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 Ninetieth Meeting
July 1, 2025

NACCIH Members Present Virtually

Dr. Helene Benveniste, New Haven, CT
Dr. Per Gunnar Brolinson, Blacksburg, VA
Dr. Nadja Cech, Greensboro, NC
Dr. Ian Coulter, Santa Monica, CA**
Dr. Daniel Dickerson, Los Angeles, CA
Dr. Benjamin Kligler, Washington, DC*
Dr. James Russell Linderman, Bethesda, MD*
Dr. Helen Lavretsky, Los Angeles, CA
Dr. Jianren Mao, Boston, MA**
Dr. Erica Sibinga, Baltimore, MD
Dr. Amala Soumyanath, Portland, OR
Dr. Katie Witkiewitz, Albuquerque, NM**

NACCIH Members Not Present

Prof. Rhonda Magee, San Francisco, CA

* Ex Officio Member
** Ad-hoc Member

I. Closed Session

The first portion of the ninetieth 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 197 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 118 scored applications, which requested $74,208,361 in total costs.

II. Call to Order

Dr. Martina Schmidt, director of the NCCIH Division of Extramural Activities (DEA) and executive secretary of the NACCIH, called the meeting to order at 12:30 p.m. ET. Dr. Helene M. Langevin, director of NCCIH, welcomed the attendees. Minutes of the Council meetings held in April 2025 and September 2024 are available on the NCCIH website.

III. NCCIH Director's Welcome and NCCIH Report

Dr. Langevin explained that this has been a momentous year for the National Institutes of Health (NIH). Many changes have taken place, and things are still very much in flux, with many new policies and requirements to deal with throughout NIH.

The new director of NIH, Dr. Jayanta Bhattacharya, has been very forthcoming in sharing his priorities, many of which are in line with NCCIH's areas of focus, including his top priority, improving the health of the population (with an emphasis on the word "health"), with a focus on the prevention and treatment of chronic diseases. This priority is consistent with NCCIH's emphasis on whole person health, prevention, and restoration. Dr. Bhattacharya's priority of ensuring that NIH-funded research results are replicable and generalizable is also consistent with NCCIH's work. NCCIH has been a leader in this area, ensuring that results of clinical research are reliable and can be generalized. Dr. Bhattacharya's priority of being respectful of dissenting perspectives is also consistent with NCCIH's belief that different ways of viewing the body and health should be respected.

There have been many changes in NIH leadership. Dr. Monica Bertagnolli, the previous NIH director, has left. Dr. Matthew Memoli has replaced Dr. Lawrence Tabak as principal deputy director. Dr. Jon Lorsch has taken on the role of acting deputy director for extramural research, and Dr. Raymond Jacobson is now the acting deputy director of the Office of Extramural Research. They are splitting the responsibilities formerly performed by Dr. Michael Lauer. Dr. Lorsch is also continuing to serve as director of the National Institute of General Medical Sciences. Dr. Nicole Kleinstruer is now acting deputy director for Program Coordination, Planning, and Strategic Initiatives, replacing Dr. Tara Schwartz. Ms. Seana Cranston has replaced Mr. John Burklow as NIH chief of staff. Eight Institute and Center (IC) directors have left; the ICs now have acting directors.

Dr. Langevin presented a list of the NCCIH staff and contractors who have left in many cases because of reductions in force. Some entire offices have been eliminated. In addition, several NCCIH staff took advantage of opportunities for early retirement. There have been four leadership departures: Drs. Emmeline Edwards and Craig Hopp, director and deputy director of the Division of Extramural Research (DER); Ms. Ginger Betson, director of the Office of Administrative Operations (OAO); and Ms. Mary Beth Kester, director of the Office of Policy, Planning, and Evaluation. Ms. Ann Ellis is now acting executive officer in the OAO. Dr. Wendy Weber is serving as acting director of the DER until September, and Dr. Wen Chen will take over this role for the rest of 2025. Dr. Alisa Johnson has joined NCCIH as facility head and staff scientist at the Pain Research Center.

The total staff losses at NCCIH—56 full-time equivalents (FTEs), representing 49 percent of total staff—have had major impacts. The OAO has been reduced from 23 to 3 employees, with no one left in the ethics, management analysis, or information technology offices within the OAO. Other ICs are assisting NCCIH in performing vital functions related to budget and ethics, but it is difficult to do this with reduced staff. The entire Office of Policy, Planning, and Evaluation and Office of Communications and Public Liaison have been eliminated. The size of NCCIH's staff had grown between FY 2019 and FY 2025, from 77 FTEs to 110. This change reflected increased NCCIH participation in NIH-wide activities, which required additional staff to coordinate. With the recent decrease in staff, NCCIH's ability to participate in NIH-wide programs is severely curtailed.

Council meetings have resumed following a pause from January to April, but among other developments, the Council delays have made it difficult to stay on track with grants funding activities. There were temporary pauses in NCCIH-sponsored workshops and meetings and in NIH staff's ability to participate in conferences. For example, NCCIH staff were not able to participate in the International Congress on

Integrative Medicine and Health (ICIMH), even though they were scheduled to speak. The reduction in internal resources has hampered NCCIH's ability to plan and participate in events; these activities will resume slowly but will be limited.

The NCCIH website is frozen; it cannot be updated, except for minimal changes such as the announcement of this Council meeting, because of the loss of the Office of Communications and Public Liaison team. Efforts to centralize communications for all of NIH are planned but have not happened yet. Currently, NCCIH has no good way to communicate with the external community. Dr. Langevin said that researchers should use the NIH Guide for Grants and Contracts to find out about new funding opportunities rather than the NCCIH website.

