National Institute of
Arthritis and Musculoskeletal
and Skin Diseases

Minutes of Meeting

June 3, 2025

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

MINUTES OF THE 117th MEETING

I. CALL TO ORDER

The 117th meeting of the National Arthritis and Musculoskeletal and Skin Diseases Advisory Council (NAMSAC) was held on June 3, 2025, in Building 31, National Institutes of Health, Bethesda, Maryland, and 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. Sarah Gebauer, Professor, Saint Louis University School of Medicine, *Ad Hoc Member*
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. Elizabeth McNally, Elizabeth J. Ward Professor of Genetic Medicine, and Director, Center for Genetic Medicine, Northwestern University Feinberg School of Medicine
Dr. Rebecca Minnillo, Chief Program and Development Officer, Society for Investigative Dermatology
Dr. Kristin Morgan, Associate Professor, University of Connecticut, *Ad Hoc Member*
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. Melissa Spencer, Professor of Neurology and Director, Neuromuscular Division, Department of Neurology, University of California, Los Angeles
Mr. Steven Taylor, President and Chief Executive Officer, Arthritis Foundation
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. Anna Mazzucco
Dr. Darren Sledjeski
Dr. Maria Garcia-Cazarin
Dr. Tamara Alliston
Dr. Stephanie Burrows
Dr. Dandre Thornhill
Dr. Susana Serrate-Sztein
Dr. Robert Carter
Dr. Raj Srinath
Ms. Shalanda Wellington
Mr. Mark Brown
Dr. Xincheng Zheng
Dr. Xibin Wang
Dr. Isaah Vincent
Dr. Emily Carifi
Dr. Marjorie Lindhurst
Dr. Charles Washabaugh
Dr. Kristy Nicks
Dr. Giuseppe Pintucci
Dr. Aron Marquitz
Mrs. Elizabeth Elliott
Mrs. Robin Wolz
Dr. Kamil Barbour
Dr. Marie Mancini
Dr. Anita Undale

Guests

Dr. Robert Gereau, Washington University School of Medicine in St. Louis
Dr. Kathleen Sluka, University of Iowa Health Care

A total of 112 NIH staff and members of the public watched via NIH Videocast.

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

Dr. Lindsey Criswell, NIAMS Director, called to order the 117th meeting of the NIAMS Advisory Council and led Council members and other attendees in a round of introductions. Dr.

Darren Sledjeski, NAMSAC Executive Secretary, reviewed the logistics for the meeting. He noted that members of the public may submit written comments at the email address NIAMScouncilmail@niams.nih.gov up to 15 days following the meeting. He reminded Council members of their conflict of interest obligations under federal law and the yearly conflict of interest reporting deadlines in February, June, and October. Further information regarding conflict of interest regulations is included in the Electronic Council Book, as are the minutes from the April 21, 2025 Council meeting.

The dates of the next three Council meetings are October 14, 2025, January 27, 2026, and June 2, 2026. Going forward the plan is to hold spring and fall meetings in a hybrid format and winter meetings virtually.

III. NIAMS DIRECTOR'S REPORT AND DISCUSSION

Dr. Criswell welcomed the two ad hoc Council members for this meeting, drawn from the pool of NIAMS mentored award grantees: Dr. Sarah Gebauer from Saint Louis University School of Medicine and Dr. Kristin Morgan from the University of Connecticut. Dr. Criswell noted that this would be the last Council meeting for scientific review officers (SROs) in the Scientific Review Branch following the announcement of NIH's plan to centralize peer review of applications within the NIH Center for Scientific Review (CSR). She thanked Drs. Chiguang Feng, Yasuko Furumoto, Archana Jha, Kan Ma, Sushmita Purkayastha, and Ms. Judith Spector for their outstanding contributions during their years of service at NIAMS. While the two NIAMS standing study sections will be discontinued, most of the SROs will continue to work on applications within the NIAMS mission areas in their new positions at CSR. Dr. Kathy Salaita, Chief of the NIAMS Scientific Review Branch, will remain at the Institute during the transition to manage receipt and referral and assist with activities in the Division of Extramural Research.

