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

MINUTES OF THE ONE HUNDRED FIFTY-NINTH MEETING OF THE
NATIONAL ADVISORY ENVIRONMENTAL HEALTH SCIENCES COUNCIL

February 11-12, 2020

The National Advisory Environmental Health Sciences Council convened the open session of its one hundred fifty-ninth regular meeting on February 11, 2020 in the Durham Convention Center, Durham, NC. The closed session of the meeting was held earlier the same day.

The meeting was open to the public on February 11, 2020 from 9:15 a.m. to 5:00 p.m. and February 12, 2020 from 8:30 a.m. to 11:00 a.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 February 11, 2020 from 8:30 a.m. to 9:00 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*) (by webcast)
José Cordero, MD, MPH
Irasema Coronado, PhD
Gary Ellison, PhD, MPH (*ex officio*)
Suzanne Fitzpatrick, PhD (*ex officio*) (by webcast)
Lynn Goldman, MD, MPH
Shuk-Mei Ho, PhD (by webcast)
Terrance Kavanagh, PhD
Katrina Korfmacher, PhD
Maureen Lichtveld, MD (February 12 only)
José Manautou, PhD
Edith Parker, DrPH
Marla Perez-Lugo, PhD
Brad Racette, MD
Susan Schantz, PhD
Andy Shih, PhD (by webcast)
Michael Slimak, PhD (*ex officio*)
Patrick Sung, DPhil
Robyn Tanguay, PhD
Robert Wright, MD, MPH

NIEHS Staff

John Balbus, MD, MPH
David Balshaw, PhD
Martha Barnes
Linda Bass, PhD
Sharon Beard
Brian Berridge, DVM, PhD
Abee Boyles, PhD
Danielle Carlin, PhD
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Jennifer Collins
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Astrid Haugen
Michelle Heacock, PhD
Heather Henry, PhD
Jon Hollander, PhD
Chip Hughes, MPH
Mike Humble, PhD
Bonnie Joubert, PhD
Alfonso Latoni, PhD
Cindy Lawler, PhD
Chris Long
Lindsey Martin, PhD
J. Patrick Mastin, PhD
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Mark Miller, MD, MPH
Rosemary Moody
Sheila Newton, PhD
Liam O'Fallon
Kristi Pettibone, PhD
Tina Powell
Alicia Ramsaran

Lingamanaidu Ravichandran, PhD
Les Reinlib, PhD
Carol Schreffler, PhD
John Schelp
Charles Schmitt, PhD
Thad Schug, PhD
Sheena Scruggs
Dan Shaughnessy, PhD
Varsha Shukla, PhD
Bill Suk, PhD, MPH
Laura Thomas, PhD
Claudia Thompson, PhD
Brittany Trottier
Steven Tuyishime, PhD
Fred Tyson, PhD
Leroy Worth, PhD
Rick Woychik, PhD
Demia Wright, MPH
Darryl Zeldin, MD

Members of the Public Present

Maureen Avakian, MDB Inc.
Michael Baker, MDB Inc.
Joally Canales, Rice University
Brianne Duncan, NIH (by webcast)
Kenneth Fasman, PhD, The Jackson Laboratory
Alesia Ferguson, North Carolina A&T
Ernie Hood, Bridport Services, LLC
Raymond Samuel, North Carolina A&T

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 attendees in the room 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 September 2019 Meeting Minutes

Approval of the September 2019 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 September 2019 Council meeting.

He updated the group on budget and appropriations matters. He noted that Congress passed and the President signed two Minibus Appropriations bills for FY2020 on December 20, 2019. NIH overall saw a 6.7% increase. NIEHS saw a 3.6% increase. Also, the Superfund Research Program received a 2.6% increase in funding.

Dr. Woychik emphasized that under his leadership as Acting Director, NIEHS will continue to follow the 2018-2023 Strategic Plan, working on the three themes in the plan: Advancing Environmental Health Sciences, Promoting Translation (Data to Knowledge to Action), and Enhancing Environmental Health Science through Stewardship and Support.

Under the rubric of Theme One, he discussed several recent science advances from DIR, DNTP, and DERT researchers. Addressing Theme Two, he described a variety of Congressional in-person meetings and telebriefings, activities by Friends of NIEHS, and the upcoming NIH Tribal Advisory Committee meeting to be held March 26-27. Under Theme Three, he reviewed several staffing changes and recent awards and recognitions. He described a variety of upcoming events, including the 59th annual Society of Toxicology (SOT) meeting, which will feature a session on March 16 devoted to paying tribute to retired NIEHS/NTP Director Linda Birnbaum, Ph.D.

Dr. Woychik discussed the 34 listening sessions he had held throughout NIEHS since his appointment as Acting Director. The meetings concentrated on the questions, "What did you like that Linda did that you want to continue?" and "What could Rick address during his [limited] tenure as Acting Director?" The overall themes that emerged from the conversations included communication, collaboration, career development, resources, strategic focus, and management of science. He said there is a commitment to address many of the issues heard during the listening sessions.

He described the data science landscape at NIEHS, which is designed to power data- and knowledge-driven discovery. Within the last two years, he noted, NIEHS has created new offices to solidify its internal data infrastructure: the Office of Environmental Science Cyberinfrastructure, the Office of Data Science, and the Office of Scientific Computing, along with expanded training opportunities in the data space.

