DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH
NATIONAL CENTER FOR COMPLEMENTARY AND INTEGRATIVE HEALTH
NATIONAL ADVISORY COUNCIL FOR
COMPLEMENTARY AND INTEGRATIVE HEALTH
Minutes of the Eighty-Eighth Meeting
September 13, 2024

NACCIH Members Present

Dr. Per Gunnar Brolinson, Blacksburg, VA
Dr. Robert Coghill, Cincinnati, OH
Dr. Daniel Dickerson, Los Angeles, CA
Dr. Jeffery Dusek, Irvine, CA*
Dr. Helen Lavretsky, Los Angeles, CA
Dr. Bruce Lee, New York, NY*
Dr. Cathryn Nagler, Chicago, IL*
Dr. Erica Sibinga, Baltimore, MD
Dr. Amala Soumyanath, Portland, OR
Dr. Susan Sumner, Kannapolis, NC*
Dr. Suzanna Zick, Ann Arbor, MI*

NACCIH Members Present Virtually

Dr. Helene Benveniste, New Haven, CT
Dr. Nadja Cech, Greensboro, NC
Dr. Margaret Haney, New York, NY
Dr. Girardin Jean-Louis, Miami, FL
Dr. Benjamin Kligler, Washington, DC**
Dr. James Linderman. Bethesda, MD**
Dr. Roger Linington, Burnaby, BC, Canada*

NACCIH Members Not Present

Prof. Rhonda Magee, San Francisco, CA

**Ex Officio Member
*Ad-hoc Member

I. Closed Session

The first portion of the eighty-eighth meeting of the National Advisory Council for Complementary and Integrative Health (NACCIH) was closed to the public, in accordance with the provisions set forth in Sections 552b(c)(4) and 552b(c)(6), Title 5, U.S.C., and Section 1009(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. §§ 1001-1014). A total of

134 applications were assigned to the National Center for Complementary and Integrative Health (NCCIH). Applications that were noncompetitive, not discussed, or were not recommended for further consideration by the scientific review groups were not considered by Council. Council agreed with staff recommendations on 77 scored applications, which requested $42,107,151 in total costs.

II. Call to Order

Dr. Martina Schmidt, director of the National Center for Complementary and Integrative Health (NCCIH) Division of Extramural Activities (DEA) and Executive Secretary of the NACCIH, convened the open session at 10:40 a.m. ET. This meeting was held in person and broadcast live for all attendees, including Council members, NCCIH staff, and the public, and was recorded. Dr. Schmidt introduced Dr. Helene M. Langevin, director of NCCIH, who welcomed everyone attending in person and via broadcast. The May 17, 2024, meeting minutes were approved.

III. NCCIH Director's Welcome and NCCIH Report

Dr. Langevin began her report with National Institutes of Health (NIH) and NCCIH news. She announced that Dr. Carolyn M. Hutter is the new director of the NIH Office of Strategic Coordination, which oversees the NIH Common Fund, a program within the Office of the NIH Director that addresses high-priority challenges and works across NIH. NCCIH collaborates with the Common Fund on several initiatives, including the Bridge to Artificial Intelligence (Bridge2AI) program.

NCCIH is now in its 25th year, which will be celebrated with a December 2 scientific symposium "Exploring the Impact of Whole Person Health" on the NIH campus. The keynote address, which will also be the 2024 Stephen E. Straus Distinguished Lecture, will be presented by Dr. Patricia M. Herman, co-director of the RAND REACH (Research Across Complementary and Integrative Health Institutions) Center. She will speak on the economic impact of whole person health.

The NCCIH Coalition for Whole Person Health will hold its first meeting on November 1, 2024. The Coalition is an independent group of nonprofit organizations, currently with 43 members, that raises awareness about NCCIH and about how research can inform integrative, whole person care. Dr. Langevin asked Council members who know of additional organizations that may be interested in participating to inform Mary Beth Kester, director of the NCCIH Office of Policy, Planning, and Evaluation.

NIH has launched the Communities Advancing Research Equity for Health™ (CARE for Health™) program, which is a pilot to test the feasibility of a national primary care research network, with an emphasis on underserved areas, starting with rural areas. This program, spearheaded by NIH Director Dr. Monica Bertagnolli, ties in with NCCIH's leadership role in the Pragmatic Trials Collaboratory, which has a focus on strengthening the national capacity to implement cost-effective large-scale research studies that engage health care delivery organizations as research partners. Dr. Langevin is one of the co-chairs of the CARE for Health

oversight committee, and Dr. Wendy Weber, branch chief of the Clinical Research Branch in the NCCIH Division of Extramural Research (DER), is on the scientific committee.

Important grant application and review changes, including a simplified review framework for most research project grant applications, will go into effect for funding opportunities with due dates on or after January 25, 2025.

Dr. Langevin explained that NCCIH's budget has been flat this year, which is challenging as salaries and other costs increase. Even with a flat budget, NCCIH strives to maximize its resources by expanding its reach through collaborations and through participation in larger initiatives that enable the Center to take advantage of the resources of NIH as a whole.

Staff Updates

Dr. Langevin announced the upcoming retirement of Dr. Robin Boineau, director and medical officer in the NCCIH Office of Clinical and Regulatory Affairs. Dr. Boineau has provided guidance on clinical research at NCCIH for many years. She played a key role in the Trial to Assess Chelation Therapy 2 (TACT2) and in the launch of the Pragmatic Trials Collaboratory. She will be greatly missed.

Dr. Richard Nahin is now the chief of the newly established Epidemiology Program in the Division of Intramural Research (DIR). Dr. Nahin, who has been with NCCIH since 1996 (when it was the Office of Alternative Medicine), was most recently NCCIH's lead epidemiologist. In his new role, he will extend the work of the DIR by leading high-quality cross-sectional and longitudinal studies aimed at providing a national public health perspective on NCCIH's research priorities, including pain management and whole person health.

Dr. Langevin welcomed Reihaneh Bahramali, who joined the DEA as a council specialist in August. Council members will work closely with her.

