

**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-Fifth Meeting
September 8, 2023**

NACCIH Members Present

Dr. Todd Braver, St. Louis, MO
Dr. Per Gunnar Brolinson, Blacksburg, VA
Dr. Anthony Delitto, Pittsburgh, PA
Dr. Helen Lavretsky, Los Angeles, CA
Dr. James Russell Linderman, Bethesda, MD*
Dr. Wolf Mehling, San Francisco, CA
Dr. Lynne Shinto, Portland, OR
Dr. Erica Sibinga, Baltimore, MD
Dr. Amala Soumyanath, Portland, OR

NACCIH Members Present Virtually

Dr. Helene Benveniste, New Haven, CT
Dr. Nadja Cech, Greensboro, NC
Dr. Robert Coghill, Cincinnati, OH
Dr. Daniel Dickerson, Los Angeles, CA
Dr. Margaret Haney, New York, NY
Dr. Girardin Jean-Louis, Miami, FL

NACCIH Members Not Present

Dr. Benjamin Kligler, Washington, DC*
Prof. Rhonda Magee, San Francisco, CA
Dr. Karen Sherman, Seattle, WA

*Ex Officio Member

I. Closed Session

The first portion of the eighty-fifth 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 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2). A total of 138 applications were assigned to the National Center for Complementary and Integrative Health (NCCIH). Applications that were noncompetitive, not discussed, or not recommended for further consideration by the scientific review groups were not considered by Council. Council agreed

with staff recommendations on 71 scored applications, which requested \$27,184,392 in total costs.

II. Call to Order and Brief Review of Council Operating Procedures

Dr. Martina Schmidt, director of the NCCIH Division of Extramural Activities, convened the open session at 11:05 a.m. ET. The May 2023 meeting minutes were approved unanimously.

III. NCCIH Director's Welcome and NCCIH Report

Dr. Helene M. Langevin, director of NCCIH, welcomed Council members and attendees. She announced new NIH staff appointments, including Stefan Pasiakos, Ph.D., FACSM, director of the Office of Dietary Supplements. President Biden has nominated Monica Bertagnolli, M.D., director of the National Cancer Institute, to be director of NIH. Patricia Flatley Brennan, R.N., Ph.D., announced her retirement as director of the National Library of Medicine.

Dr. Langevin welcomed Baila Hall, Ph.D., who joined NCCIH as a scientific review officer, and announced other NCCIH staff arrivals and departures. In FY 2023, NCCIH awarded 10 more research project competing grants than in the previous year, a 16 percent increase. Some of the increase reflects an additional \$5 million earmarked for pain research. NCCIH will continue to contribute \$1.5 million to the National Health Interview Survey (NHIS). This contribution covers costs associated with analysis of 2022 data that will be used to develop the 2027 questionnaire.

Newly funded programs include:

- Research Resource Center to Build an Open-Access Repository and Database for Anatomical and Physiological Correlates of Acupoints (from [RFA-AT-23-005](#))
- REsearch Across Complementary and Integrative Health Institutions (REACH) Virtual Resource Centers (from [RFA-AT-23-007](#))
- New studies within the Pragmatic Trials Collaboratory Program (from [RFA-AT-22-001](#)).
- New studies on Fostering Mental, Emotional, and Behavioral (MEB) Health Among Children in School Settings (from [RFA-AT-23-003](#))
- Research Networks to Promote Multidisciplinary Mechanistic Studies on Music-Based Interventions for Pain or Alzheimer's Disease and Alzheimer's Disease Related Dementias (from [RFA-AT-23-009](#))

Dr. Langevin gave an update on Helping to End Addiction Long-term[®] Initiative, or NIH HEAL Initiative[®], activities including the following:

- Understanding and Restoring Whole Joint Health in Pain Management. July 25–26. This productive workshop centered around a comprehensive understanding of the whole joint. Videos are available: [Day 1](#) and [Day 2](#).
- Toward Developing Quantitative Imaging and Other Relevant Biomarkers of Myofascial Tissues for Clinical Pain Management (R61/R33, Clinical Trial Required), [RFA-AT-24-003](#). Seven awards were funded last year. More funding opportunities are available this year, and the application deadline is October 18.