Dr. Ho thanked Dr. Woychik for his stewardship during the current period. She asked how NIEHS might participate more in the International Common Disease Alliance (ICDA) initiative known as M2M2M – from Maps to Mechanisms to Medicine, which Dr. Woychik had described in his presentation. He said that NIEHS is working to increase awareness of environmental health issues in that community. He noted that Dr. Collman will be attending the ICDA workshop to be held in Copenhagen in March. He said there

has been increasing recognition of the importance of the exposome in groups such as ICDA.

Dr. Goldman mentioned that she was involved with the advisory committee for the ECHO study and the All of Us program, and that it is important to recognize the role of the environment in those large cohort programs. Dr. Woychik said it is his pleasure to reach out to other leaders to ensure their awareness of the role of the environment, including inviting directors of other ICs to visit NIEHS.

Dr. Manautou pointed out that Council member Dr. Ho is to be recognized with the Distinguished Toxicology Scholar Award at the upcoming SOT annual meeting.

Dr. Wright asked if an integrated dissemination plan on exposome research is needed. Dr. Woychik agreed that there is a need for a better job of disseminating the information. He said that Dr. Collman will be featuring the exposome when she attends the ICDA meeting in Copenhagen. He thought it might be a good idea to conduct a reciprocal meeting, inviting some of the genomic scientists to NIEHS. He said that it would be good to adopt some of the best practices from the Human Genome Project to a Human Exposome Project.

IV.   Perspectives on Data Science Opportunities and Challenges

Dr. Mastin introduced the theme for the rest of the day's agenda: an examination of data science at NIEHS.

NTP Associate Director Dr. Brian Berridge introduced Dr. Charles Schmitt, Director of the NIEHS Office of Data Sciences.

He noted that there are two groups at NIEHS who work on data science as part of their jobs: the Office of Data Science, and the Data Science Workgroup. He listed several offices that support those efforts, and listed several offices and areas that use data science in their research endeavors.

He described the three strategic plans related to data science at NIEHS, which "fairly well align." He listed the data science needs and opportunities for NIEHS intramural programs, which reflect those of the broader community:

- Data Management
    - Diverse data sets
    - Diverse customer base
    - Curation, sharing, standards, security
- Workforce Development
    - Upskilling staff, training postdocs
- Data Cyberinfrastructure

- o   Storage management, middleware, cloud
- Data Analytics
  - o   Patient data, surveys, omics, dose-response, geo-spatial
- New Methods
  - o   Machine & deep learning, semantic engineering, artificial intelligence
- Adapting evolving methods/technologies
  - o   Identifying, evaluation, translating

He defined data science as the "combination of disciplines needed to advance data- and knowledge-driven discovery and decision support." He outlined the challenges facing NIEHS data science efforts:

- Staffing
  - o   Semantic engineering
  - o   Domain translators
  - o   AI expertise
  - o   Data engineering
  - o   Competition with industry
- Team science and "common language"
  - o   Translators especially important
- Training
  - o   Broad to support team science ("common floor")
  - o   Targeted for project needs
  - o   Targeted toward expertise development
- Adoption of methods and technologies
  - o   Determining fitness for needs
  - o   Team maturity and upskilling

Dr. Schmitt described FAIR+ standards for NIEHS-generated research data:

- Findable
- Accessible
- Interoperable
- Reusable
- Computable
- Socialized
- Mineable

He noted that the diversity of environmental health data makes achieving FAIR+ especially challenging, and described several of the ongoing investments and activities at NIEHS devoted to getting to FAIR+.

He described the many challenges involved in pursuing data integration and analysis, including the diversity of analytical challenges, the various levels at which integration may take place, and the analysis frameworks that guide data science. Semantics is a particular challenge, as it is difficult in environmental health language to achieve common terminologies and ontologies. A workshop is planned in 2020, as is the hiring of a semantic engineer. He provided background information about emerging methods in data integration and analysis.

Dr. Schmitt discussed workforce development and engagement within NIEHS, with the goal being an ecosystem where life science staff and postdocs can readily get to the point of publishing scientific tools.

V. Draft NIH Policy for Data Management and Sharing

Dr. Lyric Jorgenson, Deputy Director of the NIH Office of Science Policy, briefed the Council on the Draft NIH Policy for Data Management and Sharing. The public comment period on the draft policy was closed in January, and the finalized policy is slated to go into effect in 2022.

The goals of the draft policy are to:

- Foster a culture of data stewardship.
- Recognize that all scientific data need to be managed; not all data may be necessary to validate and replicate findings.
- Promote effective data management and sharing consistent with FAIR principles.
- Provide a flexible framework for the breadth, size, and diversity of scientific data.
- Respect autonomy and privacy of research participants; allow for protection of confidential data.

The policy would require submission of a data management and sharing plan outlining how scientific data will be managed and shared, taking into account any potential restrictions or limitations, as well as compliance with the NIH ICO-approved plans, prospectively describing effective management and timely sharing of scientific data (as appropriate) and accompanying metadata resulting from NIH-funded or conducted research. The elements of a proposed plan should include:

- Data type
- Related tools, software, and/or code
- Standards
- Data preservation, access, and associated timelines
- Data sharing agreements, licenses, and other use limitations
- Oversight of data management

Dr. Jorgenson outlined the NIH thinking on allowable costs under the proposed policy, as well as the costs not considered to be data management and sharing costs.

