

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH
NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES**

**MINUTES OF THE ONE HUNDRED SIXTY-FOURTH MEETING OF THE
NATIONAL ADVISORY ENVIRONMENTAL HEALTH SCIENCES COUNCIL**

September 13, 2021

The National Advisory Environmental Health Sciences Council convened the open session of its one hundred sixty-fourth regular meeting on September 13, 2021 as a Zoom virtual meeting. The closed session of the meeting was held earlier in the day September 13.

The meeting was open to the public on September 13, 2021 from 11:45 p.m. to 5:07 p.m. In accordance with the provisions set forth in Section 552b(c)(4) and 552b(c)(6), Title 5, U.S. Code and Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), the meeting was closed to the public on September 13, 2021 from 11:00 a.m. to 11:30 a.m. for consideration of grant applications. Notice of the meeting was published in the *Federal Register*. Dr. Rick Woychik presided as Chair.

Participating Council Members

William Cibulas, Jr., PhD (*ex officio*)
Suzanne Fitzpatrick, PhD (*ex officio*)
Andrew Geller, PhD (*ex officio*)
Lynn Goldman, MD, MPH
Irva Hertz-Picciotto, PhD
Terrance Kavanagh, PhD
Katrina Korfmacher, PhD
Edith Parker, DrPH
Trevor Penning, PhD
Marla Pérez-Lugo, PhD
Brad Racette, MD
Robyn Tanguay, PhD
Karen Vasquez, PhD
Robert Wright, MD, MPH

NIEHS Staff

Kathy Ahlmark
Sara Amolegbe
David Balshaw, PhD
Martha Barnes
Linda Bass, PhD

Sharon Beard
L. Michelle Bennett, PhD
Brian Berridge, DVM, PhD
Abee Boyles, PhD
Danielle Carlin, PhD
Toccaro Chamberlain
Jennifer Collins
Gwen Collman, PhD
Yuxia Cui, PhD
Mary V. Diaz Santana, PhD
Christie Drew, PhD
Chris Duncan, PhD
Anika Dzierlenga
Gary Ellison, PhD, MPH
Benny Encarnacion
Amanda Garton
Nidhi Gera, PhD
Kimberly Gray, PhD
Jenny Greer
Janet Hall, MD, MS
Astrid Haugen
Michelle Heacock, PhD
Heather Henry, PhD
Jon Hollander, PhD
Mike Humble, PhD
Bonnie Joubert, PhD
Helena Kennedy
Alfonso Latoni, PhD
Cindy Lawler, PhD
Lindsey Martin, PhD
Jacqui Marzec
J. Patrick Mastin, PhD
Kim McAllister
Liz McNair
Carolina Medina
Parris Milly
Nathan Mitchiner
Rosemary Moody
Srikanth Nadadur, PhD
Liam O'Fallon
Kristi Pettibone, PhD
Nicole Popovich
Alicia Ramsaran
Lingamanaidu Ravichandran, PhD
Les Reinlib, PhD
Jim Remington

Carol Shreffler, PhD
Thad Schug, PhD
Dan Shaughnessy, PhD
Varsha Shukla, PhD
Melissa Smarr, PhD
Robin Stanley, PhD
Bill Suk, PhD, MPH
Laura Thomas, PhD
Claudia Thompson, PhD
Brittany Trottier
Steven Tuyishime, PhD
Fred Tyson, PhD
Mitch Williams
Leroy Worth, PhD
Rick Woychik, PhD
Demia Wright, MPH
Darryl Zeldin, MD

Members of the Public Present

José Cordero, MD, MPH, University of Georgia (former Council member)
Jodie Fleming, PhD, CSR
Ernie Hood, Bridport Services, LLC
Helene Langevin, MD, NCCIH
Yvonne Maddox, PhD, TAThornton Foundation
Craig Newschaffer, PhD, Penn State University
Mark Pitcher, PhD, NCCIH
Carmen Velez Vega, PhD, MSW, University of Puerto Rico

I. Call To Order and Opening Remarks

NIEHS and NTP Director Rick Woychik, Ph.D., welcomed attendees and called the meeting to order. He asked Council members in the Zoom call to introduce themselves. Acting DERT Director Gary Ellison, Ph.D., went over some of the logistics for the meeting, including the conflict of interest statement.