NCCIH Research Spotlights

Dr. Langevin highlighted several NCCIH-funded publications of particular interest:

- Telehealth Mindfulness-Based Interventions for Chronic Pain: The LAMP Randomized Clinical Trial. This study evaluated a virtually delivered mindfulness intervention for chronic pain and found improvements in many measures, including pain intensity, physical function, fatigue, sleep disturbance, social roles, anxiety, and depression. The magnitude of the improvement was very small for each measure, but small changes in multiple measures might add up to a meaningful effect on the whole person. NCCIH is interested in developing instruments that would enable researchers to address the impact of multiple changes in outcomes as part of whole person research.
- Restoration of Cervical Lymphatic Vessel Function in Aging Rescues Cerebrospinal Fluid Drainage. The groundbreaking discovery of cerebrospinal fluid drainage from the brain through the lymphatic system raised the question of whether the drainage can be influenced by interventions that involve the neck. This study in an animal model indicates that the answer is yes. Manipulating the flow in the cervical lymphatic vessels with

prostaglandins reversed the effects of aging on cerebrospinal fluid drainage and increased brain clearance. Dr. Langevin noted that it's possible that other types of interventions, such as manual therapies, might also have impacts on the brain if applied to the neck.

- Residual Strain and Joint Pressurization Maintain Collagen Tension for On-Joint Lumbar Facet Capsular Ligaments. This study from one of the NCCIH-supported force-based manipulation research networks modeled stresses and strains in ligaments in the spine. Ligaments receive less attention than other tissues do, Dr. Langevin said, but they are very important for keeping the spine in a healthy configuration.
- Interaction Metabolomics To Discover Synergists in Natural Product Mixtures. This paper, which won the 2024 Scharting Award from the *Journal of Natural Products,* contrasted two metabolomics workflows, one that included interactions of multiple compounds and one that did not. This type of work is very important for understanding the interactions of components of complex natural products.

NIH/NCCIH Program News

As has been done at other recent Council meetings, Dr. Langevin presented program news for each of the five categories of research that will be emphasized in the next NCCIH strategic plan and for two cross-cutting themes. Many of the programs and events discussed cross over several of these categories.

Dr. Langevin provided updates on activities in each of NCCIH's main areas of interest, as follows:

Category 1: Whole Person Health

- The current funding opportunity Whole Person Research and Coordination Center (Whole Person RCC) U24 (Clinical Trial Not Allowed): RFA-AT-24-010 is a flagship initiative for NCCIH. It involves collaboration with 18 Institutes, Centers, and Offices (ICOs) for the creation of a framework for the whole human physiome. The application deadline is November 2, and the funding opportunity is aimed at having teams of investigators. A recording of the technical assistance webinar for this notice of funding opportunity (NOFO) is available.
- NOT-AT-24-044, Notice of NCCIH Participation in "Notice of Special Interest (NOSI): Climate Change and Health," explains NCCIH's areas of interest within an initiative led by the National Institute of Environmental Health Sciences. The notice is about promoting ways to manage and mitigate health problems related to climate change and help people deal with the related stress and anxiety.

Category 2: Pain and Pain Management

- The NIH-Department of Defense (DOD)-Department of Veterans Affairs (VA) Pain Management Collaboratory (PMC), in collaboration with the Helping to End Addiction Long-term® Initiative, or NIH HEAL Initiative®, has a funding opportunity for Pragmatic and/or Implementation Science Demonstration Projects ((UG3/UH3) Clinical Trial Required): RFA-AT-24-011. This funding initiative is aimed at identifying the next wave

of projects for PMC funding. An important new development here is that the NIH HEAL Initiative is now funding part of the PMC Coordinating Center.

- The new HEAL Initiative: Pain Research Enhancement Program (PREP) (R15 Clinical Trial Optional): RFA-AT-25-001 funding opportunity will support basic and mechanistic pain research at R15-eligible institutions, which could include complementary health institutions, such as colleges of chiropractic, naturopathy, or osteopathic medicine, that have not been major recipients of NIH support.
- NCCIH is participating in NIH HEAL Initiative: Coordinated Approaches to Pain Care in Health Care Systems (UG3/UH3 – Clinical Trial Optional): RFA-NS-24-041, led by the National Institute of Neurological Disorders and Stroke (NINDS). This NOFO, part of the NIH HEAL Initiative's Pragmatic and Implementation Studies for the Management of Pain to Reduce Opioid Prescribing (PRISM) program, focuses on implementing practices and therapies of proven efficacy in health care systems.
- NIH has launched the Native Collective Research Effort to Enhance Wellness (N CREW) program, a large effort to support research on substance use and pain in line with the priorities of Native communities and led by Tribes and Native American Organizations. NCCIH is participating in this program and has a particular interest in how traditional knowledge and traditional medicine practices may contribute to managing these complex health issues.

Category 3: Mind & Body Connection

- The NCCIH-funded force-based manipulation research networks held their annual investigator meeting in June, with portions of the meeting livestreamed to the public. Three hundred people attended live, and 400 have viewed the video since then. The meeting highlighted the importance of bringing different types of expertise together.
- NCCIH and the National Institute on Aging (NIA) have a current funding opportunity on music and health, Feasibility Trials of the NIH Music-based Interventions Toolkit for Brain Disorders of Aging (R24 Clinical Trial Required) PAR-24-168. Investigators can use this opportunity to develop early phase clinical trial data in preparation for larger scale clinical research while also testing the validity of the toolkit. Also related to music and health, NCCIH has issued a request for information (RFI), Inviting Comments on Early Career Stage Training Programs to Support Capacity Building for Music and Health Research: NOT-AT-24-052.
- At the upcoming Society for Neuroscience conference, NCCIH program directors will meet with attendees at the exhibit booth, and sessions will feature Dr. Emmeline Edwards, director of the DER, and Dr. Erin Quinlan, one of the DER's program directors.

Category 4: Positive Health Processes

- After much work by the Trans-NIH Resilience Working Group led by Dr. LaVerne Brown of the NIH Office of Dietary Supplements, the in-person workshop "Advancing the Biomedical Science of Resilience: A Discussion of Measures and Metrics" will be held by NIH on September 24 and 25.

- Dr. Edwards will present a keynote on the NIH music-based interventions toolkit and participate in a roundtable on building blocks for music-based intervention research at the conference "The Future of Music & Arts in Medicine & Health," to be held in Berlin, Germany from September 18 to 21. Dr. Langevin said that it is exciting to have Dr. Edwards serving as NCCIH's ambassador on music and health throughout the world.

Category 5: Nutrition & Natural Products

- NCCIH has two current NOFOs on Enhancing Mechanistic Research on Precision Probiotic Therapies, PAR-24-238 (R61/R33) and PAR-24-239 (R33).
- As explained in Notice of Information: Additional Priorities for NCCIH Natural Product Clinical Trial Funding Opportunities: NOT-AT-24-042, NCCIH is expanding its priorities for natural product research to include studies that examine the effects of natural products across the continuum of background dietary intake, as well as studies that evaluate the impact of nutritional status on target engagement or clinical outcomes. Dietary supplements should not be evaluated in isolation from diet and from the whole person, and NCCIH wants to make researchers aware of this going forward.

