National Institute of
Arthritis and Musculoskeletal
and Skin Diseases

Minutes of Meeting

January 27, 2026

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

MINUTES OF THE 119th MEETING

I. CALL TO ORDER

The 119th meeting of the National Arthritis and Musculoskeletal and Skin Diseases Advisory Council (NAMSAC) was held on January 27, 2026, 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, Associate Professor, Wallace H. Coulter Department of Biomedical Engineering, Georgia Institute of Technology
Dr. Karl Jepsen, Glancy Family Scholar and Professor of Orthopaedic Surgery and Bioengineering, Department of Orthopaedics, Department of Orthopaedic Surgery, University of Michigan
Dr. Douglas Kiel, Professor and Senior Scientist, Hinda and Arthur Marcus Institute for Aging Research, Hebrew SeniorLife; Professor of Medicine, Harvard Medical School
Dr. Xiaojuan Li, Professor, Department of Biomedical Engineering, Lerner Research Institute, Cleveland Clinic
Dr. Elizabeth McNally, Elizabeth J. Ward Chair, Professor of Genetic Medicine, and Director, Center for Genetic Medicine, Northwestern University Feinberg School of Medicine
Dr. Rebecca Minnillo, Chief Program, Communications, and Development Officer, Society for Investigative Dermatology
Dr. Aimee Payne, Tenured Professor and Attending Physician, Department of Dermatology, Columbia University
Ms. Sharon Smith-Terry, Executive Director, Neurocritical Care Society and the Neurocritical Care Foundation
Dr. Melissa Spencer, Professor of Neurology and Program Director, Department of Neurology, David Geffen School of Medicine, University of California at Los Angeles
Mr. Steven Taylor, President and Chief Executive Officer, The Arthritis Foundation
Dr. Jinoos Yazdany, Professor and Chief of Rheumatology, Division of Rheumatology, University of California, San Francisco
Dr. DeAnna Baker Frost, Associate Professor, Division of Rheumatology and Immunology, Medical University of South Carolina, *Ad Hoc Member*

Dr. Cory Simpson, Assistant Professor, Department of Dermatology, University of Washington, *Ad Hoc Member*
Dr. Samantha Weaver, Assistant Professor, Department of Comparative Biosciences, University of Wisconsin Madison, *Ad Hoc Member*

Staff and Guests

The following NIAMS staff and guests attended:

Staff

Dr. Lindsey Criswell
Dr. Anna Mazzucco
Dr. Tamara Alliston
Dr. Kamil Barbour
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
Mr. Jon Anthony Davis
Ms. Robin DiLiello
Ms. Teresa Do
Mr. Erik Edgerton
Ms. Jana Eisenstein
Dr. Mary Garcia-Cazarin
Dr. Melissa Green Parker
Dr. Peter Koch
Ms. Stephanie Kreider
Dr. Hiu Wan Law
Dr. Marjorie Lindhurst
Ms. Ryan Lombardi
Dr. Marie Mancini
Dr. Su-Yau Mao
Dr. Aron Marquitz
Ms. Sara Myers
Mr. Christopher Nee
Dr. Van Nguyen
Dr. Kristy Nicks
Dr. Heiyoung Park
Dr. Giuseppe Pintucci
Ms. Sahar Rais-Danai
Dr. Susana Serrate-Sztein
Ms. Anamika Singh

Dr. Kriti Sharma
Dr. Darren Sledjeski
Dr. Raj Srinath
Ms. Yen Thach
Ms. Jamie Thompson
Dr. Dandre Thornhill
Dr. Anita Undale
Mr. Herman Utama
Dr. Aneliya Velkova
Dr. Isaah Vincent
Dr. Xibin Wang
Dr. Yan Wang
Dr. Charles Washabaugh
Ms. Elisa Weiss
Ms. Shalanda Wellington
Mr. Patrick Wilson
Dr. Xincheng Zheng

Guests:

Dr. Richard Conroy, Office of Data Science Strategy, NIH
Dr. Jon R. Lorsch, Deputy Director for Extramural Research, NIH
Dr. Haluk Resat, Program Director, SysBio Project, Office of the Director, NIH
Dr. Victoria Shanmugam, Director, Office of Autoimmune Disease Research, Office of Research on Women's Health, Office of the Director, NIH

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

Dr. Lindsey Criswell, NIAMS Director, called to order the 119th meeting of the NIAMS Advisory Council at 9:30 a.m. and led Council members and other attendees in a round of introductions. Erik Edgerton, Acting Director of the Division of Extramural Affairs and NAMSAC Executive Secretary, reviewed the logistics for the virtual meeting. Members of the public may submit written comments to NIAMScouncilmail@niams.nih.gov up to 15 days following the meeting. Council members were reminded to recuse themselves from any application reviews that may constitute or appear to constitute a conflict of interest. Conflict of interest reporting updates are issued in February, June, and October, and Council members have 30 days to respond to them.

Mr. Edgerton called for any comments or corrections to the minutes of the 118th NAMSAC meeting, which took place on June 3, 2025. There were no comments or corrections, and Mr. Edgerton moved to approve the minutes as written. The motion was seconded and passed unanimously.

The dates of the next Council meetings are June 2, 2026 (in-person), September 15, 2026 (hybrid), and January 26, 2027 (virtual).