II. Consideration of June 2021 Meeting Minutes

Approval of the June 2021 meeting minutes was moved and seconded, and Council voted to approve the minutes, with all in favor.

III. Report of the Director, NIEHS

Dr. Woychik briefed Council on Institute developments since the June 2021 Council meeting.

He began his report with an update on budgetary matters. The FY2022 appropriations process has started in Congress. On July 29, the House passed the FY2022 Appropriations Minibus. It has NIEHS at a mark of approximately \$942 million, which represents an increase of approximately \$127 million over the FY2021 enacted level. It includes an increase of \$100 million specifically for climate change and health research at NIH and has additional language specific to NIEHS for harmful algal blooms and Parkinson's Disease. Ultimately, the House is recommending a budget with the NIH allocation at \$49.6 billion, an increase of \$6.7 billion over the FY2021 enacted level. The bill also includes \$3 billion to establish the Advanced Research Projects Agency for Health (ARPA-H) to accelerate the pace of scientific breakthroughs for diseases such as ALS, Alzheimer's disease, diabetes, and cancer. The Senate is continuing its work and will resume its markup of FY2022 bills after its August recess. Although overall the budget is encouraging, it is not final until Congress passes the FY2022 budget. There is strong bipartisan support for the NIH in Congress.

Dr. Woychik described several recent Congressional briefings and stakeholder engagement opportunities, as well as leadership confirmations in the new administration. He discussed the five NIEHS leadership values: workforce, innovation, collaboration, communication, and distributive leadership.

Working from the three themes contained in the NIEHS 2018-2023 Strategic Plan, Dr. Woychik described several recent accomplishments and developments. Under Theme One, Advancing Environmental Health Sciences, he mentioned several science advances, publications from DIR, DNTP, and DERT. Under Theme Two, Promoting Translation – Data to Knowledge to Action, he provided several examples of programs supporting the theme, including the Pandemic Vulnerability Index, the NIEHS COVID-19 Mouse Model, the RADx-rd Initiative, and the Women's Health Awareness Community Resiliency, Environmental Action, and Collaborations for Health (REACH) Equity program. He described the Climate Change and Health RFI, which was released July 30, 2021, and alluded to the NIEHS Environmental Career Worker Training Program and the Justice40 Initiative. Under Theme Three, Enhancing EHS Through Stewardship and Support, Dr. Woychik discussed the NIH UNITE Initiative. Over the next six months, UNITE actions and priorities will include:

- Listen and learn from a wide variety of stakeholders, including those who are not frequently engaged
- Develop actionable data dashboards that track and provide visualizations of intramural workforce and NIH HD/MH/HE research investments
- Develop programs to spur institutional culture change in support of inclusivity and equity

Turning to NIEHS staff matters, Dr. Woychik recognized the retirement of Executive Officer Chris Long and noted other leadership changes within the Office of Management. He provided staff updates as well, along with several recent awards and recognition for NIEHS staff members and fellows, including the 17 early-career scientists who won the NIH Fellows Award for Research Excellence, the FARE Awards.

Dr. Goldman commented that she was struck by the quality of the new external funding applications, particularly the work bringing together community work with molecular epidemiology and toxicology, along with much work on climate and health. Dr. Woychik thanked her for her comments and agreed that the institute is flourishing, and the science is progressing.

Dr. Hertz-Picciotto congratulated Dr. Woychik on bringing together the seven ICs for the climate initiative. She described it as a turning point in trans-NIH cooperation. She said she was impressed with the breadth of the funding applications. Dr. Woychik noted that the current climate change and health efforts are the culmination of many years of efforts, and currently involve more than 100 different members from the various ICs in the working group. He lauded the power of joining forces to deliver better science across the NIH.