Fiscal Year 2025 Budget

NIH is currently operating under the Full-Year Continuing Appropriations and Extensions Act of 2025 (H.R. 1968). Under the act, NIAMS's FY 2025 enacted budget equals the comparable budget from FY 2024 ($685,465,000). At the beginning of the fiscal year the pay line was set at the eighth percentile to allow NIAMS more flexibility to look critically at the grants that it funds. Program directors will continue to scrutinize the meritorious applications in their portfolios that score beyond the pay line to identify high priority projects for NIAMS to fund.

Fiscal Year 2026 Budget and NIH Restructuring

In May 2025 President Trump released the overview of his discretionary funding request for FY 2026. The budget request for NIH is approximately $27B, representing an $18B reduction from FY 2025 enacted levels. On May 30, 2025 the Department of Health and Human Services presented its FY 2026 budget with more details about the agency's budgetary plan for its components, including $27.5B in discretionary budget authority for NIH. The plan also proposes a restructuring of NIH to consolidate programs into five new focus areas: the National Institute

on Body Systems Research; the National Institute on Neuroscience and Brain Research; the National Institute of General Medical Sciences; the National Institute for Child and Women's Health, Sensory Disorders, and Communication; and the National Institute on Behavioral Research. The budget proposal retains the National Cancer Institute (NCI), National Institute of Allergy and Infectious Diseases (NIAID), and the National Institute on Aging (NIA) as they currently exist, while eliminating funding for the National Institute on Minority Health and Health Disparities (NIMHD), the Fogarty International Center (FIC), National Center for Complementary and Integrative Health (NCCIH), and the National Institute of Nursing Research (NINR). The National Institute of Environmental Health Sciences (NIEHS) would become part of the new Administration for a Healthy America. Dr. Criswell noted that the House and Senate will develop their own budget proposals over the next few months, which will then need to be reconciled before a final bill is presented to the President.

Activities of General Interest

Dr. Criswell highlighted two recent events attended by NIAMS Deputy Director Dr. Anna Mazzucco. Dr. Mazzucco participated in a congressional briefing as part of the Coalition of Skin Diseases' Hill Day activities. The briefing was sponsored by Representative John Joyce, who is a dermatologist, and featured inspiring skin disease patients, researchers, and health care providers. The event brought awareness of skin diseases to members of Congress, staffers, and federal agency employees. Dr. Mazzucco also attended the 2025 Acceptability Gala, organized by the Global Down Syndrome Foundation, alongside several NIH leaders and members of Congress. In her previous role in the NIH Office of the Director Dr. Mazzucco was heavily involved in the planning, coordination, and execution of the trans-NIH INvestigation of Co-occurring conditions across the Lifespan to Understand Down syndromE (INCLUDE) initiative, of which NIAMS is a participant. As part of the INCLUDE project, NIAMS-supported researchers are evaluating the safety and efficacy of tofacitinib in adolescents and adults with both Down syndrome and an autoinflammatory or autoimmune skin condition such as alopecia areata.

On April 21, 2025 NIH Director Dr. Jay Bhattacharya attended the Council of Councils meeting to introduce himself and his vision for NIH. The Council of Councils advises the NIH Director and the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI), and provides feedback on potential new NIH-wide initiatives. Dr. Bhattacharya's presentation from the meeting is available to view on the NIH videocast archive.

Recently, the NIH announced that it was adopting an initiative to expand innovative, human-based science while reducing animal use in research. New and emerging technologies such as organoids, tissue chips, and other in vitro systems can allow researchers to model human disease and capture variability to answer previously difficult or unanswerable biomedical research questions. NIH intends to establish the Office of Research Innovation, Validation, and Application (ORIVA) within the Office of the Director. ORIVA will coordinate NIH-wide efforts to develop, validate, and scale the use of non-animal approaches, serve as a hub for interagency coordination and regulatory translation, and expand funding and training in non-animal approaches.

A new Common Fund Venture Program, Systems Biology Data Platform (SysBio), will leverage data from multiple Accelerating Medicines Partnership (AMP) programs and integrated various date types. AMP projects have generated unprecedented multiomic and clinical data from well-characterized cohorts, but they are built on different platforms and use different disease-specific data standards. All Institutes and Centers (ICs) participating in the AMPs have come together with the Common Fund Venture Program to establish SysBio as a single access point for querying data across tissues and conditions studied by AMPs. The first SysBio award, a FAIR Platform for Exploration of Systems Biology data (FAIRplex), was launched in fall 2024. It aims to use FAIR principles (Findable, Accessible, Interoperable, and Reusable) to maximize the value of the AMP data ecosystem and provides a single point of entry for researchers to access diverse, harmonized data and user-friendly exploratory tools.

