

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

**MINUTES OF THE ONE HUNDRED SIXTIETH MEETING OF THE
NATIONAL ADVISORY ENVIRONMENTAL HEALTH SCIENCES COUNCIL**

June 2, 2020

The National Advisory Environmental Health Sciences Council convened the open session of its one hundred sixtieth regular meeting on June 2, 2020 as a Zoom virtual meeting. The closed session of the meeting was held earlier the same day.

The meeting was open to the public on June 2, 2020 from 11:00 a.m. to 2:05 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 June 2, 2020 from 10:00 a.m. to 10:45 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*)
José Cordero, MD, MPH
Gary Ellison, PhD, MPH (*ex officio*)
Suzanne Fitzpatrick, PhD (*ex officio*)
Andrew Geller, PhD (*ex officio*)
Lynn Goldman, MD, MPH
Shuk-Mei Ho, PhD
Terrance Kavanagh, PhD
Katrina Korfmacher, PhD
Edith Parker, DrPH
Marla Pérez-Lugo, PhD
Brad Racette, MD
Susan Schantz, PhD
Andy Shih, PhD
Patrick Sung, DPhil
Robyn Tanguay, PhD
Robert Wright, MD, MPH

NIEHS Staff

Kathy Ahlmark
Janice Allen, PhD
David Balshaw, PhD

Martha Barnes
Linda Bass, PhD
Sharon Beard
Brian Berridge, DVM, PhD
Abee Boyles, PhD
Danielle Carlin, PhD
Toccaro Chamberlain
Jennifer Collins
Gwen Collman, PhD
Yuxia Cui, PhD
Christie Drew, PhD
Chris Duncan, PhD
Anika Dzierlenga
Lisa Edwards
Benny Encarnacion
Christine Flowers
Amanda Garton
Nidhi Gera, PhD
Barbara Gittleman
Kimberly Gray, PhD
Jenny Greer
Arshya Gurbani
Janet Hall, MD, MS
Astrid Haugen
Michelle Heacock, PhD
Heather Henry, PhD
Jon Hollander, PhD
Chip Hughes, MPH
Mike Humble, PhD
Bonnie Joubert, PhD
Helena Kennedy
Heather Knox
Richard Kwok, PhD
Alfonso Latoni, PhD
Cindy Lawler, PhD
Chris Long
Lindsey Martin, PhD
John Maruca
J. Patrick Mastin, PhD
Kim McAllister
Liz McNair
Carolina Medina
Aubrey Miller, MD, MPH
Parris Milly
Nathan Mitchner
Rosemary Moody

Sri Nadadur, PhD
Aaron Nicholas
Liam O'Fallon
Nicole Popovich
Alicia Ramsaran
Lingamanaidu Ravichandran, PhD
Scott Redman
Les Reinlib, PhD
Jim Remington
Carol Schreffler, PhD
Thad Schug, PhD
Dan Shaughnessy, PhD
Varsha Shukla, PhD
Bill Suk, PhD, MPH
Laura Thomas, PhD
Claudia Thompson, PhD
Steven Tuyishime, PhD
Fred Tyson, PhD
Michelle Victalino
Mitch Williams
Leroy Worth, PhD
Rick Woychik, PhD
Demia Wright, MPH
Darryl Zeldin, MD

Members of the Public Present

Ernie Hood, Bridport Services, LLC

***** NOTE: Due to the coronavirus pandemic, this meeting was conducted virtually. *****

I. Call To Order and Opening Remarks

NIEHS and NTP Acting 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 Division of Extramural Research and Training (DERT) Director J. Patrick Mastin, Ph.D., went over some of the logistics for the meeting.

II. Consideration of February 2020 Meeting Minutes

Approval of the February 2020 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 February 2020 Council meeting.

He updated attendees on COVID-19 staff planning at NIH. NIH continues to be open for business; but is encouraging enhanced telework for all staff capable of doing so. There is an NIEHS plan for a return to the physical workspace once the infection rate in North Carolina has fallen sufficiently. Physical distancing will be emphasized once staff return to the campus. It remains uncertain when all personnel will return to campus and large group meetings can again be planned and held.

