

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

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

May 13-14, 2014

The National Advisory Environmental Health Sciences Council convened its one hundred forty-second regular meeting on May 13-14, 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 May 13, 2014 from 8:30 a.m. to 5:00 p.m. and on May 14, 2014 from 8:30 a.m. to 11:30 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 May 14, 2014 from 8:30 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)
Marie-Francoise Chesselet, MD, PhD
Vivian Cheung, MD
Lisa Conti, DVM
David Eaton, PhD (by telephone)
Kevin Elliot, PhD
Kenneth Fasman, PhD
Andrew Feinberg, PhD (by telephone)
Tomás Guilarte, PhD
Norbert Kaminski, PhD
Randall Kramer, PhD
Linda McCauley, PhD, RN
Donna Mendrick, PhD (*ex officio*)
Marie Lynn Miranda, PhD
Edward Postlethwait, PhD
Britt Reid, DDS, PhD (*ex officio*) (by telephone)
Viola Waghiyi
Elizabeth Yeampierre, JD

NIEHS Staff

Kathy Ahlmark
Janice Allen, PhD
Beth Anderson
Bruce Androphy, JD
Joellen Austin
John Balbus, MD
David Balshaw, PhD
Martha Barnes
Linda Bass, PhD
Linda Birnbaum, PhD
Danielle Carlin, PhD
Lisa Chadwick, PhD
Pamela Clark
Jennifer Collins
Gwen Collman, PhD
Yuxia Cui
Caroline Dilworth, PhD
Christina Drew, PhD
Donald Ellis
Symma Finn, PhD
Stavros Garantziotis, MD
Barbara Gittleman
Kimberly Gray, PhD
Astrid Haugen
Michelle Heacock, PhD
Heather Henry, PhD
Jon Hollander, PhD
Joseph "Chip" Hughes, Jr., MPH
Michael Humble, PhD
Laurie Johnson
Helena Kennedy
Annette Kirshner, PhD
Cindy Lawler, PhD
Alfonso Latoni, PhD
Kelly Lenox
Pia MacDonald
Robin Mackar
J. Patrick Mastin, PhD
Elizabeth Maull, PhD
Kim McAllister, PhD
Steven McCaw
Rose Anne McGee
Liz McNair
Aubrey Miller, MD, MPH
Mark Miller

Sri Nadadur, PhD
Sheila Newton, PhD
Aaron Nicholas
Liam O'Fallon
Ted Outwater
Kristianna Pettibone, PhD
Jerry Phelps
Nicole Popovich
Molly Puente
William Schrader, PhD
Wynonna Sessoms
Daniel Shaughnessy, PhD
Carol Shreffler, PhD
William A. Suk, PhD, MPH
Kimberly Thigpen-Tart, JD
Claudia Thompson, PhD
Sally Eckert-Tilotta, PhD
Frederick Tyson, PhD
Michelle Victolino
Nigel Walker, PhD
James Williams
Leroy Worth, PhD
Rick Woychik, PhD
Darryl Zeldin, MD

Members of the Public Present

Sally Darney, PhD, EPA
Rachel Dexter, PhD, NIH
Mark Goonan
Elizabeth Hodges, SSS
Ernie Hood, Bridport Services
Pia MacDonald, SSS
Michael Phillips, RTI International
Steve Ramsey, SSS
Rich Rosselli, SSS
Christopher Weiss, PhD, NIH

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 member Dr. Howard Hu and *ex officio* members Dr. Jennifer Orme-Zavaleta and Dr. Debbie Winn would not be in attendance, and that Dr. Britt Reid from NCI would be attending by phone in Dr. Winn's

stead. Dr. Kelley Brix and Dr. David Eaton also would be attending by telephone. She welcomed new council members Dr. Andrew Feinberg, Dr. Kevin Elliot, Dr. Kenneth Fasman, and Dr. Marie Lynn Miranda. She welcomed FDA *ex officio* Dr. Donna Mendrick to her first council meeting. She noted that another new council member, Dr. Jeanne Conroy, was unable to attend.

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 February 2014 Meeting Minutes

Approval of the February 2014 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 February 2014 Council meeting.