III. NIAMS DIRECTOR'S REPORT AND DISCUSSION

Dr. Criswell announced that this was the last Council meeting for Dr. Edward Botchwey and Ms. Ann Elderkin and expressed her appreciation for their service. NAMSAC has continued its practice of inviting investigators from the pool of NIAMS-mentored award grantees to serve as ad hoc Council members to both familiarize them with the work of the Council and so that NIAMS can receive input from early-stage investigators (ESIs). Dr. Criswell introduced and welcomed the three ad hoc Council members for this meeting: Dr. DeAnna Baker Frost, Dr. Samantha Weaver, and Dr. Cory Simpson. Dr. Criswell acknowledged the NIAMS staff for their outstanding effort over the past year as many new policies and priorities have been implemented, particularly recognizing the grants management specialists that managed to issue all NIAMS-funded grants for FY25. NIAMS was able to fund 25 ESIs in FY25 (six more than FY24), which is evidence of the Institute's commitment to developing and supporting scientists early in their careers.

NIH and NIAMS Budget

Dr. Criswell updated the Council on the status of the NIH and NIAMS budgets. The FY 2026 Conference Budget proposed $47,493,100,000 for NIH with $685,465,000 allocated to NIAMS. The House has passed this bill and it will soon be considered by the Senate. NIH will continue operating under a continuing resolution until January 30 and they await guidance on any budgetary requirements, such as the multiyear funding policy.

Personnel Changes

Dr. Jon Lorsch has been selected as the NIH Deputy Director for Extramural Research (DDER) after serving in this role in an acting capacity since April of 2025. The DDER serves as the principal scientific leader and advisor to the NIH Director on all matters related to the substance, quality, and effectiveness of the NIH Extramural Research Program and its administration. With Dr. Lorsch's transition to this role, Dr. Darren Sledjeski has begun a detail to NIGMS serving as their Acting Deputy Director. Dr. Criswell expressed appreciation for his willingness to continue advising NIAMS leadership on many important activities. Mr. Edgerton has agreed to move into the role of acting Director of NIAMS' Division of Extramural Activities during Dr. Sledjeski's detail. Ms. Sahar Rais-Danai will serve as the acting Chief of the NIAMS Grants Management Branch.

Dr. Anthony Letai has been sworn in as the Director of the National Cancer Institute. Dr. Kyle Walsh has been selected as the Director of the National Institute of Environmental Health Sciences, and Dr. Richard Woychik has taken on a new role in the Office of the Director to advance the Make America Healthy Again initiative.

NIH and NIAMS Activities

Dr. Criswell updated the Council on a Congressional briefing held in August to celebrate the launch of the NIH-wide Strategic Plan for Autoimmune Disease Research. The effort has been led by the Office of Autoimmune Disease Research within the Office of Research on Women's Health (ORWH) and will be discussed further during Dr. Shanmugam's presentation. NIAMS also collaborates with ORWH on many other activities, including the Accelerating Medicines Partnership (AMP) Autoimmune and Immune-Mediated (AIM) Leadership Scholars Program. An overarching goal of the program is to prepare the next generation of scientific leaders to advance women's health research. A second round of funding will provide pilot project support for four award recipients. The overall goal of the AMP AIM network is to study the cellular and molecular interactions and pathways that lead to inflammation and autoimmune/immune-mediated diseases. Enthusiasm for the program has helped raise funds that will enable the expansion of AMP AIM for an additional year, and the addition of a scleroderma focused project, extension of the rheumatoid arthritis research scope, and an increase to sample throughput. Dr. Criswell noted that the electronic council books include a summary table of some of the latest NIAMS-supported scientific advances that demonstrate returns on NIAMS' investment in research, including examples of how investigators have continued to leverage data from the AMPs for their scientific discoveries.

In 2023, NIAMS collaborated with ORWH to release two notices of funding opportunity (NOFOs) on chronic conditions understudied among women, inviting applications on chronic conditions with differential prevalence, morbidity and/or mortality in populations of women historically understudied and underrepresented in biomedical research. NIAMS was able to support a number of exciting projects this year, including research examining the mechanical and nonmechanical contributions to chronic neck, shoulder, arm, and back pain in full-busted women; exploring mechanisms driving poor outcomes in women with dermatomyositis; and studying pregnancy and cardiovascular health in caring for women with systemic lupus erythematosus.

On December 19, the U.S. Food and Drug Administration (FDA) qualified the treatment-related change in hip bone mineral density (BMD) as a surrogate endpoint for bone fractures in clinical trials of anti-osteoporosis drugs in postmenopausal women at risk of osteoporotic fractures. The new qualification will significantly reduce the time and expense required to develop and deliver much-needed treatments. The Study to Advance BMD as a Regulatory Endpoint (SABRE) developed the data and evidence for this qualification. Dr. Criswell noted that Dr. Gayle Lester, NIAMS' Director of the Division of Extramural Research (retired), served as a program director for this study.