Dr. Kavanagh praised the proactive stance taken by Aubrey Miller and other NIEHS leadership members with respect to disaster response research.

IV. Maintaining and Enriching Environmental Epidemiology Cohorts to Support Scientific & Workforce Diversity Concept

Dr. Melissa Smarr of the Population Health Branch briefed the Council about the concept.

She provided information about the background of the existing cohort maintenance program, including its goals and objects, a summary of the cohorts, outcomes, and exposures, and highlights from the program, which began in 2016.

She detailed proposed revisions to the program. Overall, there is to be greater emphasis on scientific and workforce diversity. Also, the intent is to:

- Support infrastructure to expand cohort enrollment and enhance outreach activities, with –
 - Underrepresented populations (where relevant)
 - Community partnerships
- Refine the data science element via
 - Data preparation and broader data sharing

- Develop opportunities to support collaborative science projects to utilize the resources
- Establish explicit and realistic evaluation metrics

The proposed mechanism for new funding for the program is U24, with an RFA issued for 3 years. 5-6 awards are anticipated. The total cost for the program is \$250,000 in direct costs per award per year for 5 years, or \$2.5 million annually. The earliest start date would be December 2022.

Dr. Goldman was the first Council discussant. She said that she and Dr. Hertz-Picciotto, the second discussant, agreed that the environmental epidemiology cohort (EEC) program is very important for NIEHS and should serve as a model for all of NIH. The existing cohorts are critical for understanding how various factors such as genetics, the environment, and social factors such as racism impact health. It is important to maintain the cohorts over the long term, she noted. She approved of adding the issue of scientific and workforce diversity. She expressed a concern about how it would be possible to actually implement the goal of making the workforce more diverse. She suggested bringing more consistency to the cohorts, perhaps by learning from the ECHO program (Environmental Influences on Child Health Outcomes).

Dr. Hertz-Picciotto, the second Council discussant, noted that maintaining EECs is difficult, particularly given the evolving science around the concept of developmental origins of health and disease, with outcomes much later in life. She suggested that the concept proposal could be strengthened by engaging communities more deeply in the direction of the science. She said there is great value in investing in the science long term, as it is evolving over the years, and so engaging with the communities over the long term will be important in addressing health disparities and environmental justice. Dr. Goldman added that it will be important to engage with communities over the long term so as to renew consents when that is appropriate, citing the example of the Havasupai tribe's experience.

Dr. Pérez-Lugo expressed her support for research activities between research grants. She asked Dr. Smarr to expand on what she saw as possible with community engagement activities, particularly between projects. She also asked about the involvement of the IRB community in the design of the concept. Dr. Smarr replied that some of what is being envisioned is already being supported by the R24 in some of the cohorts. In some cases, community participants choose the topics being researched, and sometimes are hired as community-based researchers.

Dr. Wright asked that Asian-Americans be explicitly recognized in the RFA.

Dr. Penning said that he was very supportive of the initiative. He noted the importance of community engagement in terms of return of information to participants. It should be

more than simply providing data to individuals but should involve reporting to the community itself.

Dr. Ellison called for a motion and second to approve the concept. Dr. Pérez-Lugo so moved, and Dr. Wright seconded the motion. Council voted in favor of the motion to approve the concept.

V. Whole Person Health

Dr. Helene Langevin, Director of the National Center for Complementary and Integrative Health (NCCIH), discussed the concept known as Whole Person Health, which is a focus of the NCCIH's new (FY2021-2025) strategic plan. Whole person health involves empowering individuals, families, communities, and populations to improve their health in multiple interconnected domains: biological, behavioral, social, and environmental. It emphasizes the relationships between those various domains, as well as the bi-directional nature of the health-disease continuum.

Dr. Langevin pointed out that more attention needs to be paid to the synthesis and integration of the various components that make up analysis: community, whole person, organs and systems, cells, and tissues, signaling pathways, and molecules. She noted that there is a range in people, from healthy to less healthy to disease. Factors contributing to poor health include psychological stress, poor diet, and sedentary lifestyle.