Dr. Manautou asked if the new policy could impact applicants who do not have strong institutional support or infrastructure for data management and sharing. Dr. Jorgenson made the point that although a data management policy will be required, it will not be subject to peer review, and applicants will be given the opportunity to establish a dialogue with program staff to help them with their plans.

Dr. Tanguay said she could foresee "a nightmare" in terms of ensuring that people follow through with their plans. Dr. Jorgenson said that was a point her group had specifically requested feedback on.

Dr. Wright asked about the costs of data sharing, and who bears them. Dr. Jorgenson replied that the issue of allowable costs was under active consideration, and study of the issue was continuing. Dr. Wright added that he was also referring to costs incurred after a grant ended. Dr. Jorgenson said that question was part of the ongoing conversation.

Dr. Coronado asked how to balance access to information to a community for decision-making and confidentiality, in relations with tribal nations. Dr. Jorgenson said there is a conversation on that subject in progress with tribal nations, which have their own unique laws.

Dr. Korfmacher said the discussion reminded her of a conversation about report back to participants of research results, which is often part of human subjects' protection requirements. She noted commonalities with that element, first, that it is an opportunity to share ethical guidelines and clear expectations of how the process will take place, second, that it guides thinking through of the costs of data sharing, and third, thinking about costs and interactions that happen after the grant has expired. She recommended using this moment to think about an opportunity to pull in some deadlines for report-back and sharing of data with participants. Dr. Jorgenson said that was an excellent point and that it is not too late to incorporate in the policy.

Dr. Kavanagh asked about the assignment of copyrights under the policy, particularly in the case of data being submitted to journals. Dr. Jorgenson said that there is a provision under the proposal to limit data sharing based on copyright, although most data should not be copyrighted.

VI.   Extramural Data Science Programs at NIEHS: Overview and Perspectives

Dr. Mastin briefed the Council on extramural data science programs at NIEHS. He emphasized that NIEHS efforts are being aligned with the NIH Strategic Plan for Data

Science. He reiterated that NIEHS-generated research needs to be FAIR+. However, there are significant challenges for advancing data science research in environmental health science, including:

- Inconsistent formats and vocabularies
- Cultural issues
  - Researcher's perspective
  - Participant perspective
- High cost/lack of support for data resources
- Insufficient data science expertise
- Diversity of research topics and data types

He noted also that the richness and diversity of data that allows exploration of the impacts of exposures on human health also present barriers to interoperability. He referred to the data science provisions in the 2012-2017 and 2018-2023 NIEHS Strategic Plans, and provided a timeline of NIEHS data science events, including several workshops.

He outlined some of DERT's efforts in data science, including enhancing data management and sharing, data coordination for the division's collaborative programs, and data science training and workforce development.

Dr. Mastin noted that the promise of applying data science to EHS data is more than simply requiring grantees to share their data, but must take into account how data are managed throughout the full data lifecycle. He updated progress on a program that was initiated one year ago to work on the issue: an administrative supplement program called Enhancing Data Management and Sharing in NIEHS-Funded Research Grants (PA-19-025). The program supported the integration of new expertise to enhance project data management. He provided examples of specific grants that emerged from the program. He also provided several examples of some of the landmark programs and more recent RFAs where data management principles were included in the RFA, such as HHEAR and TaRGET II.

Moving forward, Dr. Mastin asked the Council to consider and provide feedback on:

- How do we encourage NIEHS investigators to adopt best data practices?
- These programs have generally been fairly targeted either at programs or activities. How do we make them more flexible or reach additional populations?
- What are the next set of challenges and opportunities for data science on the horizon?
- There is value in all of these types of data and studies being available; we need to understand better how to support data reuse by grantees.

Dr. Racette commented that he could not see how unsolicited applications would be able to achieve data sharing goals unless there is considerable effort to house the data in a centralized repository. Dr. Mastin asked if he meant an environmental health science data-specific repository. Dr. Racette said it was an open concept, but there have been successful efforts in other fields such as genetics.

Dr. Kavanagh noted that Dr. Mastin had said it was premature to look at evaluation of the supplements, but suggested it might be possible to ask some of the recipients about their experiences. Dr. Mastin said that would be done, and the data would be brought to Council.

VII.   Maintain and Enrich Resource Infrastructure for Existing Environmental Epidemiology Cohorts: R24 Program Update

Dr. Kimberly Gray updated the Council on cohort maintenance, including the original and the new RFA. She delineated the goals and objective of R24 Cohort Maintenance:

- Provide stability to existing environmental epidemiology cohorts by supporting infrastructure to retain trained field personnel essential to:
  - Continue ongoing longitudinal data collection
  - Follow study participants
  - Preserve the integrity and quality of specimen collection
- Provide stable funding and opportunities for data preparation and a structure to facilitate and ensure data sharing
- Ensure that the research community has greater freedom to pursue new and interesting research directions through other mechanisms

The original RFA was issued in 2016, with the new RFA coming out in 2018. In July 2019, there was a "pause and reissue." Dr. Gray provided details of the 3 RFAs that have been issued, including the grants awarded in response to the first two RFAs. (seemed redundant to next line) Dr. Gray presented several examples of R24 award highlights, detailing cohort and data activities by grantees, as well as outreach activities.