Beginning in FY26, NIH will no longer post NOFOs in the NIH Guide. Grants.gov will serve as the NIH's single official source for grant and cooperative agreement funding opportunity announcements. The NIH Guide will continue to be used for policy and informational notices. In January, NIH phased out all notices of special interest (NOSIs) published by the ICs as part of an NIH-wide strategy to simplify and streamline the application and funding process. A new centralized resource called "NIH Highlighted Topics" will inform the research community about particular scientific areas of interest to NIH. Visiting this resource early and often when

conceptualizing research ideas will help researchers ensure awareness of some of NIH's latest scientific interests.

In November, NIH announced that it has implemented steps towards a unified strategy that will help guide clearer and more consistent funding decisions across all ICs. According to this framework, all IC funding policies should align with the NIH's mission, prioritize scientific merit, integrate a breadth of topics and approaches relevant to the IC's priorities, consider investigator career stage and promote sustainability of the biomedical research workforce, promote broad distribution and geographic balance of funding, and align with the availability of funds of the ICs. Peer review remains essential and is vital to this approach. Going forward, ICs will be considering peer review information in its entirety and Institutes will not rely on funding paylines in developing pay plans but rather consider these scores in the context of their and NIH's priorities, their strategic plans, and their budgets. IC Directors will continue to have the delegated authority to decide what is funded by their Institute. NIAMS has already implemented the select pay process, which is in line with this approach.

NIH will no longer consider applications that have been substantially developed with artificial intelligence (AI) and may take enforcement action if AI use is identified in the post-award process. NIH now only accepts six applications per PI per calendar year. The purpose of these policies is to maintain fairness and originality in NIH's research application process.

NIH has adopted an initiative to expand innovative human-based science while reducing animal use in research. To further these efforts, NIH has announced that it will no longer develop new funding opportunities focused exclusively on animal models of human disease. This policy does not change investigators' ability to use animal models in their research. The purpose of the policy is to increase the types of models submitted in response to funding opportunities.

NIH funding will no longer be used to support research involving the use of human fetal tissue from elective abortions. This policy applies across NIH's intramural program and all extramural research, including grants, cooperative agreements, other transaction awards, and R&D contracts. This policy supersedes prior NIH guidance and reflects a shift toward next generation validated research models suited to today's rapidly evolving scientific landscape.

NIH has accepted the Novel and Exceptional Technology and Research Advisory Committee's (NExTRAC) recommendations on engaging the public as partners in NIH-supported clinical research. NExTRAC has undertaken a multi-year effort to develop a road map for incorporating public voices in clinical research. NIH will begin a policy development process for the return of research results to clinical research participants. NIH has published its agency-wide principles to foster, promote, and guide the responsible conduct of research using clinical data.

As part of the agency's administrative burden reduction effort, NIH will no longer request or accept letters of intent (LOIs) as part of the application process or require applicants requesting $500k or more in direct costs in any one budget period to contact the funding Institute before application submission.

In September, NIH announced a new application and award structure for applications that request funding for international component organizations. The NOFO for the NIH Collaborative International Research Project (Parent PF5 Clinical Trial Optional) has been published to support the international research collaboration process. This funding opportunity is designed for NIH to support funded international collaborations between a domestic prime organization and foreign organizations. It should not be used for foreign consultants, purchasing unique equipment/supplies from foreign vendors, foreign collaborations that do not involve NIH funding, or any other foreign component that would not result in a foreign subaward.

NIH has released the Stephen I. Katz Early-Stage Investigator Research Project Grant NOFO to support innovative projects that represent a change in research direction. Applications for this grant cannot include any preliminary data.

Effective for application due dates on or after 10/12/2025, NIAMS will raise the maximum salary of research support provided on NIAMS' K99 awards through the parent K99/R00 NOFOs to up to $75,000 a year plus fringe benefits, an increase of $15,000 per year.

NIH is requesting public input on its proposal to establish harmonized and transparent policy requirements for protecting human participant research data. NIH proposes to establish policy requirements for which data should have controlled-access under NIH data sharing policies and for revising the current NIH Genomic Data Sharing Policy to simplify and harmonize those requirements. The deadline to submit input is March 18, 2026, and Dr. Criswell encouraged Council members to share their suggestions.

Discussion

Dr. Xiaojuan Li asked for clarification on the R01 requests over $500,000. Dr. Criswell said LOIs will not be needed and no approvals are required to proceed with applications. It is important that any budget the applicant develops be appropriate for the proposed research and programs with very large budgets can expect to receive additional scrutiny. Dr. Li asked if NIAMS is positioning itself to support smaller grants to more PIs or if it will focus more on large grants from established investigators. Dr. Criswell said NIAMS has set itself a target of maintaining the same number of investigators each year. If the multiyear funding requirement is imposed this year, it will be especially challenging. NIAMS recognizes that there will be critically important research applications and proposals with large budgets and they are not precluding the support of large proposals but need to be more thoughtful than ever about how they are spending their resources. Alignment with their priorities, strategic plan, and Highlighted Topics will be the Institute's guide in making difficult investment decisions. NIAMS' budget team is doing extensive modeling to help better understand the parameters and tools available to avoid adversely affecting the size of the investigator pool as they navigate these changes.

Dr. Karl Jepsen said the Unified NIH Funding Strategy will be a new paradigm for the musculoskeletal field and researchers will need assistance in navigating the change. Dr. Criswell recognized that this is a challenge and noted that NIAMS' payline is already so tight that they had to start implementing a select pay process. One thing they will do to address this specific

challenge is revising policies and procedures internally so that investigators know the status of their grant applications as soon as possible, with awards made throughout the year.