Category 6: Workforce Development & Special Populations

- The Maximizing Opportunities for Scientific and Academic Independent Careers (MOSAIC) K99/R00 funding opportunities have been reissued (PAR-24-225, PAR-24-226, PAR-24-227). These funding opportunities are for postdoctoral researchers transitioning to independent careers and are intended to promote diversity. They include both basic and clinical research.
- The NCCIH "Fellows and Trainees Workshop: Navigating Your Scientific Career" will be held on September 23 and 24. This is a closed virtual meeting that will provide career development resources for NCCIH-funded fellows and trainees.
- NCCIH will have an exhibit booth at the Society for Advancement of Chicanos/Hispanics & Native Americans in Science (SACNAS) National Diversity in STEM Conference, to be held October 31 through November 2, and one of the program directors will be available to meet with attendees.

Category 7: Methods & Data Science

- Dr. Aaron Lee of the University of Washington, a Bridge2AI grantee, recently presented the NCCIH Integrative Medicine Research Lecture, "Harnessing AI To Explore Health Restoration in Diabetes." This cross-cutting lecture was well received, and a video is available.
- NCCIH is participating in Building Sustainable Software Tools for Open Science (R03 Clinical Trial Not Allowed): RFA-OD-24-010, led by the NIH Office of Data Science Strategy (ODSS). This NOFO is important because it encourages the use of cloud services to make data available.
- NCCIH is also participating in another ODSS-led NOFO, NIH Research Software Engineer (RSE) Award (R50 Clinical Trials Not Allowed): RFA-OD-24-011. This unique

funding opportunity provides salary support for RSEs who can make outstanding contributions to NIH research.

Dr. Langevin announced that the next Council meeting will be held on January 24, 2025, and will be virtual.

Discussion: A Council member noted that Dr. Langevin had mentioned many activities. Dr. Langevin said that she was working on paring down her reports, and she hopes that organizing the information by themes will help people understand what NCCIH is doing and why. Dr. Kligler said that the ways in which NCCIH leverages initiatives across NIH are impressive; NCCIH is contributing to a great deal of research. Dr. Langevin said that the amount of funds NCCIH gets from co-funding and collaborations adds up to about half of what NCCIH already has from its own budget. She explained that working with other ICOs and participating in complex programs with multiple layers of administration takes extensive effort, and she credited NCCIH staff for making it possible.

Dr. Dusek commented on the impressive increase in the impact of nonpharmacologic approaches. Dr. Langevin said that this reflects culture change, which does not happen instantly. There is a growing focus on nonpharmacologic approaches at other ICOs and within the NIH HEAL Initiative. NCCIH has introduced a vocabulary to talk about these kinds of treatments. The rigor of NIH-supported science on complementary nonpharmacologic approaches such as acupuncture or yoga is the same as that for conventional nonpharmacologic approaches such as physical therapy or health coaching. People are starting to understand that the continuum of care can include all these modalities. There is no "line in the sand" between conventional and complementary approaches anymore, either in research or in health care, Dr. Langevin said.

Dr. Lee asked how NCCIH communicates its messages. Dr. Langevin said that the videocasts of Council meetings are one way and that, more broadly, the NCCIH communications team is very active in its efforts to make sure information is disseminated in a way that informs researchers, caregivers, and the public about the science on complementary therapies. In addition, NCCIH's communications efforts go beyond that to communicate messages around whole person research, including the need to develop rigorous methodology in this area. She said she welcomes Council's suggestions on how best to do this. NCCIH already uses both traditional and new media for communications but is open to new ideas.

Dr. Lavretsky said that NCCIH can play an important role in cross-NIH interest groups on topics like resilience and spirituality. Dr. Langevin said that for some people, the concept of resilience serves as a gateway to whole person health because it involves taking a multisystem perspective. The grant applications that NCCIH receives are increasingly proposing multicomponent interventions and multisystem outcomes.

Dr. Kligler said he hopes NCCIH will go beyond the Whole Person Research and Coordination Center's emphasis on the physiome, which does not capture some dimensions of health such as spirituality. Dr. Langevin said NCCIH is already planning to do this, but the physiome is a good starting point because it is a middle layer. From the physiome, one can drill down to the cellular and molecular levels and move up to the behavioral, social, and environmental levels.

Dr. Dusek thanked Dr. Langevin for including music. There is much interest in music and how it interacts with relaxation, he said. Dr. Langevin said that interest in music is universal and thanked Dr. Edwards for her extensive involvement in this area. The previous NIH director, Dr. Francis Collins, was also a champion of music research. Dr. Langevin noted that NCCIH has developed a strong partnership with NIA in this area.

Dr. Dickerson said he was excited about the resiliency research involving Native Americans. He explained that it is important to emphasize inherent strengths and avenues toward solutions, rather than simply identifying problems. More research on mechanisms is needed. Dr. Langevin said that focusing on the positive—without ignoring harms—is where NCCIH can make an important contribution. She said that we need to learn how to better support people in the journey toward health, and she is thrilled to have the opportunity to learn from Native American communities.

Dr. Zick asked Dr. Langevin for her views on implementation and policy research; much knowledge is not being put into practice. She also asked how the richness of mixed methods can be brought into different types of projects. Dr. Langevin said that NCCIH does not do research on policy but can consider what types of information policymakers and insurance payers need. Implementation science is an important type of research that can inform policy decisions. NCCIH has partnered with the Centers for Medicare and Medicaid Services in studies that are tied to coverage determinations. With regard to mixed methods, much can be done now with natural language models to extract information that could not be obtained before. As this methodology develops further, the mixed methods field is likely to explode. Dr. Sibinga added that policymakers relate to narrative, which qualitative work can provide. Dr. Langevin said that it is important both to tell good stories and to obtain analyzable data from those stories, especially when introducing new concepts.

IV. Building the NCCIH Division of Intramural Research

Dr. David Shurtleff, deputy director of NCCIH and acting scientific director of the DIR, explained that when the DIR was founded 12 years ago, a decision was made to focus entirely on pain. There is no pain institute at NIH, and with the public's extensive use of complementary health approaches for pain, it is an important topic to study.

The DIR conducts basic, clinical, and translational research focusing on the role of the nervous system, other physiological systems, and psychosocial factors in perceiving, modifying, and managing pain. Like all NIH intramural programs, the NCCIH DIR also provides a rich environment for the training and development of clinical and basic scientists. One reason for NCCIH's interest in pain is that it is a major public health challenge. More people live with chronic pain than with cancer, heart disease, and diabetes combined.