Looking forward, the plan is to revise ES18-009 and release it with specific language addressing the needs to:

- Revise the FOA with expectations upfront on structure and deliverables
- Revisit eligibility and required NIEHS investment in the cohort
- Consider Data scientist required as multi-PI
- Limit support for senior key personnel
- Milestones need to be explicit, enforced, and realistic
- Develop opportunities to support collaborative science projects to utilize the resources

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Dr. Gray also provided an advanced look at an NIEHS R24 website that is currently in development.

Dr. Wright asked Dr. Gray if there had been consideration of a centralized data center to be shared by several cohorts, becoming a data science hub, which would reduce costs. Dr. Gray said that concept would work for the birth cohorts. She added that it had been discussed internally; but is not embedded within the current RFA.

Dr. Manautou asked about the influence of migration in the cohorts, and how investigators account for movement of participants. Dr. Gray said there are a few funded grants that deal with that issue. She noted that young people tend to be most difficult to maintain participation, but community advisory boards can often help.

Dr. Racette asked about the cohorts concentrated in older populations and whether they can compete with other groups. Dr. Gray noted that there are in fact many birth cohorts and children's cohorts, and only a few grants focused on older adult cohorts.

Dr. Goldman said that in her experience, an R01 will not provide resources for some of the larger cohort work such as outreach and other maintenance activities, since the grants are hypothesis-focused and will not necessarily "fill in the cracks that need to be filled in to maintain an entire cohort operation." She said that perhaps NIEHS itself should take control of some of the issues around data management and data science.

Dr. Ellison described the NCI's cohort infrastructure and maintenance program, as well as how it is evaluated. He asked Dr. Gray if NIEHS carries out similar evaluation. She replied that the RFA was still too new.

VIII. Superfund Research Program Data Science/Sharing Activities

Dr. Michelle Heacock briefed the Council on data science and sharing activities by the Superfund Research Program (SRP).

P42 multi-project centers for collaborative science are among the SRP grant mechanisms. The centers are highly integrated, and there is a goal for the centers to leverage the data they collect.

In 2016, SRP began posting links to publicly-available data sets, in an effort to make data findable. To date, approximately 3400 data sets have been posted on the SRP website.

In 2018, P42 grants began requiring a Data Management and Analysis Core, with the goal of leveraging centers' data to accelerate the impact of the center's research.

In 2019, SRP issued data supplements to support data management, integration, and re-use, to help meet the challenges of data sharing and leverage the advantages

available. A goal is to advance the science of the SRP Centers to reflect the breadth and complexity of SRP data sets. The supplements are designed to encourage data interoperability and re-usability. They are comprised of two components: internal use case (IUC), and external use case (EUC).

IUC requires the center to:

- Build data center capability within the center
- Recruit of data science expertise, support, training, etc.
- Improve data management practices to support data sharing
- Improve data interoperability

EUC highly encourages the center to:

- Address a real-world, science-driven research question and collaborate with another SRP-funded researcher.
- Address the integration of two or more data streams
- Address barriers to interoperability and re-use
- Assess the effectiveness of strategies to improve the Fairness of SRP data

Dr. Heacock provided data emerging from the supplements IUCs and EUCs. SRP has conducted several activities regarding the supplements, and plans further webinars and a Best Practices/Needs Workshop is scheduled for early 2021.

IX.   Concept: NIEHS Program to Support Training and Workforce Development in Environmental Health Data Science

Dr. Chris Duncan presented the concept to the Council.

Workforce development is one of the NIH data science strategic goals and objectives. NIH considers it essential to equip the next generation of researchers with the skills needed to take advantage of the growing promise of data science for advancing human health.

Among the biomedical realm, EHS data are among the most diverse, complex, and challenging, dealing with all levels of biological organization and across all stages of the lifespan. The field employs diverse approaches, leading to a variety of data types. Data science and workforce development are major focus areas of the 2018-2023 NIEHS Strategic Plan: Theme 1, Goal 7, and Theme 3, Goal 1. Previously, NIEHS has been involved in the NIH Big Data to Knowledge (BD2K) Program, and in 2018, held a workshop on Developing a Data Science Competent Environmental Health Sciences Workforce. The major recommendations from the workshop were:

- Improve access to EHS data to drive innovation and training opportunities.

- Support creation or adaptation of short courses, online training, and/or core curricula at the intersection of EHS and data science.
- Foster partnerships between health researchers and quantitative scientists.
- Support data science training across career stages and knowledge levels.
- Outreach to a broader spectrum of stakeholders within and outside environmental health.

The proposed concept is a broad, multi-phased concept to advance workforce development for environmental health data science. The proposed program has 2 goals:

- To improve the data science skills of all environmental health scientists.
- To increase the number of environmental health data scientists.
    - Quantitative-trained researchers to develop tools and methods for environmental health.
    - Researchers employing advanced applications of data science for environmental health

Multiple program components are proposed to be rolled out over time. In the initial phase would be administrative supplements to NIEHS research grants to support training of data scientists in the EHS domain, along with open educational resources for environmental health data science. Dr. Duncan described each of the initial components in more detail. Later components will adapt according to evolving needs, but may include:

- Environmental health data science training coordination center
- Administrative supplements to NIEHS institutional training grants
- Fellowships in environmental health data science
- Career development or career transition awards in environmental health data science

Dr. Duncan delineated how success will be measured in several key areas.