Three NIAMS Intramural Research Program (IRP) researchers have received Office of Autoimmune Disease Research Awards. Dr. Mariana Kaplan and her collaborators will use animal models to study the impact of gut inflammation, low-grade colitis, and the natural microbiota in the incidence and severity of various autoimmune diseases. They will also investigate the co-occurrence of myocarditis and lupus and evaluate the relationship between clinical and molecular endotypes of patients presenting with overlapping or co-occurring systemic autoimmune diseases. Dr. Peter Grayson will partner with NHLBI investigators to study clonal expansion in X-linked autoimmunity. Dr. Laura Lewandowski will collaborate with colleagues at NCI to investigate shared mechanisms of autoimmunity in Sjogren's disease and lupus, with a focus on the DIS3L2 pathway. Dr. Criswell's lab in the National Human Genome Research Institute also received support for their collaboration with NIEHS colleagues to leverage longitudinal exposure data from the Sister Study to examine a subgroup of sisters of women with breast cancer who subsequently developed lupus.

The NIH released a new Public Access Policy that will accelerate broad access to NIH-funded research results. Among other changes, the policy removes the 12-month embargo period before manuscripts resulting from NIH funding must be made publicly available. NIH has also issued supplemental guidance on publication costs and on government use license and rights. The revised policy will go into effect for peer-reviewed manuscripts accepted on or after July 1, 2025, rather than December 31, 2025 as originally planned. NIH also announced an updated policy on foreign subawards. Effective May 1, 2025, NIH will not issue awards to domestic or foreign entities (new, renewal, or non-competing continuation) that include a subaward to a foreign entity. In addition, NIH will no longer accept prior approval requests to add a new foreign component or subaward to an ongoing project. NIH will allow Institutes to renegotiate the awards to remove subawards to foreign entities, and where the work can be performed domestically, to allow funds to be rebudgeted for use by the prime recipient, domestic or foreign, or a domestic subrecipient. If a project is no longer viable without the foreign subaward, NIH will work with the recipient to negotiate a bilateral termination of the project. This policy applies prospectively to all grants and cooperative agreements, but NIH will not retroactively revise ongoing awards to remove the foreign subawards at this time. NIH continues to support direct foreign awards. This policy applies to all monetary foreign collaborations but does not apply to funds provided to support foreign consultants or to purchasing unique equipment or supplies from foreign vendors.

NIH has announced a short-term extension of the Early-State Investigator (ESI) eligibility period for investigators whose last submission date for a new/resubmission application, based on ESI eligibility, is October/November 2024, February/March 2025, or June/July 2025. The new last submission date for eligible ESIs will be October 2025.

NIH has published a request for information (RFI) seeking input on effective strategies for mitigating controlled access human genomic data leakage when developing and sharing artificial intelligence (AI) tools and applications. These strategies should still promote and enable widespread innovation and adoption of responsible AI for biomedical research. In order to uphold the principles set forth in the NIH Genomic Data Sharing Policy, NIH has temporarily paused the sharing of generative AI models and their parameters based on NIH human genomic controlled access data, and the retention of these tools beyond a project's closeout. The deadline to submit an online response is July 16, 2025. Dr. Criswell encouraged attendees to check the NIH Grants & Funding website regularly for the latest NIH policy updates and funding announcements.

Dr. Karl Jepsen asked if the proposed NIH restructuring plan includes changes to the Center for Scientific Review (CSR) and how grants will be reviewed. Dr. Criswell said that some months ago a decision was made to centralize review activities, which has been a challenging process. By the end of June review staff will be consolidated within CSR and the study sections that were previously run and staffed out of the Institutes will no longer exist. She reminded attendees that while the peer-review process is very important, ultimately the Institutes still have the authority to decide which applications they will fund.