She described the latest NIEHS Strategic Plan cross-divisional implementation, with the recent formation of an exposome faculty and an inflammation faculty. She briefed the panel on recent developments related to climate change and disaster response.

She provided staff updates, including the fact that a candidate for Clinical Director has been identified. That hiring is making its way through the NIH process, and should be finalized by late summer or early fall. She also mentioned ongoing DIR and DNTP intramural reviews, which will ultimately go to Dr. Collins at NIH in September.

In her legislative report, Dr. Birnbaum reported that the outlook is for the FY 2015 NIH budget to be flat. She reminded Council that sequestration still looms after the 2014-2015 budget deal in Congress if that body cannot reduce the national debt. With ongoing deliberation about the Affordable Care Act, there will not be a finalized budget this year. She predicted that there would be a series of continuing resolutions, with the hope that there would only be one enacted in late September that would carry through the November elections. She also reported on several Congressional hearings pertinent to NIEHS and pending legislation of interest.

Turning to science advances, she briefly summarized several recent publications by NIEHS/NTP personnel or grantees. She also described recent publications from DERT, DNTP and DIR researchers, including collaborations fitting the “One NIEHS” concept.

Dr. Birnbaum reported on several items of NIEHS news and highlights in recent months, including training and mentoring events, data management and technology developments, and many recent meetings and events involving NIEHS personnel. She described several upcoming meetings of interest, including her own planned trip to Alaska in July to meet with community organizers and health care officials.

Dr. Birnbaum related several awards and recognitions recently gained by NIEHS personnel and grantees, including an honorary degree to be awarded to her by Ben Gurion University of the Negev in late May.

Referring to Dr. Birnbaum’s mention that there would be additional funding for the President’s Brain Initiative but that it would not directly benefit NIEHS, Dr. Kramer asked what role NIEHS is playing in the initiative. Dr. Birnbaum replied that the institute is one of the 27 NIH institutes and centers (ICs), but does not play a leading role in the Brain Initiative. She said there is a group of nine ICs considered to be the key institutes in the initiative, but that NIEHS is not one of them. However, she noted, that should not discourage NIEHS grantees from applying for those funds.

V. Report of the Director, DERT

Dr. Collman briefed the council on recent activities and developments within DERT.

She described the new NIH grant application resubmission policy, which allows an application to be resubmitted as a new A0 application after two rejections, within certain limitations. She called the change “the biggest thing that’s happened in the extramural community in the last couple of years.”

She outlined DERT portfolio reassignments, which are an effort to balance the workload among DERT personnel. The change is also designed to enhance strategic development of major programs, including setting new visions for the EHS Core Centers and for training and career development programs.

Dr. Collman also described a new NIH Early Career Reviewer Program. The program is designed to train qualified scientists without prior CSR review experience to become effective reviewers. It helps emerging researchers advance their careers by exposing them to the peer review process, and helps to enrich the existing pool of NIH reviewers.

Dr. Collman noted that NIEHS is currently requesting nominations for the NAEHSC. The nominations will be for new council members starting their service in FY 2015.

VI. New Insights into Regulation of the Innate Immune Response by Cholesterol

Following the tradition of giving recently tenured Division of Intramural Research (DIR) scientists the opportunity to brief the council on their work, Dr. Michael Fessler addressed the panel about his group's research on regulation of the innate immune response to the environment by cholesterol trafficking.

Dr. Fessler is a Senior Investigator in the Clinical Investigation of Host Defense Group within the Laboratory of Respiratory Biology (LRB). His talk was titled, "A bench-to-bedside study of *APOE4* in the human innate immune response."

His group hypothesizes that cholesterol trafficking and innate immunity signaling are intrinsically coupled processes, and that perturbation in one will regulate the other. He showed data indicating that the $\epsilon 4$ allele of the *APOE* gene, which encodes the key lipid-trafficking and immunomodulatory protein called apolipoprotein E, is a fundamental determinant of the human innate immune response. The investigation included studies conducted in the NIEHS Clinical Research Unit (CRU).