Grant review is being centralized at NIH. Other functional areas may also be centralized in the future, but those changes are currently at the planning stage. With the centralization, the peer review process for grant applications is changing. Previously, many applications submitted to IC-specific initiatives were often reviewed at ICs, while investigator-initiated projects were generally reviewed by CSR. Going forward, all reviews will be consolidated into CSR starting with the October 2025 Council round. Also, it is expected, moving forward, that fewer IC-specific notices of funding opportunity (NOFOs) will be issued. With these developments, Council's second-level review will become crucial to assess the relevance of research to IC priorities. At NCCIH, close to 50 percent of applications, and an even larger percentage of funded applications, have traditionally been reviewed at NCCIH. Applications for clinical trials and those involving specialized topics were usually reviewed in house. The change of the locus of review to CSR for all applications will have a major impact. It will take time for investigators and staff to adjust to the change.

It is expected that fewer NOFOs will be issued across NIH in the future. NCCIH previously used NOFOs to address specific program needs. An increased use of parent NOFOs is expected. In addition, a new level of approval by the Department of Health and Human Services (HHS) has been added to the oversight process for issuing NOFOs. While a NOFO is going through this process, it is listed as a "forecasted" NOFO on the Grants.gov website. Investigators can search Grants.gov for forecasted NOFOs to see opportunities that may be coming soon but should use the NIH Guide to identify current NOFOs.

There has been a change in the policy for foreign subawards. In the past, when grants had foreign components, it was difficult to track how money was flowing from NIH to the primary award recipient and the foreign component. The new policy requires collaborating with foreign entities to submit subprojects, which will enable the flow of money to be more easily tracked. This change is in the process of being implemented, and current grants with foreign components are being adjusted.

NCCIH's total appropriation for FY 2023–2025 has been about $170M each year, but in the President's Budget for FY 2026, the appropriation for NCCIH is zero. Dr. Langevin said NCCIH is waiting to see what happens at the House and Senate budget meetings; the President's Budget is just a first step, and the final budget voted on by Congress may be very different.

Efforts are underway to ensure that a certain percentage of every IC's budget goes to grants with multi-year funding (MYF) starting in FY 2025. With MYF, up to 4 years may be funded all at once at the beginning of a grant or, alternatively, the final years of an award can be funded. MYF may help NIH to avoid some of the impact of forecasted budget cuts on currently ongoing projects, like for example to enable them to finish a clinical trial that is nearly completed. NCCIH is working on how best to make use of MYF.

The NIH public access policy is changing today. Under the new policy, final peer-reviewed manuscripts reporting NIH-funded research that are accepted for publication on or after July 1, 2025, must be immediately deposited in the National Library of Medicine's digital archive, PubMed Central, starting at the manuscript's official date of publication. Embargo periods are no longer permitted.

Turning to good news, Dr. Langevin explained that NCCIH's focus on whole person health is well aligned with the current administration's emphasis on addressing the chronic disease burden. Despite high health care expenditures, the United States is not doing well regarding life expectancy and chronic diseases compared to other developed countries. There is a need to assist individuals in managing predisposing factors within their control, such as stress, poor sleep, poor diet, sedentary lifestyle, and environmental exposures, to prevent and reverse the course of diseases before they become irreversible.

The development of NCCIH's next strategic plan has been put on hold for the moment. NCCIH's thematic areas of focus—nutrition and natural products, positive health processes, the mind and body connection, pain and pain management, whole person research, workforce development, and methods and data science—will serve as a blueprint for NCCIH's funding interests until a new strategic plan is created.

In December 2024, NCCIH celebrated its 25th anniversary with a landmark event exploring the impact of whole person health. A recording is available. A paper on the economic model discussed by Dr. Patricia Herman at that event, which contrasted whole person care with conventional care, has been published in *Global Advances in Integrative Medicine and Health*. NCCIH will make an announcement soon about the award for a Whole Person Research and Coordination Center—our flagship program to develop a whole person human physiome. This Center has broad NIH support, with more than 20 NIH partners. The Whole Person Health Index, to be discussed in more detail later, is also an important initiative in that context.

One of the projects in the NIH Common Fund's Bridge to Artificial Intelligence (Bridge2AI) program focuses on salutogenesis, developing an AI-ready dataset with type 2 diabetes as a model. Ethically sourced, deidentified data for more than 1,000 participants are now available for public access. Two important papers from the NCCIH-funded force-based manipulation research networks were published recently, one on a framework and taxonomy and one on mechanisms of manual therapy. NCCIH supported a symposium on pain in sickle cell disease (SCD) as a whole person health challenge at a major SCD meeting in June.

The leaders of NCCIH, the Office of Nutrition Research (ONR), the Office of Dietary Supplements (ODS), and the National Institute for Nursing Research have published a collaborative paper on the rationale for integrating the entire continuum of human nutrition. Dr. Langevin spoke on whole person health and the nutrition continuum at an ODS seminar in June; a recording is available. A paper on the Natural Products Magnetic Resonance Database, a project co-funded by NCCIH and ODS as part of the Consortium for Advancing Research on Botanicals and Other Natural Products (CARBON) program, was recently published; this database is a freely accessible web-based resource and the largest open-access repository of its kind. ONR has published its new strategic plan, which focuses on nutrition in the context of whole person health throughout the lifespan. The National Cancer Institute and ODS are adding dietary supplement intake to existing digital dietary assessment tools—a daunting challenge but essential to a full understanding of what people are consuming. The new tools will be incorporated into the *All of Us* program. Two important Pragmatic Trials Collaboratory papers have been published recently, one on ethical considerations and one on virtual implementation of the Guiding Good Choices Program.

The NCCIH Coalition for Whole Person Health has grown to include 94 organizations. Its steering committee is doing wonderful work, Dr. Langevin said, and is continuing to raise awareness of the research NCCIH is doing.