- Novel Targets for Opioid Use Disorders and Opioid Overdose: [RFA-DA-24-063](#) (R01 Clinical Trial Not Allowed); [RFA-DA-24-064](#) (R21 Clinical Trial Not Allowed). NCCIH is interested in the development of microbial-based therapies (probiotics) as a complementary approach.

Recent NCCIH-led or involved events include:

- NIH Consortium for Advancing Research on Botanical and Other Natural Products (CARBON) Meeting.
- [2nd Annual Force-Based Manipulation Investigator Meeting](#). Dr. David Ginty of Harvard Medical School presented the keynote.
- [Integrative Medicine Lecture Series \(ILMS\): Unleashing the Power of Prevention To Enhance Well-Being Across the Lifespan](#) by Margaret Kuklinski, Ph.D.
- [ILMS: New Insights Into Prevention and Management of Chronic Pain in Children and Adolescents](#) by Tonya M. Palermo, Ph.D.
- [Hot Topics Webinar: Launching a Career in Health Disparities Research](#). The webinar highlighted three NCCIH-funded early career investigators engaged in health disparities research focused on HIV populations.
- [Technical Assistance Webinar. Research Network to Promote Multidisciplinary Mechanistic and Translational Studies of Sickle Cell Disease Pain \(U24\)](#). June 14, 2023.

In addition, NCCIH representatives made presentations at multiple events sponsored by outside organizations.

Upcoming events include:

- [2nd Annual NIH Investigator Meeting for Interoception Research](#). November 11, 2023. Deadline for registration is October 20, 2023.
- [American Public Health Association \(APHA\) Session Panel. Using Complementary and Integrative Approaches to Address HIV-Related Comorbidities: Research Highlights and Opportunities](#). November 13, 2023.
- Society for Neuroscience Symposium. Mechanisms and Modulations of the Brain Lymphatics System. November 13, 2023. Chair: Dr. Helene Benveniste, Yale School of Medicine. Co-Chair: Dr. Inna Belfer, NCCIH.
- Music as Medicine: The Science and Clinical Practice. December 14–15, 2023.
- 2024 International Congress on Integrative Medicine and Health. April 9–13, 2024.

Discussion: Dr. Lavretsky asked for clarification on how funding across different programs is distributed. Dr. Langevin explained that many initiatives are collaborations with other NIH Institutes and Centers (ICs). This allows NCCIH to co-fund, spread research dollars, and take advantage of existing programs to fund more research.

IV. Intramural Research Report

David Shurtleff, Ph.D., Deputy Director, NCCIH

Dr. Shurtleff, acting scientific director, Division of Intramural Research (DIR), provided a broad overview of the DIR and the recently formed [Pain Research Center](#) (PRC). The intramural research program focuses on the study of pain. More than 30 percent of Americans live with chronic pain—more than the numbers with cancer, heart disease, and diabetes combined. The DIR conducts basic, clinical, and translational research on the roles of the nervous system, other physiological systems, and psychosocial factors in pain. A major focus of the DIR is training the next generation of researchers. The DIR strives to be multidisciplinary and collaborative across NIH and to conduct cutting-edge robust research. Since NIH doesn't have an IC focused on pain, the NCCIH DIR has taken the lead to expand pain research on the NIH campus.

Dr. Shurtleff recognized the DIR leadership staff and highlighted some of the work in their labs.

Miroslav (“Misha”) Bačkonja, M.D., is the acting clinical director and supervisory physician of the Clinical Investigations Branch. He is responsible for coordinating research projects related to assessing pain, providing medical supervision, and ensuring research participants’ safety for NCCIH’s clinical research program. Dr. Bačkonja’s research has led to the publication of more than 100 peer-reviewed articles, and his pain education efforts have resulted in a series of articles and book chapters, as well as numerous didactic presentations at national and international meetings.

Yarimar Carrasquillo, Ph.D., leads the Behavioral Neurocircuitry and Cellular Plasticity Section in the NCCIH intramural division. The main goal of the lab is to identify anatomical, molecular, and cellular mechanisms that underlie pathological pain states. Research focuses on the amygdala, a structure in the limbic brain system that plays critical roles in the modulation of tactile hypersensitivity, pain-related aversion learning, and pain-induced changes in anxiety-related behaviors in rodent models of persistent pain.