Dr. Racette was the first Council reviewer. He said that overall, he was enthusiastic about the concept, and strongly agreed with the importance of NIEHS leading big data research. He said there may be some additional opportunities under the training and workforce development concept. He said his main complaint was that the concept was too incremental, and that he would like to see a much more aggressive effort in the area. He felt that it would be unrealistic to expect all EHS researchers to improve their data science knowledge, and it would not be necessary, but collaboration would be the critical component. He mentioned the concept behind the ViCTER program as a model, where collaborations are required. He said he was most enthusiastic about the next tier

program components articulated by Dr. Duncan. He said that when considering future funding opportunities, it will be important to consider that much of the work that occurs in the big data science realm may not involve hypothesis testing and may be difficult to get through standard study sections.

Dr. Tanguay was the second Council reviewer. She noted that many in the field lack the skillset to perform data integration when asked to and find collaborators with the appropriate skills. She said that as much as she applauds NIEHS for driving that trend, she did not think the level of investment outlined in the concept would get there. She agreed with Dr. Racette that it would be difficult for purely data scientists to succeed with study sections. She said that ideas such as the Superfund Data Management and Analysis Cores (DMAC) were good, allowing data science to "bake in the cake." She emphasized that there is no need for all trainees to be data scientists, but that there is still a need for data collectors. She said that overall, she was very supportive of the long-term effort.

Dr. Manautou asked Dr. Duncan about the potential eligibility of for-profit organizations in the educational space for the open educational resources' initiative. Dr. Duncan said that for-profit organizations would probably not be eligible, given the obligation for open dissemination.

Dr. Kavanagh asked whether the concept of fellowships might include internships. Dr. Duncan said the idea had been considered in his group and would be beneficial.

Dr. Mastin called for a motion and second to approve the concept, which were received. The Council voted electronically in favor of the concept.

X.   Full Council Discussion

Dr. Cindy Lawler moderated a discussion between Council members and a panel of the presenters on data science: Dr. Duncan, Dr. David Balshaw, Dr. Schmitt, Dr. Heacock, and Dr. Gray.

Dr. Fasman cited his 30 years of involvement with The Jackson Laboratory, and said over the course of that time, he had seen the development of its data science program from infancy. He noted that Jackson is now in the midst of a dramatic expansion of its data science activities, and is facing many of the same data science issues as NIEHS. He lauded the NIEHS plans for talent acquisition and talent development. "The arc of the development of data science ideas at NIEHS and the environmental health science community has been terrific to watch grow," he said. He felt that guidance from NIH may be lacking, and said that given the unique mission and diversity of data types with

NIEHS, the institute should continue what it has been doing and should not await orders from the central command. He said that long-term data stewardship is a critical issue for the global biomedical research community. He said it would be important to focus on what is the life cycle of key pieces of data, and that not everything would need to be maintained for all time. The lifetime of a data set should not be measured in R01 renewals. He recommended taking a portfolio approach, beyond simply making individual decisions one at a time. He emphasized the importance of ontologies, standards, and metadata, referring to his experience with the Mouse Genome Project. "It's important that you set aside a portion of your funding activities to continue to promote ontology development in this space, because nobody else is going to do it," he said.

Dr. Lawler agreed that "ontologies are key to everything." She alluded to past workshops on the topic, noting that they are not just "one-and-done," and that a sustained momentum needs to be built. She added to Dr. Fasman's comments about stewardship of the data over time. NIH is considering the issue of how data can remain accessible after a grant runs out, for example.

Dr. Duncan said that NIH is considering long-term data storage in a tiered approach, depending on the size of the dataset. "There are several ongoing efforts to modernize the ecosystem in this area," he said, including a workshop on the role of generalist repositories in the biomedical domain, and a pilot figshare program. Also, NIEHS participates in two new RFAs, one to support new biomedical repositories using a U24 mechanism. Also, for very large datasets, NIH is undertaking the STRIDES initiative to store data in the cloud.

Dr. Goldman noted that NIEHS has been "incredibly creative" in finding ways to move forward without creating a large new program. She said she would support an effort that brings more data science expertise into NIEHS. She noted that there has been a certain duplication of effort. She said it would good to produce efficiencies by developing standards, such as those that emerged in the gene sequencing field.

Dr. Coronado said she was excited but concerned. She said that cost/benefit is an important consideration with data. She was worried about gender issues, as computer science is dominated by males. She asked how more data would improve people's environmental health.

Dr. Korfmacher focused on equity. She said that when talking about the need to balance cost and openness, you're really talking about the opportunity to then shape a research agenda. She said she learned in her past experiences that it was important for the data to have structures for interaction among multidisciplinary experts, as well as the importance of community engagement, to ensure that the concerns of people who may

not have access to the data be facilitated. She cited decision support tools that could aid the linkage of the technical structures being discussed with the theme of equity.

Dr. Cordero said he thought that data science is here to stay, and will become a standard area of science. He asked, "How do we promote the development of academic programs that actually develop data science? What is needed to push beyond just starting to actually getting established?" He said that data science should be thought of as an evolving issue.