Dr. Douglas Kiel asked if the growing emphasis on autoimmune disease is expected to change the allocation of the broad programs NIAMS supports. Dr. Criswell said NIAMS looks for collaboration and leveraging resources wherever possible and pointed to AMP AIM as a good example. She highlighted several recent interactions promoting NIAMS' work on musculoskeletal and skin projects, in addition to their focus on autoimmunity. They are very cognizant of the fact that NIAMS needs to seek balance across their portfolio, while taking into consideration opportunities or gaps, as well as the areas for which NIAMS is the only funding Institute.

Dr. DeAnna Baker Frost asked if the increase in funding opportunities for ESIs will continue in the future. Dr. Criswell said that NIAMS and NIH are deeply committed to increasing support for ESIs. One of the considerations in NIAMS' funding approach is the stage of the investigator. They are aware that ESIs feel threatened and vulnerable in the current shifting scientific landscape. She hopes NAMSAC can help the Institute better understand which groups are the most impacted or are now more critical than ever. The upcoming retreat for extramural program staff will also address this topic.

Dr. Cory Simpson asked if NIAMS will have a policy about supporting ESIs to replace the verbiage in its funding plan around having a separate payline committed to ESIs. Dr. Criswell said that all of the payline language across the NIH is going away. The Unified Funding Strategy calls out the stage of investigators as a key consideration, signaling that this still counts in funding decisions even in the absence of distinct paylines. NIAMS is developing ways to track all of this to monitor the impact.

Dr. Edward Botchwey asked if there is authoritative guidance explaining what NIH means by "substantially developed by AI" and who makes the determination. He also asked if there are best practices investigators should use to demonstrate originality to remain compliant. Dr. Criswell said this is a rapidly evolving area. In addition to hearing from Dr. Lorsch about this later in the meeting, she requested that staff seek to have Dr. Bruce Reed from the Center for Scientific Review address the Council at a future meeting on this topic. The issue of AI-developed applications became a focus for CSR when they began seeing a small number of investigators submitting over 30 applications in a year. This is why the AI restrictions were paired with the yearly application limits for PIs. Using AI for spellchecking and refining the language in an application is acceptable but AI should not be used to develop the research idea itself or generate the list of references. Mr. Edgerton provided a link to the Office of Extramural Research (OER) page for the notice, which includes FAQs on the use of AI.

Dr. Melissa Spencer asked if NIAMS is interested in funding host-vector interaction research. There is no Institute that has this as a priority, and it could have a major impact on the clinical application of therapies for patients across many different diseases within the scope of NIAMS' portfolio. Dr. Criswell said there is an ongoing issue of topics not falling neatly into the organizational structure within NIH. She noted that AMP has a Bespoke Gene Therapy Consortium that NIAMS contributes to that may offer a mechanism for some of these scientific

areas that are insufficiently understood. NIAMS is also deeply involved with the Muscular Dystrophy Coordinating Committee (MDCC) and they have a congressional mandate to fund centers of research related to this, for which gene therapy is a major component. These are two areas to explore to ensure NIAMS is not missing opportunities. Often the concern for an area that may be falling through the cracks is that either none of the ICs seem to want to take it on or the applications do not seem to be as competitive. One of the advantages of the Unified Funding Strategy is that it gives ICs more flexibility to fund grants that may not get funded in a payline approach but that are highly meritorious. She encouraged Dr. Spencer to follow up with Mr. Edgerton to connect with the appropriate program officer.

IV. THE OFFICE OF AUTOIMMUNE DISEASE RESEARCH

Victoria Shanmugam, MBBS, MRCP, FACR, CCD, Director, NIH Office of Autoimmune Disease Research in the Office of Research on Women's Health (OADR-ORWH), provided a briefing on the NIH-wide Strategic Plan for Autoimmune Disease Research for FY 2026-2030. In response to a National Academies of Sciences, Engineering, and Medicine' (NASEM) report on the current state of NIH research on autoimmune disease and how it might be enhanced, Congress instructed NIH to establish the OADR-ORWH and provided six directives for the office. Dr. Shanmugam went through each of these directives and provided updates on their current status.

OADR-ORWH's strategic plan will guide their consideration of a list of 144 different diseases and conditions in the autoimmune disease research portfolio. These include conditions across every body system and incorporate components of fundamental immunology, necessitating a coordinated approach to facilitate the collaboration and scientific discovery that needs to happen. The plan presents data on the prevalence of autoimmune diseases in the U.S. to demonstrate the relevance of the work they are doing. Autoimmune diseases are some of the most prevalent chronic diseases in the U.S., far exceeding coronary heart disease and COPD. Many autoimmune diseases co-occur, and the NASEM report recognized the difficulty of studying areas that fall under the missions of different ICs. OADR-ORWH is attempting to create a more coordinated approach to address this challenge. Autoimmune diseases of all types increase cardiovascular risk, and a coordinated approach will help improve understanding of the immune triggers and drivers of cardiovascular disease risk and many other chronic diseases.