Dr. Fessler speculated that the findings could lead to new strategies for risk stratification by following people with the *APOE4* allele, and to tailored therapies such as APOE mimetic peptides or statins to prevent or treat inflammatory diseases, potentially even including Alzheimer's disease.

Dr. Fasman asked Dr. Fessler to comment on the potential protection strategy he could imagine based on his research. He said there is a possibility of either APOE supplementation or the use of cholesterol-targeting therapies such as statins.

Dr. Guilarte asked whether the *APOE* allele influences the transport of cholesterol into mitochondria. Dr. Fessler said that there is early evidence that *APOE4* can be associated with mitochondrial dysfunction, and that cholesterol efflux pathways impact mitochondrial cholesterol levels in a way that may impact apoptosis and other mitochondrial functions.

Dr. Postlethwait asked whether the cysteine produced by *APOE3* mutation is redox-active, if it becomes oxidized, and if it may influence downstream cell signaling, which would not happen with the *APOE4* cysteine. Dr. Fessler noted that the changes in cysteines and arginines translate to changes in protein folding, and engagement of the protein on the LDL receptor. He said that there is much interest in oxidative stress impacting a number of apolipoproteins, and that there is a strong likelihood that that may be the case with APOE.

Dr. Miranda asked Dr. Fessler to elaborate on the high incidence of African-Americans with the *APOE4* allele in the CELEG sepsis study. Dr. Fessler said there was no evidence of a race-specific effect on the biology, but that interesting questions about surveillance and risk would arise at the population level. Ms. Yeampierre asked why the study had not included Latinos. She said there should have at least been an explanation about why they were not included in the cohort. Dr. Fessler was not familiar enough with the CELEG cohort to comment, but said that in his group's studies, Hispanic subjects had been included.

Dr. Birnbaum asked whether the E4 homozygotes are exquisitely sensitive to the phenomena Dr. Fessler had described. He replied that it is thought to be a gene dosage effect, particularly in risk for Alzheimer's. He noted that even one E3 copy does appear to rescue some of the function lost in E4 homozygotes.

VII. Disaster Response Research

Senior Medical Advisor Dr. Aubrey Miller briefed the council on developments related to the NIH Disaster Research Response (DR2) Project. He provided background information on the elements that led up to the initiation of the project, including slow deployment of research and loss of perishable data in the cases of the Gulf oil spill and Superstorm Sandy. Thus the DR2 Project was established, with a project timeline of August 2013-September 2014. It is seen as a pilot project to help galvanize and accelerate needed infrastructure for disaster research response, as part of a larger HHS effort. It includes a central repository for data collection tools and protocols being developed in collaboration with the National Library of Medicine (NLM). NLM has launched a new website to host these tools (now over 100 available) plus other information to help facilitate rapid baseline data collection and research in future disaster situations. Additionally, NIEHS Division of Intramural Research is developing a plug-and-play protocol for rapid environmental responses that will soon be reviewed by the NIEHS IRB, and hopefully available for NIEHS and the public to use by the Fall.

- Dr. Miller reported that a new Environmental Health Science Disaster Research Network involving NIEHS intramural and extramural researchers, NIEHS-sponsored research centers, the Worker Education and Training Program (WETP), and community partners, is also being formulated. The goal is to build a national network of trained researchers and experts to help identify EHS research priorities and respond to future environmental threats and disasters.

He emphasized that the project has already reaped benefits in terms of the establishment of important new relationships with federal government and other stakeholders, recognition of the important role of NIEHS in responding to environmental

health concerns, and building new infrastructure and capacity to perform timely research in response to disasters or other emerging threats for all to use.

Following Dr. Miller's presentation, Chip Hughes from the NIEHS Worker Education and Training Program (WETP) introduced a short video depicting a recent Disaster Response Tabletop Exercise hosted by NIEHS and held in Los Angeles in April, which brought together over 140 people including NIEHS senior leadership, researchers from NIEHS Core Centers and WETP grantees, representatives from other federal agencies, California state and local health, labor, and environment officials, and representatives from workers and the community to discuss the needs and strategies for conducting health research during and after environmental disasters.