Dr. Tanguay pointed out the need for raw data and the need to save it.

Dr. Racette said that the post-processing methods often used to come up with data change all the time, but the underlying data may be incredibly valuable five years down the line.

Dr. Balshaw said that in the metabolomics community, the workbench is actually handling both types of data – the raw data and the processed data. He pointed out that it is a challenge that a lot of the data can only be analyzed with proprietary software that required very expensive licensing. Storing data in the cloud offers an aid, but re-use often costs a significant amount.

Dr. Kavanagh said that as academics there is a risk of losing trainees and postdocs. Retaining them is important to include in programs.

Dr. Wright asked what role NIEHS will have in creating a common ontology, because it will not happen organically, but will need to be driven centrally. He suggested that partnerships toward that could be established with institutions such as the National Library of Medicine. Dr. Mastin asked whether there is a role for the societies in helping to establish common ontologies.

Dr. Fasman said that most of the ontologies he could think of came from extramural support, starting with R01 grants. He said he could think of only one instance where a society played a convening role. Typically the process is driven by the passion of a small number of scientists who recognize the problem, he noted.

Dr. Lawler mentioned that she was part of the BD2K standards efforts. She said that they heard again and again that standards development usually happened close to a project, with volunteer time plus a small, dedicated, passionate group working to develop and implement the ontology for the particular project, and when the project was complete, the resources were not there to maintain or carry it forward. She noted that it is difficult to establish community-based standards, as there is a very small number of people who can do the work well, and funding is a real issue.

Dr. Collman cited the experience of the Human Genome Project in responding to the challenge of establishing ontology. She said that several years ago, NIEHS went to the societies and told them that the future is sharing, and encountered resistance. She noted that there are some ontologies, such as the one developed by the HHEAR program. She asked how adoption can be incentivized, and how can demonstration projects be created outside of HHEAR to get researchers to adopt it and then build upon that in a community-based way. She asked for advice about how to get where the institute wants to go, given that everyone knows where to go. There is an opportunity for the next generation of scientists to get on board with the effort, she said. "We're going to share data, but why should every group have to re-harmonize and re-adopt standards, and create something else, and do it a hundred or more times?" she asked.

Dr. Fasman said that ontology workshops are one of the most valuable NIEHS activities. He felt that this meeting had shown that NIEHS was ready to go beyond simply funding workshops to funding pilot grants to get the ontologies off the ground.

Dr. Manautou said that thus far the discussion had not addressed the issues of cybersecurity and the protection of intellectual property.

Dr. Lawler observed that most of the group have had experience working collaboratively to develop data as a resource that is meant to be broadly accessed. However, most of what NIEHS supports are investigator-initiated projects that generate small to medium-sized data sets. She asked those who generate such data sets think about their utility for sharing and their feasibility.

Dr. Kavanagh said that it is critical that metadata be finely tuned to the smaller data sets.

Dr. Manautou said it is important to share data with someone with whom you have a good, trusting relationship, who will be a good steward of the data. Dr. Lawler asked how you would capture the characteristics that would lead you to trust a data set. She asked about elaborating metadata enough to provide the context that would lead one to trust data from the particular lab.

Dr. Perez-Lugo noted that there is much competition in the field, and there is no incentive to share anything. "The issue is not an IT issue, it's a cultural issue, it's a structural issue" she observed.

Dr. Lawler said she thought there had been some warming of the climate around data sharing in the last 15 years.

Dr. Goldman said there should be more training in data science in the environmental health community. She said that she is familiar enough with data to ascertain its

reliability, but most people in the field are not. She said that some level of standardization will help, but people will not be reassured by that if they do not understand it. She noted that "we really are behind times in environmental health compared with other areas." She recommended making the tools that have been developed more broadly accessible.

Dr. Woychik asked what suggestions the group would have for NIEHS to reward the types of behaviors that will ultimately facilitate the sharing of data. One suggestion, he said, would be for environmental scientists and data scientists to engage in discussions about how to collect data so that everyone would generate data that is seamlessly integratable.

Dr. Fasman suggested it might be useful to require grant applicants to discuss their past data sharing activities, making it an incentive in the review process.

Dr. Woychik said that fundamentally the sociology and psychology of how data is shared and working collaboratively together must change. Dr. Perez-Lugo said that NIEHS must create the system for comparability.

Dr. Gray noted that the heterogeneity seen in population studies make NIEHS unique compared to other agencies, so homogeneity across populations is unlikely. However, if there was a minimum requirement of common elements, it would be a game-changer for population-based science.

Dr. Cordero suggested that the ECHO cohorts could yield some helpful information. There has been a requirement to share data, and it has not been easy. Looking at what works and what does not work in ECHO could give important insight about where incentives could be placed to support data sharing.

Dr. Tanguay noted that it is not a new problem. He suggested that a reporting function may help. Dr. Woychik added that requiring applicants to list specifically where they have shared information in the past may be useful.

Dr. Kavanagh said that he had had the experience years ago when applying for a nanotechnology grant that sharing of data was required. There was then an understanding of embargo, which worked well.

Dr. Goldman said that publication in EHP is a motivating factor, including making data public. She added that not allowing for cost recovery of data sharing is a negative factor.