The NCCIH DIR strives to be a multidisciplinary, collaborative research program that focuses on acute and chronic pain and associated processes and conditions including those that apply to whole person health and health restoration. The program works to provide cutting-edge pain research; an environment that supports the next generation of pain scientists; a commitment to expand the presence of pain research at NIH; a strong commitment to equity, diversity, and

inclusion; and service to patients affected by pain and admitted to the NIH Clinical Center through the Pain Research Center (PRC). The DIR has lab and clinical space on the NIH campus and new office space in a recently converted house on campus.

The DIR was recently reorganized to build out the program, adding the Epidemiology Program and the Office of the Clinical Director under Dr. Miroslav Bačkonja.

- Dr. Bačkonja's group does research on patients with complex pain disorders and provides oversight and safety and regulatory monitoring for the clinical program.
- Dr. Lauren Atlas's lab studies pain with a multidisciplinary approach, looking at affect, cognitive and emotional experience, and clinical outcomes.
- Dr. Yarimar Carrasquillo's lab studies cellular plasticity in the nervous system, the role of the central amygdala as a pain rheostat, and sex differences in perception of pain.
- Dr. Alex Chesler's lab studies the basic mechanisms of sensory inputs including mechanosensation and how they affect behaviors.
- The Pain Research Center serves as a research hub for the entire NIH Intramural Research Program (IRP), giving clinical researchers the opportunity to study pain among patient populations who come to NIH, many of whom have conditions comorbid for pain.
- As mentioned earlier, the Epidemiology Program was recently brought over from the Office of the Director; it is responsible for surveys and longitudinal studies and, now that it is located within the DIR, it can collaborate with other epidemiology programs across NIH.

The DIR has a flat structure, with all sections reporting to the scientific director except for policy and safety functions for which the clinical director reports to the director of the Center.

Recent accomplishments include Dr. Atlas and Dr. Carrasquillo receiving tenure; the reorganization of the DIR; Dr. Bačkonja being appointed clinical director and Dr. Nahin being appointed chief of the Epidemiology Program; Dr. Chesler receiving an outstanding rating at his third Board of Scientific Counselors review; new staff hires and promotions; and recruitment of a new facility head who is expected to join the PRC soon. Plain language summaries of selected DIR studies can be found on the NCCIH website.

The NIH HEAL Initiative has launched an intramural pain research program called I-HEAL. The overall NIH HEAL Initiative was launched in 2018, with special support from Congress, after the third of three waves of increases in opioid overdose deaths prompted the Department of Health and Human Services to declare the opioid crisis a public health emergency. The initiative has funded more than 1,000 extramural projects to address the opioid epidemic. It has been a game changer for the extramural community in terms of improving understanding of pain treatment, management of opioid use disorder, and prevention and treatment of opioid misuse and addiction. With I-HEAL, the intramural program will also become involved in the initiative. I-HEAL will focus on the unique strengths of the IRP; leverage existing IRP infrastructure; use funding processes that are competitive, with rigorous peer review; include only proposals that address the goals of the NIH HEAL Initiative; be scalable and flexible based on available funds

and interest; and represent minimal cost to the overall NIH HEAL Initiative (less than 1 percent of the budget).

The NCCIH DIR is hiring. A search for a new scientific director will begin soon, and new research fellows are being recruited for the Epidemiology Program and Dr. Bačkonja's group. The other intramural labs are also seeking postbaccalaureate and postdoctoral fellows. The DIR website was recently refreshed, making it easier to find information on each of the labs.

NIH has always been a top location for research training, with opportunities in the biomedical, behavioral, and social sciences at all levels—basic, translational, and clinical. It has outstanding resources for science and training, as well as a unique clinical center with labs next to clinics. Opportunities are available at all stages of training from summer internships for college undergraduates through postdoctoral fellowships. NIH also recruits at the faculty level for more than 30 tenured and tenure-track positions a year, as well as for unique non-tenure-track staff scientist positions. The NIH virtual tour, which includes a stop at Dr. Atlas's lab, can give you an idea of the research NIH is pursuing.

Discussion: Dr. Coghill said that it is great that NCCIH is taking a lead in pain research on the NIH campus. He referred to a previous pain research program led by the National Institute of Dental and Craniofacial Research (NIDCR) as a model and said he looks forward to seeing the NCCIH program fill the gap left by its breakup. He asked how easy it is to move a compound to commercialization after in-house research. If the compound seems to be helpful, can it move to a full clinical trial outside NIH? Dr. Shurtleff said that NIH does have public/private partnerships, although they are not well known. Currently, a metabolite of ketamine that was developed for depression and taken through phase I by the National Institute of Mental Health (NIMH) is also being investigated as a possible analgesic. NCCIH wants to follow the lead of the NIDCR program but in ways that open up pain research to the entire IRP so investigators studying conditions comorbid with pain can become involved. One goal is to do a natural history study, and it may be possible to combine extensive phenotyping with genotyping.

Dr. Soumyanath asked whether intramural/extramural collaborations are possible. Dr. Shurtleff said that cooperative agreements can bring in extramural researchers, and this may happen more extensively now that the infrastructure of the NCCIH DIR has been built up. Many intramural researchers have longstanding collaborations with extramural scientists that were initiated through personal contacts. Dr. Shurtleff said he could facilitate such connections.

Dr. Sumner brought up the importance of nutrition in pain and pain management and suggested looking at nutrient cocktails that would augment benefits of drug treatment and offset side effects. Dr. Shurtleff said that one of the benefits of being on the NIH campus is being able to work with other ICOs. This topic might be of interest to the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), and NCCIH could work with them through the PRC.

Dr. Langevin said that Dr. Shurtleff has done an amazing job over the past 4½ years as acting scientific director in addition to his role as deputy director of NCCIH. Dr. Shurtleff said that the scientists and staff in the DIR are the ones making the program succeed. Everyone is pulling their weight and doing a fabulous job, he said.

V. Nutrition Continuum Symposium

Dr. Langevin welcomed Dr. Stefan Pasiakos, director of the Office of Dietary Supplements (ODS) and Dr. Andrew Bremer, director of the Office of Nutrition Research (ONR), who will speak at this mini-symposium, and Dr. Stephanie George, deputy director of ODS, who will be a discussant. Dr. Langevin said that NCCIH's partnership with ODS and ONR is very important. NCCIH and ODS have long worked together and currently are integrating the research they collaborate on into a wider view of how dietary supplements fit into the context of overall nutrition.

