

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

**MINUTES OF THE ONE HUNDRED FORTY-FIRST MEETING OF THE
NATIONAL ADVISORY ENVIRONMENTAL HEALTH SCIENCES COUNCIL**

February 19-20, 2014

The National Advisory Environmental Health Sciences Council convened its one hundred forty-first regular meeting on February 19-20, 2014 in the Rall Building, Rodbell Auditorium, National Institute of Environmental Health Sciences, Research Triangle Park, NC. Dr. Linda Birnbaum presided as Chair.

The meeting was open to the public on February 19, 2014 from 8:30 a.m. to 4:30 p.m. and on February 20, 2014 from 8:30 a.m. to 9:30 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 20, 2014 from 9:35 a.m. to 11:30 a.m. for consideration of grant applications. Notice of the meeting was published in the *Federal Register*.

Council Members Present

Kim Boekelheide, MD, PhD
Kelley Brix, MD, MPH (*ex officio*) (by telephone)
Julia Brody, PhD
Marie-Francoise Chesselet, MD, PhD
Vivian Cheung, MD (by telephone)
Lisa Conti, DVM
David Eaton, PhD
Tomás Guilarte, PhD
Andrea Hricko, MPH
Howard Hu, MD, MPH, ScD (by telephone February 19, 2014)
James Johnson, PhD (*ex-officio*)
Norbert Kaminski, PhD
Randall Kramer, PhD
Mary M. Lee, MD
Yvonne Maddox, PhD (*ex-officio*)
Linda McCauley, PhD, RN
Thomas McKone, PhD (by telephone February 20, 2014)
Edward Postlethwait, PhD
Deborah Winn, PhD (*ex-officio*, February 19, 2014)
Elizabeth Yeampierre, JD

NIEHS Staff

Kathy Ahlmark
Janice Allen, PhD
Bruce Androphy, JD
Robin Arnette, PhD
Joe Balintfy
David Balshaw, PhD
Martha Barnes
Linda Bass, PhD
Sharon Beard
Linda Birnbaum, PhD
Bernard Brown
John Bucher, PhD
Danielle Carlin, PhD
Trisha Castranio
Lisa Chadwick, PhD
Kelly Chandler
Pamela Clark
Jennifer Collins
Gwen Collman, PhD
Yuxia Cui
Christina Drew, PhD
Dorothy Duke
Lisa Edwards
Benny Encarnacion
Symma Finn, PhD
Christine Flowers
Mary Gant
Stavros Garantziotis, MD
Barbara Gittleman
Kimberly Gray, PhD
Jonathan Hollander, PhD
Michelle Heacock, PhD
Jerry Heindel, PhD
Heather Henry, PhD
Joseph "Chip" Hughes, Jr., MPH
Michael Humble, PhD
Laurie Johnson
Helena Kennedy
Annette Kirshner, PhD
Cindy Lawler, PhD
Alfonso Latoni, PhD
Kelly Lenox
Chris Long

Robin Mackar
J. Patrick Mastin, PhD
Kim McAllister, PhD
Steven McCaw
Rose Anne McGee
Liz McNair
Mark Miller
Kindra Morrison
Sri Nadadur, PhD
Sheila Newton, PhD
Liam O'Fallon
Ted Outwater
Kristianna Pettibone, PhD
Jerry Phelps
Molly Puente
Leslie Reinlib, PhD
Elizabeth Ruben
John Schelp
William Schrader, PhD
Thad Schug, PhD
Daniel Shaughnessy, PhD
Carol Shreffler, PhD
William A. Suk, PhD, MPH
Claudia Thompson, PhD
Sally Eckert-Tilotta, PhD
Frederick Tyson, PhD
Christopher Weiss, PhD
Leroy Worth, PhD
Rick Woychik, PhD
Darryl Zeldin, MD

Other NIH Staff

Lawrence Tabak, DDS, PhD

Members of the Public Present

Ernie Hood, Bridport Services
Pia MacDonald, SSS
Michael Phillips, RTI International
Pam Schwingl, SSS

I. Call To Order and Opening Remarks

NIEHS/NTP Director and Council Chairman Dr. Linda Birnbaum welcomed attendees and called the meeting to order. She asked all present in the room to introduce themselves, which they did. She mentioned that Council members Dr. Vivian Cheung, Dr. Howard Hu, Dr. Thomas McKone, and *ex officio* member Dr. Kelley Brix would be attending by telephone. She noted that Dr. James Johnson from EPA would be filling in for *ex officio* member Dr. Jennifer Orme-Zavaleta, and that Viola Waghiyi, Dr. Tom Gasiewicz, and *ex officio* member Dr. Jesse Goodman were unable to attend. She recognized the retirement from Council of members Dr. Julie Brody, Dr. Andrea Hricko, Dr. Mary Lee, and Dr. Tom Gasiewicz.

II. Review of Confidentiality and Conflict of Interest

Designated Federal Official Dr. Collman reviewed the Conflict of Interest and Confidentiality procedures, which had been provided earlier to Council members in written form, and reviewed various other administrative matters.

III. Consideration of September 2013 Meeting Minutes

Approval of the September 2013 minutes was moved and seconded, and Council voted unanimously to approve the minutes. Dr. Collman noted the dates of the upcoming Council meetings for members to put on their calendars.

IV. Report of the Director, NIEHS

Dr. Birnbaum updated Council on institute developments since the September 2013 Council meeting.

She reported that there has been significant progress in NIEHS Strategic Plan implementation in the eight areas that were deemed to be cross-divisional. Among the activities she described was the launch of a WHO/NIEHS Collaborating Center scheduled for February 20, 2014.

Another new initiative, aligned with Goal 5 of the NIEHS Strategic Plan, was the establishment of an NIH Disaster Research Response (DR2) Initiative, which NIEHS is leading and administering. It is designed to provide ready-to-go research data collection tools and establish a network of trained research responders.

In her legislative report, Dr. Birnbaum said that since a budget has been agreed upon and the debt ceiling has been raised, there should be no government shutdown for the next two years. NIH and NIEHS, however, are still below the FY2012 appropriation. NIH has seen more than two-thirds restoration of the cuts made under rescission and

sequestration. The NIEHS appropriation for 2014 is \$665 million. She summarized relevant legislation under consideration, and reported on recent Congressional meetings.

Turning to science advances, she briefly summarized several recent publications by NIEHS/NTP personnel or grantees, including a paper from her lab on mimicking of estradiol binding by flame retardants and their metabolites. She also described recent publications from DERT, DNTP and DIR researchers.

She reported on several new developments in the area of data management and technology, including enhancements to the Comparative Toxicogenomics Database, new chemical screening data released by Tox21, the NTP Non-neoplastic Lesions Atlas, the DREAM Toxicogenetics Challenge winners, and the IOM Roundtable Workshop on Data Sharing for Environmental Health.

She detailed several recent meetings and events, including recent meetings of the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM), the American Public Health Association, the Breast Cancer and the Environment Program, and a Gulf of Mexico Oil Spill conference. She also outlined several upcoming meetings, including the Society of Toxicology meeting March 23-27 in Phoenix.

Dr. Birnbaum related several awards and recognitions gained by NIEHS personnel and grantees.