Dr. Woychik asked to what extent people found that IP issues were a serious impediment. Dr. Kavanagh mentioned a case that had had to go through the state

attorney general's office. Dr. Cordero described a recent example of a Zika study that took three months for approval to share samples.

Dr. Perez-Lugo observed that sharing is not the same as creating a structure for the data to be able to be integrated. Dr. Collman agreed that they are different, but very much related. A common ontology would facilitate data sharing.

Dr. Goldman said that IP issues were being talked about all the time. "The real issue for the institutions is whether or not there are speed bumps to access." She said there should be a process for access to data.

Dr. Coronado suggested that the ICPSR at the University of Michigan may be a good model for accessible data (https://www.icpsr.umich.edu/icpsrweb/).

Dr. Parker mentioned the past experience when CBPR began being required, and said she felt that requiring attention to data science would pay off.

Wrapping up the session, Dr. Mastin thanked everyone who had participated.

XI. Report of the Director, Division of Extramural Research and Training

Dr. Mastin updated the Council on recent development in the division.

He welcomed several new DERT staff members.

He outlined the annual process of approving Council-Delegated Authorities, which are actions delegated to DERT staff that require no follow-up action with Council. He called for and received a motion and second to approve the action. Council voted in favor.

Dr. Mastin described two Superfund Research Program (SRP) RFAs, part of the SRP R01 concept clearance. He provided background and historical information about the SRP R01. The current solicitation involves continuation of the current concept of biogeochemical interactions, and using materials science to optimize conditions for bioremediation of hazardous substances. The awards will be bestowed in 2021. He asked for and received a motion and second to approve the concept. The Council voted in favor.

Dr. Mastin presented another concept clearance: SRP R25 Occupational and Safety Training Education Programs on Emerging Technologies. He described the two existing RFAs covering the programs, as well as highlights from the current R25 program and focus areas for a future RFA. The awards would be made in April/May 2021. He requested and received a motion and second to approve the concept. The Council voted in favor.

Dr. Mastin described the NIEHS-funded Epidemiology Resources webpage, a web tool created to organize and share information about NIEHS-funded environmental epidemiology studies. It provides information on DERT epidemiology grants and on the populations supported by those grants. The tool now contains information on 72 study populations and 236 NIEHS-funded grants. A new search function allows users to quickly find information about epidemiology studies funded by DERT.

Dr. Mastin provided a summary of the FY2019 DERT budget allocations. Total funding for all extramural grants was $350.6 million. Total RPG funding was $264.4 million for 618 competing and non-competing grants. The payline was kept at 10%. Dr. Mastin broke down the allocations according to a number of analyses. He reported on budget projections for FY2020.

He provided an overview of several of the activities DERT support since June 2019, including relevant meetings, conferences, and trainings.

He announced a new opportunity for experienced data and computer scientists and engineers, the Data and Technology Advancement (DATA) National Service Scholar Program, being sponsored by the NIH Office of Data Science Strategy, with applications due April 30. He also announced the availability of the Human Health Exposure Analysis Resource (HHEAR), which is designed to provide researchers access to high-quality exposure assessment services.

Dr. Mastin also announced an RFI inviting comments and suggestions for a proposed research initiative to decrease maternal mortality.

Following Dr. Mastin's presentation, Dr. Woychik presented a certificate of appreciation to retiring Council member Dr. Lichtveld.

XII.   PEPH Update

Liam O'Fallon, coordinator of the Partnerships for Environmental Public Health (PEPH) program, updated the Council on PEPH.

He explained the program, including its goals:

- Coordinate programs and projects that involve community and scientist collaborations
- Develop and evaluate strategies to communicate environmental public health messages
- Create and distribute materials to increase awareness and literacy about environmental health risks

PEPH is designed to provide and promote multiple ways for researchers and communities to obtain support for innovative and creative activities within the PEPH network.

Mr. O'Fallon described the many accomplishments and benefits of the PEPH, dating from its inception in 2008 to the present. In terms of coordination and communication activities, PEPH is involved with:

- PEPH webpage
- PEPH Resource Center
- Monthly newsletter
- Podcasts
- Webinars
- Grantee Highlights
- Twitter
- LinkedIn
- Annual meeting

Mr. O'Fallon provided numerous examples of those activities, along with details about PEPH network-building efforts, which include PEPH meetings and professional meetings. He delineated PEPH research contributions to activities such as environmental health literacy, citizen science, and community-engaged research. He described the PEPH Annual Meeting, which was being held simultaneously with the Council meeting at the Durham Convention Center.

Dr. Perez-Lugo said that PEPH could be the model for many other initiatives in the other federal agencies.

Dr. Parker suggested that the PEPH Resource Center be made available to people other than grantees. Mr. O'Fallon agreed that that was a good point and bears further discussion.

Dr. Korfmacher said she was amazed and impressed by the breadth of PEPH activities. She focused on translation of environmental health to public health. She asked about progress through PEPH in terms of development of social science and environmental health disciplines. Mr. O'Fallon said there had been one T32 program to help create the opportunity to bring in social science to the environmental public health sphere.

Dr. Lichtveld suggested that PEPH focus on what communities can do in terms of the factors that influence susceptibility, particularly exposomics. She also felt that the PEPH network should be made more explicit in RFPs. Mr. O'Fallon said those were good suggestions.