He provided a summary of budget and appropriations affecting NIEHS. He said the FY2020 allocation was received earlier this year. The final NIH allocation increased the NIEHS budget by 3.6%, at just over \$802 million. The Superfund Research Program received a 2.6% increase, to \$81 million. Much of the increase is directed toward the extramural division, which has allowed the division to maintain a 10% payline. He summarized the special NIH COVID-19-related allocations over the past several weeks. The NIH has received a total of approximately \$3.5 billion, through three different bills, Phase 1, Phase 3, and Phase 3.5. Most of the funding has gone to NIAID, although NIEHS did receive \$10 million to support its Worker Training Program. He noted a \$1 billion allocation to the Office of the Director (NIH), which Congress has directed toward the development of diagnostic COVID-19 tests. Dr. Woychik has been asked by Dr. Collins to serve as a co-chair on an executive committee which will oversee planning and distribution of the funding.

Dr. Woychik recounted the three themes incorporated in the NIEHS Strategic Plan: Advancing Environmental Health Sciences, Promoting Translation – Data to Knowledge to Action, and Enhancing Scientific Stewardship and Support. He elaborated on the goals inherent in Theme One.

Referring to Theme One, he discussed several recent science advances from DIR, One NIEHS, DNTP, and DERT. He also described what he termed “an exciting opportunity for environmental health scientists,” an NIH program called Accelerating Leading-Edge Science for ALS (ALW²). The new funding opportunity, which will result in up to five transformative R01 awards, is part of the High Risk/High Reward Research Common Fund Program in the NIH Director’s office. Its purpose is to explore innovative and bold new ideas on how to define the environmental exposures that may be working in concert with genetic predispositions to trigger ALS. The FOA will be issued “shortly.”

Referring to Theme Two, Dr. Woychik described some of the COVID-19 outreach activities being conducted by NIH, including seven cross-IC, cutting edge, collaborative

efforts. NIEHS is involved with several of the programs. He focused on the \$1 billion NIH Rapid Acceleration of Diagnostics (RADx) Initiative, which has five critical components, each of which he briefly described. He noted that the NIEHS cryo-electron microscopy program has worked to derive structures of SARS-CoV-2 protein complexes.

He presented the Pandemic Vulnerability Index (PVI), a new tool developed by Dr. Alison Motsinger-Reif and her colleagues in the SRP at NCSU and Texas A&M University. It gauges the status of the pandemic with multiple input variables that appear as slices of a pie to calculate a pandemic vulnerability index. It is a powerful data visualization tool that incorporates a variety of population-level data to understand which communities may face higher risk.

He described the NIH/NIEHS WTP COVID-19 Virtual Safety Training initiative, which stems from WTP receipt of \$10 million from the 2020 Coronavirus Preparedness and Response Supplemental Appropriations Act. The initiative will work toward increasing health and safety awareness for responders and workers who face potential exposure to COVID-19.

Dr. Woychik went over several recent NIEHS events and activities, including the Partnerships for Environmental Public Health meeting held in February and the kickoff lecture in the Climate, Environment and Health Seminar Series, held May 6.

Referring to Theme Three, he went over recent new hires and a variety of awards and recognitions earned by NIEHS personnel and grantees. He provided further information on the International Common Disease Alliance (ICDA), with an NIEHS working group led by Richard Kwok working to integrate environmental exposures into the ICDA white paper, which will discuss the Maps to Mechanisms to Medicine (M2M2M) concept.

He described the exposome concept, which is a major component of precision health. There is great interest in developing the exposome as the environmental “genome project.” There is a proposal for a spring 2021 workshop on Integrating Multiscale Environmental Exposure Data with Large Population-Based Genomics Studies. He said he will provide more details as they become available.