Dr. Shanmugam discussed some of the information gathering efforts OADR-ORWH has undertaken to inform their planning process. The input they heard from the community stressed that autoimmunity does not happen in a vacuum and that the focus needs to include the preclinical stage. The period of asymptomatic autoimmunity can last up to 15 years in a disease like multiple sclerosis, prior to a period of autoimmunity that may or may not be fully diagnosable until the point of clinical disease. Genetics play a role in autoimmune disease, but its rate of increase amongst the population has been too rapid to be explained by genetics alone. Researchers believe there are other exposures/triggers that happen across the course of a lifespan that play a role in the development of autoimmunity.

The mission of the NIH-Wide Strategic Plan for Autoimmune Disease Research is to coordinate and advance efforts to support rigorous, high-priority, innovative, and collaborative autoimmune disease research. Dr. Shanmugam presented the strategic priorities and objectives of the plan to advance autoimmune disease research at NIH. These are:

(1) Include accelerating fundamental scientific discovery in diagnosis, treatment, prevention, and cure of autoimmune diseases;
(2) Promote research that focuses on enhancing health of people living with or at risk of developing autoimmune diseases;
(3) Provide support that understands the full complexity of autoimmune diseases across the lifespan and will accelerate research for clinical trials and expand research into co-occurring/comorbid conditions;
(4) Support research that will build and maintain capacity for autoimmune disease research across NIH, including supporting efforts to sustain the scientific workforce; and
(5) Build and support partnerships and interdisciplinary collaborations across the autoimmune disease community. Themes that cut across all the priorities in the plan include harnessing cutting-edge technologies and supporting multi-modal data-driven approaches to accelerate autoimmune disease research.

OADR-ORWH has a very modest budget compared to the ICs; however, they have taken a broad approach to ensure they touch all the diseases they have been asked to consider in the portfolio and work across every IC. OADR-ORWH has conducted a baseline portfolio analysis of NIH's autoimmune disease research for the five years prior to its establishment and will continue to do one annually going forward. Autoimmune disease research is part of many ICs' portfolios but owned by none, with NIDDK currently the largest funder.

Autoimmune disease research is still underfunded relative to disease impact and prevalence in the U.S. Despite the significant progress that has been made in this field over the last 30 years, this coordinated structure across NIH is needed to advance scientific discoveries and improve the health of Americans with these diseases.

Dr. Shanmugan highlighted several programs as examples of the many ways OADR-ORWH has supported planning, collaboration, and innovation:

- the Exposome in Autoimmune Disease Collaborating Teams PLANning (EXACT-PLAN) awards,
- the AMP AIM program, Autoimmunity Centers of Excellence (ACE), and
- the Network for Exposomics in the U.S. Coordinating Center (NEXUS).

Another mechanism they have utilized to provide resources for collaboration and innovation is the NIH's Challenge Opportunity. OADR-ORWH launched the Nutrition for OUR Immune System Health (NOURISH) Autoimmunity Challenge, a crowdsourcing ideation competition to engage the community and generate bold ideas on how to integrate diet and nutrition into autoimmune disease research. They hope to announce the winning proposal in conjunction with Autoimmune Disease Awareness Month in March 2026.

Congress tasked OADR-ORWH to develop and oversee a repository for autoimmune disease research, and they have launched a pilot program, the Autoimmune Disease Analysis Platform Testing Space (ADAPTS), which leverages a federated data platform model allowing a single unified view across multiple distributed sources without moving data.

Discussion

Dr. Jinoos Yazdany asked, given the recent disruptions at the Centers for Disease Control and Prevention (CDC) and in their chronic disease program, where the home for foundational epidemiology in autoimmune disease should be and how these changes fit into OADR-ORWH's strategic plan. Dr. Shanmugam said the NASEM report recognized this gap and that there are no large coordinated epidemiological studies in this area in the U.S. This is a larger issue than this strategic plan will be able to tackle. Dr. Kamil Barbour said that he was reviewing the responses to NIAMS' RFI on this and they will be very helpful in moving forward.

Dr. Spencer asked if the federated data platform is being viewed purely as a data repository or if there will be an option for investigators to make data available to the public. She also asked whether the platform would allow researchers to access the data in real time. Dr. Shanmugam said the platform is not one repository but rather a mechanism that allows investigators to look across existing distributed datasets and analyze them in place. It could potentially be scaled to allow users broader functionality, but currently it is entirely within the NIH firewall as it is being tested. She strongly encouraged the members to look at the RFI Dr. Criswell mentioned during her remarks and provide input on what they are looking for from controlled access repositories.

Dr. Kiel asked if OADR-OWRH is partnering with the AMP program's distributed knowledge portal or other already established portals. Dr. Shanmugam said they have reached out to some programs with established portals and have looked at several that currently exist. The platform they have stood up is still in its initial pilot testing phase. It will take time to develop but it is essential to have a system that creates protections for human subjects in research in any venue.

Dr. Botchwey asked if their thinking about preclinical autoimmunity includes supporting mechanistic animal/in vitro model work to test causal pathways and exposures or if the emphasis is on presymptomatic human cohorts and human data platforms. Dr. Shanmugam said fundamental research happens on many different levels and they encourage investigators to continue the science that needs to be done but to be aware of the general policy shifts in how NIH is approaching some of their research models. NIH's end goal is improving human health, and they need to focus on the human-related component of all the research they do.