Dr. Mastin read a message from Dr. Shih, who agreed that PEPH should serve as a model for other institutions, particularly those involved with mental health and child health.

Dr. Wright wondered if there might be some value if PEPH sponsored joint meetings with other ICs. Mr. O'Fallon felt that was a great idea in terms of how to amplify the network and build it further with more partners. Dr. Woychik agreed that was a great idea, perhaps leading to a central NIH community engagement program with an integrated message. Dr. Ho agreed that such a centralized network would be of great value. She noted that it is difficult to find mechanisms to publish this kind of work and suggested that perhaps EHP or other journals might accommodate it.

Dr. Goldman said that PEPH might consider having guests in its newsletter and podcasts to broaden participation by the community, and to address publication challenges. She suggested that PEPH become more involved with some of the special interest communities, such as breast cancer and autism, as well as other ICs. Dr. Woychik observed that with 27 ICs, there is a bit of a silo effect, and it would be good to partner with them, particularly the disease-oriented institutes. He suggested one way to do so would be to invite people from NCI or NICHD to write pieces for the PEPH newsletter.

Dr. Korfmacher said it would be important to understand both the merits and problems associated with silos, and to be "really clear about what problem we're solving." When reaching out to other institutes, it would be important to be quite clear about what is unique and special about the EH field. She felt that the kind of engagement being discussed could be quite helpful to other institutes.

Dr. Ellison commented on some of the relevant NCI programs. Mr. O'Fallon noted that some of NCI's activities focus on communication and communication research, which would be a good fit with PEPH interests.

Dr. Coronado observed that one impediment is access to scientific journals and recommended pushing for open access.

XIII. NIEHS SBIR/STTR Program Update and New Concepts

Dr. Lingamanaidu Ravichandran updated the Council on the NIEHS small business grants program.

He provided an overview of the SBIR/STTR program, including the underlying legislation, the program's goals, and details about SBIR and STTR. The programs use both omnibus and targeted RFAs to promote NIEHS goals. The targeted RFAs involve emerging areas, topics unique to environmental science, areas with needs, areas for

which only a few applications typically received.   To illustrate how the process works, he detailed several examples of recent focused FOAs.

Dr. Ravichandran presented four new SBIR FOA concepts for Council's approval:

- Developmental Neurotoxicity-related Tools and Assays for Environmental Sciences
- Artificial Intelligence and Machine Learning Approaches to Advance Environmental Health Sciences
- Biomarkers/Biomonitoring of Biological Response to Environmental Exposures
- Environmental Exposure Assessment Sensor Validation – Phase II/IIB

He provided details of each of the concepts, including potential mechanisms and a timeline.

Dr. Ho was the first Council reviewer. She said this type of program is important to aid translation. The most impressive aspect is that the small companies were able to use the seed money effectively. Regarding the developmental neurotoxicity concept, she suggested that it might be good to expand it to include study of the aging brain. She said she liked the "very forward-looking" research in artificial intelligence in machine learning, areas where NIEHS should be taking the lead. She said she was highly supportive of the program. With many of the initiatives leading to intellectual property/patent components, she pointed out that the funded PIs need to be US citizens.

Dr. Kavanagh was the second Council reviewer. He agreed with Dr. Ho's comments. Regarding the developmental neurotoxicity concept, he suggested adding reference to the peripheral nervous system as well. He said that biomarkers have been a substantial area of investment and continues to be an important area. For the artificial intelligence and machine learning concept, he felt that it was consistent with past investments in science, and that it is important to have commercial partners to work with in the area. Regarding sensor validation, he said it is important to continue with areas that have already seen substantial investment. He suggested emphasizing in the RFA the availability of support for intellectual property ideas and technologies, as well as advanced ideas in marketing and promotion, including connecting to the PEPH program.

Dr. Ravichandran noted that extra money is available to aid with marketing and promotion purposes.

Dr. Lichtveld asked how the program tracks the outcome of the products. Dr. Ravichandran said that that is a challenge, particularly after a grant ends. Dr. Lichtveld suggested that it should be beefed up in order to track investment. Dr. Christie Drew,

chief of the Program Analysis Branch, added that there is an internal system for collecting and tracking information for all grants, including SBIR/STTR.

Dr. Goldman said that it would be good practice to periodically conduct an evaluation of which initiatives have proven to be good investments. She suggested that NIEHS SBIR FOAs tend to be rather small, and there would be more of a return by doing it for larger funding opportunities. She asked whether NIH an evaluation process has, since every IC is required to have an SBIR/STTR program. Dr. Woychik asked if there were best practices at the NIH level.

Dr. Mastin asked for and received a motion and second to approve the concepts. Council voted in favor of the motion.

XIV. Adjournment

Dr. Mastin thanked the Council members for their contributions, and the staff members who had contributed to a very successful meeting. Dr. Woychik thanked the Council and complimented Dr. Mastin on coordinating his first Council meeting as chair. He adjourned the meeting at 11:04 am, February 12, 2020.

CERTIFICATION:

____/s/_____	____/s/_____
Rick Woychik, PhD	J. Patrick Mastin, PhD
Chairperson	Executive Secretary
National Advisory Environmental	National Advisory Environmental
Health Sciences Council	Health Sciences Council

Attachment:
Council Roster