Alexander (Alex) Chesler, Ph.D. heads the Section on Sensory Cells and Circuits. The lab is interested in the neurons and circuits of the somatosensory system. Currently, research in the lab is focused on discovering new molecules involved in the transduction of somatosensory stimuli. One key component of the lab has been to characterize the Piezo-type mechanosensitive ion channel component 2 or Piezo2. Dr. Chesler’s lab has identified a cohort of patients with a rare inherited disorder affecting mechanosensation due to damaging mutations in the gene *PIEZO2*. Studying these patients helped define the role of this particular gene in human mechanosensation and to explore basic questions about the role select sensory inputs play in perception.

Lauren Y. Atlas, Ph.D., leads the Section on Affective Neuroscience and Pain in the NCCIH intramural research program. The lab’s work focuses on characterizing the psychological and neural mechanisms by which expectations and other cognitive and emotional factors influence pain, emotional experience, and clinical outcomes. The lab’s research approach is multi-modal, integrating experimental psychology, neuroimaging, psychophysiology, computational approaches, and other interventions to understand how psychological and contextual factors influence subjective experience. Recently, Dr. Atlas and her team examined data from a web-based mental health survey on COVID-19 stressors during the pandemic. The survey ended with an open-text free-response prompt, “Is there anything else you would like to tell us that might be

important that we did not ask about?” Using text analysis methods on these free responses, Dr. Atlas and her colleagues investigated the characteristics of the content of responses, how responses changed over time, and how language use reflected the participants’ mental state. They hypothesized that free-text responding may be therapeutic, may be an outlet to express negative emotions, or may help COVID loneliness.

Dr. Shurtleff encouraged attendees to read about these and other studies on [Selected Research Results](#).

Expanding Intramural Research

Epidemiological research at NCCIH is expanding, and the NCCIH DIR is currently looking for a senior intramural epidemiologist. Epidemiology currently resides under the NCCIH Director but will soon be under the scientific director, where it will continue to operate in the same manner. Moving the program will provide better training for the next generation of epidemiologists and improve collaboration with other epidemiology departments across NIH.

Previous research has shown that approximately 18 percent of U.S. adults have chronic pain, but little has been known about how chronic pain rates have changed over time. The epidemiology group, led by Drs. Richard Nahin and Termeh Feinberg, analyzed data from the 2019-2020 National Health Interview Survey (NHIS) and found 61.4 percent of adults with chronic pain in 2019 continued to have chronic pain in 2020. Among survey respondents who were pain free in 2019, 6.3 percent reported chronic pain in 2020, with an incidence of 52.4 cases per 1,000 persons per year (PY). The incidence of chronic pain was high compared with other chronic conditions such as diabetes (7.1 cases/1,000 PY), depression (15.9 cases per 1,000 PY), and hypertension (45.3 cases/1,000 PY).

NIH Training and Career Opportunities

NIH offers training and career opportunities in biomedical, behavioral, and social sciences at all levels and in several locations around the country. Dr. Shurtleff highlighted several training opportunities, including summer internships, undergraduate scholarship programs, and postbaccalaureate programs that set the stage for future careers, and urged meeting attendees to encourage students to explore these options.

Clinician scientist training is another area of opportunity. NCCIH feels that people who are both clinicians and researchers are the most informed about current problems and can do important translational work. Programs include the [Clinical Research Fellowship in Translational Pain Medicine](#), [Clinical Electives Program](#), and [Medical Research Scholars Program](#).

NIH hires approximately 30 tenure-track faculty positions annually across the Intramural Research Program (IRP). These scientists lead independent research laboratories, conduct research, and play a major role in training and mentoring, with resources provided by the IRP. More information is available about [faculty-level scientific careers](#) and [Stadtman Tenure-Track Investigators](#). There are also opportunities for staff scientists to support long-term research or run specific core facilities, including an opening for a staff scientist to run the PRC.

V. NIH Pain Research Center (PRC) (Led by NCCIH)

David Shurtleff, Ph.D.