Dr. Kaminski asked Dr. Birnbaum to describe in a bit more detail an upcoming workshop on inflammation that she had mentioned. She said that the meeting was still in the planning stages, particularly since the budget situation had been clarified so recently. She predicted that the workshop, which would be relatively small, might be held at RTP in September, or perhaps November. (Note: Since the Council meeting this conference has been rescheduled tentatively to April 2015.)

Regarding the priority activities under the Strategic Plan described by Dr. Birnbaum, Dr. Hu asked whether the epigenetics core facility would become a resource for external investigators. She speculated that if an external investigator was collaborating with DIR or DNTP researchers, that would be acceptable, but added that the facility would not be "for hire."

Lauding NIEHS activities related to the Gulf Oil spill, Dr. McCauley said that interaction between ecosystem and human health researchers is vitally and increasingly important, but that often the two groups are not aware of each other and do not communicate. Dr. Birnbaum agreed that the issue is related to the One Health approach.

Regarding the NIH Disaster Research Response Initiative, Ms. Yeampierre said she was particularly excited about the effort because of the need for baseline data on communities, which was a challenge after Hurricane Sandy, especially related to brownfields and Superfund sites after the storm surge and the ensuing contamination spilled into the surrounding communities. She asked whether the initiative would help to provide the needed baseline data. Dr. Birnbaum agreed that the lack of good baseline data is a significant problem. She said that the DR2 effort would arm people with the tools they need to go out and get information at the time when an emergency occurs, allowing measurement of peak exposures.

V. Report of the Director, DERT

Dr. Collman welcomed Dr. Jon Hollander, who joined the DERT Genes, Environment and Health Branch as a program administrator in December, 2013.

She described proposed changes to the Council Delegated Authorities, focusing on changes in the language related to early Council concurrence using the Electronic Council Book.

Dr. Kramer asked Dr. Collman if she had any more details she could share regarding the proposed changes, specifically, which pilot programs might be under consideration. She replied that paradigms that might impact both the timing and expediency of conducting grant actions may be tested. She said that she and her staff would be exploring how other NIH institutes use the mechanism to their advantage in making their operations more efficient.

Dr. Boekelheide expressed his support for the idea, but questioned whether the example provided in the proposed language was necessary.

Dr. McCauley asked how much time the changes involving early Council concurrence might save in terms of funding decisions. Dr. Collman replied that at different times of the year, early Council concurrence would help very much, particularly in the summer, when staff are up against fiscal year end deadlines.

Dr. Collman asked for a motion and second to approve the Council Delegated Authorities, which she received. Council voted unanimously to approve the measures.

Turning to the FY 2013 budget, Dr. Collman provided details concerning the distribution of grants, pay lines, and success rates. She also described initiatives planned for FY 2014.

She reviewed the topics covered and issues raised in the “retreat” held at the last Council meeting in September, 2013, along with several proposed actions in response to Council input.

She described a new proposal for seeking Council input on selecting grants that received scores that are not in established the pay line. That would include setting a conservative, fixed pay line, and identifying a zone for consideration (ZOC) for selecting raise to pay/specials. She opened the floor for Council discussion of the proposal.

Dr. Postlethwait noted that the proposal was very responsive to the discussions held at the retreat. However, he said, “If we’re to help you in making these kinds of decisions, I still think somehow we’ve got to have access to the grant applications.” He said that if Council is still allowed access only to summary statements, it would be stuck in the existing loop of relying on what someone else had said relative what Council members may or may not see in the application. Dr. Collman said she had anticipated that question, and noted that it is not common practice to share full applications with Council members, because Council members are not being asked to peer review the applications. She said a balance is needed to give Council members what they need to provide advice about priorities without crossing over the line to have a second peer review. She said that there had been discussion about what pieces of applications to provide to Council, and how to incorporate those into staff statements. She said that relevant information could be picked out on a case-by-case basis.

Dr. Hu felt that the proposed process would be working at the margins, and that the outcome would still be basically the same, that there would be “some winners and some losers.” As an investigator, he said he was missing the sense of why a grant application was rejected. He was concerned that some applications were given lower scores simply because they lacked enough preliminary data to convince reviewers that their proposed approach would work. He proposed that in such cases, NIEHS might offer a limited budget for one year, so that the investigator could enhance preliminary data. Dr. Collman replied that there is a process such as the one Dr. Hu described, called R56, which is employed perhaps two or three times each year. It allows investigators to continue to develop their proposals and add to the quality of their applications upon re-submission. Dr. Hu asked if that subjected them to second rejections, resulting in “two strikes.” Dr. Collman said that that is a possibility, but that good results had been seen generally with the R56 awards.

Dr. Kaminski said he was very concerned about setting a conservative pay line, as it could continue to drift downward as money becomes more and more scarce. He said he would hate to see the appearance that the peer review process is being circumvented, with grants being cherry-picked. Dr. Collman replied, describing the philosophy behind the current distribution of funds, with 50% of funds going to the pay

line. She noted that where to set that line was a topic of frequent discussion by DERT staff. Dr. Kaminski noted that dropping the pay line from 15% to 10% would be “a huge, huge shift,” and that was his main concern. Dr. Birnbaum noted that there were many non-competes this year to be funded. She added that although there had been some restoration of funds following sequestration, the institute would still be nowhere near the FY 2012 funding level. She said that it was important to attract more scientists to environmental health sciences, and that in fact the number of submissions had increased. Also, she noted that it is important to live the Strategic Plan, and that having a conservative pay line would allow more flexibility in funding decision-making. She said that many institutes have gone to conservative pay lines, and that 10% (the proposed pay line) is not very conservative compared to those of some of the sister institutes.

Dr. Winn described the National Cancer Institute’s approach to pay line issues. She said that at NCI, special grants are assessed at the Scientific Program Leader level, which occurs prior to review of applications by their council. That is set at 9%, she said, noting that NCI does not refer to it as a pay line. She added that grants above that level are considered on a case-by-case basis, and are paid when there is consensus among the Leaders.

Dr. Boekelheide recommended establishing a philosophy of a percent of the grants that will be paid without further considerations, and articulating that philosophy to constituents. That percent would be set by Council, and would change from year to year. He agreed that it would be “nice to see some words from the actual investigator...something that speaks from the heart of the investigator so that we’re not looking through the glass darkly all the time.”

Dr. Hricko said that perhaps NIEHS could provide some additional guidance as to elements that need to be in the summary statements. Lacking that information makes it difficult for reviewers to evaluate applications.

Dr. Maddux noted that the proposed process is very difficult, with many contributing factors. She noted that NCI deliberations are limited to one disease, while NIEHS is more like NICHD, her institute, with “a huge complexity of scientific disciplines that we represent, as well as various diseases and conditions that we approach through various technologies and various mechanisms.” She said that NICHD has tried hard to take an approach to select pay and special funding, which inevitably concerns or angers outside entities. She said that NICHD does have a group of select pay criteria, and described the NICHD approach in detail, noting that it is a complex balancing act, using their Council to help with decisions.

Dr. Brody asked Dr. Collman for her thoughts about what substantively would be communicated to applicants both before the application round and after the funding decisions are made. Dr. Collman said that currently on the web page, the raise to pay/special criteria are not posted, but that would be one method of communicating the ideas to applicants. She noted that it would take some time to work the process out, so perhaps next year, once it has been tried a few times in pilot mode, it would be appropriate to add material about the process to the website. She described some of the criteria that have been used by program staff on a case-by-case basis to prioritize.