Ms. Yeampierre said the video was a powerful emotional experience, since she lives and works in a waterfront community that was impacted by Sandy. She noted that the resources described by Dr. Miller need to be in the hands of a variety of stakeholders. She said that it will be important to determine how to make waterfront businesses climate-adaptable, and provide them with the resources to be integrated into the decision-making process. She said that it had been found with Sandy that the most vulnerable communities were the most impacted. Dr. Miller noted that climate change issues are certainly energizing much of the current discussion and ability to be prepared, as well as highlighting the need to acquire longitudinal, hypothesis-generating research, instead of *ad hoc* responses to individual situations.

Ms. Waghiyi noted that when discussing disaster preparedness related to climate change, it will be important to include food security issues. She described the impact climate change has already had on her native population on St. Lawrence Island, where the availability of traditional foods has been severely curtailed by climate change. Dr. Miller added that her remarks helped to emphasize the importance of citizen science, with the communities being able to collect and provide timely information to support public health responses and future preparedness.

Dr. Conti felt that the DR2 Project was an excellent opportunity for the growing number of centers for "One Health" pursuits to become involved. She also mentioned that it would be good to have training to be included in the National Incident Management System (NIMS), so that people going through that training would be more attentive to the need for research. She added that it would be great to have a repository of data collection tools that had been vetted.

Dr. McCauley said she hoped to see university IRBs also pro-actively approving disaster research protocols. Dr. Birnbaum added that NIH is working to update the Common Rule so that there could be a single IRB of record for many different studies, negating the delays inherent in multiple IRB situations. Dr. McCauley said that most

communities could narrow their potential types of disaster and begin looking at some of the available tools.

Dr. Elliot said he was pleased with Dr. Miller's emphasis on community partnerships and citizen science. He said that local communities would have expertise in their ability to collect information, but what kinds of information, such as exposure pathways or impacts of concern. He said it would be important not only to have rapid research response capabilities, but also to have openness to talking with communities to determine the key issues that they are concerned about. Dr. Miller agreed, stating "All situations are local."

Dr. Mendrick asked if Dr. Miller was talking with the Medical Countermeasures people at the FDA. Dr. Miller replied that he is.

Dr. Fasman asked whether Dr. Miller had considered the need to mount IT infrastructure quickly in a disaster response situation, along with data collection. Dr. Miller said that HHS is working on some of those issues, and that looking forward, standardization is a key concern.

VIII. Breast Cancer Concept

Dr. Caroline Dilworth presented a concept to the council regarding the Breast Cancer and the Environment Research Program (BCERP), which has been funded by NIEHS and NCI since 2003. It was renewed in 2010 as a multi-RFA program. She related BCERP history and its record of accomplishments as well as the 2013 publication of a report by the Interagency Breast Cancer and the Environment Research Coordinating Committee (IBCERCC), which was also led by NIEHS and NCI.

She described the overarching goals for the next phase of the program, along with its continued components, new directions, and key questions to be addressed. The next phase is to employ a multi-pronged approach, incorporating a Transdisciplinary Research Initiative (TRI) and a Communication Research Initiative (CRI).

The TRI will involve individual research projects with community-academic partnerships, with a Coordinating Center to integrate efforts across the network of individual projects.

Dr. Symma Finn presented more information about the CRI, which will seek to disseminate key messages about breast cancer risk, and assess and validate environmental risk messaging related to breast cancer. The CRI will evaluate the effectiveness of existing messages, assess the level of cultural acceptance of risk messages, examine existing tools and approaches, and investigate whether messaging impacts behavior, along with other research priorities.

The TRI FOA will be two companion RFAs utilizing a U01 grant mechanism, with a grant period of five years, being released summer of 2014. The CRI FOA will likely be released 3-6 months later, consisting of one or more RFAs, using R21 and R03 grant mechanisms, with a grant period of two years. The program would be funded at \$38 million over the five-year period, with costs shared by NIEHS and NCI.