NCCIH is bringing together clinical researchers to study pain through the PRC. NIH Clinical Center researchers study a broad range of conditions, and many are comorbid for pain. The PRC provides opportunities for clinical researchers across NIH to study the pain aspect of a disease. The PRC's mission is to serve as a research, training, and diagnostic hub for the clinical intramural program for studying pain; identify and better understand mechanisms of diverse pain states; develop and test therapies to better manage pain and prevent development of chronic pain and opioid misuse; and study individual patients with rare and unusual pain states. NCCIH received seed money from the NIH Director's Challenge Innovation Award in 2020 to help launch the Center. There are current openings for a facility head to run the PRC and a patient coordinator to help with recruitment of specific pain populations. The National Institute of Neurological Disorders and Stroke (NINDS) provides generous support to monitor protocol development. The PRC's resources include dedicated testing rooms in outpatient clinics, microneurography (under development), experimental allodynia/hyperalgesia testing, and consults for experimental design.

One exciting new project, focused on the temporomandibular joint (TMJ), is [TMJ SYMPHONY \(Systems-integrated Model and Mechanisms of Patient-centered Holistic Outcomes and Network-Supported Training and Therapy\)](#), which involves a network of national and international collaborators. This project is headed by the National Institute on Dental and Craniofacial Research, with the PRC providing standards on testing and diagnosing pain.

Upcoming studies will include Assessing Peripheral Nerve Function in Individuals With Mutations in the PIEZO2 Gene Using Microneurography; [Patient-Centered Assessment of Symptoms and Outcomes \(P-CASO\)](#); and Nociception Phenotype in Individuals with Intellectual Disability. Ongoing studies focus on a variety of conditions including sickle cell disease, fibrous dysplasia/McCune-Albright syndrome, functional movement disorders, Morton's neuroma, and post-acute sequelae of SARS-CoV-2 (PASC).

The PRC is very interested in translational research—bringing the bench to the bedside to make sure preclinical research is useful and progresses to the next level. For example, studies of PIEZO2 function in preclinical models and humans have provided insights on interoception, organ function, and reproductive health. The preclinical models are providing new ideas about what loss of PIEZO2 means in terms of physiology, which can then be cross-validated in the patient population. Future translational research will include assessing the analgesic effects of hydroxy-nor-ketamine (HNK), studying the role of the amygdala in pain perception in research participants, and the TMJ SYMPHONY project described earlier.

Dr. Shurtleff said that patients frequently reach out to NIH in hope of finding treatment for their conditions. He shared a case study, "Behavioral and Neural Correlates of Noxious Stimuli in a Pain-Insensitive Patient," in which a young person did not feel pain despite no apparent brain or spinal cord abnormality. Neuroimaging showed reduced activation in the ACC, S1, S11,

thalamus, and insula regions. Signals were reaching the brain, but the brain was not responding, which limited the patient's ability to recognize painful events.

In summary, the PRC has become a hub for conducting pain phenotyping in diverse patient populations across NIH, which is critically needed. It provides opportunities to help patients and advance the study of pain, as well as facilitating translation of research from the bench to the bedside and characterizing pain in patients with rare phenotypes.

Discussion: Dr. Soumyanath said she was pleased to see the breadth of activities that the Center is leading. She asked if some of the mechanistic knowledge could be developed into screens for new drugs. Dr. Shurtleff explained that NCCIH is working with the National Center for Advancing Translational Sciences (NCATS), which has a screening center. NCATS is developing compounds to target the loss of PIEZO2 through their high-throughput screening discovery platform. Hits found in the early discovery phase will go to Dr. Chesler's lab. If his preclinical findings look promising, they will then go to the PRC. So, there is a conduit to do early discovery work all the way through clinical research. Dr. Soumyanath said that this is encouraging for natural products researchers. Dr. Shurtleff said that the NCATS facility is open to new ideas and looking for new compounds to screen.

Dr. Haney noted a case study of a woman who had loss of function in her FA gene who had high endocannabinoids and no pain sensitivity and asked if there has been testing for that. Dr. Shurtleff said the PMC has not done that, but it is the type of work that could be done. Dr. Haney also asked if loss of PIEZO2 function is common. Dr. Shurtleff said it is quite rare, and only four or five cases have been identified in the world. The work being done in the lab has provided a better understanding of what people were experiencing and what is happening to them.