Dr. Eaton commented on the R56 process. He noted that it was an obscure mechanism, and that he had never previously heard of it. He asked what criteria would be used to trigger it. He said it sounded promising, and encouraged expansion of its use. Dr. Collman said that program staff members do go over summary statements with investigators, and staff meet prior to Council review and sometimes agree that an application might meet the criteria for an R56. She added that since 1995, 31 R56 awards have been funded, of which 18 have been converted to funding.

Dr. Lee applauded efforts to develop the proposed approach. She expressed concerns about whether there should be grants pulled out from the 10th percentile and not funded, as a result of funding some of the raise to pay/special grants. She disagreed with that idea, since the reviews would have already considered significance. She felt that once a percentile was established as a zone of certainty, it should be adhered to. Dr. Birnbaum observed that it has been very rare that a grant has been pulled out, and then only because it was completely inappropriate for NIEHS.

VI. Updates from the NIH Principal Deputy Director

Dr. Lawrence Tabak, NIH Principal Deputy Director, provided Council updates in four areas: the NIH budget, initiatives to enhance the translation of data into knowledge, programs to ensure a robust and diverse biomedical workforce, and challenges in supporting the best science.

He noted that “there’s good news and there’s bad news” concerning the budget. The really good news, he said, is that there is actually an appropriation, and that the budget recovered somewhat from sequestration. However, the not-so-good news, he observed, is that effectively NIH has become “un-doubled” in terms of its buying power. He emphasized that that message needs to be communicated to members of Congress and their staff.

Dr. Tabak went over the challenges involved with Big Data, and particularly since it involves a variety of data types, all capable of producing high volumes of data. He

described several of the initiatives NIH is undertaking to tackle the Big Data problem, including the Big Data to Knowledge (BD2K) program.

He reported on plans being pursued by NIH and individual ICs to enhance reproducibility, including several pilot programs designed to address key concerns in that area. He also described the Accelerating Medicines Partnership, a new program where 10 drug companies and several non-profit organizations are joining with NIH to study Alzheimer's disease, rheumatoid arthritis, and lupus, with the intent of distinguishing targets of the diseases most likely to respond to therapies.

Dr. Tabak went over NIH initiatives involving the biomedical research workforce and diversity. He reviewed the challenges associated with ensuring a robust workforce, and described several NIH initiatives in that area, including the DP7 BEST program, a Common Fund program seeking innovative approaches to complement traditional research training in biomedical sciences at institutions that receive NIH funds. He also reported on the challenges involved in enhancing workforce diversity and NIH initiatives in that important area.

He discussed the challenges involved in supporting the best science, including issues related to improving the peer review process. He described the issues surrounding approaches to supporting science, including how to enhance support for extramural research without increasing costs.

Regarding issues of reproducibility, Dr. Postlethwait said that in the last ten years, there has been a convergence of journals trying to increase the number of papers they publish by decreasing the amount of methodological descriptions in manuscripts, along with other factors reducing reproducibility. He asked Dr. Tabak whether NIH has discussed those factors. Dr. Tabak agreed that "the methods sections of many journals have become methods tweets, and they are insufficient to reproduce anything." He did not agree that that causes a reduction in the methods sections of grant applications, which are not designed to facilitate replication. He suggested that methods sections of journals should be expanded, or should be posted on line. He noted that NIH is working to address those issues through better training, through dialogue with journals, and striving to be better reviewers.

Dr. Chesselet noted that NIH has a leadership role to play worldwide, beyond how things are done in the US. She added that as much concern as there should be about the consequences of imperfect data and the need for replication, it should not discourage exploratory science. Dr. Tabak agreed about the need to be judicious in enhancing replication, so that innovative research is not compromised.

Referring to diversity enhancement efforts, Ms. Yeampierre noted that by 2042, people of color will constitute a majority of the US population, a group of people who historically

have had poor access to health care, historical trauma, environmental harm, poor diet, and other disparities. She asked Dr. Tabak how the commitment to diversifying the work force is going to help address those larger concerns. He replied that NIH cannot be expected to address those larger issues, but must focus on what it can do to ensure that the training opportunities NIH supports are made available to everyone, as well as ensuring that unintended bias filters do not enter into hiring and other forms of decision-making. He added that he wished to see young people of color entering into scientific pursuits such as biochemistry, and not focusing exclusively on disparities research, although those might be the challenges that affect them most directly.

Dr. Guilarte asked Dr. Tabak about NIH efforts to enhance flexibility for investigators, including longer duration of support. He noted that it often takes a long time to investigate developmental issues in various species, and asked if there is a mechanism for NIH support to last longer than 4-5 years. Dr. Tabak said that NIH is actually working through approval to extend the life of a sub-set of grants. He noted that the intent of NIH MERIT awards was to encompass support for the duration of an experiment, providing stability to the investigative team and allowing an investigator to take greater risks.

Dr. McCauley commented that young people are graduating with so much student debt today that their career choices are being affected, often resulting in pursuing more lucrative careers than science can offer. She said that there needs to be a better way to fast-track trainees, not to simply develop a pipeline but to shorten the pipeline for advancement to add economic value sooner. Dr. Tabak agreed, noting that NIH has some small programs in progress that allow individuals to go from their graduate degrees directly to independent funding.

Dr. McCauley noted that there is a huge workforce need in data analytics, and she hoped to see NIH try to level that need. She said that there is a need for a curricular track to address the basic education in biostatistics at an early stage. Dr. Tabak agreed, and said that the issue is what elements to put in a standard curriculum aimed at the non-specialist.

Dr. Lee asked a fundamental question about study section grading of applications, noting that there is no gold standard, raising a complex concern. Dr. Tabak said, "You've put your finger on it – what is the gold standard? And at present, despite all of the efforts in analytics, literally hundreds of papers being published about this, the gold standard remains expert opinion." He noted that most of the time, participants in study sections can come to a consensus.

VII. Research on Parkinson's Pre-motor Symptoms: Clinical and

Etiological Implications

Dr. Zeldin introduced speaker Dr. Honglei Chen, head of the Aging and Neuroepidemiology Group within the NIEHS Epidemiology Branch. Chen updated the Council on his group's research on the clinical and etiological implications of pre-motor symptoms in Parkinson's disease.

He described the social and economic impact of Parkinson's, which is the second-most prevalent neurodegenerative disorder in the US. Parkinson's develops over the course of decades, and by the time the characteristic motor symptoms appear and allow definitive diagnosis it is too late for any effective intervention. Thus improved characterization of the so-called pre-motor symptoms – loss of smell, daytime sleepiness, REM sleep disorder, constipation, depression and anxiety – is critical to facilitating earlier diagnosis and potential early treatments modalities. The pre-motor symptoms may present many years before the motor symptoms begin, and help lend insight into the potential environmental triggers associated with the disease.

Chen presented material on how pre-motor pathology may work, and related epidemiological evidence of their association with Parkinson's. He shared data about his group's approach to pre-motor symptoms research, which involves screening large existing cohorts with extensive environmental data. They are working to identify an intermediate phenotype that can help identify high-risk populations, particularly to study what environmental factors may influence or modify the process of disease development.