V. SYSBIO AND AMP SYSTEMS BIOLOGY OF INFLAMMATION: A VISION FOR AMP DATA – MAXIMIZING VALUE BEYOND THE SUM OF THE PARTS

Anna Mazzucco, PhD, Deputy Director, NIAMS, discussed a major data effort that NIAMS is leading, which has implications for several large NIH programs and relevance to data strategy work happening across NIH. To set the stage, she briefly discussed AMP programs, a suite of public-private partnerships that include NIH, FDA, biopharmaceutical companies, nonprofit organizations, and the Foundation for the NIH (FNIH). The focus of these partnerships is

innovation in the precompetitive space to find new therapeutic approaches for disease. NIAMS has had significant involvement in these projects over the years, and the projects have generated unprecedented multi-omic and clinical data from well-characterized cohorts, which makes them a particularly valuable resource as a starting point to interrogate shared mechanisms of disease. Pilots that began in 2022 have provided a glimpse into the value of these data for cross-disease comparisons when data from multiple AMP programs can be accessed by researchers. As shown by these pilots, which uncovered shared and distinct genes and pathways, comparisons and contrasts across patient cohorts and tissue types allow exploration of system-level changes in both healthy physiology and across disease states. Many of the biological aspects of this are of great relevance to the NIAMS community's areas of interest. Cross-disease comparisons are essential to identifying underlying shared mechanisms of disease that cut across traditional disease classifications. Another strength of this approach is in addressing data reproducibility issues.

The current AMP data resources were built on different platforms and there is an opportunity to further leverage these data assets through a unified data approach, an interoperable AMP data solution to make these data more available for cross comparisons for researchers. Initial cross-AMP analysis pilot projects encountered various challenges in order to conduct their analysis due to a lack of centralized data access, varying metadata descriptions, and data use approval processes. The participating ICs came together to address this common challenge and were successful in accessing strategic funds from the Office of the Director's Common Fund Venture Program, which helped them launch SysBio in FY 2025. The SysBio effort is the data strategy needed to fully integrate and make available AMP data, and they hope lessons learned from this effort can also be expanded to other datasets beyond AMP projects. The ultimate goal of SysBio is to enable an integrated view of human diseases with AMP datasets as a starting point. SysBio components will enable discovery via a single portal for researchers to quickly and easily find relevant AMP data and tools in one place. SysBio's FAIRplex (FAIR PLatform for EXploration of Systems Biology) approach will enable one-stop access to AMP datasets via ongoing authorization and governance work within the project and a flexible approach to data model development will address use of different data standards and formats to enable harmonization across various data modalities.

Common Fund Venture Program covers project support from FY25 through FY27, and AMP SBI will provide sustainability for the platform to be carried forward. Planning for expansion of the work is underway as well as development of new cohorts and new data collection, which will broaden the scope to additional cell communities, tissues, disease states, and treatment response lenses. Several participating ICs have been planning for the future of this work as SysBio is being built out.

Dr. Mazzucco concluded by framing this work in the context of broader data efforts at the NIH, highlighting data and systems as a shared challenge and sharing some of the ongoing activities in this area, including the NIH Cloud Platform Interoperability (NCPI) effort and the Common Fund Data Ecosystem, which are both synergistic with the SysBio approach and have laid important groundwork that SysBio is building upon.

Discussion

Dr. Aimee Payne asked at what point they expect SysBio to evolve into being more PI-initiated, where investigators are adjusting the questions and able to develop them on their own. Dr. Mazzucco said they expect the project to evolve in different phases, and the focus currently is on developing the data enablement piece. Many of the tools in FAIRplex allow for a wide variety of users to leverage the AMP datasets and they foresee this growing into a very flexible platform built on an open science approach that investigators can use for their own questions.

Dr. Criswell asked if the team would speak more to the issue brought up earlier of integration/coordination of different efforts across the NIH. Dr. Haluk Resat said they are building a data model built on common data elements (CDEs) and there has been a big push across the NIH to use CDEs. This platform enables integration with other NIH projects and investigators can also bring their own data to the platform to use along with the existing datasets. Dr. Richard Conroy added that there is also a broad effort across the NIH to ensure a high level of interoperability across different data platforms NIH supports.

Dr. Jepsen asked about the flexibility of the platform to include other conditions and link them up to existing databases, citing the emerging understanding about inflammation's contribution to other conditions. Dr. Mazzucco said this is exactly the goal of SysBio. Inflammation is the perfect testbed to demonstrate the value of this type of cross-disease analysis. There will not be a single solution for doing this and they are trying to make the most appropriate tools available for different researchers.

Dr. Barbour asked for clarification on how researchers would bring their own data to the platform to analyze with existing datasets. Dr. Resat said the repositories need to be interoperable, but for R01-type projects in which an investigator generates their own data, they will be able to analyze those datasets with existing AMP data and other resources available in the platform. Dr. Conroy added that they are creating a workspace where researchers can upload their own data, pull data in from other repositories, and utilize other people's code. This is the vision for SBI's effort and other commercial efforts have similar offerings.

Dr. Kiel asked whether SysBio will allow querying of individual-level data versus summary data from large studies. Dr. Muzzocco said it will allow this, but findability remains a challenge, which is why part of their effort focuses on the data governance side. SysBio is also serving as a use case at NIH to simplify data use agreements.