Dr. Cech said she appreciated the comment that there is no Center at NIH focusing on pain and was happy to see NCCIH being a leader. She especially liked the "bench to bedside" development of treatments for pain and commented that natural products can play an important role. She asked if there are more outwardly facing requests for applications to bring more investigators into the natural products area and work with them. Dr. Shurtleff said the goal is to bring together the intramural program and develop connections to extramural research.

Dr. Craig Hopp, deputy director, Division of Extramural Research, shared that NCCIH has an ongoing, active program with NINDS called the [IGNITE Program](#), which asks investigators to propose novel analgesic assays. If the assay is validated, it moves to the R33 phase, in which investigators are encouraged to screen large natural product libraries. Dr. Shurtleff reiterated that early discovery studies can help move this research forward.

VI. CSR's Initiatives To Strengthen Peer Review

Noni Byrnes, Ph.D. Director, Center for Scientific Review

Dr. Byrnes explained that the mission of the [Center for Scientific Review \(CSR\)](#) is to help identify the strongest, highest impact proposals so NIH can fund the most promising research. CSR does this by ensuring that grant applications receive fair, independent, expert, and timely reviews that are free from inappropriate influences. In FY 2023 CSR reviewed more than 60K

applications, which is more than three-quarters of all applications submitted to NIH. There are 275 scientific review officers (SROs), who engage with more than 19,000 individual peer reviewers in more than 1,200 review meetings. In addition to standing study sections, CSR handles many special emphasis panels for initiatives that involve more than one NIH IC.

CSR's strategic framework for optimizing the peer review process includes components central to the quality and fairness of peer review: study sections, reviewers, and process.

1. Study sections:
 - Scientific scope
 - Output
 - Size appropriate for competition
2. Reviewers:
 - Reviewer training
 - Broaden/diversify reviewer pool
 - Incentivizing service
 - Reviewer evaluation
3. Process:
 - Confidentiality/integrity
 - Fairness/bias Mitigation
 - Assignment/referral of applications
 - Review criteria and scoring system

These three components are built upon a foundation of transparency, data-driven decisions, stakeholder engagement, and staff engagement, training, and development.

Dr. Brynes discussed five current CSR efforts: (1) the Evaluating Panel Quality In Review process (ENQUIRE), (2) simplifying review of research project grants (RPGs), (3) improving review of National Research Service Award (NRSA) fellowships, (4) promoting fairness, and (5) diversifying panels.

ENQUIRE: ENQUIRE, launched in 2019, is a systematic, data-driven, continuous process to evaluate study sections to see how well they map onto the current state of the science. About 20 percent of study sections are evaluated each year. The process can and often does lead to substantive changes, including creation, merger, or elimination of study sections.

RPG Review: The two main goals of proposed changes to RPG review are to refocus first-level peer review on providing advice regarding the scientific/technical merit of grant applications, and to mitigate reputational bias in the peer review process by refocusing the evaluation of investigator and environment in the context of the proposed research project. The development of these proposed changes began in January 2020 with two CSR Advisory Council working groups, followed by a report to the full Advisory Council, internal NIH input, and an RFI to obtain public input. Most RFI respondents were very supportive of the changes. Many recommended that CSR develop strong training resources to socialize the changes for reviewers,

study section chairs, and SROs. The trans-NIH implementation committee will consider RFI input to develop a rollout strategy. The implementation target is January 2025.

Fellowship Review: Changes to the NRSA fellowship review process were developed in response to concerns that NIH was leaving out promising scientists because of a process that favors elite institutions and has a narrow emphasis on traditional markers of success. A data analysis of more than 6,000 applications supported these concerns. The new approach to strengthening fellowship review involves two changes: (1) revising the fellowship application to present the candidate's accomplishments in the context of opportunities they have had and (2) revising the review criteria to focus on the applicant's potential, strength of the science, and quality of the training plan without undue influence of the sponsor's or institution's reputation. This should help with identifying the most promising trainees and training programs and help achieve the goal of preparing outstanding scientists and researchers. In 2022, the CSR Advisory Council presented the recommendations to NIH leadership, which approved them without changes. An RFI was recently released for public input and so far, responses are very supportive of the proposed changes. More information can be found [here](#).

