-19 pandemic is an example of how decades of basic science can lead to lifesaving treatments and interventions, but the current struggle to address long COVID highlights the challenges the research field faces when that basic science understanding is lacking.

Dr. Bertagnolli addressed the challenges being faced at NIH due to budgetary constraints. NIH is working hard to maintain its intramural workforce and protect its vulnerable early-career researchers. Dr. Bertagnolli supports the decision of many ICs to lower the payline in order to fund the same number of awards as in previous years but acknowledged that smaller grants are by no means ideal, particularly for younger scientists. This decision is also supported by academic institutions based on Dr. Bertagnolli's conversations with academic leadership. NIH remains open to recommendations from its advisory councils and external interested parties about how it can improve.

Dr. Bertagnolli regularly highlights exciting new NIH-funded research on her NIH Director's Blog, and she presented examples of recently published NIAMS-funded studies. These included a study on the maternal brain hormone CCN3 which may hold potential for treating osteoporosis and bone fractures, a study that used ML to explore why some people have rheumatoid arthritis pain without inflammation, and research on the immune checkpoint PD-1 that has potential implications for treating cancer and autoimmune disease.

Dr. Bertagnolli concluded her remarks reiterating NIH’s core principle that its work is not finished when scientific discoveries are achieved; its work is finished when all people are living long and healthy lives.

Discussion

Ms. Sharon Smith-Terry asked Dr. Bertagnolli if she foresaw budget repercussions based on the results of the presidential election this fall. Dr. Bertagnolli replied that the President proposes an initial budget, but the purse strings are ultimately controlled by Congress; in her experience, NIH enjoys broad bipartisan support on Capitol Hill.

Dr. Payne asked Dr. Bertagnolli to comment on the fact that NIAMS' budget has stayed flat in recent years compared to other ICs. Dr. Bertagnolli replied that Congress sets the budget allocation for specific ICs. NIH and NIAMS leadership, along with professional societies and advocacy groups, play an important role in identifying trans-NIH research priorities and developing trans-NIH initiatives and resources that NIAMS can leverage.

Dr. Emily Wakefield expressed enthusiasm for the inclusive nature of the CARE for Health initiative and Dr. Bertagnolli's prioritizing engagement of marginalized communities. She noted that true community engagement means partnering with the community at the design and methodology stage and providing compensation for this participation, but funding mechanisms generally do not account for these activities. Dr. Bertagnolli agreed with Dr. Wakefield's comments and noted that one of the purposes of the CARE for Health pilot phase is to look into best practices for community engagement. One of the goals of the project as a whole is to leverage the resources of NIH to be able to engage communities holistically over the long term, rather than study by study or disease by disease.

Dr. Xiaojuan Li said she was excited to see the focus on community and patient engagement at both the NIAMS and NIH level and she encouraged NIH to explore partnerships with advocacy groups, such as the Arthritis Foundation, to enhance these efforts. Dr. Bertagnolli said the NIH is always open to partnerships with its external stakeholder groups.

Dr. Goodman commented that the surgeon-scientist is a dying breed and asked what NIH can do to help foster a new generation. Dr. Bertagnolli said that surgeons bring important expertise and insight to particular questions, and their inclusion in NIH-funded research can be enabled by team science approaches. Dr. Bertagnolli acknowledged the unique scheduling and lifestyle challenges for surgeons interested in both research and maintaining an active surgical schedule, which she experienced herself as a surgeon-scientist. Seeking out and leveraging partnerships and team science opportunities are vital to make such a career possible.

Other topics discussed with Dr. Bertagnolli included the importance of including telehealth modalities in the CARE for Health project and the need for more outreach on existing NIH and NLM data science resources.

V. COMMUNITY ENGAGEMENT PRESENTATIONS

Dr. Criswell invited Dr. Robert Walker to moderate the panel presentation session on community engagement. Dr. Walker opened the session by emphasizing NIAMS' and NIH's commitment to diversity, equity, inclusion, and accessibility (DEIA) at the institutional level, as well as to prioritizing health disparities and health equity research. The community engagement panel builds off the patient engagement panel session at the last Council meeting. Dr. Walker introduced the three community engagement panel members: Dr. Shannon Zenk, Director, National Institute of Nursing Research (NINR); Dr. Karriem Watson, Chief Engagement Officer, NIH *All of Us* Research Program; and Dr. Monica Webb Hooper, Deputy Director, National Institute on Minority Health and Health Disparities (NIMHD).