Dr. Eaton (by telephone) was the first reviewer of the proposed concept. He said that based on his prior experience in the area, the communication aspect of the dual RFA would be important. Regarding the U01 component, he said it was his impression that each project would have multiple investigators but would not be a center. He noted that community engagement was one of the requirements, but felt that it might be a challenge for some studies to determine at what level that would occur. He said it would be important to clearly define what is meant by "engaged community partners," noting that true Community-Based Participatory Research (CBPR) is complex. He also asked how broadly "environment" would be defined. He mentioned light at night or shift work and diet as potential factors that may or may not fall into the definition of environment. In terms of the CRI, he said that the biggest challenge would be to achieve consensus about what represents a validated, true environmental risk factor, and how to go about shaping a message around that. It is a challenge to determine how much evidence is sufficient to formulate and disseminate a message.

Dr. Dilworth said that not all of the projects would rise to the true level of CBPR, although some might. She agreed that community engagement should be more clearly defined. Regarding the definition of environment, she said that a broad definition would be used, including light at night, which is already in the portfolio. NIEHS does not generally support diet research alone, but it is certainly recognized as a potentially very important modifier along with the environmental chemicals of more direct interest to NIEHS.

Dr. Finn added that the BCERP program over its last ten years had been exemplary in terms of community partners inserting themselves deeply into the research. In terms of the communication research, she noted that the toolkits are largely based on the Precautionary Principle, giving information based on animal studies and other available data, in the absence of human data. In addition, since the public is already receiving a great deal of information, sometimes the messaging must address misperceptions or misinformation delivered from non-validated sources.

Dr. Birnbaum noted that the NTP would be addressing the light at night/shift work issue in the Report on Carcinogens.

Dr. McCauley was the second council reviewer. She felt that the proposal was "very ambitious," and endorsed the model, with NIEHS in the forefront of bringing

communication and discovery closer together. Regarding communication, she felt that the R03 level of funding would be good for developing tools for the toolkit, but that it may be inadequate to fund the larger, societal/cultural research aims. She felt that the concept proposal was “very prescriptive,” and was unsure how the mechanistic and human studies researchers would work together effectively. She approved of the community engagement aspect, and agreed that the environmental exposure piece needs to be large, but felt that with the many components, it would be a challenge for one investigative team to incorporate all of the needed elements. Dr. Dilworth said the group realizes it is “a very tall order,” but that the very sophisticated extramural community often already has established community partnerships, and that applicants already have considerable transdisciplinary partnerships in place. She said that they would continue to consider which elements might be required, with others being highly encouraged.

Ms. Yeampierre was the third council reviewer. She felt that the proposal represented a very thoughtful and comprehensive approach. She described a group of elder Latinas she works with on environmental justice issues who are “fierce” breast cancer survivors. She suggested looking at transgenerational issues such as poor food, exposure to environmental burdens, etc. She also felt that regional approaches would be important. She noted that in some cases changing behaviors would not change adverse environmental conditions, and recommended interagency involvement in addressing those issues. She noted that communication about early onset of puberty needs to reach younger women and girls. She said that overall, the effort is a tall order, and is even bigger than what is addressed in the proposal.

Dr. Chesselet agreed that the proposal is exciting, but cautioned that putting so many concepts into a single construct could lead investigators to try to fit their resources into the framework. She said she would argue for a very open project, to capture the creativity needed to transform the research.

Dr. Postlethwait asked about what the group perceived regarding the mix of funding. Dr. Dilworth speculated that it would be one coordinating center and 7-8 U01s. Dr. Postlethwait added that by using the U mechanism, there would be the opportunity to steer the program to help gain return on the research investment. He agreed with the open-ended idea, but cautioned that it could result in applications that are “all over the board.” So he recommended that the group ensure that the verbiage in the RFA is very clear about what is desired in terms of the environmental component, to preclude the possibility of receiving applications that are of little interest or that do not fulfill the program’s mission. Dr. Dilworth appreciated Dr. Postlethwait’s point.

Dr. Eaton added a comment, focusing on the TRI. He said it needs to be very clear in the RFA as to whether the transdisciplinary aspect is the result of the individuals across

the different U components, or whether there is an expectation that within a single U01 grant there are multiple disciplinary aspects within each individual one. He said it would be important to define transdisciplinary.