Discussion: Dr. Kligler commended NCCIH staff for their heroic efforts to move science forward despite challenges. He said that the efforts to position NCCIH as the lead in promoting the whole person health concept, including the Coalition and the upcoming Whole Person Research and Coordination Center, may encourage Congress to find a way to help support this work through funding. NCCIH's goals are too congruent with HHS Secretary Robert F. Kennedy Jr.'s mission to not be facilitated by Congress. Dr. Langevin said that as Dr. Bhattacharya has pointed out, the budget is a result of a negotiation between the different parties involved. She is also encouraged by conversations within NIH about the importance of whole person health. She is hoping for a positive outcome.

Dr. Benveniste asked what will happen to the Whole Person Research and Coordination Center if NCCIH is no longer funded. Dr. Langevin said that if this happens, other participating ICs might pick it up. In general, because NCCIH is involved in so many collaborations, programs may not simply disappear.

Dr. Cech expressed concern about the inability to update the NCCIH website—a valuable source of evidence-based information that people rely on for many topics, including dietary supplement safety. With the recent rise in the use of dietary supplements, being able to disseminate this type of information is particularly important. Dr. Langevin agreed on the value of the website and said that NCCIH is heartbroken about what has happened to it. She hopes that at some point a consolidation of communications within NIH will make it possible to provide updated information again. However, a plan to move this forward is still being worked on.

Dr. Soumyanath pointed out that many of NCCIH's topics are unique within medicine and asked what can be done to ensure that grant applications are assessed appropriately at CSR. Dr. Langevin explained that most of NCCIH's review staff has now moved to CSR, so there are individuals there who can contribute expertise. All NCCIH can do is adapt and watch carefully how the next rounds of review go. NCCIH program staff will be able to help investigators interpret reviews and resubmit if necessary. The change in review processes is likely to be most challenging for newer investigators. Resources such as the RAND Research Across Complementary and Integrative Health Institutions (REACH) Center that can help investigators navigate the grants process will become more important than ever. Dr. Soumyanath asked whether specific expertise can be requested on panels. Dr. Langevin said it can be, but this is not the same as having dedicated in-house review panels.

Dr. Dickerson thanked Dr. Langevin and the NCCIH staff for all the work they have done to keep things moving forward. Native Americans have historically conceptualized health as including physical, mental, and spiritual aspects. Seeing how the conventional silos can be removed and how whole person health will change how clinicians communicate will be interesting, and NCCIH is central to this conversation. Dr. Langevin explained that she likes to be optimistic. Despite the current turmoil, it is encouraging that the administration's priorities on health, chronic disease, and prevention may have long-lasting impacts, including changes in how health care is delivered. It is important to be alert for opportunities to support positive developments. NCCIH can provide leadership in research on body, mind, and spirit and in implementation science—for example, through its involvement in the NIH-wide Care for Health program, which involves embedding research into primary care. NCCIH can and will make a difference.

Dr. Coulter suggested that while NCCIH is losing the ability to run its own review panels, requests for applications (RFAs) would provide another way to forcefully structure the agenda. Dr. Langevin explained that the number of RFAs is expected to go down. Dr. Coulter said that MYF appears to be a

good strategy but asked whether funding committed in this way could be taken back. Dr. Langevin said that anything is possible, but normally this would not happen. Regarding review, she added that assembly of NOFO-targeted special emphasis panels will still be possible but may be trickier. NCCIH will need to find a different way to communicate its research priorities to the community.

IV. Recognition of Council Members' Service

Dr. Langevin thanked the four former Council members who recently completed their service and noted the areas where their expertise had been especially helpful—Dr. Robert Coghill with regard to pain research, Dr. Margaret Haney for cannabinoid research, Dr. Girardin Jean-Louis for sleep research and whole person health, and Dr. Karen Sherman for basic, fundamental aspects of complementary and integrative health. Dr. Schmidt also thanked the departing Council members for their service.

V. Review and Approval of Council Operating Procedures

Dr. Schmidt presented a review of Council operating procedures. Council is required to review its procedures annually to determine whether they continue to serve NCCIH's needs. The procedures describe NCCIH's and Council members' responsibilities regarding NCCIH reports to Council, secondary review of grant applications, concepts for research initiatives, adjudication of appeals, and feedback on policy and research priorities.

NCCIH reports to Council on current scientific, budgetary, and/or legislative issues that may have an impact on NCCIH, as well as significant changes to NCCIH and/or NIH, including personnel changes.

Before each Council meeting, materials for secondary review of grant applications are provided to Council members. Both Council members and NCCIH staff may identify applications needing discussion or special Council action. Applications with no special concerns may be approved en bloc by Council. These include applications that are relevant to the NCCIH mission; have no concerns regarding human participants, animals, or biohazards; have no issues regarding inclusion of women, children, and/or minorities; come from domestic organizations; and have no associated appeals.

Applications needing special consideration are reviewed by Council in closed session. These include applications nominated for high or low program priority; those with concerns related to human subjects, animals, or biohazards; those with issues regarding inclusion of women, children, and/or minorities; foreign applications; and those with an appeal by the applicant. Council also conducts a special review of applications for additional awards to investigators who are currently receiving $2 million or more in total costs. Options available to Council as they relate to applications under consideration include concurring with the scientific review group; recommending an application for high or low program priority; deferring for additional information, later consideration, or additional input from the review group; recommending a change in scope, budget, or duration of support; and not recommending the application (which removes it from consideration for funding). Some administrative decisions following Council do not require Council recommendations, including change of principal investigator, change of institution by the principal investigator, applications deferred for re-review, and administrative supplements. NCCIH staff informs Council of these and other staff actions even though Council concurrence is not required.