Dr. Zenk presented first on community engagement efforts at NINR. She described the community engagement continuum from outreach and consultation to deeper community involvement, collaboration, and shared leadership. Another way to view the continuum is the evolution of the participant from mere object of research to active agent, and ultimately a driver of the research. The challenge for institutions looking to move up on the continuum is knowing

how to do so in an effective manner. NINR believes that the commitment towards community engagement cannot rest with individual investigators; it must be an institutional effort. Dr. Zenk believes NINR is uniquely prepared for a robust community engagement strategy because of the personal relationship-based nature of nursing. Community engagement practices are embedded in the NINR strategic plan's research lenses. NINR takes an equity-centered approach to research by prioritizing studies that address health disparities, include a focus on structural factors, and meaningfully engage the community. Dr. Zenk presented examples of NINR-led funding opportunities that either encourage or require community engagement in the research, including two in which NIAMS is a partner: Strategies to Improve Health Outcomes in Rural Populations and Transformative Research to Address Health Disparities. Dr. Zenk also highlighted a study that has emerged from the Advancing Integrated Models (AIM) of Care to Improve Maternal Health Outcomes among Women Who Experience Persistent Disparities program that looked at the effect of Medicaid-eligible doula programs in New York City. Another NINR program that is in the planning phase will focus on building capacity for community-partnered research by leveraging existing community partnerships and accelerating research infrastructure development at colleges and schools of nursing. Dr. Zenk also described how NINR prioritizes community-engaged research in its intramural program, which offers unique opportunities for long-term engagement and training for the next generation of researchers. NINR has recently hired two intramural investigators with expertise in community-engaged research and has been spotlighting community engagement efforts at recent NINR Council meetings. NINR also participates in a number of NIH-wide initiatives that contain community engagement components, including Community Partnerships to Advance Science for Society (ComPASS), which is unique in that it directly funds community organizations to lead research. So far, ComPASS has funded 25 community organizations, and the ultimate goal is to create a new model of community-led health equity research.

Dr. Webb Hooper presented on her experience with community engagement as a researcher and in her role at NIMHD, and examples of successful NIH-wide community-centered initiatives. She began by clarifying definitions of community engagement as compared to community-engaged research. Community engagement is a broader concept at the organizational and strategic levels, while community-engaged research requires more specific skills and resources to develop rigorous methodological approaches and develop equitable partnerships and collaborators from among the affected communities, among other aspects. There has been an increased focus at NIH since 2020 on minority health and health disparities research, and community engagement and community-engaged research have been two of the cross-cutting themes of this research. Community-engaged research can seem simple in theory but can often be quite challenging and complex in practice. Dr. Webb Hooper highlighted some best practices that she has gleaned from the literature and her own experience. These include working to develop trust, meaningfully involving the community in planning, sharing results with the community, ensuring mutual benefit, being prepared to adapt and be flexible, and regularly evaluating processes and outcomes. Dr. Webb Hooper emphasized that successful community-engaged research provides many benefits to the research enterprise by increasing research relevance, improving data quality, increasing participant trust, and enhancing research impact, among other benefits. She highlighted two examples of major NIH initiatives that are based on community-engaged research principles, both of which were established in response to the COVID-19 pandemic. The Community Engagement Alliance (CEAL) Against COVID-19

Disparities used community-engaged strategies to increase education, awareness, trust, access, and inclusion of underserved communities in COVID-19 treatment and prevention strategies. The Rapid Acceleration of Diagnostics-Underserved Populations (RADx-UP) program has applied community-engaged research methods to increase access and uptake of COVID-19 diagnostics in underserved and vulnerable communities. The program eventually engaged over 350 community partners in over 150 projects across the U.S. and its territories and is currently in its final stage of dissemination of findings related to implementation and interventions. Over 300 publications have emerged from RADx-UP to date, including a supplement in the American Journal of Public Health that was published this May. Among the interventions that were found to be effective in the program were culturally tailored communications, mobile testing units, incentivization, and integrated health services. Dr. Webb Hooper closed her remarks by stressing that community engagement cannot be an afterthought and that institutions must strive to prevent "helicopter research." Community-engaged research principles are valid and beneficial for all types of research, not only minority health, health disparities, or health equity research.