Promoting Fairness: CSR released bias awareness training for reviewers in 2021 targeted toward mitigating the most common biases in the peer review process. To date, 22,000 CSR reviewers have taken the training, and it has been well received. It will be required for all NIH reviewers in early 2024. CSR also has a Review Integrity Training Module that was updated in August 2022. It will be required for all NIH reviewers beginning with February/March 2024 review meetings. Another tool to promote fairness in review is the Direct Bias Reporting Mechanism, through which applicants, reviewers, and program staff can report any bias they observe during the peer review process. CSR's chief diversity officer, Dr. Gabriel Fosu, and senior management investigate every allegation, and if there is agreement that bias has occurred, (roughly one-third of the time) the application will be re-reviewed and the applicant will be informed. If there is not agreement, the official NIH appeals process through the IC Council remains available to all investigators. Most individuals who are notified of bias will acknowledge the behavior, apologize, and take steps to correct.

Diversifying Panels: Dr. Byrnes presented the CSR Reviewer Finder Tool, which is used to find "lesser-known" well qualified reviewers and draws from multiple data sources, including recommendations from scientific societies, early-career reviewers, and IC recommendations. CSR's current focus is on enhancing diversity on special emphasis panels, which traditionally had very low diversity. Dr. Byrnes shared a graph that illustrated the increasing representation of women and underrepresented minorities on review panels since 2019.

Discussion: Dr. Lavretsky asked how CSR trains less-experienced reviewers and if they are more critical than more senior reviewers. Dr. Byrnes said CSR has a robust training program. She said she believes that improved training lessens the risk of any reviewer being too critical and improves their assessments. Dr. Braver commented that the data about the fellowship applications was informative and asked if there will be outreach to the other NIH ICs to improve a culture shift. Dr. Byrnes said there is a multipronged effort to share this information and encourage applicants from a more diverse pool of academic institutions but recognizes this won't

solve everything. Dr. Soumyanath asked if authentication of key biological and chemical resources will still be on the list of review considerations for RPGs. Dr. Byrnes confirmed they will be.

Question from chat: Are you concerned that only evaluating data from 2021 might have slightly exacerbated the trend, as larger or more established institutions and principal investigators (PIs) were better able to weather uncertainties during that timeframe? Dr. Byrnes explained that they generated the data for review of fellowship applications by looking at the information they had for that year. She agreed that they should look at a broader set of data. Question from chat: Is there any special training for chairs in the efforts to reduce bias? Dr. Byrnes explained that bias training is required for chairs and highly recommended for reviewers.

Dr. Langevin asked if there is a sense of skepticism about the review process in general across the research community. Dr. Byrnes replied that the more that is done to be transparent and communicate with the extramural community, the more people will become aware and can correct misperceptions. Question from chat: Do you have data and comments on the ethnic breakdown on researchers submitting grants? Dr. Byrnes said that information for NIH is publicly available on the Office of Extramural Research site.

VII. Concept Approval: Consortium Advancing Research on Botanicals and Other Natural Products (CARBON) Program

Barbara Sorkin, Ph.D., Office of Dietary Supplements and D. Craig Hopp, Ph.D., NCCIH

The focus of the [CARBON](#) program is on transdisciplinary research to understand the effects on humans of ingested, chemically complex botanicals. During its duration an external expert panel has advised on the program's strengths, weaknesses, and promising research directions. The program's specific scientific approaches have evolved over time in response to panel recommendations, new technological opportunities, and shifting research needs. Early on, CARBON focused primarily on the conduct of Phase III efficacy trials of botanicals. However, it became clear that knowledge of molecular mechanisms of action was insufficient at the time and not rigorous enough to support these clinical trials. The trials did not show the expected benefits and did give not enough information to allow understanding why this is the case.

The program refocused on filling gaps in understanding mechanisms of action, with an overall focus on the effects of chemically complex natural products on human resilience. The CARBON Program includes Botanical Dietary Supplements Research Centers (BDSRC), two Centers focused on enhancing methods and resources for research on the health effects of complex natural products, and pilot projects collaborating with the Centers. The ODS-supported pilot projects, awarded in response to PAR-20-228, collaborate with these Centers to extend the understanding of products studied in the BDSRC, or to leverage methods in use in the CARBON Program for early phase research relevant to natural product dietary supplements.