With the unprecedented reduction in life expectancy in the U.S., there is a convergence of multiple crises, such as socioeconomic disparities, the COVID-19 pandemic, the obesity epidemic, climate change, the pain crisis, and the opioid crisis.

Dr. Langevin described the many layers involved in the multilevel whole person health framework, including the biological, behavioral, social, and environmental factors. She discussed the role of many forms of stress contributing to ill health. She cited several examples from the literature showing that stress reduction can lead to improvements in health.

She discussed the concept of “salutogenesis,” with factors contributing to improvements in health status, and the contribution of resilience – the capacity to resist, adapt to, recover, or grow from a challenge, which is being addressed by the Trans-NIH Resilience Working Group on Whole Person Health Research.

Dr. Woychik said that he was pleased to see the community element of whole person health. He asked if enough time was being devoted to community engagement and implementation science. Dr. Langevin agreed that implementation science is a vital

piece of the equation. She said that meeting the community where it is to push for implementation is extremely important.

Dr. Geller asked if NCCIH is looking at environmental justice data as it contributes to stress and poor health outcomes. Dr. Langevin expressed great interest in pursuing the conversation on that issue.

Dr. Vasquez noted that Dr. Langevin had alluded to the fact that establishing correlations is quite challenging, particularly without understanding mechanisms. Dr. Langevin mentioned that the upcoming event, [Methodological Approaches for Whole Person Workshop](#), to be held September 28-29 in Bethesda, would directly address that issue.

Dr. Parker expressed concern that stress mitigation approaches are focused on the individual, which may increase health disparities in certain populations. She cited the importance of research on primary prevention measures. Dr. Langevin noted that with the pandemic, some of the interventions that were previously primarily delivered in person are now being delivered in groups. She cited acupuncture as an example.

Dr. Penning suggested adding attention to Circadian rhythm to the list of health issues Dr. Langevin had discussed, with so many Americans being shift workers.

Sharon Beard asked if there would be a focus on the impacts of occupational safety and health, especially health disparities and work. Dr. Langevin replied that work safety in terms of environmental exposures during work as well as work stress are included in the research plans.

VI. DERT Director's Report

Acting DERT Director Dr. Gary Ellison briefed Council on DERT activities and accomplishments since the February Council meeting.

He provided a staff update, noting the hiring of Carolina Medina in the Program Analysis Branch. He described meetings DERT has participated in since February, along with a look at upcoming DERT meetings.

He updated DERT efforts in Diversity, Equity, and Inclusion (DEI). He provided new data illustrating the fact that processing time for Diversity Supplements is at its lowest, although more awards have been made. He listed several DEI activities with relation to the extramural community, such as listening sessions with Historically Black Colleges Universities (HBCUs) and Minority Serving Institutes (MSIs). Internal DEI initiatives address internal workforce culture through training, conferences, and internal discussions.

NIEHS has awarded 17 administrative supplements and competitive revisions and 5 time-sensitive R21s under the Notice of Special Interest (NOSI) on support for understanding the impact of environmental exposures on COVID-19. The NIH/NIEHS Worker Training Program received \$10 million from the 2020 Coronavirus Preparedness and Response Supplemental Appropriations Act, allowing implementation of a national health safety training response that has trained more than 70,000 workers.

Dr. Ellison reviewed the DERT portfolio. He noted that one of the major challenges is to provide some of both breadth and depth in the portfolio. NIEHS funding appropriations from FY2016-2020 totaled \$2.165 billion. Fewer solicited grants were funded, but they cost more. He reviewed the activity code groupings for the funded grants. The largest categories were R01-equivalent and Center/Cooperative. Grants were also coded by scientific topic, with approximately 70 unique codes. Organ-related codes were categorized as:

- Heart, Lung, Blood, and Immunology
- Neurobiology
- Nutrition and Metabolic Disorders
- Microbiome
- Other Organs or Systems Research
- Reproductive and Developmental Biology

Additional topic groups included:

- Basic Cellular and Molecular Research
- Epigenetics, Genetics, Genome Integrity, and Carcinogenesis
- Climate Change/Oceans
- Exposure Research
- Tools and Technology
- Translational Science, Outreach, and Education
- Superfund Research Program
- Worker Education
- Training and Career Development

Key takeaways from the portfolio analysis were:

- Investments have been rising over time.
- The split of solicited vs. unsolicited awards has stayed consistent over the past 5 years.
- Most topics were funded largely by R01-equivalent, and secondarily by Center/Cooperative and Small R mechanisms.
- Nearly all topics were represented in both the solicited and unsolicited portfolios.

Dr. Ellison presented an analysis of the NIEHS portfolio FY2010-2020 in terms of climate change and human health. There were 263 discrete grants conducting three kinds of activities: 36 for Worker Training Program cooperative agreements, 120 for climate change research grants, and 109 for climate change-adjacent activities, including small business.

Dr. Vasquez asked Dr. Ellison to discuss the types of climate change grants being funded. Dr. Ellison provided some highlights of the grants funded under the R21 announcement. Dr. Vasquez asked whether future longitudinal studies are planned under the R21 mechanism, via R01s or program grants. Dr. Ellison said that that is among the issues being discussed currently across NIH. Dr. Woychik noted that the Request For Information (RFI) is on the street to gather input on climate change and health research.

Dr. Wright asked whether the indirect effects of climate change will be part of the initiative. Dr. Ellison noted that the discussion about potential initiatives are still in development, but indirect effects may well be part of the discussion. Dr. Collman said that the interest is in health effects, but also in adaptation strategies.

Dr. Ellison related a question Dr. Korfmacher had posted in the chat area. She noted that a 2010 report had emphasized mental health and asked how stress and mental health are reflected in the portfolio today and going forward. Dr. Ellison replied that his presentation had been a very high-level overview of what NIEHS had funded. Dr. Christie Drew added that at the project level, there were 16 projects related to psychosocial stress or mental health. Dr. Woychik noted that the director of the National Institute of Mental Health is one of the other IC directors on the Executive Committee of the recently formed Climate Change and Health Working Group and cited several other examples. Dr. Collman added that some of the early targeted funding announcements that Dr. Ellison had referred to were multi-institute programs. Dr. Woychik mentioned that it will be important to craft a research strategy for the intramural program as well as the extramural programs. He thanked everyone involved with the portfolio analysis for their work. Dr. Ellison also acknowledged the working group within DERT for its efforts. He pointed out that NIEHS has been a leader in climate change and health research for more than a decade.

Dr. Hertz-Picciotto observed that some COVID-19 grants had been awarded quickly given the emergency nature of the pandemic and wondered if that approach might be applied in other areas, such as climate change. Dr. Collman said that it certainly is part of the time-sensitive grants portfolio approach. Dr. Mastin noted that recently a tool for competitive revision of grants had been employed.

Dr. Ellison pointed out that a [link](#) to the climate change and health RFI had been posted.

VII. NAEHS Council Working Group on Anti-Racism, Diversity, Inclusion, and Equity

Dr. Vasquez updated the Council on the progress of the Council Working Group on Anti-Racism, Diversity, Inclusion, and Equity, which she chairs. She announced that the group has completed its membership roster. She reviewed the group's charge and provided examples of its upcoming activities. She emphasized that it exists in addition to the many other similar efforts currently underway, such as the NIH UNITE committees, and is specifically charged to advise the Council. She related the group's roster, which includes members of Council, former members, members from academia, industry, and government, and representatives from NIEHS. The working group has also established four subgroups:

1. Workforce
Chair: José Cordero
Members: Ken Ramos, Craig Newschaffer
2. Funding – extra- and intramural
Chair: José Cordero
Members: Ken Ramos, Craig Newschaffer
3. Trainees
Chair: Fred Tyson
Members: Andy Shih, Mary Diaz Santana
4. Community engagement
Chair: Yvonne Maddox
Members: Carmen Velez-Vega, Peggy Shepard

Within its two-year time frame, the working group will meet as a large group at least once per month, or more if needed. The subgroups will meet as often as needed. The first goal will be to decide how many topics can be tackled by each subgroup, potentially 3-5 topics. Then, the subgroups will gather data related to each topic, and will formulate suggestions that will be presented to Council. Eventually, the group will provide a written report to NIEHS leadership.