Dr. Guilarte asked Dr. Chen whether it would be possible to correlate the symptomatology with a clinical endpoint early on to allow diagnosis of Parkinson's, similar to what is currently being done in Alzheimer's. Dr. Chen reported that NIH currently has two programs in progress, attempting to diagnose Parkinson's earlier through alpha-synuclein biomarker detection and imaging. He predicted that the biomarker would need to be incorporated into his own line of research.

Dr. Hu asked what markers would be used to assess previous environmental exposures in the large cohorts Dr. Chen is accessing. Dr. Chen noted that the ARIC Study provided rich clinical data, but very little data on environmental risk factors. However, the Ag Health Study did include environmental data, particularly exposures to pesticides.

Dr. Chesselet inquired whether Dr. Chen was seeking to identify particular risk factors that might lead to particular types of Parkinson's disease, given that there appear to be multiple forms of the disease, with different progress profiles or different symptoms. Dr. Chen acknowledged that the concept that Parkinson's may not be a single disease is

important for the whole field. He said that once subtypes are established, it would be a potential direction for his research.

Dr. Lee asked Dr. Chen whether he had an idea of why the predictive value of the complex of pre-motor symptoms is so different in males and females, and whether the inclusion of some of the pre-motor symptoms with the risk factors might increase the accuracy of the predictions, with some of the symptoms being relatively non-specific. Dr. Chen noted that many of the non-motor symptoms such as constipation and depression are more prevalent among women, and that only a small percentage would be due to Parkinson's. He said that as to disease prediction, everything should be included, such as risk factors, genetics, biomarkers, and subtle motor dysfunction.

VIII. Training Update

Dr. J. Patrick Mastin, DERT Deputy Director, introduced a session designed to update Council on the NIEHS extramural training program. Based on Council suggestions at the retreat in September, the update is intended to involve Council earlier in the process of evaluating and developing a proposal for the future of the training program, before a fully formed proposal is presented. The session began with short presentations from Dr. Michael Humble, Dr. Carol Shreffler, and Dr. Christie Drew.

Dr. Humble provided an overview of the training program and described the new NIH F31 predoctoral fellowship program and discussed approaches to funding what might be a large number of these applications. He noted that in 2013, \$18.6 million had been allotted for NRSA training slots. He reported that with the upcoming April 8, 2014 due date, the program would begin offering the NIH F31 Individual Predoctoral Fellowships, which would necessitate creation of new slots, based on the number of applications received. He said there would be three options for creation of new slots: cutting back on the number of T32 programs, cutting T32 programs by 1 or 2 positions each, lowering the Fellowship success rate, or some combination of all three options.

Dr. Shreffler updated Council on T32 institutional training grants. They are designed to foster cross-disciplinary training, to recruit trainees from other disciplines, and to increase diversity within EHS training programs. Also, they help to ensure effective opportunities for young investigators' transition to independence, to promote the integration of EHS into medical education, and to build worldwide EHS research capacity. She described the topic distribution of T32 programs and trainees, along with data on universities with more than one funded T32 grant. She also described the three sub-aims of the Strategic Goal #

Dr. Drew described resources for conducting evaluations of the training program, which included the CareerTrac and Portfolio Coding programs. She mentioned that the group had just completed its first major push to populate the CareerTrac system with trainee outcome, making it a good time to focus on assessing the training programs, with the aim of fostering continuous improvement. The CareerTrac data is from nearly 3,000 T32 trainees that were active from 1995-2012. Dr. Drew demonstrated analyses that can be done, including breakdowns by science area, scientific topic, and publication data. She also presented data related to trainees' employment outcomes.

Dr. Eaton moderated the Council's discussion on training programs. He noted that in addition to T32 and F grants, many training dollars are included in R01s, and asked what fraction of trainees were supported by R01s. Dr. Drew replied that that information was not available. Dr. Birnbaum noted that the institute directors had been talking about the issue, and hoped that the tracking for postdocs would also apply to predocs, so that anyone funded by NIH would be captured and tracked regardless of the funding mechanism. Dr. Eaton said that at his institution (the University of Washington), R01s could be split out, with the vast majority of trainees coming under R01s.

Dr. Postlethwait asked about the role of minority supplements to grants. Dr. Drew said that they would be able to track those individuals, but they are not in the data she had presented. She noted that CareerTrac only covered T32s at present. Dr. Shreffler observed that minority supplements are funding by a different mechanism. Dr. Birnbaum reiterated that the movement is toward tracking everyone funded by an NIH grant.

Dr. Eaton turned to the topic of moving money out of T32s to support more F31s. He wondered if that would close the door on faculty and their trainees who are not traditional environmental health scientists, which could be an unintended consequence of the change, in opposition to the strategic goal of bringing more people from outside the EHS discipline into the field. He noted that that could happen given a flood of F31 applications by trainees associated with established EHS researchers. Dr. Kaminski suggested that a solution to that issue might be to restrict the number of years of funding through the F and T mechanisms. Dr. Eaton noted that that already exists, with support restricted to five years. Dr. Birnbaum added that many of the training programs only support trainees for the first year or two of their training, after which they must be included in R01s or some other funding.

Dr. Chesselet said she would support reducing the size of T32s to have a solid pool of F31 trainees.

Dr. Postlethwait said that the inverse of the unintended consequence Dr. Eaton had described would be that institutions with very robust T32 programs might enjoy a

selective advantage in getting F31s funded, which could restrict success at other institutions. Dr. McCauley agreed, noting that less than 10% of postdocs go on to get R01s, which is a serious issue. She said that often the least motivated students stay on T32s. Also, she averred, the training experience must be equalized, regardless of where the funding comes from – it should not be easier to be on a T32 than an R01, for example. Dr. Eaton cautioned against drawing too much from the statistic Dr. McCauley had cited, because the only postdocs who typically go on to get R01s are that fraction who go on to work in academia, which is a minority. “The more telling number would be the percent of those who go into academia that get an R01,” he observed. Dr. McCauley felt that the number of trainees going into academia was quite discipline-specific. Dr. Eaton noted that the statistic applied overall to NIH trainees.

Dr. Eaton asked Council members to consider what advice they would offer NIEHS regarding moving T32 dollars into the F31 program, which will be required by NIH. He cited the three options presented by Dr. Humble. He noted that another option would be to limit the number of training grant applications per institution.

Dr. Kaminski asked the panel to consider what the overall goal of expanding the F series grants. He noted that at his institution, training grants are all treated the same, and that all students are required to write a grant application as part of their dissertation prerequisites. Dr. Eaton said that his institution goes to great lengths to ensure that there is no difference between a graduate student supported on an R01 and a student supported on an F31 or T32.

Dr. Postlethwait said that one implicit benefit of the F program is to the trainees, as they would have competitively won funding on their CVs. However, as it is a zero-sum game, the distribution of the training slots must be worked out. Dr. Lee noted that productivity and career choice are factors to be considered. She said she was struck by the low number of publications in the data presented by Dr. Drew, given that the expectation is that most students and postdocs will have publications. She wondered if that was because of multiple authorships, and how they are treated in the data. Dr. Drew said that PIs are encouraged to credit a publication to every trainee’s record in the case of multiple authorship. She agreed that the denominators are always complicated.