Dr. Watson began his presentation by providing an overview of the *All of Us* Research Program. The program has been intentional in reaching out to all parts of the country, because place and space matters when it comes to engaging populations historically underrepresented in research. This intentional engagement effort has led to far more diverse enrollment in the *All of Us* Research Program when compared to other genomic studies, enabling its studies to better represent the demographics of the U.S. *All of Us* is now the largest secondary dataset of sexual and gender minority populations, and almost 8% of its participants reside in rural areas. However, Dr. Watson stressed that the goal of community engagement is not merely enrollment, but also to foster equitable relationships and enhance trust over the long-term. Dr. Watson noted that the program is disease-agnostic, which means its datasets can help lead to discoveries across all NIH mission areas. In addition to genomic data, *All of Us* collects biospecimens, physical measurements, lifestyle information, survey data, electronic health records, and data from wearables. Dr. Watson highlighted the critical community engagement principles of outreach and awareness, education and access, enrollment and retention, participants as research partners, and knowledge mobilization. The *All of Us* Research Program has funded 18 partners to conduct engagement activities in historically underrepresented populations. Dr. Watson provided examples of how *All of Us* and its partners are operationalizing the aforementioned community engagement principles on the ground. He highlighted the importance of returning value to the community, which for the *All of Us* program has involved offering free genetic counseling and conducting educational outreach events in the community setting, among other activities. Finally, Dr. Watson spotlighted two research projects using *All of Us* data in NIAMS mission areas to study the burden of psoriasis and psoriatic arthritis and family history of arthritis, osteoporosis, and carpal tunnel syndrome and risk of these conditions.

Discussion

Council members discussed with the panel how research teams can go about building long-term relationships with communities when most research studies are necessarily limited in time and resources. Dr. Webb Hooper said that occasionally checking in with community partners after specific studies are completed goes a long way, even if there is no active study. Seed funding and pilot grants can also be leveraged during these gaps between active larger studies. Participating

in community health fairs or screening activities are another way to stay present in the community. Researchers can also invite community members to sit in on lab meetings on occasion to foster an environment of co-learning. Dr. Watson added that NIH administrative and diversity supplements can be powerful tools for supporting community-engaged research activities.

Dr. Edward Botchwey described his career trajectory as a basic science and biomaterials researcher, and how he did not always view his work as directly impacting patient communities until he began partnering on projects later in his career. He asked the panel to comment on the role of basic science in community-engaged research. Dr. Watson said that it is always important to communicate the findings of basic science forward on the translational spectrum and added that the team science model can often be amendable to basic science components. Dr. Wakefield raised the challenges researchers face trying to build trust and conduct other engagement-related activities prior to enrollment; these efforts take time and are not accounted for in traditional funding mechanisms.

Dr. Jinoos Yazdany asked if there are metrics for assessing the success of community engagement efforts beyond recruitment numbers. Dr. Watson said *All of Us* takes a mixed methods research approach that includes qualitative aspects such as community surveys and conversations with community members. Dr. Criswell highlighted the need for a central source for guidance and resources on community-engaged research for investigators. Dr. Webb Hooper pointed towards the CEAL Consultative Resource as an example of a guide that attempts to meet this need for researchers. Dr. Watson added that other NIH ICs and programs have resources available along these lines.

VI. CONCEPT PRESENTATION

Dr. Sledjeski reminded the Council that concept clearance is the planning process by which the NIAMS receives feedback on the merits of proposed concepts and approval from the Advisory Council. Concepts are developed by the NIAMS extramural program to address critical research priorities and inform the research community of NIAMS interest areas and potential future funding opportunities. There was one concept for consideration at this meeting.

Dr. Gayle Lester invited Dr. Su-Yau Mao, Program Director of the Arthritis Biology Program, to present the renewal concept for the NIAMS Small Grants Program (R03). The goal of the program is to help early-stage investigators (ESIs) transition to independent research by providing support for developing preliminary data for future R01 applications. The awards cover up to $50,000 in direct costs per year for a two-year period for NIAMS K awardees in their second through fourth years. The R03 awards can support projects such as feasibility and pilot studies, secondary analyses, and the development of research methodology and technology, among other smaller projects.