Dr. Wright asked for assurance that Asian-Americans would be included in the working group's efforts. Dr. Vasquez said that that group will certainly be considered and not left behind.

Dr. Maddox, who had just joined the meeting, introduced herself and expressed that she was honored to be included in the working group.

Dr. Woychik noted that Dr. Trevor Archer from NIEHS is the co-chair of the I Committee and said there should be some interaction between him and the working group. He also noted that he is committed to hiring a diversity officer at NIEHS, and when that person is brought on board, he or she should be integrated into the working group's activities. He reiterated that the subject is a topic of very high priority for the institute.

VIII. SARS2 Nsp15 is Mad about U

Dr. Zeldin introduced Dr. Robin Stanley, a Stadtman Investigator who leads the Nucleolar Integrity Group in the Signal Transduction Laboratory.

In the Council meeting's scientific presentation, Dr. Stanley related her laboratory's recent work on the SARS-CoV-2 virus, which is responsible for the current pandemic affecting millions worldwide. Nsp15 is a viral endoribonuclease found in all coronaviruses that processes viral RNA to prevent detection by the host immune system. Nsp15 is a promising anti-viral target, but how it cuts RNA is poorly understood. Through the combination of cryo-EM, mass spectrometry, biochemistry, and molecular dynamics, Stanley and her group are defining how Nsp15 recognizes and processes viral RNA. Atomic resolution structures of Nsp15 bound to RNA in pre- and post-cleavage states revealed the significance of active site residues in uridine specificity and catalysis. The structures, along with a series of biochemical assays, have revealed molecular details of how Nsp15 recognizes viral RNA and will hopefully aid in the design of urgently needed anti-viral therapeutics.

Dr. Vasquez asked Dr. Stanley about Nsp15's status as a hexamer. Dr. Stanley replied that it appears from her group's experiments that it must be a hexamer. Dr. Vasquez asked whether the sequence selectivity is due to steric hindrance or from secondary structure of the RNA. Dr. Stanley said it is likely due to a bit of both factors.

Dr. Kavanagh asked if there is any evidence of some mechanisms that Nsp15 is engaging in that helps to minimize host RNA processing. Dr. Stanley said it had been hypothesized years ago that one of the ways Nsp15 works is by degrading mRNAs associated with the immune system. However, it appears that Nsp15 is only targeting the viral RNA.

Dr. Woychik asked if there are any sequence variations in Delta that are associated with its more aggressive infectivity. Dr. Stanley said that in consultation with the Bioinformatics Core they had detected a number of variants of Nsp15, and work is ongoing to determine which may affect function.

Dr. Penning asked about inhibitor design. With hydrolysis being the slowest step, he wondered whether that might be a good target. Dr. Stanley said that of the many potential inhibitors seen in computational work just one had shown activity in the

laboratory thus far, a uracil derivative. She said that targeting the slowest step may not be the right approach for Nsp15.

IX. Adjournment

Dr. Woychik thanked everyone for their participation in the meeting. He said it was “the best yet.”

Dr. Mastin thanked the members of Council, as well as Liz McNair and Rose Moody, Nathan Mitchiner and Parris Milley.

Dr. Ellison thanked Dr. Mastin and everyone associated with the meeting.

Dr. Woychik adjourned the meeting at 5:07 pm, September 13, 2021.

CERTIFICATION:

/s/

Richard Woychik, PhD
Chairperson
National Advisory Environmental
Health Sciences Council

/s/

Gary L. Ellison, PhD
Executive Secretary
National Advisory Environmental
Health Sciences Council

Attachment:
Council Roster