Dr. Chesselet said that the T32 training program is quite valuable, and that the pool should be large. Dr. Boekelheide agreed, but noted that writing an F31 application would be excellent experience as well. Dr. McCauley said that having an F31 would be good preparation for writing a K99 application, skipping the F32 completely. The K99, she observed, is a bridging mechanism that allows talented students to get higher salaries.

Dr. Collman said that it was not known what proportion of the total pool of F31 fellows at other institutions come from T32s, as opposed to those who received F31s directly as a result of being in an environment where they get the help they needed to get through the F31 process. She said it would be helpful to have that information to determine the appropriate proportion for NIEHS. Dr. Eaton noted that since NIEHS has not been funding F31s previously, there are no data. He suggested looking at the data from other ICs. Dr. Birnbaum added that it would be important to find out where in their careers people getting F31s at other ICs are.

Dr. Shreffler said that there would be some proportion of the applications that would not be assigned to NIEHS, including predocs who may be more appropriately assigned to other ICs. Dr. Eaton mentioned that when a graduate student and mentor apply for an F31, it goes into CSR just like a grant, not applying directly to NIEHS.

Dr. Postlethwait noted that a T32 is generally written by the leadership of the training grant in the context of the training program, whereas with an F31 it is between the trainee and the mentor to formulate a program. "A T32 is written by people who know what they're doing....," he said. Dr. McCauley replied, "You can't even apply for an F31 unless your mentor has R funding." Dr. Collman suggested that there should be outreach activities through professional societies and other channels to ensure that the abilities of the pool of applicants would come up to speed in terms of being able to write effective applications.

Dr. Kaminski said that most graduate programs now require a student to write a grant proposal in the format of an F31 NIH grant as part of their comprehensive exam, so typically students applying for an F31 would be finishing their second year, which is when students often defend that proposal. He felt that the F mechanism may actually spread the money out a bit more across institutes.

Summarizing the discussion, Dr. Eaton said it would be important to look at the NIEHS Strategic Plan in the context of these issues, and attempt to determine what benefits there might be to NIEHS of moving money out of T32s and into F31 programs. Dr. Boekelheide said he had been considering the strategic goal of interdisciplinary training, and whether through RFA mechanisms, the F31 could be directed to address dual training strategies. Dr. Eaton said that at his institution, if you are not an NIEHS-funded investigator and you apply for a pilot project, you must identify a sponsor who is an environmental health scientist. He suggested that that approach may be a model for the F31 application process.

Dr. Humble said NIEHS staff was particularly concerned about the nimbleness of the F31 program, and that perhaps some targeted RFAs could be put out if there was a

need to boost training in specific scientific areas important to the future of the environmental health sciences.

IX. MEEED Concept

Dr. Dan Shaughnessy briefed Council on a proposed research program focusing on mitochondria, energetics, epigenetics, environment, and DNA damage response (MEEED), on behalf of a cross-divisional planning committee.

“This concept brings together several research areas of interest to NIEHS,” he said, “[such as] the effects of environment on epigenetic regulation, DNA damage response, and how toxicants affect mitochondrial function.” He noted that the focus is on how those pathways are integrated in a way that allows cells to respond to environmental stress, particularly whether there are persistent responses in those signaling pathways that might be indicators of disease risk.

He said that the goals of MEEED are to understand how stress to the mitochondria affects cellular pathways, and the reverse – what happens when the pathways are perturbed, and mitochondria respond by changing energy production, metabolism or other functions. The cross-talk or signaling between mitochondrial functions and the response pathways are a major interest, both under normal stress and under adverse conditions. Comprehensive understanding of these conditions would bring better prediction of cellular responses to multiple hazards.

Dr. Shaughnessy described several previous, related NIEHS activities, including a March, 2013 workshop on MEEED, from which various recommendations emerged, leading to the formulation of the proposed concept.

The group is proposing a two-phase approach. The first phase, utilizing an R21 mechanism for 2 years followed by an R33 mechanism for 2-3 years, focuses on technology development, with pilot studies of the new technologies. Phase 2 would employ an R01 for 5 years, during which novel methods would be applied to study mitochondrial-cellular responses to environmental stressors, through *in vitro*, animal, and population studies.

Dr. Cheung (by phone) was the first reviewer of the concept proposal. She supported the two-phase approach. She recommended that the investigators be allowed to decide on models and stressors to be studied.

Dr. Guilarte was the second reviewer. He also agreed with the two-phase approach, in that it is extremely important to have development and validation of methods. He noted that there is much uncertainty about the pathways and how mitochondria are affected,

and that it would be very difficult to tease out the pathways involved due to considerable cross-talk. Eventually, he said, a systems biology approach would be very important.

Dr. Postlethwait noticed that mitochondrial haplotype was not mentioned in the presentation. Dr. Shaughnessy acknowledged that that was a good point, and with much scientific activity in that area currently it would certainly be included.

Dr. Kaminski inquired whether the two-tiered approach was setting up for people getting the first phase grants to go on to continue with the R01s. Dr. Shaughnessy acknowledged that that would be a possibility, but noted that groups are independently working in some of these areas, so there could be people coming in from other fields as well.

Dr. Boekelheide observed that the concept might be hard to explain to the scientific audience. Dr. Shaughnessy agreed that to write the RFA effectively, it would need to be narrowed. He said that the first phase is specifically tool development, to help determine what methods will be ready for the R01 phase.

Dr. Guilarte noted that not all mitochondria are the same, and wondered how those differences, representing another level of complexity, would be teased out. Given that complexity, "at the end, what would you be able to learn?" he asked.

Dr. Birnbaum asked Dr. Shaughnessy to define "fluxomics." He explained that it is an emerging field looking at the formation and disappearance of metabolites as a way of examining dynamic changes in cellular metabolite levels.

Dr. Postlethwait recommended that when the RFA is written and reviewed, it would be critical that the differences in mitochondrial functions in different tissues and organs, for example the lung, be accounted for. By the same token, he noted, some areas may need to be excluded. Dr. Guilarte reiterated that those issues should be left to the investigators to define.

Dr. Collman called for and received a motion and second to approve the concept. Council voted unanimously in favor.

X. Open Council Discussion

Council returned to its discussion of training issues, with Dr. Eaton continuing to moderate. He reiterated that the DERT staff should consider what the goals would be for NIEHS to move money from T32 to F31 programs. He liked the idea that had been raised about having RFA focus to F31s, because that would be a good way to target the programs directly to Strategic Plan goals.

He moved on to the discussion questions that had been raised by Dr. Shreffler, looking more explicitly at the T32 program. He noted the need for a strong research base in T32s. He asked Dr. Shreffler about specific guidelines for T32s. She said that at one time there were guidelines, but now there are no specific guidelines for either the number of slots per T32s or restrictions to applications similar to other institutes. Dr. Eaton said that it would be useful to have some guidelines to help people apply effectively. Dr. Birnbaum noted that if part of the objective is to bring people into the environmental health sciences who have not previously been in the field, perhaps they may not qualify, and it should be ensured that they be included, perhaps through co-mentorship. Dr. Eaton agreed that the grants should be crafted in such a manner as to preserve recruitment from other fields, but that the applicants should be able to document an association of their proposed research with environmental health sciences.