ICs may streamline en bloc concurrence to expedite funding actions through the Expedited En Bloc Concurrence process. Eligible applications must be peer reviewed and assessed as "scientifically meritorious"; come from a domestic applicant; have no unresolved human, animal subjects, biohazards, or inclusion issues; and be relevant to NCCIH's mission. They may also require the availability of time-limited unique resources. EEC occurs 6 to 8 weeks prior to the regular Council meeting. All regular

Council members may vote, applications must receive at least two votes for and no votes against concurrence, and the applications will then be eligible for a funding decision and processing. EEC actions are communicated to Council during its regular meeting.

In exceptional situations, the NCCIH director has the authority to act based upon extenuating circumstances. The director may consult with a subset of Council members, and actions will be documented and reported to Council.

Concepts for research initiatives may originate from staff, the scientific community, constituency organizations, or Congress. NCCIH staff prepares concept summaries for Council review in open session. Council votes on each concept and may recommend approval, modification, deferral, or disapproval. Approved concepts may lead to one or more funding opportunities. In line with a recent update in procedures, ICs now first formulate the idea for a concept, which is submitted to NIH leadership for approval. After approval, the concept is presented to Council for clearance. Following clearance by Council, the concept is published in Grants.gov in the form of a forecast report, and IC staff start developing NOFO(s) focusing on the scientific topic outlined in the concept. Published forecasts of concepts give potential applicants a heads up and allow them to be aware of upcoming initiatives and to get ready to prepare applications.

An applicant may appeal the assessment of their grant application by a scientific review group. Relevant criteria for an appeal include factual errors that might significantly change the score, reviewer bias, conflicts of interest, and lack of scientific expertise on the review panel. Criteria that are not relevant include errors of omission and differences of scientific opinion. If program and review staff agree that an appeal is justified, the grant is deferred for re-review. If staff disagree, the Center's appeal officer adjudicates, and if the appeal officer supports the appeal, it is sent to Council for resolution. If an appeal is judged as unjustified, the applicant's appeal letter is provided to Council as an information item only.

Generally, Council members serve as a resource to develop, recommend, and set policy and research priorities. Special Council working groups, such as the working group on spiritual health, may be formed to examine and address critical scientific or policy issues of importance to NCCIH and its constituencies.

A motion for approval of the Council Operating Procedures was moved and seconded and has been approved.

VI. Advisory Council Working Group on Spiritual Health—Final Report

Dr. Benveniste, chair of the Council working group on spiritual health, presented the group's final report. Dr. Lynne Shinto, Professor of Neurology at Oregon Health & Science University, a former Council member and ad hoc member of the working group, joined Council for the discussion of the report.

The purpose of the working group was to evaluate whether the concept of spirituality should be integrated into NCCIH's whole person health model, and if so, to determine the best way to achieve it. Dr. Benveniste thanked the working group members, Drs. Brolinson, Coghill, Dickerson, Lavretsky, Sibinga, Soumyanath, and Shinto, for their hard work and thoughtful deliberations, and Dr. Schmidt, executive secretary of the working group, for her support.

Dr. Benveniste said that the literature includes many different definitions of spirituality and religion. The working group chose to focus on the definition of spirituality proposed in 2014 by Puchalski et al. and the explanation of the difference between spirituality and religion proposed by Koenig et al. in 2023.

- **Spirituality:** "Dynamic and intrinsic aspect of humanity through which persons seek ultimate meaning, purpose, and transcendence, and experience relationship to self, family, others, community, society, nature, and the significant or sacred. Spirituality is expressed through beliefs, values, traditions, and practices."
- **Spirituality vs. Religion:** Religion is "the phenomenon wherein a system of beliefs and practices unites adherents into a community with a shared vision for attaining union with, or the experience of, the divine or transcendent," whereas spirituality is defined as "a set of individual beliefs, practices, and ways of being that are intended to assist in attaining union with, or experience of the divine or transcendent."

Statistics from the Pew Research Center from 2023 indicate that 70 percent of U.S. adults identify as being spiritual and 21 percent as neither spiritual nor religious. Gallup data from the same year indicate that 47 percent of U.S. adults say they are religious, 33 percent say they are spiritual, and 18 percent say they are neither spiritual nor religious.

NCCIH has had a long-standing interest in spirituality, dating back to the early 2000s, when a talk on spirituality and health was presented as part of the NCCIH distinguished lecture series. Spiritual practices were mentioned in the 2021–2025 NCCIH strategic plan in a graphic on the primary therapeutic input of approaches within NCCIH's portfolio. Responses to NCCIH's 2022 request for information on identification of a set of determinants for whole person health showed interest in examining spiritual health as a component of whole person health. An August 2023 message from NCCIH's director invited comments on including spirituality in a fuller picture of research on whole person health. The working group was then formed in early 2024.

NCCIH's charge to the working group was to address these questions:

- How do spiritual practices and spiritual health fit in the concept of whole person health? Should "spiritual" be a separate whole person health domain?
- What research gaps need to be addressed with respect to spiritual practices (as a therapeutic input or independent variable) and spiritual health (as a therapeutic output or dependent variable)?
- What research methods are needed to address these gaps?
- Under what research category would spiritual health best fit? Mind and body connection? Positive health outcomes? Whole person health? More than one?

The working group met several times and invited expert guest speakers to present information on the state of the field. The speaker presentations informed and inspired the group's deliberations.