Dr. Pérez-Lugo asked Dr. Woychik to speak more about what acceptance and response the PVI program has received from other agencies, and how widely the tool has been shared with stakeholders at the local and federal levels. Her second question was about who is the target audience for the Climate, Environment, and Health Seminar Series. Dr. Woychik noted that the PVI is a very new program in its relatively early stages. The algorithms are being fine-tuned, but it is up and working. He said he has been telling other IC directors about the tool. It is not yet the gold standard for evaluating pandemic vulnerability, but the developers will be working to make it more predictive on the county

level. Dr. Pérez-Lugo asked if there was a particular outreach strategy for the tool. Dr. Woychik asked Dr. Zeldin to respond. He said that Dr. Motsinger-Reif would be best to answer the question. Dr. Pérez-Lugo asked what kind of response there has been from other agencies and stakeholders, and whether there is a particular outreach strategy spread the word, beyond word of mouth. Dr. Zeldin said it is too early to assess response, since the tool only went live a short time ago. He said that Dr. Motsinger-Reif is currently working on a manuscript to evaluate the predictability of the index. Dr. Hall said she could provide a bit more information. She said that the developers have been being creative in terms of pulling in the public sources of data to be able to inform the decisions. She said that although it is happening very quickly, the tool is still very much a work in progress. She said that the goal is to have the predictive part of the tool ready within a few days for people to utilize.

Dr. Woychik circled back to Dr. Pérez-Lugo's question about the lecture series. He said it will be a broad-based lecture series, getting information to both EHS scientists and the general public. He noted how important it is to get the message out about climate and health. He described Dr. Balbus' kickoff lecture, "How Climate Changes Health and Why You Should Care."

Dr. Cordero asked for more information on the M2M2M concept, and how it will combine mechanisms with environmental or other interactions of genes and environment. Dr. Woychik said that if the concept of precision medicine is to deliver on its promises, there must be a conscious effort to bring the environment into the M2M2M concept. He said that the challenge will be to determine exactly what to do. It will involve trying to get people from the environmental health sciences community with the genomic sciences community to work together. He encouraged everyone in the EHS community to look at how variations in genes that are highly significant predispose to phenotypic outcomes in individuals. Dr. Cordero added that epigenetic changes should also be considered. Dr. Woychik agreed, and encouraged Dr. Cordero and anyone else interested to contact Dr. Kwok and get their ideas into the ICDA white paper.

Dr. Wright asked about "the giant natural experiment that is occurring right now" with shelter in place changing the environment in complicated ways. He asked if there were any plans in place to study the impact of shelter in place, and what the best practices might be to study people in this situation. Also, he asked about the impact on community engagement. Dr. Woychik said the question is how to capitalize on the natural experiment to gain important insights into several elements of the environment. He said it will be important to get that question into the discussions of the senior NIEHS leadership team. He asked Dr. Collman to address Dr. Wright's questions in terms of funding opportunities. She agreed with Dr. Wright that in this moment there are opportunities to learn new things. She discussed the NIEHS Notice of Special Interest (NOSI) that has been on the street, along with several others emanating from the Office

of Behavioral and Social Science Research, which are focused on how the social, behavioral, and economic factors are affecting population health. She said that DERT program staff are familiar with the opportunities and would be happy to speak to interested investigators. She acknowledged that the question of best practices for how to conduct research in the “new normal” is tremendously important. She said that the upcoming August virtual meeting of the International Society for Environmental Epidemiology could be a forum for discussion of the topic among people within the discipline. Dr. Woychik commented that there are several cross-IC, cross-cutting projects, not all based on COVID-19 testing.

Dr. Goldman commented on the fact that environmental exposures differentially affect gene expression at different points in the lifespan, particularly the epigenome. She talked about the importance of the temporal element. Dr. Woychik agreed, and said he would continue to emphasize the issue with Dr. Collins. Dr. Goldman said that it might be exciting to begin to take arrays of exposures and map them onto SNPs in terms of creating gene expression variability. She added that she was delighted that the social environment is included in the exposome concept. “I think that it’s time to start talking about racism as an environmental exposure,” she said, noting that racism has been recognized as a public health threat. Dr. Woychik said that Dr. Collins had sent out an all-hands message highlighting the Minneapolis situation. He agreed that racism is a very important variable in evaluating an individual’s health. Dr. Zeldin described the research of Dr. Chandra Jackson, who leads the Social and Environmental Determinants of Health Equity Group at NIEHS. Dr. Woychik said that it will be important to include that type of research in the funding aimed at COVID-19.