Dr. Collman asked how to balance emerging new training programs versus re-competitions of existing programs. Dr. Postlethwait noted the ongoing issue of what is the objective. He said, "We all realize that not everybody, in fact probably a relatively small percentage of people trained using NIEHS funds are going to end up as NIEHS investigators." He felt the institute could prioritize in this area, with the initial goal being to have an ES-trained pre- or postdocs end up as an ES-funded independent investigator. The second tier could be for that researcher to stay in the biomedical sciences, with the third tier being within science. Dr. Drew asked if he was outlining a definition of success for the program. He said he was, but that it would also be an evaluation metric and what goes into T32 or F applications in terms of the training plan. "What is the return on investment that NIEHS is looking for, for spending not an insignificant amount of money?" he queried. Dr. Birnbaum said it should be noted that there is an evolution in what NIEHS is trying to do in training investigators, knowing that the majority are not going to end up in academia, but acknowledging that there is a wider need for people with environmental health sciences training. Thus, some of the metrics being used, while interesting, may not be telling NIEHS what to do with its training.

Dr. Kramer asked Dr. Drew about whether the metric data showed any difference in payoff for training pre-doctorals versus post-doctorals. Dr. Drew replied that the data can provide information on this question, and that she is very interested in what Council would like to know. Dr. Kramer said that that information could help answer the "What do we fund?" question.

Dr. Guilarte noted that many doctoral trainees do not continue in academia, but go to regulatory agencies such as EPA and FDA. He agreed that the metrics in that area would be very important to acquire.

Dr. Brody observed that if it is accepted that funding and tenure track positions will be limited in the near future, then consideration should be given to training people for roles in environmental public health, by strengthening the pathway into careers in government and NGOs. Dr. Conti asked Dr. Drew to elaborate on why “other” was the second-most cited career pathway on the bar chart she had presented. Dr. Drew agreed that it was a subject of great interest, and hoped to have more information on that soon. Dr. Conti and Dr. Drew discussed how “industry” is defined within the data. Dr. Shreffler added that many toxicology trainees end up going into the pharmaceutical industry, and so would be represented that way in the data. Dr. Drew noted that they can perform a secondary analysis of the actual job titles that people enter in their responses, but that they have not had the opportunity to pursue that line of inquiry. Thus, she said, it is helpful to hear Council’s concerns and interests. Dr. Conti said that some of the respondents under “industry” may be in other areas. Dr. Eaton agreed, and asked how non-profit institutes would be coded. Dr. Drew said the process started with coding, looking at the types of jobs they knew people were in, and thinking about how to classify them. Then, that was turned around and put into their instructions. Dr. Birnbaum noted that there are several other categories beyond just academia, government and industry, such as policy, communications, work with community groups, etc. Dr. Drew noted that they had also asked a question regarding the emphasis of the job, whether it was research or administration or something else, which provided another piece of data. The approach to classification was to ask multiple questions with a few answers, and then try to triangulate. Dr. Drew noted that part of the effort was to streamline what would be the most valuable information. She said that NIEHS is pioneering the way for NIH in this area. Dr. Collman asked to bring this discussion topic to a close, and inquired whether Council would like to have a few members volunteer to continue to work with staff on the evaluation questions and some of the other aspects they had put forward, in order to continue to work on the questions without taking Council time. Council members indicated that they would be interested in pursuing that approach.

Dr. Collman asked Council to address the issue of coordination of multiple grants at institutions. Dr. Eaton noted that NSF has very explicit rules regarding cost-sharing – that they either completely disallow it, or they require it. They do that, he said, in order to level the playing field. He asked what guidance or expectations NIEHS provides to investigators writing a T32 for institutional support. Dr. Shreffler said that NIEHS cannot require cost-sharing or institutional support, and that although reviewers are expected to look at those elements, “it’s kind of all over the place in terms of what we get in.” Dr. Eaton reiterated that it might be appropriate to provide additional guidance regarding institutional support. Dr. Collman said that it was an area that would be worked on. Dr. Eaton felt that it speaks directly to the question raised by Dr. Collman about coordination of multiple grants at institutions. She noted that the phenomenon seems to be on the rise, and that “if this is a new trend, we need to think about how to be clear

about what the expectations are, rather than making decisions about them on an ad hoc basis.” Dr. Eaton said it would be useful for there to be an explicit statement in the guidance that if it is an application for a training grant and there is already an existing one at the institution, it should be explained how the two would relate and differ. Dr. Birnbaum said that although the trend is to track all NIH-funded trainees at all levels, there will be an effort to ensure that training is coordinated across disciplines, while there is no reason that statements could not be included in NIEHS requests.

Dr. Birnbaum acknowledged Dr. Drew’s leadership in providing information for all of NIH to be moving forward in the area, thanks to “a phenomenal effort” on her part. She then returned to the issue of the pay line or success rate, reminding Council of Dr. Tabak’s remarks about the un-doubling of NIH funding. Dr. Kaminski noted that in the earlier discussion, it was suggested that very transparent policies on how the issue would be dealt with should be put forward. He said that rather than a fixed, conservative percentile, which would change according to the availability of resources from year to year, perhaps a percentage of the funding should be earmarked for the “zone,” so that no one would feel they had been mistreated in the process. Dr. Birnbaum noted that Dr. Collman had addressed the issue to a certain extent when she mentioned that 75% of NIEHS funding goes into the unsolicited RPG line and is not based on RFAs, and that the percentile has dropped from where it was a number of years ago, but there has not been as much change in percent success rate, which may be a measure of the institute’s success in attracting more people into the field. Dr. Kaminski said that what the percentile of the extramural budget to be devoted to “the grey zone” is going to be is a major point of discussion.

Dr. Birnbaum acknowledged the need for clarity and transparency, as Dr. Kaminski had mentioned. She noted that the staff has done “a fabulous job” supporting anything that was raised to pay, as well as the skips that had been done. She said that in her five years at NIEHS, she could only recall two grants that were below the pay line that were not funded, and that was because they were inappropriate for NIEHS.

Dr. Boekelheide suggested that there should be a philosophical discussion about what percent of the available funds get paid in sequence from the top number down, concentrating on what is thought to be an appropriate number, and then what is available for the zone of consideration. That would involve a conversation about how it all affects the Strategic Plan. Dr. Birnbaum noted that NIH leadership have been discussing these issues, with clear movement toward more flexibility, due to realization of the inequality of percentiles, and the recognition that applications that differ by just a few percentile points are actually often equivalent. She said there is a growing feeling that there should be more consideration given to a broader gray zone. Dr. Boekelheide said the rest of the world is very scared of putting that type of flexibility in the hands of managers as opposed to the review bodies, although everyone recognizes the issues.

Dr. Birnbaum said that no one is talking about going all the way there, but that as money becomes tighter and tighter, it's important to look very closely at some of the issues in funding.

Dr. Maddux noted that the NICHD had been having the same types of discussions at their Council. She said she was very impressed with the data on the average size of NIEHS grants, in that that is an issue NICHD had been looking at closely. She said that NICHD had been applying an across-the-board reduction in the budgets that applicants were submitting. She saw two separate issues: what policy and procedure would be used to make discretionary decisions on applications that are in the zone of consideration, and also the size of the pie itself available for zone of consideration funding. Dr. Collman agreed that NIEHS has large average costs, even after recent cuts. Having a portfolio with large average grants, she said, really impacts where you draw the line in terms of raise to pay/specials. She said the issues involved in those decisions are quite complicated.