In response to the question of whether "spiritual" should be a separate whole person health domain, the working group noted that the whole person health model for an individual currently includes biological and psychological factors, which are measurable, and social and environmental factors, which are accepted as determinants of health, but the model does not routinely incorporate spiritual health/well-being as a separate factor. The group concluded that "spirituality" could be considered a domain of the individual whole person health model but with some important considerations and recommendations:

- Well-designed research is needed to evaluate the role of spirituality to justify its inclusion as a domain.
- Currently, most research studies on spirituality and health are confounded and biased, as they often overlap with mental health concepts and include tautological associations rather than cleanly formulated hypotheses.

- Most existing research studies consider religiosity and spirituality together and do not specifically assess spirituality.
- Emphasis should be placed on both the positive and negative effects of spirituality and religion to more objectively assess their impact on health.
- It is important to recognize that about 20 percent of U.S. adults do not consider themselves religious or spiritual, suggesting that the spiritual domain may not be relevant to everyone.

The spiritual domain could be included in the conceptual framework of whole person health, similar to the biological and psychological domains, if (1) the spiritual interventions studied are well defined, standardized, and reproducible and are studied in comparison to controls, and (2) the spiritual outcomes studied are measurable, have biomarkers, and include assessment of both efficacy and adverse effects. Domains can interact as mechanisms or covariates for interventions. For example, an analgesic might relieve chronic pain (biological domain), resulting in greater inner peace and feelings of universal unity (spiritual domain), resulting in less anxiety or depression (psychological domain).

Scientific evaluation of the spiritual domain as an aspect of whole person health could include considering it

- As a dependent variable (output) when investigating the ability of interventions to improve spiritual health/well-being by directly targeting the spiritual domain or targeting one of the other domains
- As the independent variable (input) when spiritual interventions are used to investigate changes in other domains (Research of this type is already in progress with regard to religiosity and spirituality considered together but not for spirituality separately.)
- As both independent and dependent variables when spiritual interventions are used to investigate changes in the spiritual domain

Critical research gaps that need to be addressed for future studies include the following:

- There is a need for unbiased measures of spiritual health/well-being.
- There is a need for scales that can capture and measure spiritual distress.
- Metrics of spirituality separate from "religiosity" need to be developed.
- Spirituality-based measures are needed for populations with specific sets of beliefs. There is a gap in knowledge regarding many aspects of religiosity/spirituality such as belief values and practices that are not well characterized.
- The scientific rigor of research in the spiritual domain needs to be enhanced to the level required for studies in the biological and psychological domains.

Dr. Benveniste identified these critical needs for future studies:

- Spiritual interventions need to be well defined, standardized (even if tailored to individuals), reproducible, and evaluated versus controls.
- In general, spiritual interventions need to be generalizable to the population as a whole, cross-culturally acceptable/applicable to all, and respectful of the diversity of spiritual and/or religious attitudes/affiliations of participants. However, some interventions need not be generalizable if a study is developed for a population or group of individuals with specific beliefs (e.g., Native American people, Christians, Buddhists).
- Spiritual outcomes need to be defined and measurable.

- Both efficacy and adverse effects must be evaluated for spiritual interventions, as they are for other domains and interventions.

Dr. Benveniste noted that adverse effects need not be in the same domain as the efficacy outcome. For example, a spiritual intervention may have a psychological or biological adverse effect. However, it is also important to consider what a "spiritual adverse effect" may be.

Major challenges in the field in terms of addressing gaps in research methodology include:

- Developing methods to separate religion and spirituality (which is challenging because many spiritual practices come from specific religions).
- Developing methodology to define spiritual well-being or health in ways distinct from mental health parameters.
- Defining parameters and standards for spiritual health as an outcome measure.
- Embracing diversity within the exploration of spirituality and spiritual interventions.
- Designing strategies to tailor spiritual interventions to individuals.
- Allowing for individual variability in understanding and defining spiritual health.
- Recognizing that not everyone agrees that spiritual health exists or that spirituality is important to human health. Therefore, it is especially important to ensure the scientific credibility and rigor of including spirituality as a domain for research. This may involve developing best practices for studies of spiritual health.

The working group concluded that spiritual health might fit in the mind and body connection or whole person health research categories or in more than one category but not in the positive health processes category.

The working group's first-step recommendations are to

- Arrive at consensus on spirituality measurements and how to use them (drawing on the work of Dr. Harold Koenig of Duke University, one of the experts who spoke at a working group meeting)
- Hold a workshop on spirituality research that includes all stakeholders, including NIH, the Department of Veterans Affairs, clinicians, chaplains, neuroscientists, and others
- Promote spirituality research in a stepwise fashion, first with spirituality as a covariate, then studying spirituality as an outcome, and then focusing on mechanisms of spirituality-based interventions
- Encourage the field to study both positive and negative effects of spirituality and develop consensus on the measures to be used for each
- Encourage the field of mind-body therapies to use spirituality scales to measure changes in spirituality along with changes in health
- Implement new studies of the underlying mechanisms, similar to the neuroscience of contemplative research

Discussion: Dr. Langevin thanked Dr. Benveniste for her well-crafted report, and members of the working group shared their thanks as well. Dr. Dickerson noted that spirituality is a challenging topic, given the diversity of people's experiences and views and the different communities they represent. Dr. Langevin said that NCCIH has been dancing around the concept of spirituality for a long time, always with a sense of its complexity and difficulty, but it took the efforts of this group to move toward actionable recommendations for research.