Dr. Douglas Kiel asked about the new, multilayered review process for concept proposals and notices of funding opportunity (NOFOs), noting that this seems to result in delays in posting notices. Dr. Criswell said that there has been a longstanding effort by the Department of Health and Human Services (HHS) to simplify NOFOs, and various priorities from the current administration have prompted NIH to take this process a step further. The review process is still subject to change, but currently it consists of a high-level concept summary that is sent to HHS for review and approval. After the concept is sent back to NIH and evaluated centrally, it is presented to councils for approval. There have been some delays to NOFOs as this process was developed and the new simplified review criteria were introduced. Dr. Criswell also noted that at any given time NIAMS has relatively few NOFOs compared to other Institutes. Dr. Aimee Payne asked if there was any guidance for investigators formulating vertebrate animal research sections for ongoing award and continuing renewals, given the NIH's efforts to reduce the use of animals in research. Dr. Sledjeski said that ORIVA was working to develop guidance in this area, and Dr. Criswell asked staff to make a note to follow up with Dr. Nicole Kleinstreuer, who will be deeply involved in this effort.

Dr. Elizabeth McNally asked if there were any anticipated changes related to gold standard research, which has been a subject of comments from NIH leadership. Dr. Criswell said that her interpretation of these comments was that there will be a renewed focus on rigor and reproducibility, replication studies, and robust methods, but it is not clear whether this will lead to significant changes. Dr. McNally also pointed out that though Dr. Bhattacharya (NIH Director) showed data that suggests that trust in scientists has decreased over the last few years,

the same data shows an even greater decrease in trust of politicians. Dr. Edward Botchwey asked whether the scientific review process was also changing significantly. Dr. Criswell said that the simplified review criteria, which went into effect in January, were introduced to decrease reputational bias and focus assessments on project needs. They do not impact the way that investigators should prepare and format applications. Dr. Botchwey asked whether these changes in the format might change the feedback NIAMS receives from scientific review committees. Dr. Criswell replied that she did not think this would be the case and added that NIAMS has many tools that allow them to consider other factors beyond the score.

Dr. Jinoos Yazdany asked about any expected changes to NIAMS's funding priorities. Dr. Criswell replied that NIAMS felt that its priorities and programs, including AMP, SysBio, and data interoperability, align very well with the current administration's priorities. Dr. Payne noted that health and disease in diverse populations is included in NIAMS' cross-cutting scientific themes and asked about requests for applications (RFAs) in that area of research. Dr. Criswell said that given their tight pay line it has been challenging to set aside funds for RFAs, but NIAMS will continue to refer to the Strategic Plan to identify areas where investment is needed and issue notices of special interest (NOSIs) to encourage research in those areas.

IV. INTRAMURAL RESEARCH PROGRAM UPDATE

Dr. Tamara Alliston, NIAMS Scientific Director and head of the NIAMS Intramural Research Program (IRP), presented updates on IRP's recent work. The budget for the IRP is $79M, which represents 11.5% of the total NIAMS budget. Within IRP is the Scientific Program, headed by Dr. Alliston and consisting of approximately 25 investigators conducting basic, translational, clinical, computational, and population research, as well as the NIAMS Research Cores; the Clinical Program led by Dr. Colbert, which operates through the NIH Clinical Center and includes consult services on rheumatology and dermatology; the training program, consisting of around 90 trainees; and the administrative branch.

Dr. Alliston highlighted some of NIAMS IRP's unique strengths, including: the opportunity for translational discovery through human-centered basic science that is close to patients, rare disease and longitudinal cohorts, integrated scientific cores, precision medicine, and technology transfer; and a scientific workforce with MD and PhD investigators who are erasing boundaries between basic and clinical research, as well as long-term staff scientists, core scientists, and a post-baccalaureate and post-doctoral training environment. She introduced the tenured IRP investigators, whose work spans the NIAMS mission areas, as well as the tenure track and additional NIAMS investigators.

The Office of Scientific Operations, led by Dr. Janelle Hauserman, supports IRP's career development and training mission with a focus on post-bac trainees, post-doctoral scientists, clinical rheumatology fellows, and summer students. It also engages in outreach and recruitment and supports a wide range of IRP activities, including the retreat. The Office of Science and Technology, led by Dr. Stefania Dell'Orso, oversees a range of cores that provide intramural investigators with expertise in genomics, translational immunology, light imaging, flow cytometry, biodata mining and discovery, and laboratory animal care and use. The

Administrative Management Branch, led by Valerie Green, works tirelessly to maintain a robust intramural program as different challenges have emerged.