Dr. Langevin provided an introduction, focusing on the idea of a nutrition continuum and how it fits into the overall concept of whole person health. She showed a slide illustrating the need for both analysis and synthesis/integration—breaking things down and putting them back together. In the biomedical sciences, there is a strong pull toward analysis, but synthesis is also essential. Consideration of different scales—ranging from molecular to planetary—is also important; each level influences the others. The individual person is at the middle of the range of scales. From the person, the levels go down to cells and molecules and up to the social, family, community, and planetary levels. The importance of a range of scales is a fundamental principle of ecology, but it is not often applied to medicine. Nutrition can be thought of in terms of multiscale networks, including growing, distributing, preparing, and consuming food, understanding its components, and understanding the roles of individual molecules.

Some current trends, including overuse of fertilizers and pesticides, mass-produced farming, food deserts, fast food, food addiction/craving, nutrient-poor diets, and the use of dietary supplements instead of food, are undesirable. Because these issues are interrelated, the full nutrition continuum includes research at a variety of levels. Until recently, NCCIH was primarily concerned only with the study of natural products and their bioactive constituents. This area is still of interest, and so is NCCIH's more recent emphasis on the microbiome, but these topics could be better integrated into study of other aspects of nutrition. Collaborations with other parts of NIH, such as ONR, ODS, and NIDDK, can make this possible. Research on a variety of topics related to nutrition, including precision nutrition, food as medicine, and medically tailored meals, needs to be integrated in the context of the overall nutrition continuum. NCCIH is also excited about looking at the social and environmental aspects of nutrition, in collaboration with the National Institute of Nutrition Research (NINR), and about developing a better understanding of the foods people eat and the environment in which the foods are grown. For example, flavonoids play roles in resilience both in plants and in the humans who consume them, and microbes, including those from the soil and the gut, influence the metabolism of flavonoids across the nutrition continuum. Nutrition is not an isolated topic; it relates to multiple aspects of health such as physical activity, sleep, and stress, and it plays important roles in maintaining and restoring the health of both people and the environment.

The Office of Dietary Supplements: Representing the Nutrition Continuum

Dr. Pasiakos explained that he looks at all of science from an integrative perspective and therefore was enthusiastic about joining with NCCIH, ONR, and NINR in work on the nutrition

continuum. This work builds on ODS's longstanding partnership with NCCIH and will advance whole person health.

The nutrition continuum is a multiscale network that links food and health throughout life. It includes food production and processing, marketing and distribution, acquisition and preparation, and consumption, as well as the concept of whole foods and the roles of nutrients, bioactive food constituents, and dietary supplements.

ODS was established in 1995 in response to the Dietary Supplement Health and Education Act of 1994. ODS explores the role of dietary supplements in health care; promotes dietary supplement research, conducts and coordinates it within NIH, and collects and compiles research results; and advises various components of the Federal Government on issues related to dietary supplements. Notable activities include the NIH Consortium for Advancing Research on Botanicals and Other Natural Products (CARBON) program (an ODS/NCCIH partnership for more than 25 years), ODS's annual Mary Frances Picciano Dietary Supplement Research Practicum, and the upcoming workshop on resilience led by Dr. Brown that was mentioned earlier in the meeting. Dr. Pasiakos highlighted a special journal issue on harmonizing the science of resilience produced by the Trans-NIH Resilience Working Group.

The ODS 2025–2029 strategic plan, to be published soon, will set the stage for the Office's future work. It prioritizes innovation through collaboration and accountability and reflects a shift from discrete projects and programs to a more interoperative, collaborative approach. Priorities center on examining the effect of dietary supplements on resilience and health across the lifespan in diverse populations through work in the biological, population, and analytical sciences. The focus will be on broader public health issues rather than individual supplement ingredients, and on a proactive rather than reactive posture. Focusing on rigor, reproducibility, and transparency is essential in dietary supplement science. ODS expects to increase its participation in NIH-wide projects and working groups under the new plan.

ODS and NCCIH have long collaborated on work focused on analytical methods and research integrity through CARBON and other projects. To understand whether dietary supplements influence human health, it is necessary to know their constituents and metabolites and how they act in the body. Analytics are therefore crucial, but they are only one part of dietary supplement science. The next iteration of CARBON, approved in 2023, will move beyond focusing only on analytics and will include more translational and clinical research, leveraging existing databases for this purpose.

Of projects co-funded by ODS from 2013 to 2023, 20 percent were collaborations with NCCIH. Most recently, both NCCIH and ODS contributed to a workshop on complementary and integrative interventions to prevent and mitigate the effects of endocrine-disrupting chemicals—a workshop that took a whole person approach to this crucial topic.

ODS's priorities align with whole person health, and ODS sees the nutrition continuum as an opportunity and necessity for new research. Dietary supplements, which are used by about 60 percent of the U.S. population, are an integral component of the continuum. Now is an appropriate time for a new framework for nutrition science because much knowledge from

nutrition research is not being effectively applied in practice. For example, one quarter of U.S. adults have heard of the MyPlate plan, but only 8 percent have tried to put it into practice. The high prevalence of obesity also reflects lack of adherence to dietary guidelines. People do not respond to stimuli in a vacuum, but organizational, financial, and academic structures promote studying nutrition and health in isolation. Failure to account for all the factors that relate to nutrition and health limits the extension of scientific findings. The nutrition continuum provides an opportunity to come together and advance whole person health.

The Office of Nutrition Research: Nutrition and Whole Person Health

Dr. Bremer began by saying that now is an exciting time for nutrition, and ONR can work with NCCIH and others to move the science forward to make a difference. ONR and ODS are located within the Office of the Director of NIH, which gives them access to other components of NIH to break down silos. Nutrition is a cross-cutting discipline; it touches everything—every cell and system at every age and stage of life—and it relates to the missions of many NIH Institutes and Centers (ICs), as well as Federal partners beyond NIH, who take NIH's discoveries and apply them to improve public health. Diet-related diseases are the leading cause of morbidity and mortality worldwide.

ONR is developing an Office-specific strategic plan to guide its efforts to advance nutrition science across and beyond NIH and to provide service, technical assistance, and coordination to advance the domestic and global food, nutrition, and health research agenda. Nutrition connects the foods people eat to their overall health and is inextricably linked to all aspects of health and disease. Nutritional status is a fundamental biological variable, like age and sex; it is both an input and an outcome of health and disease. Nutrition is important for every person, every family, every society, and the planet. It interacts bidirectionally with food systems, human health, and planetary health.

Nutrition is crucial because the United States and the world are facing an urgent nutrition-related health crisis, with malnutrition, in all its forms, as the leading cause of morbidity and mortality. In the United States, suboptimal nutrition threatens public health, the economy, and national security. Many Americans cannot qualify for military service because of diet-related health problems. Suboptimal nutrition is estimated to lead to the death of about 15,000 Americans each week, and its adverse health impact costs the U.S. economy more than $1.1 trillion per year. As many Americans die each year from diet-related illnesses as died during the entire American Civil War and World War II combined.