Dr. Collman noted that the discussion had centered on issues that had been considered in-house for some time, and appreciated council's guidance. She called for a motion and second to approve the concept, which she received. Council voted 8-0 in favor of the concept, with one abstention from a council member who had been absent for much of the discussion.

IX. Discussion of "Rescuing US biomedical research from its systemic flaws"

Dr. Richard Woychik briefed Council on the major points presented in the provocative paper as presented in PNAS in March, 2014 (<http://www.pnas.org/content/early/2014/04/09/1404402111>). The authors posited a severe imbalance between dollars available for research and the still-growing scientific community in the US. They believed that the biomedical research enterprise is "on an unsustainable path." Dr. Woychik related the authors' ideas about the sources of the dilemma, particularly the damaging effects of "hypercompetition." They described the challenges of training the next generation of scientists and the "perverse incentives" in research funding as it is currently practiced.

Dr. Boekelheide presented the recommendations included in the article, and moderated the ensuing Council discussion. Chief among the many recommendations were:

- Create a 5-year NIH budget process
- Decrease the number of trainees and increase staff scientists
- Fund the individual instead of the project
- Create sunset provisions for large projects
- Encourage risky or innovative grants
- Limit the amount of funding granted to any single investigator
- Change the perverse financial incentives

Council engaged in a robust discussion of the assertions and recommendations contained in the paper, several of which proved quite controversial. Major elements of the discussion:

- There is a need to clearly define what a staff scientist is within the context of the recommendations.

- The group felt that the article was narrowly focused on academia, particularly as it urged limiting the number of trainees, because there is a wide variety of opportunities for trainees beyond academia – not all postdocs go into academic research. There may be ways to help promote such opportunities, including those in communication or policy. It would be of interest to assess the number of non-academic job opportunities available for Ph.D.-trained scientists. Postdocs who commented noted that very few of their colleagues are going into academia, partly due to the fact that so few of the mentors are retiring, with the workforce aging as a result.
- Some of the points in the article were seen as paradoxical, such as the idea of raising postdoc and staff scientist salaries, which would lead to less money being available for research overall.
- It was noted that the NIH intramural program has already instituted many of the changes suggested by the authors, with a decrease in the number of trainees and a small increase in the number of staff scientists. There have been some unanticipated adverse consequences.
- Opposition was voiced to the concept of funding the investigator rather than the project, with the concern that it would result in an elite, exclusive group of researchers. Dr. Birnbaum noted that the concept has little support at the NIH directors' level. Support was voiced, however, for career awards supporting individual investigators. It was pointed out that the HHMI model has been successful, with one advantage being the opportunity to fail. On the other hand, the viewpoint was expressed that study sections are risk averse, stifling innovation as a result. The point was also made that the NTP funds neither individuals nor projects, and instead funds programs, with good results, encouraging team science, and that that might be an alternative to be considered.
- The suggestion was made to cap indirect costs, which may have grown out of control and are used to subsidize other programs at institutions.
- The group discussed at length the suggestion in the article that there may be too much emphasis on human translational research. It was noted that the public has demanded translational research, and the connection made in the article with hypercompetitiveness was disputed. The need for a clear definition of translational research was raised.
- Peer review may need to be re-examined, as the process is becoming both untenable and unsuccessful. There was general agreement that the peer review system is in considerable need of reform.

X. Core Centers Evaluation

Dr. Kristi Pettibone briefed the Council on the Environmental Health Science Core Centers (EHSCC) Program Evaluation. She described the two prior evaluations that had been conducted in 2004 and 2010. The purpose of the 2014 evaluation will be to assess the ability of the core centers program as a whole to support and produce complex, translational, and emerging environmental health research. As such, both process and outcome data will be collected. Dr. Pettibone focused much of her presentation on defining the concepts of complex, emerging and translational research. Work on the evaluation began in November 2013 and is expected to continue through April 2015, with findings to be presented to Council in September 2015. As with the previous evaluations, an evaluation advisory committee will be convened to review the findings, provide comments and insights, and draw conclusions based on the findings. However, the committee, which will be active from May 2014 through May 2015, will not be asked to make recommendations for structural program changes.