Dr. Langevin asked why "positive health processes" is not a category where spirituality would fit. Dr. Benveniste said that this decision reflected the group's united sense that spirituality and religion can have both positive and negative effects. She noted, however, that members of the working group may have been speaking from different perspectives because a common vocabulary on these concepts has not yet been developed. Dr. Dickerson said that the relationship between spirituality and positive health processes could be a hypothesis for a study. Dr. Langevin suggested that someone might move from a state of spiritual distress to spiritual well-being over time. NCCIH would be interested in knowing what promotes this type of positive process and measuring it over time. Dr. Soumyanath said it is also important to recognize that a substantial portion of the population does not consider spirituality significant. Dr. Sibinga said that some of the expert speakers found it challenging to differentiate between positive and negative aspects of spirituality. Dr. Langevin said that similar considerations apply to other activities as well; for example, exercise can lead to injury as well as beneficial effects. The potential for bidirectional effects is important. Dr. Shinto said that some of the religiosity and spirituality measures that experts presented to the working group seemed biased toward the positive. New measures may need to be created. She also noted that the Pew data indicate that religiosity has decreased over time. Some people who were once spiritual or religious may have changed their views in response to negative experiences.

Dr. Coulter asked what constitutes a spiritual intervention and how providers need to be trained to do it. Dr. Benveniste said that this question is important, but the gaps in knowledge and methodology, including the need for development of measures and the separation of religion from spirituality, are so great that the working group was not ready to address it. Dr. Benveniste said that one of the guest speakers, Dr. Luana Colloca of the University of Maryland, reported that she was able to separate religiosity from spirituality in studies of responses to a pain stimulus, which is a step forward though not an intervention. Tools are needed before interventions can be developed.

NCCIH Deputy Director Dr. David Shurtleff said that insights from contemplative science—an interdisciplinary field that studies the effects of contemplative practices, like meditation and mindfulness, on the mind, brain, and body—may be helpful. Some of the constructs studied in this field relate to spirituality. They are measurable, have some psychological underpinnings, and may relate to brain mechanisms. Dr. Benveniste agreed that considering contemplative practices may help the study of spirituality move forward. This is mentioned in the last of the working group's recommendations. Dr. Soumyanath said that brain measures would be helpful for understanding mechanisms. She also explained that the working group did not get as far as defining interventions but did emphasize the importance of interventions being reproducible and well defined.

Dr. Langevin asked whether the concept of resilience came up in terms of its relationship to spiritual growth. She said that in the Trans-NIH Resilience Working Group, there has been discussion of spiritual growth in people with terminal illnesses, leading to resilience to illness or impending death. Dr. Benveniste said that Dr. Colloca presented data on people with chronic pain in which a resilient subgroup of patients seemed to tolerate pain better, perhaps because they were more hopeful.

Dr. Sibinga said that a variety of adjacent areas of research may help to inform research on spirituality and health, including psychedelic research. Dr. Shinto added that psychedelic researchers have measures of altered states, including a measure of transcendence or mystical experience, that can also relate to religiosity and spirituality. It may be worthwhile to examine the research in this area to avoid reinventing measures.

Dr. Lavretsky said there is a disconnect between the old science of spirituality and the new science of psychedelics. Bringing together all the stakeholders and learning from each other would be informative.

Many measures of spirituality and religiosity already exist, but they don't overlap with the newer measures being developed for psychedelic research. There is also a disconnect between contemplative science and both the spirituality and psychedelic research fields. A common language for all these areas of research is needed. Dr. Lavretsky also noted that despite 50 years of research, most spirituality studies are still observational and don't reach definite conclusions. Dr. Langevin said it sounds like a workshop is needed, and Dr. Lavretsky agreed.

Dr. Langevin said that in developing the whole person health domains, NCCIH looked at how the recognized domains of human health relate to planetary health. She asked how the planet fits in with spirituality. For example, American Indian/Alaska Native spiritual practices don't distinguish between the health of people and the health of the world. Dr. Lavretsky mentioned the concept of unity consciousness, related to a therapeutic sense of oneness, that enters into both contemplative science and psychedelic research; the planetary health concept could relate to it. Older research that involved praying for another person's health could also be relevant because it involves connectedness. Dr. Benveniste said that the psychedelic experience can be an extreme version of a spiritual experience. Dr. Lavretsky said that people may have a spiritual experience of God's presence under the influence of a psychedelic but return to atheistic beliefs afterward. It is important to recognize that there is a spectrum of beliefs, she said. Dr. Shinto said that measures of connectedness used in psychedelic research show that the phenomenon of connectedness with people or the environment can linger past the end of the dosing time, perhaps reflecting a change in perception. Dr. Lavretsky mentioned research that found similar changes in brain physiology in response to phenomena that involved connections to art or meditations related to the cosmic soul. However, connectedness to nature was processed in a different way. Research of this type might provide a better understanding of the different aspects of transcendence. Dr. Dickerson said that some of the scales related to connectedness used in studies of Native American culture have questions along these lines related to planets, nature, and even ancestors.

Dr. Langevin closed the discussion by agreeing with the working group that a workshop is needed and thanking them for their work. Dr. Schmidt also thanked the working group and the guest speakers who participated in their meetings.

VII. Triennial Report on Clinical Studies and Representation

Dr. Kevin McBryde, acting director of the NCCIH Office of Clinical and Regulatory Affairs, presented the triennial report on compliance with NIH policy on inclusion of women and minorities in clinical research. He explained that NIH established a policy for inclusion of women in clinical research in 1986, and the policy was formalized by Congress for both women and minorities in 1993. There are multiple strategies for ensuring compliance, including peer review of recruitment plans, Council review of aggregate data, second-level Council review of applications with inclusion issues, program staff review of inclusion information in grant applications, and monitoring of actual enrollment in annual progress reports provided by principal investigators. The goal of the policy is to ensure that research findings are generalizable to the U.S. population, not to satisfy a quota. The actual populations studied depend on the scientific question and the prevalence of the condition under investigation in different subpopulations.

This report presents aggregate data from investigators' annual progress reports for 2022, 2023, and 2024, for domestic enrollment only, and for both extramural and intramural research projects. All NIH-defined clinical research and Phase III trials are included.