ONR's "why" is to lead NIH and other partners in stimulating actionable, solution-focused, implementable research to address key elements of the domestic and global nutrition enterprise. The "how" includes enhancing precision in nutrition science, appreciating nutrition as part of a holistic ecosystem, and adopting the conceptual framework of a nutritional ecology, expanding the study of nutrition beyond a focus on single nutrients to that of foods, dietary patterns, and the expansive nutriome. Nutritional status can be defined as "the operational measure of the adequacy of the diet to support health." Nutrition is not limited to only an understanding of food

and exposure; its assessment must include a full appreciation of its ecology and the factors that influence the environment.

ONR's "what" is to engage efforts across NIH and the Federal Government to advance nutrition science from a translational perspective to inform solutions, to coordinate the development of a national nutrition science strategy to promote the equitable translation of nutrition science discovery to clinical practice, and to improve the precision of nutritional assessment, attribution, and interventions. ONR's science synergizes with NCCIH's science and the concepts of the nutrition continuum and whole person health. Nutrition is a field where the whole is more than the sum of its parts, and there is an opportunity for several components of NIH, including ONR, NCCIH, ODS, and NINR, to put it all together, connecting food systems with human and planetary health.

Discussion: Dr. Sumner asked how an integrated, holistic approach to nutrition may impact how foods are supplemented or fortified. Will the fortification needs be different in urban versus rural or polluted versus cleaner areas? Dr. Bremer said that having a better understanding of nutritional status and needs and how they are impacted by geography and location can inform intentional fortification for vulnerable populations. This type of precision nutrition approach can be bidirectional with food science, informing the engineering of beneficial products.

Dr. Soumyanath asked how one might look at the impact of nutrition on the efficacy of a botanical dietary supplement. Are appropriate tools available? Does the scale of clinical studies need to be expanded? How will the field change? Dr. Pasiakos said that measures of nutritional status and biomarkers need to be improved, and methods need to be available to measure the intended outcome of consuming a dietary supplement. However, if a pragmatic approach is taken to knowledge gaps, not every nutrition project needs to balloon. Dr. Bremer said that NIH has made a major investment in the Nutrition for Precision Health program powered by the *All of Us* Research Program. This program involves more than 8,000 individuals and is asking questions about how individuals respond to dietary challenges and patterns. Tools will become available publicly because of this work and can be used to develop new models. Dr. George said that the focus needs to be on the public health issues and what can address them. This will include methods development pieces. ONR and ODS can pull in partners in this work. Dr. Langevin provided a concrete example: if you are studying fish oil, it makes sense to also look at how much fish people are eating. Similarly, although the situation is more complex, if you are studying a botanical, how much of the components it contains can already be found in people's food? Although progress will be gradual, there is a need to move in an integrative direction.

Dr. Dusek asked whether there is a brief way for clinical researchers to measure nutritional status. Dr. Bremer said no agreed-upon method exists yet, but it is important to develop one, both for scientific consensus and for clinical care. Dr. Lee suggested that artificial intelligence can help. Clinical trials and observational studies have limitations; new paradigms are needed. (Later in the discussion period, Dr. Bremer referred back to Dr. Lee's comment, thanking him for his expert input regarding paradigm shifts and novel study designs.) Dr. Pasiakos said that the proposals regarding the nutrition continuum are ambitious, but it is important to start somewhere. Dr. Lavretsky noted that in clinical research studies, the results of dietary questionnaires and

blood nutrient levels may not correlate. She said that standards are needed for research methods and risk reporting.

Dr. Shurtleff asked whether the framework of primary, secondary, and tertiary prevention is helpful in the nutrition space. Can it help guide decisions about when and where to intervene? Dr. Bremer said that this framework could be helpful, and that developing a consensus about trackable, measurable baseline elements will be helpful for both research and conventional care. The paradigm of prevention is important to the food as medicine concept, for example, but the concept will only achieve maximal efficacy if appropriate methods are used. A diagnosis and understanding of the etiology of a condition are necessary before interventions can be made. Some applications of food as medicine, such as fortification, may be targeted to population groups as primary prevention of a disease, while others may be targeted to individuals who already have the disease. Dr. George mentioned the overlaps among prevention, public health, and health across the life course. It is also important to think about health disparities as they apply to prevention, she said. In addition to being efficacious, prevention interventions need to be accessible, equitable, and culturally competent.

In response to earlier mentions of standardization, Dr. Pasiakos mentioned the "noisiness" and heterogeneity in dietary supplement science. Much more can be done to improve tools, methodologies, and clinical trial design, but it is a big lift. ODS is taking steps in this direction.

Dr. Zick pointed out that the current agricultural system is not consistent with planetary, ecological, or nutritional priorities. For example, if even 15 percent of people in the United States followed official dietary recommendations for consuming greens and beans, they would wipe out the country's supply of these foods. Dr. Bremer agreed that current agricultural practices need to change and suggested that artificial intelligence and other scientific approaches can be used to inform the solutions. Dr. Coghill pointed out that foods, including those that appear to consist of one ingredient (e.g., raw chicken), may actually contain added ingredients that could have long-term undesirable health consequences. Dietary supplements might also have subtle long-term health effects. Dr. Langevin added that this concern applies to many types of products that people consume or apply to their bodies. Dr. Bremer said that NIH scientists discuss these issues frequently with colleagues from the U.S. Food and Drug Administration (FDA), and that the evidentiary bar for regulating food is a challenge. NIH and FDA will hold a workshop on regulatory science in December.

VI. Communities Advancing Research Equity (CARE) for Health: Advancing Clinical Research With and for Primary Care

Dr. Langevin introduced Dr. Amy P. Patterson, interim scientific and medical director of NIH's new CARE for Health program. Dr. Langevin is one of the three co-chairs of this initiative.

Dr. Patterson said that the "why" for the CARE for Health program is that the health of the U.S. population is declining, and the decline is steepest among medically underserved populations, many of whom are also historically underrepresented in research. This lack of representation compromises the generalizability of research findings, creates evidence gaps, and compounds

health disparities. There is a need to extend opportunities for research participation to underserved and underrepresented groups in the places where they live, work, and seek care.