Dr. Christie Drew added that the group was seeking at least one or two Council representatives to participate in the committee. Dr. Miranda said it was her impression that almost everyone on the Council would have a conflict in evaluating the EHSCCs. Dr. Collman noted that such potential conflict questions had arisen in past evaluations, and that it had been addressed by excluding center decision-making leaders, but not excluding people who may have had a grant from a center. She added that it would be of interest to hear Council's impressions about how deep the conflicts should be recognized, and how biased results might be. Dr. Miranda said she did not mean to infer that it would inherently lead to biased results. Dr. Collman said it would make no sense to have only people with no knowledge or experience with centers as part of the evaluation. She stressed that it is a high level evaluation, not evaluating individual Center grants. Dr. Pettibone said that to get the most effective feedback and input on the program, it would be necessary to have people with experience and first-hand knowledge. "We want people who are involved," she said.

Dr. Kramer said that the provision that evaluation advisory committee members would not be asked to make recommendations for changes seemed odd. Dr. Pettibone clarified that they were not looking for any structural changes to the program, such as changing the RFA. Dr. Collman said that the goal is not to re-do the program in its entirety or make major changes, but is to make improvements to the program.

Dr. Cheung felt that it was odd to ask the people in the program to define the "complex, emerging, and translational" terms. Dr. Pettibone noted that asking the grantees for that input is just one step in the process, which also includes Council's ideas. Dr. Drew added that the approach was one way to encourage and empower respondents to develop their own metrics, rather than the metrics being dictated to them.

Dr. Elliot suggested that community partners should be included in the process, perhaps by participation on the committee, particularly in helping define and evaluate translational research. Dr. Collman agreed that community partners, particularly Community Outreach and Engagement Core stakeholders, should be involved, especially as interview subjects during the evaluation process.

Dr. Pettibone noted that the “complex, emerging, and translational” terms are not seen as mutually exclusive or strictly distinct. She asked for further Council discussion and feedback about the terms.

Regarding “complex” research, Dr. Mendrick commented that all research builds over time, and that that is not an attribute specific to complex research. Dr. Fasman said that to him, complex research implies a systems-level view. Dr. Boekelheide recommended a TED talk on the difference between complex and complicated research. Dr. Conti compared the idea of complex problems to the “wicked problems” concept from the IT world. Dr. McCauley said she would like to see a bit more attention to the complexity of community engagement and involvement.

Dr. Drew asked how to define the research that happens or is supported by a core center that cannot be done under an R01, and said that is where the team needs Council’s help.

Dr. Postlethwait said he was having a problem reconciling the three terms with the overall format of the NIEHS core centers, because they depend upon the individual research that is making use of the cores. Thus, the evaluation seems to be of the research that the core is supporting, rather than the core itself. Dr. Pettibone agreed, but elaborated that one of the goals is to evaluate the strategies, infrastructure, and resources being provided by the core centers to help facilitate the research.

Dr. Pettibone asked for Council feedback on the “translational” term. Dr. Miranda said that her understanding is that most people think that the most important activity of the core centers is the pilot projects program. She asked if gathering information on it was part of the plan for the evaluation. Dr. Pettibone said that it would be, since the pilot projects are one of the tools used by the core centers. Dr. Collman noted that it was one of the bullets included in Dr. Pettibone’s slide about the goals of the evaluation, and that questions about the pilot projects would certainly be prominently included in the process.

Dr. Miranda wondered whether a more robust discussion may have taken place if the questions being presented were not at such a high level. Dr. Collman replied that it was an attempt to maximize use of the collective brainpower offered by Council members, and the decision was made not to burden the group with detailed questions.

Referring to Dr. Pettibone's slide depicting the components of translational research, Dr. Boekelheide said he would want something to go across the entire spectrum of those components to be considered translational research. Dr. Drew asked whether those members who conduct translational research could fit their work into the framework presented on the slide. She added that it would be important to define the concept, and either use the framework as presented, or fix it.