Over the past year 132 publications have showcased a range of projects in NIAMS' mission areas. Dr. Alliston shared two recent examples accepted for publication in Cell: a paper on understanding the role of the microbiome in pathogen resistance on the skin by Dr. Heidi Kong and another focusing on the role of sphingolipid signaling and NK cells in infection and immunity by Drs. Tasha Morrison and John O'Shea. She also highlighted Dr. Vittorio Sartorelli's work, which began looking at the role of histone deacetylase (HDAC) first in regulating muscle cell differentiation, then in regulating muscle gene expression and muscle cell fusion. From there his team looked at the way that inhibition of HDAC with a pharmacologic agent was able to improve outcomes in mouse models of muscular dystrophy. In March 2024 the FDA approved the first nonsteroidal treatment of Duchenne muscular dystrophy on the basis of this fundamental research that began 20 years earlier in Dr. Sartorelli's lab.

Dr. Alliston listed several other recent accomplishments from NIAMS investigators: Dr. Peter Grayson recently received NIH tenure; Dr. Mariana Kaplan became a Hedwig van Ameringen Executive Leadership in Academic Medicine Fellow; Dr. Keisuke Nagao secured a Bench to Bedside grant with NHLBI collaborators; and Dr. O'Shea was named a 2025 Distinguished Fellow of the American Association of Immunologists. The NIAMS IRP retreat was held the week before this meeting, with approximately 100 posters presented over the course of two days and several distinguished keynote speakers. Looking to the future, NIAMS IRP has established a leadership chain with Drs. Alliston and Colbert as well as Dr. Kaplan as the Deputy Scientific Director, Dr. Heidi Kong as the Deputy Clinical Director, and Dr. Sartorelli as an advisor providing guidance on how to take advantage of NIAMS' core infrastructure and integrate with the cores across NIH. The program is currently working on a strategic plan, which will build off of the above-mentioned strengths in translational discovery and the scientific workforce. They are also currently looking for a medical dermatologist to join the Dermatology Consult Service in the Clinical Center.

Dr. Botchwey asked if IRP has seen an impact on applications for post-bacs and post-docs due to the changing landscape at NIH. Dr. Alliston said that she was not sure of the specific numbers, but the post-bac and post-doc programs have been affected by delays caused by hiring freezes. Dr. Botchwey asked about the degree to which engineering is represented within the IRP portfolio of investigators. Dr. Alliston said that NIAMS IRP investigators have been using resources available through the National Center for Advancing Translational Sciences (NCATS) and the National Institute of Biomedical Imaging and Bioengineering (NIBIB), and she has spoken with those ICs to explore ways of doing similar work in NIAMS.

Dr. Kiel asked about possibilities for interaction between the intramural and extramural programs. Dr. Alliston said that she sees a great deal of opportunity to strengthen the ties between intramural and extramural investigators in ways that maintain the appropriate separation of resources. She noted that many intramural investigators serve as significant contributors without salary on extramural grants, and specific funding opportunities to enable collaboration.

V. CONCEPT PRESENTATION

Dr. Sledjeski reminded the Council that concept clearance is the planning process by which 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 were three concepts for consideration at this meeting.

Dr. Mary Garcia-Cazarin, interim Director of the Division of Extramural Research, led the discussion. She invited Dr. Heiyoung Park, Program Director, Scleroderma, Fibrosis, and Autoinflammatory Disease Program, to present the concept for NIAMS Ancillary Studies to Ongoing Clinical Projects (Clinical Trial Not Allowed). The purpose of the concept is to support time-sensitive ancillary studies related to the NIAMS mission in conjunction with privately or publicly funded ongoing clinical projects; to leverage established resources and maximize return on existing investments in parent projects; to generate new information to enhance the clinical and scientific content of the original project; and to improve the research community's understanding of a disease or organ system in the NIAMS portfolio, and thus possibly identify novel targets for diagnosis, treatment, and prevention of disease in the NIAMS mission. The concept is currently expired; if approved the clearance would be effective for five years.

NIAMS has supported ancillary studies since 2010, and to date a total of 48 grants have been awarded across the NIAMS mission area, with an overall success rate of 22%. Compared to other NIAMS-funded studies, ancillary studies have shown higher average relative citation ratios (RCRs) and higher average RCR divided by total award cost. Approximately half of ancillary studies have parent studies funded outside NIAMS. Parent studies are ongoing clinical projects that can be funded by public or private sources, can be on any topic, and must last long enough to accommodate the ancillary study. Ancillary studies must be within the NIAMS mission, require approval from a parent project, must justify time-sensitivity, and must not interfere with the parent project or unduly burden participants. Mechanistic studies are encouraged but non-mechanistic studies are allowed. With this concept, NIAMS would like to see collaboration encouraged between basic and clinical investigators and partnerships with private entities, and junior investigators encouraged to take a leading role in clinical research with the support and collaboration of senior investigators.