CARE for Health is a new research network with the overarching goal of working toward a future state where clinical research is routinely embedded into primary care so it will be applicable to real-world situations across the population. CARE for Health will support primary care-based clinical research in mission areas spanning prevention and treatment, with a focus on health equity and whole person health. It will establish a foundation for sustained engagement with communities underrepresented in clinical research and will implement innovative study designs suitable for primary care settings, addressing issues of importance to frontline health care providers and their patients, with a focus on dissemination and implementation. Fortunately, Dr. Patterson said, this effort does not have to start from scratch. There is already substantial expertise from existing practice-based health research networks to draw upon, and CARE for Health will work in partnership with these and other programs.

Planning for CARE for Health began with listening sessions that provided perspectives from research networks, hospital systems, primary care providers and organizations, patient and community organizations, and Federal agencies. Major themes that emerged included the importance of building sustainable and effective partnerships (rather than an episodic model of engagement), demonstrating trustworthiness through balanced and bidirectional partnerships, and understanding the diverse needs of communities. The listening sessions also highlighted the need to consider the already heavy workloads of primary care providers, align practice needs with research structures, and use innovative study designs and technologies to reduce provider burden. Addressing financial sustainability and valuing patient and community contributions were also identified as important priorities.

CARE for Health will begin its work during the current fiscal year by partnering with existing clinical research networks and providing resources to expand collaborations as the program grows. The initial studies will focus on underrepresented rural populations. Awards for the initial network research hubs will be made by the end of September 2024 and will total $5.6 million. In 2025 and beyond, additional studies will be planned and launched, and the budget will increase as the program ramps up. NIH-based infrastructure will include facilities to support community engagement, a clinical science center that draws on the expertise of the Pragmatic Trials Collaboratory, an operations center, independent review and monitoring boards, and opportunities to explore partnerships with the private sector. Although the initial focus will be on rural communities, future focus populations will also include pediatric populations, Tribal nations, women, people without homes, and racial and ethnic minorities.

CARE for Health is currently at the beginning of a 2-year pilot phase, focused on funding the network research hubs in rural areas and initiating new research. Before the end of the second year, NIH will evaluate which approaches and efforts are working and are suitable for broader implementation.

Discussion: Dr. Langevin commented on the enormous amount of work required to get this program going. Dr. Dickerson said that this effort is needed because the research and clinical

worlds have not been merging. There is a huge need to integrate research knowledge and infrastructure into the clinical setting. He said that he hopes behavioral health will be included. Dr. Patterson said that one of the goals of the program is to provide infrastructure and be a resource for all ICs, including the smaller ones that may not have research networks of their own. She also said that CARE for Health anticipates including behavioral health in the program.

Dr. Dusek asked whether CARE for Health could include complementary interventions in primary care. Dr. Patterson says some complementary interventions could fit nicely into primary care. Collaborative care models, in which teams of specialty services are engaged through primary care, could also be used.

Dr. Zick asked whether the Southwest Oncology Group model will be used. Dr. Patterson said that CARE for Health did not choose specific models. As the program develops, many models may be used. The infrastructure is not top down. The studies themselves will be developed organically. Dr. Zick also asked about the choice of rural populations rather than more heterogenous groups. Dr. Patterson said that the program had to start somewhere, and rural populations were chosen because they are one of the groups most challenging to reach. The focus will broaden after the first year. Dr. Zick asked whether collaboration with nonprofit organizations would be possible. Dr. Patterson said that the program is open to this. Dr. Langevin closed the discussion and pointed out that the awards would be made very soon. CARE for Health is in its first stages as a pilot program but has great potential, she said.

VII. Concept Clearances

Advancing the Science of Complementary and Integrative Health Approaches To Improve Maternal Health Outcomes

Dr. Beda Jean-Francois, a program director in the DER, began by thanking her colleagues, Dr. Lanay Mudd and Dr. Whitney Ratliff, who are collaborating with her on this initiative. The United States has the highest maternal mortality rate among high-income countries. Responding to the maternal health crisis and addressing health issues of women across the lifespan are national priorities and are addressed across the Federal research portfolio and budget. NIH is investing in several initiatives related to women's health, including the Implementing a Maternal health and PRegnancy Outcome Vision for Everyone (IMPROVE) initiative—an NIH-wide effort to support research to address the high rates of pregnancy-related complications and deaths in the United States. IMPROVE was created to build the evidence base of maternal health-related solutions for all women to promote maternal health equity. Its goals are to reduce preventable causes of maternal morbidity and mortality; address disparities in maternal health outcomes; expand implementation of evidence-based maternal health care practices before, during, and after pregnancy; build research capacity in community-based organizations; promote access to maternal health care with innovative technology; and enable real-world research with electronic health record standards. IMPROVE initiative programs are located in many parts of the country.

The component of IMPROVE relevant to this concept is the Maternal Health Centers of Excellence (CoE), a national network to develop, implement, and evaluate community-tailored interventions to address health disparities in maternal health. There are currently 12 CoEs, supported by a data innovation and coordination hub and an implementation science hub. These CoEs are conducting more than 20 research projects, and they have a robust training and professional development program for maternal health investigators. The CoEs are funded for 7 years; they recently completed their planning year and will begin implementing their research projects for the next 4 years. The final years of the program will focus on translating the research results and sustaining their findings.

Although the CoEs are exploring a wide variety of topics and conditions, complementary and integrative health approaches are not currently represented in their proposed interventions. Thus, there is an opportunity to expand the CoEs' science to include them. The use of complementary and integrative health approaches to promote maternal health is understudied at NIH, and systematic reviews and meta-analyses have noted methodological challenges in this research and several research gaps. More rigorous research is needed to inform clinical practice guidelines on the use of nonpharmacologic interventions to enhance maternal health outcomes.

The goal of this proposed initiative is to develop a funding opportunity to support research to improve the evidence base of complementary and integrative health approaches, including nutritional, psychological, and/or physical approaches, to promote healthy pregnancies and improve maternal health outcomes. The outcomes of interest can include depression, anxiety, sleep, stress, substance use, pain, and obesity. This initiative aligns with NCCIH's strategic priorities on whole person health and addressing health disparities.

The initiative proposes that NCCIH would leverage the infrastructure of the funded CoEs to expand current projects or add new pilot projects on complementary and integrative health approaches. The initiative would also stimulate the NCCIH maternal health portfolio by developing a cadre of investigators in this field and promote partnerships between IMPROVE investigators and those studying complementary and integrative health. Dr. Jean-Francois said that the leaders of IMPROVE are excited about this potential initiative and see the value added by incorporating nonpharmacologic approaches into the research.

Discussion: Dr. Coghill asked whether part of this research could be connected to the NIH HEAL Initiative's research on substance-exposed neonates by looking at factors that could minimize substance use in the mothers. Dr. Jean-Francois said that this could be possible. The IMPROVE network connects with other existing networks, including the NIH HEAL Initiative. Investigators from that initiative could apply and become part of the IMPROVE network.