Dr. Eaton noted that the CTSA's had recently spent much time working to define the whole cycle of translational research, with a specific definition of each step. He recommended looking at that framework. Dr. Drew said it had been looked at previously, but that that framework had evolved over the past five years, and should be re-examined.

Dr. Kaminski said he had the impression that the group was trying to go beyond the traditional definition of translational research. He approved of that approach, but cautioned that there may be some discomfort overall with the three concepts as being too limiting. He said that the questions should focus more on how the core centers bring value.

Dr. Pettibone asked Council to turn the discussion to the third concept, emerging research.

Dr. McCauley asked about the role of innovation and high-risk initiatives, and whether funding such research is among the things a center can do. Several Council members commented that that is the role of pilot projects, and why they are so popular. If so, Dr. McCauley said, they should be included in the materials on emerging research.

Dr. Postlethwait recommended that emerging research include both methodologies and topics. Dr. Pettibone agreed.

XI. Open Council Discussion

In the remaining time available for the day, Council engaged in an open discussion period.

Returning to the previous discussion about the Alberts *et al.* paper, Dr. Postlethwait asked the NIEHS leadership at the meeting to comment on whether there were specific issues raised in the paper that they thought were relevant to the Institute, and whether Council could help with any related questions. Dr. Birnbaum replied that the intent was to simply raise the topics, and that they may get back to Council with more specific questions. She reiterated that many of the topics had been discussed recently by NIH IC directors. She said there was tension currently between basic research and the need

for it to lead to something, resulting in more interest in translational research. She said she was not convinced that too many people are being trained in the field, but that the system may be broken in terms of what they will do and what their expectations are. She felt that what is learned by trainees is less important than development of their skills in asking the right questions, which can be applied in many different directions. She noted that in the intramural program, staff scientist is not a tenured position, and is dependent on the PI in terms of employment. Thus, job security is an important issue. Tenure is under discussion as to whether it is achieving the appropriate goals or an impediment. Within that discussion, there is consideration about asking for Congressional approval to issue grants longer than four years. She said that everyone is interested in Council's ideas and constructive suggestions.

Dr. Kaminski said that the idea of non-tenure stream or "fixed-term faculty" is a long-standing concept in academia, and their numbers have grown. Lack of security is an issue, which could be taken care of with extended contracts. He cautioned, however, that creation of another class of faculty thought of as second-class faculty should be avoided.

Dr. Boekelheide said that in the paper, the authors appear to be referring more to staff scientists as senior research associates, support personnel who may not be able to apply for grants on their own. Dr. Kaminski said there is a variety of versions of individuals in that gray area, depending on the institution. When they are designated "research assistant professor," which they must put on grant applications, they will not be considered seriously by study sections, because they are known not to be independent.

Dr. Birnbaum observed that the discussion was drifting into larger topics than those covered in the paper; huge societal issues beyond the scope of NIEHS to tackle. Dr. Kramer said that many of the issues raised in the paper occur outside of health sciences, and wondered if there was a similar conversation going on at the National Science Foundation, and if so, if there is crosstalk between the two organizations. Dr. Birnbaum said there is some crosstalk related to peer review. Dr. Collman said that many sources of research funding are threatened or disappearing. "The federally supported science model is in jeopardy everywhere," she said.

Dr. McCauley said she was shocked at the ages of investigators at NIEHS, and was concerned about what is going on in academic settings. At this point, she noted, there is no incentive for a senior investigator to give up their position and focus instead on mentoring the young. If one can still get an R01 at age 65 or 70, what is the incentive to stand back and push someone younger forward, she inquired. She said the problem is not just in academia, but in the private sector as well. She suggested that there should be a way to provide a meaningful next career move for those 65-80. Dr. Birnbaum

observed that Dr. McCauley brought up another huge societal issue, citing the example of Social Security, which had been designed for a system where people were not living as long. Dr. McCauley said that in academia, the senior personnel often give up their classrooms but keep their research going.

Dr. Birnbaum thanked everyone for their participation, and closed the day's proceedings.

At the conclusion of the open Council discussion period, Council adjourned for the day. Council re-convened in closed session at 8:30 a.m., May 14, 2014.

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