Dr. Postlethwait noted that he does favor the proposal, but that clearly some boundaries need to be established. He said he was concerned about issues of perception in the ES community regarding how this decision-making would occur. He wondered if there would be a way to ensure that the process is fair and unbiased.

Dr. Boekelheide asked for a "guesstimate" of what the current amount of the R01 portfolio is used for not paying sequentially from the top down, but is used in the discretionary zone of consideration. Dr. Collman estimated that in 2013, the majority of the funds went out along the pay line, and the amount of select pays made was "way fewer" than in years past. That was a direct effect of a moving pay line within the year, lack of a budget, and other matters; so ultimately the 25% mark was not achieved as it would have been in years past when things were more stable. She said that ultimately the question is, what is the value of defining and communicating a pay line? NIEHS did not do so for a very long time, and received criticism for that, and moved in the last five years to having a pay line and trying to operate within that. Because of budget crunches, the issue of where to go and communicating that decision clearly remains. She said that although the concept of a pay line was well known in the community, but if that is changing and people understand the realities, it can be determined how to adapt to that changing situation. Dr. Eaton noted that it is also subject to rumors and misinterpretation when it is not clearly articulated and communicated.

Dr. Postlethwait said that the fixed process would raise questions for people, for example if their application was scored at 11 when the fixed pay line was 10. Dr. Collman said that that had always been the situation, but that there also had always been a way to pay beyond the pay line, and that if that option was eliminated, it would be an entirely different conversation. Dr. Postlethwait noted that the pay line allowed

applicants to relax a bit, because they got a score that was less than the pay line. If the score is near the pay line, they would still be as anxious as they were. Dr. Kaminski said he was not suggesting that announcement of the pay line be eliminated, but that the pay line would shift, as it always has, based on the amount of dollars available to fund grants. He said he was concerned that the percentage of monies allocated for the gray zone should not drift, that it should stay consistent. He did not think that arbitrarily setting the pay line at 10%, for example, would work, because funding would continuously shift. He observed that it would make more sense to allocate 15-20% of funds to the gray zone, regardless of the actual pay line from year to year. He said it would be important to avoid the impression that grants are being hand-picked at the expense of the peer review process, which all still believe in.

Dr. Birnbaum asked for more discussion about how these issues tie in to addressing relevance to the Strategic Plan, which is actually a block that must be filled in by the program administrator when nominating for raise to pay. Dr. Maddux noted that the discussion should carefully describe "percentile" rather than "percent."

Dr. Collman said that the opportunity exists every year to advertise this information on the Funding Strategies website page. She said that success rate, percentile, and several other factors are included. She suggested that perhaps that communication should be changed to put in a percentage range of monies available for different mechanisms. Then communication should be beefed up in terms of how those decisions are made, to help educate the group of investigators each year. She said she never meant to assume that NIEHS would pick a pay line and stick to it for the next five years. She felt that no one could conceive of doing that, and that every year it would be re-evaluated. She said she wanted to get a feel from Council about what they would like to see kept constant, and she perceived that Council would like to see a constant percentage of dollars available for programmatic selection, in order to meet Strategic Plan goals, and for consideration of all of the other factors that go beyond a straight percentile. Then, outcomes and success would be reported back to Council each year, for updated advice and guidance.

Dr. Kaminski said that if this was articulated as being designed to meet the strategic objectives of the institute, it would likely be very well accepted, since the RFA mechanisms is put forth in much the same fashion.

At the conclusion of the open Council discussion period, Council adjourned for the day. Council re-convened in open session at 8:30 a.m., February 20, 2014.

XI. Centers of Excellence on Environmental Health Disparities

On behalf of the Population Health Branch program staff, Dr. Symma Finn presented a concept for research on environmental health disparities (EHD) through the establishment of Centers of Excellence in EHD.

She related EHDs to NIEHS strategic goals, provided definitions of health disparities and EHDs, and delivered background information about historical environmental health sciences investments in the area, as well as federal efforts and coordinated programs.

Regarding the proposed concept, Dr. Finn said "This program is intended to develop research projects similar to those funded through our existing PEPH (Partnerships for Environmental Public Health) Research to Action program, but with a greater emphasis on an integrated approach that incorporates both the environmental drivers of health disparities and the socioeconomic aspects." She said such a program would allow focus on the most vulnerable and affected populations, as well as addressing both historical and emerging environmental factors that lead to health disparities. She noted that the environmental contributions may be more amenable to intervention and prevention than socioeconomic underpinnings.

Possible areas of interest for projects in the proposed program would be:

- Determining how environmental toxicants and socioeconomic factors interact to influence human health
- Developing cost effective/sustainable prevention and intervention strategies to mitigate environmentally-induced diseases such as diabetes; obesity; breast cancer; or cardiovascular, renal and respiratory diseases in health disparate communities
- Developing tools and methodologies for data capture, measurement, analysis, and risk assessment that foster integration of multiple factors that contribute to EHDs
- Collaborative training and capacity building to:
 - Develop the next generation of EHD researchers
 - Increase the diversity of EHD researchers
 - Develop a training pipeline for established scientists to enter the field of EHD
 - Raise the environmental health literacy of community partners in the research
 - Train EHD researchers in culturally sensitive methods for community engagement in research and translation of findings
- Communication and translational goals would also be critical to the program

Dr. Finn noted several possible mechanisms for funding including R01, R21/R03, P01, or P20. She said that NIEHS is considering committing a total of \$1-\$1.5 million in FY

2015. If approved, the RFA would be finalized and published in the summer of 2014, with applications to be received beginning in the winter of 2014 or spring of 2015.

Dr. Brody was the first reviewer. She said that the concept is very much responsive to perceived needs in the environmental justice network, is very clearly aligned with the NIEHS Strategic Plan, and represents an opportunity for primary prevention. She felt that the program is an opportunity to encourage and require community capacity-building, and said she hoped it would “take more of the old environmental justice funding program, which required the community partner to be, in some cases, the PI or leader of the grant, and in all cases to be involved throughout the process.” She noted that a big current problem is that there is no environmental public health infrastructure similar to the existing medical infrastructure to support such research. Thus, it is difficult to translate research into action. “In order for this program to be successful, it needs to build in strengths that will create sustainability and translation into public health policy and community-based change,” she said. She felt that the program would also present an opportunity to serve some of the training needs that had been discussed earlier in the meeting. She noted that there are now models of community-based mechanistic studies, so they should be included in the program. She said she would favor including emerging environmental factors.

Dr. McCauley was the second Council reviewer. She liked the combination of looking at the effect of social determinants of health and environmental exposures. She noted the importance of resiliency in communities, particularly those impacted by disasters. She felt that the multi-level approach expressed in the proposal, ranging from basic science to outreach and education, is intriguing, but very much dependent on funding and capacity. Noting the success of the Centers for Children’s Environmental Health, she pointed out that it was due to adequate funding for a multi-level, center approach, with rich community engagement and basic science. She said that expertise is important, and that environmental health scientists should partner with other disciplines such as health services research and other social scientists in these projects.

Describing her background as resident of an environmental justice community where health disparities were prevalent and as part of the environmental justice movement, Ms. Yeampierre said the proposal was personal for her. She reiterated her previous comments about changing demographics, and felt that the Centers initiative “lays the foundation for the direction that we are going to have to move in.” She liked the sensitivity with which Dr. Finn had described many of the stressors that create an unwell community. She discussed the importance of adequate resources, the mining of collective knowledge, and the creation of replicable templates.