A motion to approve the concept was made, seconded, and approved.

Advancing and Coordinating Interoception Research Across the National Institutes of Health

Dr. Wen Chen, branch chief of NCCIH's Basic and Mechanistic Research Branch, presented this concept, which would involve an expansion of the NIH Blueprint for Neuroscience Research

initiative on interoception. Inadequate understanding of how the brain interprets and regulates signals from the body can impede treatment of many conditions such as chronic pain, substance use disorder, and anxiety disorders.

Interoception is defined as the brain's ability to sense, integrate, and interpret information about the inner states of the body and regulate those states. It influences emotions, decision making, and physical well-being. This concept aims to foster a stronger and more coordinated research community, expand NIH's interoception research portfolio, and ultimately pave the way for more effective interventions.

NIH's concerted effort to enhance interoception research began with a 2019 workshop on the roles of interoception in nervous system disorders. This event brought together experts to discuss key issues including brain-body connections, interoceptive neurocircuitry, disease mechanisms, and computational models. The workshop also identified a clear message: understanding interoception is essential to addressing some of the most pressing medical challenges, from brain health to chronic illness. The momentum from the workshop laid the groundwork for the broader efforts seen today.

One product from the workshop was a special 2020 issue on interoception in *Trends in Neuroscience.* One of the most significant gaps identified was the limited understanding of the neural circuits connecting the brain to the body at a fundamental level. The NIH Blueprint, led by NCCIH, responded to this challenge with a special funding opportunity on functional neural circuits of interoception in mammalian models. Funds were awarded for seven interoception projects in 2021. The projects have uncovered unexpected connections through vagal and spinal pathways between internal organs and specific brain areas, which are redefining the understanding of how interoceptive signals regulate physical and emotional health. Additional NIH ICs not involved in the NIH Blueprint have also funded interoception studies, some of which relate to systemic rather than neurological diseases, and overall, the number of NIH grants on interoception has nearly tripled. Many of the awards come from body-centric ICs such as NIDDK and the National Heart, Lung, and Blood Institute rather than brain-centric ICs such as NINDS and NIMH. The importance of interoception research is also reflected in the growing number of publications in this field, especially in high-impact journals, and in two recent successful and well-attended investigator meetings.

Despite the momentum, challenges and gaps remain, including the lack of a professional society or established network to bring together the diverse groups involved in interoception research, the lack of a formal structure to support regular large-scale interactions, difficulty in coordinating interoception research across NIH ICOs, challenges in translating basic research findings into clinical science, and the need for new technology and computational models.

To address these challenges, NCCIH proposes two key initiatives:

- Establishing an NIH Blueprint Coordination Center for Interoception Research (NBCCIR) to create a governing body of experts, facilitate community building and collaborations, develop digital communication/collaboration platforms, and publish white papers on taxonomies, research standards, common data elements, emerging

technological gaps, and opportunities. The ultimate goal of the NBCCIR would be to develop a sustainable research ecosystem that will accelerate progress in the field.

- Developing a suite of initiatives to support multidisciplinary research funding opportunities on interoception with emphases on technological innovation, bidirectional translational research, and theoretical and computational model development. The goal of this initiative is to facilitate the study of the complexity of brain-body connections and ensure that basic science can be effectively translated into clinical practice.

Discussion: Dr. Zick said that it surprises her that people think the brain is not a part of the body that would communicate with other body organs and that it took this long to recognize that communication is happening. Dr. Langevin thanked Dr. Chen for her work with the Blueprint. She has been relentless in inspiring that community about the importance of interoception, with superb results, Dr. Langevin said.

A motion to approve the concept was made, seconded, and approved.

VIII. Reissuing NCCIH U24 NOFOs

Dr. Weber gave a brief update on a technical issue. She explained that the grant review process is being revised across all of NIH, and many funding opportunities will need to be reissued because of the move to a simplified review framework. This new framework is intended to simplify the review of grant applications, reduce reviewer burden, and mitigate the effects of reputational bias. It reorganizes the five standard review criteria into three factors. Two of the factors—importance of research and rigor and feasibility—will be scored using the NIH grant application 9-point scale scoring system. The third—expertise and resources—will be evaluated for sufficiency only and not given a numeric score.

Unlike most research project grant mechanisms U24 funding opportunities will not move to the new review framework. The NCCIH U24 NOFOs often are companion funding opportunities that accompany UG3/UH3 NOFOs for large-scale studies (either mind and body or natural product clinical trials). Applications in response to the UG3/UH3 and U24 NOFOs must be submitted together. The language regarding the Plan for Enhancing Diverse Perspectives (PEDP) is being updated in the UG3/UH3 NOFOs along with updates to the review framework. The PEDP language in the U24 NOFOs, therefore, must also be updated to maintain consistency with the UG3/UH3 NOFOs. The U24 NOFOs will be reissued to update this language only. Without this update, the U24 and UG3/UH3 NOFOs would have different and conflicting PEDP instructions.

Discussion: Dr. Dusek asked whether there will be much training for review panel members about the changes. Dr. Weber said that a lot of information about the new review framework is already online. The changes will affect applications with due dates of January 25 or later, so it will be a few months after that before they have an impact on review. Dr. Jessica McKlveen, director of the NCCIH Office of Scientific Review, explained that the changes will affect summer review meetings in 2025. Materials and guidance for reviewers are being developed, and NCCIH will make sure that everyone is prepared for the changes.

IX. Public Comments

Dr. Schmidt stated that current procedure requires that any member of the public who wishes to submit comments may send them in writing to Dr. Schmidt by email (Martina.Schmidt@nih.gov) or postal mail, no later than 15 days prior to the date of the Council meeting. All written comments must be under 700 words in length, which is consistent with a 5-minute oral presentation. Written comments will be provided to Council members in the Electronic Council Book in advance of the Council meeting. Dr. Schmidt will acknowledge receipt of these comments during the open session. No public comments were received for this meeting.

X. Final Remarks and Adjournment

Dr. Schmidt thanked NCCIH staff for their work in making this meeting possible and thanked Council members, including the ad hoc members, for their hard work and participation. Dr. Langevin thanked Council members and said she was glad so many could attend in person. The next Council meeting will be virtual and will be held on January 24, 2025. The meeting adjourned at 3:59 p.m. ET.

We hereby certify that, to the best of our knowledge, the foregoing minutes are accurate and complete.

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Martina Schmidt, Ph.D.
Executive Secretary
National Advisory Council for
Complementary and Integrative Health

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Helene M. Langevin, M.D.
Chairperson
National Advisory Council for
Complementary and Integrative Health