VI. CONCEPT PRESENTATION

Mr. Edgerton 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. Mary Garcia-Cazarin, Interim Director, Division of Extramural Research, introduced Dr. Pete Koch, Program Director, Epidermis, Dermis, and Skin Senses Program, to present the concept entitled the CCRP Initiative: Promoting a Basic Understanding of Chemical Threats to Skin. The concept was developed by NIAMS in conjunction with NIAID and there is a plan to develop an R01 mechanism under it. The Chemical Countermeasure Research Program (CCRP) is an NIH-wide program initiated in 2006 with a goal to develop medical countermeasures to treat large groups of people that have been exposed to toxic chemicals. NIAMS would focus on chemicals that affect the skin, primarily vesicants used in chemical warfare. The Department of Homeland Security creates a list of about 100 chemicals of concern, any of which can be part of the CCRP. There are currently nine Institutes participating in the CCRP and a multi-organ approach is needed to understand the effects of these chemicals. Funds for skin research under the CCRP do not come from the dedicated NIAMS budget but rather additional funds allocated for this work. The end goal of the CCRP research is to transition their findings over to the Biomedical Advanced Research and Development Authority (BARDA) to develop a drug or compound that can be FDA approved. NIAMS currently supports translational research in the development of medical countermeasures but lacks a basic research mechanism to investigate chemicals of concern and identify new medical countermeasure targets. This concept is designed to develop a basic science mechanism specifically designed to address CCRP skin priorities to accelerate the understanding of chemically induced skin injury and identify new therapeutical targets.

Discussion

Dr. Kiel asked how this research falls within NIH's scope as opposed to DoD's. It would seem to be seeking to put a significant amount of the NIAMS scientific effort into addressing a hypothetical situation that could instead be directed to commonly encountered accidents or skin reactions. Dr. Koch said DoD has a research arm dealing with this in war scenarios, which are quite different than civilian settings. There have been several terrorist incidents in the past few years using chemical agents and so they are looking for compounds that can be used to treat large numbers of people who are exposed. Currently, the few treatments that exist are all highly toxic in themselves. There is a perceived need by Congress to find new approaches, which is why they have allocated the funds. There will also be cross-fertilization with other research that will have broader applications. Dr. Criswell noted that not only do these funds not come out of NIAMS' budget, they also do not compete with the NIAMS budget.

Dr. Jepsen asked what specific model systems would be supported under this concept. Dr. Koch said animal models have been the gold standards but there are new approaches to doing this work, including skin explants.

Dr. Botchwey asked if the CCRP will explicitly encourage inclusion of diverse human skin types in the model systems and validation pipeline. Dr. Koch said it will, and they are still developing the standards.

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. Ms. Sharon Smith-Terry asked about research around chronic conditions understudied among women, specifically if the demographics of those studies will be broken down and how researchers navigate potential diversity, equity and inclusion (DEI) issues related to this. Dr. Criswell said she did not have the information at-hand, but they can take the question back to find out more about the team's plans. The approach to DEI has been under a lot of discussion, but she emphasized that health disparities research to improve health outcomes is something NIAMS is deeply committed to. Dr. Botchwey said NIAMS' support for ESIs is important but asked if NIAMS is tracking mid-career attrition risk as they move away from strict paylines. Dr. Criswell said they are not getting reports specifically about mid-career investigators, although they do hear about at-risk investigators. It is a concern for the Institute, and she is asking colleagues about what data they want to have available to inform their decision making. If they can identify the issues that reflect the mid-career challenges, they can better address them. She invited the Council to share thoughts on how NIAMS could get a better handle on this. Dr. Botchwey said any type of guidance on how to communicate most effectively with NIAMS and Program Officers specifically could be helpful for investigators at this career stage. Dr. Isaah Vincent said they track who is going up for their first R01 renewals and take that into funding consideration as well. They may need to look beyond the ending of ESI status. Members also discussed with staff the logistics in the changes to paylines and the future of advisory councils at the NIH.

VIII. NIH EXTRAMURAL RESEARCH ACTIVITIES

Jon R. Lorsch, PhD, Deputy Director for Extramural Research, discussed his new role overseeing the setting and implementing of policies related to grants and funding, as well as coordinating across ICs on issues related to funding and grants. The key priorities for the Office of Extramural Research for the next couple years include (1) Reducing administrative burden and complexity; (2) Promoting innovation, experimentation, and evaluation in funding approaches; (3) Promoting research integrity; (4) Enhancing biosafety and laboratory safety; (5) Detecting and disrupting foreign interference; and (6) NIH/national strategy for shared research resources.