Dr. Geller asked Dr. Woychik to expand on the concept of precision health and how it is associated with primary and secondary prevention. Dr. Woychik said that precision health starts with the individual and how the individual responds to the environment.

IV. Report of the Director, DERT

Acting DERT Director Dr. Mastin updated the Council on recent development in the division.

He discussed the NIH response to COVID-19. He noted that NIH is open for business, with extramural staff working from home to award and process grants and to conduct virtual peer review meetings. He noted that the situation is rapidly evolving. He described guidance about COVID-19 applicable to the applicant and grantee community, including information on application deadlines, salaries and stipends, donation of research supplies, human subject and animal research, administrative flexibilities, and accommodations for loss of research time. He presented COVID-19

funding opportunities through competing revisions, administrative supplements, and new awards.

Dr. Mastin noted that DERT is also open for business, with its usual activities continuing along with COVID-19-related activities, including developments at the NIEHS Worker Training Program (WTP), a DERT COVID-19 Notice of Special Interest (NOSI), DERT staff deployment to the DHHS Office of the Assistant Secretary for Preparedness and Response, and DERT's adjustment to fulltime telework.

WTP has added a Biosafety and Infectious Disease Response Training component to its portfolio. Dr. Mastin presented the timeline of events in WTP activation for COVID-19 training. WTP has received \$10 million from the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 to increase health and safety awareness for responders and workers who face potential exposure to the virus. WTP has released a NOSI related to coronavirus and infectious disease response training.

The DERT/NIEHS NOSI relates to a research objective of promoting rapid understanding of potential contributions of exposure to environmental agents that may exacerbate COVID-19 susceptibility, disease severity, and progression. Dr. Mastin provided several examples of research interests under the NOSI, as well as NIEHS contacts for more information.

He described the NIEHS collaboration with NIDDK on Chronic Kidney Disease of Unknown Origin (CKDu). He provided details about the condition, and past NIH workshops on the topic. Part of the collaboration will be a "CKDu in Agricultural Communities" research consortium, with 3-4 field epidemiology sites, a scientific data coordinating center, a renal analysis core, and HHEAR.

Dr. Mastin outlined DERT activities since the last Council meeting, and anticipated future DERT activities.

V. Short Courses R25 Concept: Broadening Skills in Environmental Health Sciences

DERT Health Specialist Amanda Garton presented the concept for a training program to enhance the skills of researchers and broaden access to training in emerging topics and modern methods and tools for environmental health sciences through the use of short courses.

She reported on the research she had done about the use and availability of short courses in the field, looking at the need to be addressed and whether short courses would be a good option to fill that gap. The goals of the program are:

- To speed the pace of research and discovery by providing specialized training in advanced methods and techniques for environmental health research
- To enable researchers from a diverse range of institutions to engage in cutting edge environmental health sciences research

She noted that the program fits under Theme 3 of the NIEHS strategic plan. She acknowledged that NIEHS already supports many training and career development programs, but limitations include:

- Most mechanisms require long-term commitment both by and to the participant.
- They are specific to career stage.
- Conferences and workshops supported by NIEHS generally do not include hands-on training.

Short courses may address those challenges by systematically making brief, intensive, hands-on training opportunities in EHS available to a wide range of scientists. They would be shorter than one month, would be open to participants regardless of career stage, and may require a “lab,” hands-on component.

Ms. Garton identified several areas where there is a clear need to support hands-on training in advanced methods.

The program is to be known as NIEHS RISE (NIEHS Research Intensive Short Courses and Educational Opportunities). It will encourage use of innovative educational models and methods such as experiential or project-based learning, or virtual and remote tools to enhance the training experience.

NIEHS RISE would use the R25 Research Education funding mechanism. Ms. Garton described the evaluation and metrics to be employed, both by grantees and by NIEHS.

The program would involve up to \$200,000 direct costs/year for 5 years, with 2-3 new awards each year for 3 years. The anticipated RFA is August-September 2020, with an initial receipt date of December 2020. First awards would be made in early FY2022.