Dr. Eaton applauded the initiative, calling it “uniquely NIEHS.” He commented briefly on the three discussion questions. He agreed that the RFA should be written so that the

PIs could and should be encouraged to be from community groups, often in partnership with academia. He said he favors mechanistic research, but that given the limited resources available to this initiative, it should be focused on the community engagement aspect. Due to those limited resources, he said he would argue against a P20 or P01 mechanism.

Dr. Guilarte said the topic is extremely important, but wished to comment from a basic science perspective. He noted that in working in research with environmental toxins, at times the context of exposures is not taken into account, although it is very important. Elements such as high stress, poor nutrition, lack of health care, and other elements contribute to outcomes, he said, as do some positive contextual aspects, which can sometimes mitigate exposure effects. He advocated partnership between basic science and community-based studies.

Dr. Conti agreed with Dr. Brody's comment that the public health infrastructure is broken for environmental health, although it is still there, and felt that participation by federal agencies in partnerships such as those being discussed was important.

Dr. Johnson said that EPA is very interested in the initiative and plans to participate. He noted that EPA likes the idea of a Center, and community-based participatory research.

Dr. Maddux added that NICHD is also very interested in the proposed program, and wanted to ensure that the pediatric component of health disparities is not left out. She cited the example of infant mortality, describing NICHD's concept that it exists metaphorically as an iceberg, with the known elements above the water line, but major contributors such as environmental factors and behavioral factors under it.

Dr. Kramer said he was initially worried that the proposed program was underfunded, but was reassured by collaborative opportunities with EPA and NICHD. He agreed that it would be important to link EHS scientists with a variety of social scientists to maximize the impact of the funded studies.

Dr. Collman called for and received a motion and second to approve the concept. Council voted unanimously in favor.

XII. Worker Training Update

Joseph "Chip" Hughes, Jr. and Sharon Beard presented a Worker Education Training Program (WETP) concept clearance for Hazardous Materials Worker Health and Safety Training (U45) and Hazmat Training at DOE Nuclear Weapons Complex (U45).

Mr. Hughes said that the major objective of the cooperative agreements is to prevent work-related harm by assisting in the training of workers in how best to protect themselves and their communities from exposure to hazardous materials, waste, and chemical emergency response. The Hazardous Materials Worker Health and Safety Training FOA represents three distinct program areas including the Hazardous Waste Worker Training Program, the Minority Worker Training Program, and the Hazmat Disaster Preparedness Training Program.

He reported on WETP's partnerships with several federal agencies and non-profit training organizations, and the program's major successes through the years.

Ms. Beard discussed the components of the three programs. She related the programs' plans and next steps, including funding requests:

- Hazardous Waste Worker Training Program (HWWTP) - ~\$20 million
- Minority Worker Training Program (MWTP) - ~\$3.5 million
- Hazmat Disaster Preparedness Training Program (HDPTP) - ~\$2.5 million
- DOE-Nuclear Weapons Hazmat Training (DOE-WETP) - ~\$9.5 million

She predicted that the RFA would be released in the summer of 2014, with applications due in November, 2014. The focus is on development of consortia by grantees to facilitate a national or multistate scope. She noted that the WETP encourages new initiatives by program awardees in order to respond to emerging technologies and meet the needs of new training audiences.

Dr. Conti was the first Council reviewer. She felt that the presentation answered the question as to why NIEHS is involved, despite the fact that there seems to be no research component. Regarding the order of new initiatives and emerging issues, she recommended "a more temporal context," citing the example of hydraulic fracturing. She said that the program touches on several goals in the NIEHS Strategic Plan, particularly Goals 5 and 8. She very much supports partnerships and collaborations in this area, particularly working with the local and state preparedness groups such as the Association of State and Territorial Health Officers, state environmental health directors, and state EPA liaisons. She wondered whether there might be a role for research in the programs.

Dr. Hricko was the second Council reviewer. She thanked Ms. Beard and Mr. Hughes for their excellent work over the years in what clearly has been a very successful program. She said she was particularly interested in the many emerging issues the program has had to deal with since its inception in 1986. She wondered how the grantees stay on top of the issues they need to learn about as they arise. She wondered if there may be some partnerships available beyond those the program

already has. She agreed that the program involves many of the goals of the NIEHS Strategic Plan. She felt that fracking, climate change, and chemical security should be the highest priorities, and asked that there also be information about some of the unexpected issues that have arisen, when there were surprises requiring rapid response.

Mr. Hughes noted that the program requires every organization to have an advisory board, including all of the regional and local stakeholders in hazardous materials response, building connectivity in terms of expertise. He described the experience of the Gulf oil spill, when vessels of opportunity, including Vietnamese fishermen, were employed in the clean-up efforts. He said the challenge was to quickly determine the training needs for unqualified workers based on the anticipated tasks they would be employed to perform. He cited similar experiences with Hurricane Sandy. "We don't have the infrastructure anymore where there's some wonderful Federal army that's going to come here and solve your problems," he said, explaining that environmental health issues in such situations become poor because there is not a previously trained workforce to perform the necessary remediation tasks.

Dr. Hricko asked Mr. Hughes if he saw a role for research centers in the communities. He said that he did, and hoped that the partnership with the Centers program could be deepened so that it is not just something that happens in response to a disaster.

Ms. Yeampierre noted that Sandy was a superstorm, not a hurricane, and that it is important to make that distinction. She said that what was frequently heard from people in the community was that they were the first responders. What was learned, she said, is that in extreme weather conditions there is much unpredictability, and that the people who are going to go out and help are unprotected and do not know what they are going to be exposed to. She recommended investing in social media and apps to reach people at a grassroots level, and in having a set of tools that are available to everyone everywhere. She said that disaster response has become an industry, with people parachuting into disaster areas, but that the path to resilience is local.

Dr. Maddox asked about the thought process behind the distribution of funds in the elements of the program. Ms. Beard replied that it was how the distribution had been approached historically, because the hazardous waste program is the established core. She noted that funding for the Minority Worker Training Program and Hazmat Training Program had incrementally increased over the years. She added that some hazmat training programs include minority worker training elements as well. Dr. Maddox said it should be clear that minority workers are not excluded from any of the programs. Ms. Beard and Mr. Hughes stressed that that is certainly not the case. He described some of the partnership programs with Historically Black Colleges and Universities such as

Dillard University. "We encourage diversity, and want to make sure that we are addressing it in all of our programs," said Ms. Beard.

Dr. Collman called for and received a motion and second to approve the concept. Council voted unanimously in favor.

The February 20, 2014 open session portion of the meeting adjourned at 9:30 a.m.

XIII. Consideration of Grant Applications

This portion of the meeting (9:35 a.m. – 11:30 a.m., February 20, 2014) was closed to the public 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).

XIV. Adjournment

The meeting was officially adjourned at 11:30 a.m., February 20, 2014.

CERTIFICATION:

/s/
Linda S. Birnbaum, PhD, DABT, ATS
Chairperson
National Advisory Environmental
Health Sciences Council

/s/
Gwen W. Collman, PhD
Executive Secretary
National Advisory Environmental
Health Sciences Council

Attachment:
Council Roster