Approximately 250 inclusion enrollment reports are submitted to NCCIH each year, with about half reporting human subjects enrollment during the year. Very few NCCIH-funded studies recruit only female or male participants. All of the Phase III clinical trials for 2022 through 2024 were extramural, there were

about a dozen trials, and all included both female and male participants. For extramural and intramural NIH-defined clinical research, between 35,000 and 50,000 participants were enrolled each year, with a close to equal split between male and female participants, and only a small number of participants of unknown sex. Between 450 and 650 participants were enrolled in intramural clinical research each year, with about 56 percent female. For Phase III clinical trials, there was a sharp drop in enrollment between 2022 and 2023 because several trials were completed; about 45 to 50 percent of participants were female.

Total minority enrollment in extramural and intramural NIH-defined clinical research was about 30 percent in each of the 3 years. Less than 1 percent were American Indian/Alaska Native, 2 to 4 percent Asian, 16 to 20 percent Black/African American, less than 1 percent Native Hawaiian/Pacific Islander, and about 1.5 percent more than one race. For the intramural program, total minority enrollment was higher, at about 60 percent, with much higher enrollment of Asians (12 to 15 percent) and a slightly higher percentage of Black/African American participants (30 to 35 percent). For Phase III clinical trials, the average minority enrollment was about 30 percent, with less than 1 percent American Indian/Alaska Native, 2 to 4 percent Asian, 12 to 24 percent Black/African American, less than 1 percent Native Hawaiian/Pacific Islander, and about 2 percent more than one race. Total enrollment of Hispanic/Latino participants in NIH-defined clinical research in 2022–2024 was between 6 and 8 percent for extramural clinical research. For the intramural program, it was 9 to 10 percent, and for Phase III trials about 9 to 15 percent.

Overall, Dr. McBryde said, during 2022 to 2024, the enrollment of female participants, members of racial minority groups, and Hispanic/Latino participants was generally stable at about 50 percent, 30 percent, and 6 to 8 percent, respectively. He compared this with 2020 census data, which showed 51 percent females, 24 percent racial minorities, and 18 percent Hispanic/Latino. The data will be uploaded to the Research, Condition, and Disease Categorization (RCDC) website.

Discussion: Dr. Dickerson said that he does not believe there are any studies on strategies for recruitment of Native Americans. He has been part of teams that have developed recruitment approaches for studies focused exclusively on Native Americans, but there is a need to study recruitment more broadly. He said he would be happy to help with research of this type. Recruitment within Native American communities generally requires a community-based approach and relationship building, he said. Dr. Langevin said that although it's important to have specific initiatives within communities, research involving Native Americans should not be segregated. It is important for American Indian/Alaska Native participants to be included in all clinical research across the board.

VIII. The Whole Person Health Index (WPHI)—A Patient-Focused Tool Assessing a Person's Overall Health

Dr. Langevin provided an update on the development of the Whole Person Health Index (WPHI). The goal was to develop a brief, succinct, patient-reported measure that captures the main components of health. The process started with a request for information, input from the community, and internal discussions, and continued with a collaboration with the Centers for Disease Control and Prevention (CDC), which desired a similar measure, with no more than 10 questions, for the National Health Interview Survey (NHIS). Working together, NCCIH and the CDC developed a set of nine questions, each of which asks respondents to rate a specific aspect of their health on a 1 to 5 scale, where 1 is poor and 5 is excellent. The nine topics are health in general, quality of life, social and family connections, diet, physical activity, ability to manage stress, sleep, meaning and purpose, and health management. The individual questions can be combined on a graph that individuals can use to get a sense of their own health or start a discussion with a health care provider. The questions can also be useful in research to

follow an individual over time. For example, if the total score for the 9 questions (the WPHI value) is 18 at Time 1 and 31 at Time 2, that would indicate an improvement in health over time. If the total score decreased, it would indicate declining health.

When this measure was first developed, NCCIH did not know whether there would be interest in using it. It turns out that there is a great deal of interest. CDC's National Center for Health Statistics is incorporating the WPHI in the 2025 NHIS, which will include about 27,000 U.S. adults, and the index may be used again in subsequent years. The WPHI will also be added to the *All of Us* research program's participatory study starting this year and will be administered three times as part of the study's questionnaires. *All of Us* has more than 800,000 participants and collects a very large number and variety of measurements. All its data are open source. There will be many opportunities to collect information on how WPHI values change over time and how they relate to the other measures collected in *All of Us,* including medical records, Fitbit records, genotyping arrays, physical measurements, and responses to other study questionnaires. The WPHI is also of interest to the NIH Clinical Center, starting with the NCCIH-led Pain Research Center. Pain is not an isolated symptom; obtaining data on many aspects of the patient's life is important, and the WPHI will help with this.

NCCIH is encouraging investigators to use the WPHI as an additional outcome in clinical studies. This will enable pilot data to be collected before the WPHI can be used as a primary outcome measure. The WPHI may be particularly useful in studies of nonpharmacologic interventions that may lead to small improvements in multiple health outcomes. It can show how the overall impact of the intervention might add up, even if changes in single outcomes are relatively small.

The WPHI questionnaire is available, free, and easy to use. Information about it is currently provided on the NCCIH website. A paper is being submitted to *Global Advances in Health and Medicine* and should be published soon. Power calculations will eventually be available and will make it possible to use the WPHI as a primary outcome.