Dr. Parker was the first Council reviewer. She said she was “really supportive of this concept,” as it addresses an identified need amongst environmental health investigators. She approved of the idea that NIEHS would align with similar mechanisms at other NIH ICs. She said the program would enhance interdisciplinary aspects of research. She endorsed the hands-on, experiential focus, the mixture of in-person and on-line experience, and the longer time period for the short courses than some of the traditional workshops or boot camps. She felt that the proposed funding was reasonable. She liked the diversity of potential topics, and the potential of the program to assist with great workforce diversity. She suggested the program might be

integrated with other NIEHS research career support or training opportunities. She said it would be important to develop a method to track how people use the skills they acquire. She wanted a definition of what criteria would be used to ensure diversity of participants in the training, not just among the individuals but also diversity of institutions involved.

Dr. Schantz was the second Council reviewer. She concurred with Dr. Parker's comments, and said she was excited about the program. She said that as director of a T32 for almost twenty years, she could imagine how excited pre- and postdocs in the training program would be about being able to participate. She endorsed the mix of different career levels in the program, with the resultant opportunities for mentoring and networking for people at different levels over the training period. She speculated that there would be many opportunities to build collaborations. She approved of the strong evaluation component. She felt that there may need to be flexibility in terms of how much of the program would be online.

Ms. Garton thanked the reviewers for their thoughts, and pledged to consider how to incorporate their suggestions.

Dr. Tanguay asked Ms. Garton whether she had considered an externship model when developing the program. Ms. Garton said that the courses would be shorter than an externship, and that there are economies of scale to be realized by having a centralized, defined course.

Dr. Korfmacher asked how diversity would be captured under the evaluation scenario presented by Ms. Garton. She said it would be a good opportunity to institute social network analysis, including mechanisms for post-program support. She felt that the opportunity to interact in person would be important and suggested calculating costs in greenhouse gas emissions associated with remote vs. in-person models. Ms. Garton agreed that it would be a good idea for applicants to address those considerations.

Dr. Kavanagh asked whether there would be opportunities for applicants to acquire additional funding from private partners or professional societies to help augment the program's budget. Ms. Garton said that would need to be explored and cited some of the short course examples she had provided as instances of funding from multiple sources.

Dr. Mastin asked for a motion to approve the concept. Dr. Goldman so moved. Several seconds were heard. Council voted to approve the concept.

VI. Superfund Research Program Update

Dr. William Suk, director of the Superfund Research Program (SRP), updated the Council on the program.

He introduced the SRP team and reminded the Council of the SRP mandates and current funding mechanisms, focusing on the P42 multi-project centers mechanism. He also described the R25 occupational training grants and R01 individual research projects, both of which supplement center research. They recently released Requests for Applications.

- Optimizing Natural Systems for Remediation: Utilizing Innovative Materials Science Approaches to Enhance Bioremediation (R01)
- Occupational Health and Safety Training Education Programs on Emerging Technologies (R25)

Dr. Suk provided further background on the SRP, and illustrated the structural complexity of the P42 grants, where at least four research projects are supported by core elements designed to support the center's goals. He noted the diversity of SRP research, which is multidisciplinary and published in a wide variety of journals. SRP's mandate areas encompass broad transdisciplinary research, translation, engagement, and training. SRP has supported more than 2,250 trainees over the years. The program's research impact begins with basic environmental science and engineering research. The SRP facilitates the translation of its grantees' scientific accomplishments through research translation and community engagement.

Dr. Suk delineated programmatic updates and new grants under the SRP. A few years ago, the review cycle was changed to every 2.5 years, which has helped to:

- Enable functional changes to the RFA and programmatic modifications to address emerging problems
- Provide opportunities to more strategically fill gaps in program mandates with a larger applicant pool per cycle
- The change in review cycle also:
 - Has the potential for growth should the budget improve
 - Can take advantage of additional NIH mechanisms
 - Can take advantage of the advancements in data science

He described the restructured timeline for P42 SRP Centers, which are now on two tracks. He provided details about the 10 Centers funded in 2017. Eleven more Centers were added in 2020. The two cohorts are connected as part of the program in various ways, especially through initiatives to enhance data sharing, integration, and reuse. SRP grantees also have the opportunity to take part in the Human Health Exposure Analysis Resource (HHEAR).