Dr. Lorsch spent the majority of his presentation on the first of these priorities. The number of NOFOs released in FY26 will be reduced by 50% compared to last year (~900 in FY25) and they will be shortened and simplified. Part of the effort around simplifying them is to increase the use of Parent NOFOs. NIH has launched the Highlighted Topics webpage where ICs can advertise scientific areas they would like to get applications on, which should significantly reduce the number of NOFOs. They will be collapsing the different flavors of NOFOs into a single type, which can still include IC-specific instructions. NIH no longer requires letters from applicants requesting more than $500,000 in direct costs in a year, and they have stopped requesting letters of intent from applicants to certain IC NOFOs. NIH will be ending the modular budget pilot begun in 1994 but they intend to use some of the principles of the pilot, such as not requiring detailed budgets at the time of application. NIH is also looking to simplify the data management and sharing plan implementation by converting it into a few yes/no questions with further

explanations only required for no responses. The focus will be on general assent to sharing useful scientific data rather than providing specific details on what data types they will produce. NIH intends to set up a data sharing complaints mailbox so they can take action if NIH-funded investigators do not share data as they agreed to. NIH plans to begin moving basic experimental studies involving humans (BESH) out of the clinical trials definition. Other plans for reducing burden include: reducing the number of Career Development activity codes from 26 to around five, exploring increasing the use of just-in-time information, issuing a Request for Information (RFI) for input on additional requirements that could be simplified or eliminated, and working with the White House Office of Science and Technology Policy (OSTP) and the National Science Foundation (NSF) on additional approaches to administrative burden reduction.

Discussion

Dr. Payne said there is a lot of focus on reducing the burden on the NIH side and asked what kinds of things could be done to reduce burden on the receiving institutions, which drives up indirect costs. Dr. Lorsch acknowledged the tension between reducing administrative burden and maintaining oversight and safety. Most requirements were put in place for a reason and whether they are effective is what NIH needs to delve into. Hopefully, everything NIH is doing will also improve burden on the institutional side. The NASEM report noted that a lot of the burden on institutions is lack of harmonization across the government in different areas of requirements. These are the kinds of things NIH is talking to OSTP about, and greater consistency could lead to big improvements in this area.

Dr. Jepsen sought clarification on whether applications can be submitted with greater than $500,000/year in direct costs. Dr. Lorsch noted that ICs have different policies about when this is justified and it will still be within their purview to decide. In response to Dr. Jepsen's questions about the modular budget, he said they are ending the pilot and to the extent possible not requiring detailed budgets in applications for standard issue research grants.

Dr. Kiel asked if the Highlighted Topics will include which ICs are interested in which areas. Dr. Lorsch said different ICs can sign on to Highlighted Topics just as they can NOFOs. Dr. Kiel also commented on the need for rollout testing and debugging of new applications that are designed to streamline administrative hurdles. Multiple members mentioned the glitches and difficulties they have encountered with SciENcv.

Dr. Elizabeth McNally encouraged NIH to allow for the inclusion of a simplified table in budget justifications, which can be very valuable to reviewers. She also said that the burden of making sure investigators share their data often ends up falling on the journals and asked if there is something journals should be doing if NIH-funded investigators are not sharing data. Dr. Lorsch said they could ask the person complaining to also notify NIH if the grant was funded by NIH.

Dr. Botchwey asked to what extent fairness considerations factor into redesigning policies to improve efficiency and if there are mechanisms in place to track unintended disparate effects of policy changes. Dr. Lorsch said they are trying to think prospectively about where those things might happen. He encouraged members to reach out to the Office of Extramural Research with any considerations that should be factored into their thinking.

Dr. Baker Frost asked if NIH plans to offer assistance in navigating the new reduced categories for K awards. Dr. Lorsch said there will be a communication plan as part of the rollout, which will be further out in the future.

Dr. Criswell asked what mechanisms are available to define mid-career investigators and track how well they are faring. Dr. Lorsch said there have been various analyses looking at these questions and that usually after the renewal of their first R01 they are considered an established investigator.

Dr. Kiel asked about the aging of the investigator population and a proposed plan to provide senior investigators with a transitional grant to cultivate the next generation. Dr Lorsch said he has heard this idea several times in different forms, but it has never gotten much traction.

Dr. Criswell asked what mechanisms are available for the Office of Extramural Research to hear from ICs about particular challenges that NIH might be able to influence. Dr. Lorsch said they will be releasing an RFI seeking input on what the community would like to see NIH work on. They routinely talk to the major professional organizations who make recommendations to NIH.

IX. CLOSED SESSION

This portion of the meeting occurred during closed session.

X. REVIEW OF APPLICATIONS

The 119th National Arthritis and Musculoskeletal and Skin Diseases Advisory Council met in person on January 27, 2026. Eleven Council members and three Ad-Hoc Council members attended virtually. En bloc concurrence was unanimously approved for 883 primary and 180 secondary applications. The total cost requested in a year - 01 for all applications was $351,116,322.

XI. ADJOURNMENT

The 119th National Arthritis and Musculoskeletal and Skin Diseases Advisory Council adjourned at 3:54 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.

Timothy E. Edgerton -S Digitally signed by Timothy E. Edgerton -S Date: 2026.03.02 10:12:59 -05'00'

Erik Edgerton, M.B.A.
Executive Secretary, National Arthritis and Musculoskeletal and Skin Diseases Advisory Council
Acting Director, Division of Extramural Activities
National Institute of Arthritis and Musculoskeletal and Skin Diseases

Anna E. Mazzucco -S Digitally signed by Anna E. Mazzucco -S Date: 2026.03.17 15:45:06 -04'00'

Anna Mazzucco, Ph.D.
Chairman, National Arthritis and Musculoskeletal and Skin Diseases Advisory Council
Acting Director, National Institute of Arthritis and Musculoskeletal and Skin Diseases