Dr. Hopp explained that CARBON has focused on conducting translationally relevant research and on developing novel methodologies and technologies. The most recent expert panel review

supported continuing this dual approach and provided several suggestions for strengthening the program. Based on those recommendations these shifts in focus were developed:

- Continue innovative mechanistic research and increase focus on translational relevance of effects of natural products on human resilience.
- Increase focus on computational components by leveraging big data to understand how products work.
- Maintain a sustainable data repository and transition to an independent model without continuous NIH support.
- Diversify research teams and capitalize on innovative ideas generated by diverse points of view moving forward.

The proposed concept will maintain the three current components of the CARBON program—translational botanical research, resource development, and technology and methodology development—while incorporating the other recommendations.

Discussion: Dr. Soumyanath asked if innovative computational methods would be considered part of technology and development component or part of translational botanical research. Dr. Hopp said there is currently a component focused on computational methodology, but computational methods could be included in another application. Dr. Cech asked if computational methods are the only type of new strategy included in technology and methodology development. Dr. Hopp explained that computational tools will be at the forefront and the hope is for all applications to have a computationally driven focus. Dr. Cech asked for clarification about models for long-term sustainability and if NIH will be involved in helping programs be sustainable. Dr. Hopp said that NCCIH and ODS have invested in the program and have a lot of incentive to ensure projects sustain themselves. There are a variety of models for how that can happen, but hopefully they can collaborate with other sponsors/industries that have a vested interest in supporting this program. He is also confident that models can be created that don't impinge on open access. Dr. Cech agreed and mentioned leveraging existing databases that already have an infrastructure. Dr. Langevin added that it is up to investigators to submit creative applications and propose models that lead to sustainability. Dr. Sorkin reiterated that the intention is to ensure these are fair and open to all. Dr. Lavretsky said it is important to recognize that machine learning and artificial intelligence will put researchers in the position of vetting complex healing practices. Dr. Hopp agreed and said studies of traditional systems of medicine are encouraged as part of CARBON. Dr. Soumyanath said that CARBON is valuable to the natural products community for its training opportunities. She asked for clarification if sustainability is just for databases or also for translational projects. Dr. Hopp said it is primarily for the resource component.

The concept was approved unanimously.

VIII. Concept Approval: NCCIH Methods to Extend Research In Time (MERIT) To Promote Innovation and Diversity in Complementary and Integrative Health Approaches Awards

Wen G. Chen, M.M.Sc., Ph.D., NCCIH

Within the NIH Common Fund programs, two prominent awards are at the forefront of supporting innovative and groundbreaking research by recognizing and encouraging scientists with an exemplary track record of creativity or ideas to pursue novel approaches to address significant challenges in scientific discovery. The NIH Director's Pioneer Award supports scientists with outstanding records of creativity, pursuing new research directions to develop pioneering approaches to major challenges in biomedical, social science, and behavioral research. The NIH Director's Transformative Research Award supports both individuals and teams undertaking transformative projects that are inherently risky and untested with the potential to reshape current scientific paradigms.

Dr. Chen noted that over the last decade, NCCIH has successfully secured nine Pioneer Awards and four Transformative Research Awards. They are primarily supported by the Common Fund and were awarded to NCCIH because they align with our research focus areas such as interoception, the microbiome, structural biology, the social brain, and functional genomics. Although NCCIH has made progress in attracting Pioneer and Transformative Research awardees to our portfolio, Dr. Chen pointed out several challenges, including retention. Very few awardees have continued their research programs in the direction of complementary and integrative approaches. She also mentioned that some investigators have switched direction to align with other NIH ICs—even though their project highly aligned with NCCIH's mission—due to a perception that more long-term funding opportunities are available at these ICs. Another challenge has been the lack of diversity of trainees. She noted that although common in high-impact programs, recruitment of trainees with diverse backgrounds and scientific research experience must be prioritized.