Discussion: Dr. Dickerson said he plans to use the WPHI immediately. It touches on cutting-edge topics including sleep, diet, and spirituality. He asked whether it is difficult to create the diagram of WPHI scores shown on Dr. Langevin's slides. Dr. Langevin said the diagram is simply a radar plot, but the data could also be presented in other ways. *All of Us* focus groups will compare different graphics to see which is most intuitive. NCCIH has already received feedback that the initial way of presenting the scale of 1 to 5, where 1 was the best, needed to be changed to the other way around, with 5 as the best score. Dr. Dickerson said state policymakers may like the WPHI because of its simplicity. Dr. Benveniste asked how the WPHI compares with Patient-Reported Outcomes Measurement Information System (PROMIS) measures. Dr. Langevin explained that PROMIS is large; it can't be completed in a few minutes. For the WPHI, NCCIH wanted an instrument that people could fill out quickly, for example in a doctor's waiting room. In the meeting chat, Dr. Kligler said that the WPHI is one of NCCIH's most important contributions, and Dr. Linderman agreed that it is a great tool. Dr. Lavretsky said that it would be helpful to include the WPHI as an extra outcome measure in studies that are primarily focused on a narrower outcome. Dr. Langevin said it was enlightening to see how much interest there is in the tool across NIH.

IX. Concept Updates

Updates were presented on two concepts that Council had previously approved.

Complementary and Integrative Health Approaches To Promote Whole Person Health Restoration via Emotional Well-Being Mechanisms

Dr. Erin Quinlan, an NCCIH program director, explained that one of the objectives in NCCIH's strategic plan involves fostering research on health promotion and restoration. Health restoration is defined as the process by which individuals move to a healthier state, and it is complex and multifactorial. As Dr. Langevin discussed earlier, the WPHI can be used to assess whole person health restoration, which is reflected by positive changes in the index over time.

Emotional well-being is also a priority for NCCIH. NCCIH and other NIH ICs have funded six research networks in this area that have grown this field and developed valuable resources for the research community.

Very few studies have assessed the impact of complementary and integrative health approaches on emotional well-being mechanisms and the potential for restoring whole person health. To help fill this gap, NCCIH has proposed a whole person health restoration initiative that would support highly innovative research programs to

- Advance understanding of how complementary and integrative health approaches impact emotional well-being and the extent to which engagement of emotional well-being mechanisms impacts whole person health restoration
- Include prospective mechanistic clinical trials of emotional well-being target engagement and association with the WPHI
- Include multisite trials to assess fidelity of intervention delivery and feasibility across sites
- Ultimately lead to efficacy or effectiveness trials of health restoration that assess whether the impact is mediated through emotional well-being mechanisms

Studies should include a complementary and integrative health approach, an emotional well-being mechanistic target, and the WPHI.

The first grant opportunity forecast for this initiative is now available at NOT-AT-25-006. It is titled "Mind and Body Interventions to Restore Whole Person Health via Emotional Well-Being Mechanisms." NCCIH hopes to have a related NOFO published soon, with a fall submission deadline, and anticipates having additional funding opportunities related to this initiative. The original concept, which includes some information not captured in the forecast, is available on the NCCIH website.

Discussion: Dr. Benveniste asked how genetically determined diseases might fit in. Dr. Quinlan said that she could not speak to the specific scope of the NOFO, which has not yet been published, but in general, whole person health restoration and emotional well-being can certainly be assessed in the context of genetic disorders. Dr. Benveniste noted that the trajectories of some genetic disorders rapidly lead to death, and these conditions might be exceptions to the whole person health model. Dr. Lavretsky noted that in some instances, people can have fulfilling lives despite genetic disorders and explained that many diseases are partially genetically determined. Dr. Langevin said that for many diseases, genetic influences are relatively small compared to other determinants; these diseases do not need to be excluded. Dr. Shurtleff added that other factors may modulate a genetic disorder, affecting the quality of life. Efforts can be made to improve overall well-being in people with such disorders. Dr. Langevin said that individuals with genetic predispositions may be more sensitive to some types of stress.

Dr. Benveniste said that the word "restoration" is what she stumbles on; in some cases, health cannot be completely restored. Dr. Langevin agreed that once a certain point is passed, pathology is fixed. With

genetic diseases, this may happen earlier. Early intervention is desirable to try to prevent permanent damage.

The Role of Hormesis in Whole Person Health

Dr. Wendy Weber, acting director of the DER, gave a brief update on this concept, which received Council concurrence in March. The concept was included in the agenda for this meeting to help inform the scientific community that this concept had been approved. However, more time is needed before staff will be ready to make a full presentation on the next steps for this concept. A detailed presentation will be made at a future Council open session. The published concept is available on the NCCIH website.

X. Acknowledgment of Public Comments

Dr. Schmidt said that three public comments had been received. They have been shared with Council members and selected NCCIH staff. One was from Dr. Dave James, a naturopathic physician, who commented on the inclusion of licensed naturopathic doctors as providers under Medicare. The second was from Dr. Richard Goldberg, a nutritionist, who rebutted the assertion that nutritional supplements have few if any benefits. The third comment, by Ms. Elizabeth Meeks, provided suggestions on expanding and refining NCCIH resources and research on yoga and complementary therapies. 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 a Council meeting. All comments must be under 700 words, which is consistent with a 5-minute oral presentation. Comments will be provided to Council members and acknowledged during the open session of the meeting.

XI. Adjourn

Dr. Schmidt thanked NCCIH staff, whose work made this meeting possible, and the Center for Information Technology at NIH, whose help was essential in setting up the event as a Microsoft Teams Town Hall meeting.

Dr. Langevin expressed her thanks to the NCCIH staff as well, with a shout-out to former NCCIH colleagues who are much missed as well as staff currently at NCCIH who are currently doing the work of two or three people. She announced that the next Council meeting will be held on September 19 and is planned as an in-person event.

The meeting adjourned at 4:30 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	Helene M. Langevin, M.D. Chairperson National Advisory Council for Complementary and Integrative Health