Dr. Kiel asked if the program was historically capped at a lower budget than the traditional R01. Dr. Park said that the budget size was smaller compared to regular parent R01s, but the return on investment is much better for ancillary studies. Dr. Jepsen asked if these would be reviewed administratively or through the peer review system, and Dr. Park said that they are reviewed by CSR. Dr. Melissa Spencer asked if completely pharma-supported trials that collected samples would still qualify, and Dr. Park said that it would; the important factor is that the parent trial committee consents to support ancillary studies.

The Advisory Council voted unanimously to approve the concept.

Dr. Aron Marquitz, Program Director, Musculoskeletal Tissue Engineering and Regenerative Medicine Program, presented the concept for the Regenerative Medicine Innovation Project (RMIP). The RMIP was established with funding from the 21st Century Cures Act and is

managed by a trans-NIH group of program officers. It directs NIH, working in coordination with the Food and Drug Administration (FDA), to support research to advance the field of regenerative medicine using adult stem cells. A set amount of $30M funding was authorized and the program requires recipients to identify one-to-one matching, for a total of $60M in project costs supported. Dr. Marquitz reviewed some awards that have been made by RMIP thus far, noting that the program started with supplements in 2017 and then moved into funding opportunities for clinical trials in regenerative medicine using adult stem cells and preclinical studies to promote more clinical trials in the future. NIAMS investigators have been successful in applying for RMIP in the past.

Every funding opportunity from RMIP has required investigators to provide either source stem cells or a clinical grade product to a central hub at Georgia Tech for use in in-depth cell characterization projects. This data from these projects is put into the NHLBI BioData Catalyst and will be made available to the community. Dr. Marquitz shared an example of one of these studies from Dr. Luis Garza, whose RMIP project involves injecting autologous volar fibroblasts into the stump site to allow pressure adaptation and enhanced prosthetic use in amputees.

For this concept NIAMS is proposing short term follow-up studies for projects currently funded through RMIP. This initiative seeks to leverage the work already being done through RMIP to advance the field of regenerative medicine using adult stem cells and will take advantage of the remaining funds authorized through the 21st Century Cures Act.

The Advisory Council voted unanimously to approve the concept.

Dr. Melissa Green Parker presented the concept for the Core Centers for Clinical Research (CCCR) (P30 - Clinical Trial Not Allowed). The CCCR is a successful NIAMS program with the goal of advancing prevention, diagnosis, and treatment of NIAMS-relevant diseases and disorders by developing and fostering the implementation of novel methods, metrics, and outcome measures that address critical existing and emerging clinical research needs. The grants are intended to accommodate and address the most pressing needs of the NIAMS clinical research community while keeping in mind existing and/projected gaps in knowledge, breadth of concepts, and issues of feasibility and adoptability.

NIAMS established the CCCR program in 2017 as one of several NIAMS-specific center grant mechanisms. Ten Type 1 CCCR grants and several competitive renewal grants have been awarded to date. The Centers are located across the U.S. and address a number of research areas within NIAMS's mission including arthritis/osteoarthritis, lupus, musculoskeletal health, health informatics/bioinformatics, joint replacement, fibromyalgia, pediatric rheumatology, and back pain. The general CCCR structure consists of a strong methodologic core providing innovative approaches and expertise to support new and ongoing local research projects, an administrative core, led by two directors, that engages with the external advisory committee and has the flexibility to address pressing needs, and optional components such as Resources Cores and Pilot and Feasibility (P&F) projects. Patient and community representation is incorporated throughout the project.

Dr. Kiel asked how the program's success has been evaluated. Dr. Green Parker said that a formal evaluation has not been conducted since 2013, but NIAMS held a workshop in December 2024 where they received feedback from grantees about how they would like to see some of the Centers evolve. Dr. Garcia-Cazarin added that this was an internal workshop with program directors and NIAMS staff, and they are looking into ways to formalize evaluation of the Centers.

The Advisory Council voted unanimously to approve the concept.