Dr. Chen proposed that NCCIH could provide long-term funding opportunities to attract Pioneer and Transformative Research awardees to NCCIH but also allow more integration of complementary and integrative research approaches in their research programs. This might also encourage investigators to extend their training- and diversity promotion- and inclusion efforts. Doing so may also attract current NCCIH grantees and investigators to pursue innovative work.

Dr. Chen suggested that NCCIH participate in the NIH MERIT award as an efficient way to provide long-term or sustained funding to highly productive and impactful investigators. The process begins with a regular investigator-initiated R01 application that goes through peer review and receives a fundable score. Among this pool of fundable R01 applications, program staff may nominate potential MERIT awardees based on established special selection criteria set by the IC. Then, the IC leadership and Advisory Council review, prioritize, and approve or disapprove the MERIT award nominations. If approved, these R01 applications are converted to R37 MERIT awards. About 6 months prior to the end of the first 5 years of the R37 awards, the PIs submit extension applications, similar to R01 competitive renewal applications, to the IC. Program staff, followed by IC leadership and Advisory Council members, review the scientific progress, the scientific merits of the extension research, and whether the awards have met other established extension criteria.

This proposed initiative would establish the MERIT funding mechanism at NCCIH to address the challenges and opportunities described earlier by 1) providing highly competitive 10-year

funding support for current and former NCCIH Pioneer and Transformative Research Awardees to develop innovative and cutting-edge research programs specifically aimed to study complementary and integrative health approaches; 2) requiring the development and implementation of a plan focusing on the recruitment and training of diverse trainees; and 3) including a 5-year interim review and evaluation process conducted by NCCIH program staff, the NCCIH director, and Council to help determine the benefit of extending the MERIT awards to the second 5-year funding cycle.

Discussion: Dr. Delitto said MERIT awards are not only nice but necessary. Dr. Braver asked for clarification of the eligible pool of applicants, commenting that it sounds like only 13 people would be eligible. Dr. Chen explained that each IC establishes its own criteria for nominations, but the concept is the same across all, which is to extend the research to up to 10 years. Dr. Braver asked if one receives a Pioneer Award, do they submit a separate application for a MERIT award. Dr. Chen clarified that an R01 application would be submitted as usual. Dr. Braver said that a Pioneer Award should cover salary, and Dr. Chen explained that only a percentage of the salary is covered. She also confirmed that several NCCIH awardees have received MERIT awards from other ICs. Dr. Langevin said NCCIH is not planning on funding large numbers of these awards. Dr. Braver asked if a Pioneer awardee could receive a MERIT award as part of the Pioneer award. Dr. Chen clarified that Pioneer awards typically are not NCCIH mission-specific but they are very innovative research work, so NCCIH wants to attract these investigators to make the Center's research more cutting edge. Dr. Lavretsky commented that it seems that this is not a personal award but more of a team award. Dr. Chen explained that if a researcher had a Pioneer or Transformative Research award from NCCIH in the past, that makes that researcher eligible to be considered for a 5-year MERIT award that could be extended potentially to a 10-year award.

The concept was approved unanimously.

IX. Public Comments

Since members of the public are attending virtually, in-person comments are not possible at this meeting. The current procedure—which differs from that used previously—requires those who wish to submit comments to send them to Dr. Schmidt by email (Martina.Schmidt@nih.gov) or postal mail no later than 15 days prior to the Council meeting. All written comments must be less than 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 January 2024 meeting. No comments were submitted for this meeting.

Dr. Langevin asked for suggestions on topics of interest for the next meeting. Dr. Braver suggested a deeper discussion on spirituality. Dr. Langevin shared that she has heard concerns that focusing on spirituality would cause the Center's scope to be spread too thinly. Spirituality may take the Center in a much broader direction and could impact its modest budget. There was general discussion that complementary and integrative health by nature is very broad. Including spirituality could be considered, although it would be challenging. Discussion will continue during future meetings.

X. Final Remarks and Adjournment

Dr. Schmidt thanked Council and staff. NCCIH would not be able to pursue its mission without Council's expertise and feedback. She noted this is the second hybrid Council meeting and acknowledged and appreciated the tremendous amount of work required to hold this meeting. The meeting adjourned at 3:55 pm.

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

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

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