Dr. McNally raised the possibility of opening the R03 to ESI researchers receiving grant support from other organizations within NIAMS mission areas. Dr. Lester said that is an idea worth investigating but cautioned that there might be budgetary implications for expanding the scope

beyond K awardees. In response to a question from Dr. Li, NIAMS staff clarified that R03 applications should expand the scope of or otherwise go beyond the K awardee's originally funded research. NIAMS assured the Council that it is working to assess the impact of the R03 program, along with the rest of its funding portfolio. Dr. Wakefield encouraged NIAMS to see what it can do to make the K awardee population aware of the R03 program and perhaps consider expanding the eligibility window.

The Advisory Council voted unanimously to approve the concept for further development.

VII. OPEN DISCUSSION

Dr. Criswell opened the floor to the Council to raise topics of interest for further discussion. Dr. Louise Thoma returned to the topic of postdoc training and career progression and said she was supportive of the recommendation to promote training and professional development for both postdoc scholars and their mentors. In her experience as a mentor and mentee, not enough emphasis has been placed on valuing successful mentorships. Dr. Vincent said that NIH has been working to improve the review process for applications to take into account mentorship and training activities. Dr. Criswell encouraged Council members and other interested parties to provide responses to the RFI on postdoctoral career progression. Dr. Payne said it was important to find the right balance and to not overburden PIs with added responsibilities. She also pointed to the fact that a relatively small number of K awardees go on to receive an R01 grant within five years. This means that many K awardees will experience a significant funding gap which has detrimental effects on their ultimate decision whether to remain in research. Dr. Payne suggested there might be value in redirecting some of the R03 funds towards an extension grant that would help bridge this gap. Dr. Criswell agreed that bridge awards are important. Budget decisions are always difficult, and the Council's input is one of the many factors that inform NIAMS' funding decisions. The ongoing analysis of the R03 program, and NIAMS' portfolio as a whole, will also inform future decisions. Dr. Vincent noted that NIAMS' K awardee data shows higher success rates for obtaining research project grants than the numbers Dr. Payne cited. He also emphasized that it is possible to secure faculty positions and have a successful research career without having received a K or F award. Dr. Lester added that foundations and the NIAMS Coalition organizations have an important role to play in providing bridge funding and other support that complements NIAMS' mechanisms. Dr. Minnillo said the NIAMS Coalition could be a venue to compare and align the strategic plans of its member organizations and assess the impact of their bridge awards. Mr. Taylor added that this conversation also has important workforce development implications.

Dr. Kiel suggested inviting noteworthy NIAMS-funded investigators to present their research before the Council. Dr. Criswell said this was a good suggestion and added that researchers could also be invited to discuss how support from NIAMS influenced their career or what types of support would have been helpful at various stages of their career.

Council members discussed ways to advocate for more support for NIAMS with Congress. Dr. Sledjeski reminded members that they can interact with Congress in their personal capacities, but not as Council members. Mr. Taylor said it is important to be able to frame the case in different

ways, but he believes that NIAMS has a powerful argument to make for the potential impact of discovery in the NIAMS mission areas. Dr. Criswell noted that interest in autoimmune research is high, as evidenced by the new Office of Autoimmune Disease Research (OADR) that has been created within the Office of Research on Women's Health. This office is led by Dr. Victoria Shanmugam, who was in attendance at the Council meeting. Dr. Shanmugam said she enjoyed the Council's discussions and reminded attendees that autoimmune diseases affect upwards of 23.5 million Americans. OADR has been working with NIH ICs to identify areas of collaboration to tackle fundamental questions about autoimmune diseases. An NIH-wide strategic plan for autoimmune diseases will be issued in 2025.

VIII. 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.

1X. REVIEW OF APPLICATIONS

The 115th National Arthritis and Musculoskeletal and Skin Diseases Advisory Council met on September 17, 2024. Fourteen Council members and two Ad-Hoc Council members attended. En bloc concurrence was unanimously approved for 758 primary and 160 secondary applications. The total cost requested in year -01 for all applications was $403,926,103.

X. ADJOURNMENT

The 115th National Arthritis and Musculoskeletal and Skin Diseases Advisory Council adjourned at 4:00 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
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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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Date: 2024.11.05 12:12:23 -08'00'

Lindsey A. Criswell, M.D., M.P.H., D.Sc.
Chair, National Arthritis and Musculoskeletal and Skin Diseases Advisory Council
Director, National Institute of Arthritis and Musculoskeletal and Skin Diseases