VI. HEAL STRATEGIC PLAN PRESENTATION

The NIH Helping to End Addiction Long-term (HEAL) Initiative was launched in 2018, and in 2024 an executive committee of experts was convened under the National Institute of Neurological Disorders and Stroke (NINDS) in order to develop a new five-year strategic plan. The HEAL Pain Strategic Research Priorities Executive Committee engaged in an in-depth process to propose and prioritize forward-looking strategic research priorities for the next phase of pain research supported by the HEAL Initiative. Several NIAMS program directors and program analysts contributed to this process, which involved working with experts from the research community and people with lived experience of pain to inform the final research priorities. The committee approved the proposed research priorities at the May 14, 2025 meeting of the NINDS Council. Dr. Mazzucco introduced the co-chairs of the planning committee, Dr. Kathleen Sluka and Dr. Robert Gereau, to give the presentation.

When HEAL launched in 2018, Congress added $500M to NIH's annual base appropriation for a new initiative to research opioid addiction, development of opioids alternatives, pain management, and addiction treatment. Early investments were guided by the 2017 Federal Pain Research Strategy and a series of Cutting Edge Science Meetings to End the Opioid Crisis. From 2018-2023 HEAL was led by the NIH Office of the Director; since 2023 it has been led by Dr. Nora Volkow in the National Institute on Drug Abuse (NIDA) and Dr. Walter Koroshetz in NINDS as the co-Scientific Directors. Since 2018 HEAL has had more than 2,200 research projects in all 50 states, totaling over $3.9B; collaboration across 19 NIH Institutes, Centers, and Offices; more than 40 FDA approvals for investigational new drugs or devices; and more than 300 clinical trials currently under way. As many of the initial projects launched at the beginning of HEAL are wrapping up or reaching a transition point, the HEAL Multidisciplinary Working Group (MDWG) recommended developing a strategic plan to guide future HEAL investments. Since 2018, HEAL pain funding has accounted for 21% of total NIH pain research funding. Some highlights from the HEAL pain research portfolio to date include validation and development of non-opioid targets, understanding pain biology and identifying biomarkers, devices for pain management, clinical trials, and significant workforce investment.

In June 2024 NINDS and NIDA issued joint RFIs to solicit input on the future of HEAL from stakeholders. The Working Group then convened around scientific focus areas and formed seven subcommittees: health equity and pain across the life course; non-addictive therapeutics development; pain biomarkers and predictors; optimization of interventions to improve pain; implementation and health services research; intersection of pain and substance use disorder; and pain research workforce and training. The subcommittees met and deliberated, informed by

meetings, workshops, and RFIs, and developed lists of research priorities for their focus areas. The Working Group then narrowed the subcommittee recommendations using a modified Delphi process to prioritize recommendations based on their ability to advance the HEAL pain mission. This process identified ten scientific research priorities and a set of core principles, which are cross-cutting and emerged as consistent themes across subcommittees.

The proposed core principles: involvement of people with lived experience (PWLE) in NIH HEAL research (training of investigators, inclusion in basic and clinical research, inclusion from design through data analysis); education of public and providers (research dissemination of findings, community engagement for clinical trials and implementation, public campaign); methodological principles for preclinical and clinical trial research; interdisciplinary teams should be employed to capitalize on unique skills and methodologies; and secondary analysis of existing data and biological samples, many of which are already stored in the HEAL Data Ecosystem.

The ten scientific research priorities are as follows:

- Support comprehensive fellowship, career development, and mentored research scholar awards for individuals across all career stages, including non-U.S. citizens (support established pain researchers and those with no prior pain experience but strong potential).
- Support the development of mechanistically varied and highly efficacious pain therapeutic pharmaceutical modalities.
- Invest in discovery research with a focus on human biology to support the development of novel therapeutics.
- Develop pain prevention strategies to prevent the development of chronic pain throughout the lifespan, particularly during key transitions across the life course.
- Develop biomarkers for predicting treatment response, safety, target engagement and/or that may serve as surrogate endpoints in clinical trials.
- Evaluate whether individualized, tailored, mechanism-based treatments improve outcomes (through composite pain "signatures"/deep phenotypes; investigating mechanisms underlying non-pharmacological interventions; testing personalized approaches).
- Develop and test evidence-based guidance on the appropriate initial pain therapy, order and timing of multimodal approaches, and non-specific effects to achieve maximal benefit for the individual patient without undue risk.
- Prioritize clinical- and community-embedded research, hybrid implementation-effectiveness studies, and pragmatic trials for real-world impact, scalability, and sustainability.
- Identify populations that are disproportionately and highly impacted by both pain and substance use, understand mechanisms that differentially impact these populations, and develop and test interventions to address the disproportionate impact.
- Support research on non-drug approaches to treatment and prevention of chronic pain, including in patients with co-occurring substance use disorder.

In reference to the priority that addresses disproportionate impacts on populations, Ms. Sharon Smith-Terry asked if they would be looking at all populations and making a measure of where there are issues around pain management, substance abuse, and tolerance for pain. She noted that

there is data on bias regarding pain management among certain races/ethnicities, particularly African Americans. Dr. Sluka said that that priority was meant to look broadly at different aspects of disparities between groups (including race/ethnicity, sex, and age) and whether different strategies and implementation methods are needed. Dr. Spencer asked if the move to diversify away from small molecules towards new therapeutic modalities could include adeno-associated virus (AAV)-mediated gene therapy. Dr. Gereau said that it could, and that priority was meant to encourage innovation in that space, as different approaches are needed for some of the pain targets.

Dr. Criswell highlighted several previous and ongoing investments from the HEAL Initiative: the Back Pain Consortium (BACPAC) Research Program, a translational, patient-centered effort to address the need for effective and personalized therapies for chronic low back pain; Restoring Joint Health and Function to Reduce Pain (RE-JOIN), which aims to understand more about the innervation of different tissues within specific joints; and, moving forward, a project that will focus on chronic pain in children and another that will use an integrative approach to look at musculoskeletal pain.

VII. OPEN DISCUSSION

Dr. Criswell opened the floor to the Council to raise topics of interest for further discussion. Dr. Sarah Gebauer asked about any initiatives that NIAMS has in place to enhance expertise in data science. Dr. Criswell mentioned the SysBio effort, which focuses on data interoperability and has garnered support across the NIH, as well as the NIH Director's interest in real-world data platforms, which NIAMS is following closely. Prior to the completion of their strategic planning process NIAMS also had a working group that was focused on data science. Dr. Mazzucco added that they view SysBio as a use case in addressing data interoperability issues across NIH. NIAMS has also taken advantage of the resources through the HEAL data ecosystem to ensure that programs such as BACPAC and RE-JOIN provide integrated resources for musculoskeletal pain to NIAMS communities. Dr. Criswell noted that, as part of the Accelerating Medicines Partnership, NIAMS is also working with NIA and others to develop the Arthritis and Autoimmune and Related Diseases Knowledge (ARK) Portal, which will make AMP data more accessible.

Dr. Payne said that the HEAL Initiative's recommendation to incorporate non-U.S. citizens in training programs was critical given that there is a shortage of researchers in the country. She asked if this could be incorporated into other training grant initiatives to expand the talent pool. Dr. Criswell agreed that this was an important consideration; she noted that NIH is currently working through some challenging issues related to collaborations with foreign entities through subawards, as well as discussions around trainees who are hosted by NIH but paid by a foreign country. She was hopeful that they could circle back once those issues are resolved and take advantage of the opportunities that are presented by reaching out to the broader community. Dr. Gereau added that the HEAL Initiative priorities were developed under the previous administration, but the goal remains the same; the mechanism for rolling it out will need to be worked out under the new administration's policies. Dr. Sledjeski highlighted the work of the NIAMS Grants Management Branch, which is working hard to implement the changes that are being rolled out across NIH.

VIII. CLOSED SESSION

This portion of the meeting occurred during closed session.

IX. REVIEW OF APPLICATIONS

The 117th National Arthritis and Musculoskeletal and Skin Diseases Advisory Council met in person on June 3, 2025. Elven Council members and two Ad-Hoc Council members attended both in person and virtually. En bloc concurrence was unanimously approved for 834 primary and 185 secondary applications. The total cost requested in a year - 01 for all applications was $355,087,192.

X. ADJOURNMENT

The 117th National Arthritis and Musculoskeletal and Skin Diseases Advisory Council adjourned at 3 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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Lindsey A. Criswell, M.D., M.P.H., D.Sc.
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Director, National Institute of Arthritis and Musculoskeletal and Skin Diseases