

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

**MINUTES OF THE NATIONAL ADVISORY ENVIRONMENTAL HEALTH SCIENCES
COUNCIL**

February 15, 2007

The National Advisory Environmental Health Sciences Council was convened for its one hundred twentieth regular meeting on February 15, 2007 at 8:30 a.m. in the Rall Building, Rodbell Auditorium, National Institute of Environmental Health Sciences, Research Triangle Park, NC. Dr. David Schwartz presided as Chair.

The meeting was open to the public on February 15, 2007 from 8:30 a.m. to 12:45 a.m. and reopened to the public 3:00 p.m. to 4:45 p.m. In accordance with the provisions of Public Law 92-463 the meeting was closed to the public from 1:50 p.m. to 2:50 p.m. for consideration of grant applications. Notice of the meeting was published in the *Federal Register*.

Members Present

Kathleen Dixon, Ph.D.
Stefani Hines, MS
Daniel Liebler, Ph.D.
Martin Philbert, Ph.D.
Peter Spencer, Ph.D.

Members Present by Teleconference

Teresa Bowers, Ph.D.
David Christiani, M.D.
John Essigmann, Ph.D.
Elaine Faustman, Ph.D.
Bruce Freeman, Ph.D.
Joseph Graziano, Ph.D.
Lisa Greenhill, MPA
David Losee, J.D.
Altaf Wani, Ph.D.

Ad Hoc Members Present

Kevin Stephens, M.D.

Members Absent

Frank Talamantes, Ph.D.
Peter Thorne, Ph.D.

Ex Officio Members Present

COL James S. Neville

Liaison Members Present

Jennifer Sass, Ph.D., NIEHS Public Interest
Liaison Group

NIEHS Staff

Janice B. Allen, Ph.D.
Beth Anderson
Ralph Ball, Ph.D.
David Balshaw, Ph.D.
Martha Barnes
Linda Bass, Ph.D.
Sharon Beard
Ebony Bookman, Ph.D.
John Bucher, Ph.D.
Gwen Collman, Ph.D.
Dorothy Duke
John E. French, Ph.D.
Sally Eckert-Tilotta, Ph.D.
Benigno Encarnacion
Christine Bruske Flowers
Elliot Gilmore
Kimberly Gray, Ph.D.
Thomas Hawkins
Jerry Heindel, Ph.D.
Heather Henry, Ph.D.
Marc Hollander
Michael Humble, Ph.D.
Ethel Jackson, D.D.S.
Laurie Johnson
Marian Johnson-Thompson, Ph.D.
Annette Kirshner, Ph.D.
Steven Kleeberger, Ph.D.
Dennis Lang, Ph.D.
Cindy Lawler, Ph.D.

Robin Mackar
Joyce Martin, J.D.
William Martin, M.D.
J. Patrick Mastin, Ph.D.
Elizabeth Maull, Ph.D.
Kimberly McAllister, Ph.D.
Rose Anne McGee
Elizabeth McNair
Sheila Newton, Ph.D.
Theodore Outwater
Michelle Owens
Jerry Phelps
Christopher Portier, Ph.D.
Leslie Reinlib, Ph.D.
James Remington
Anne P. Sassaman, Ph.D.
John Schelp
William Schrader, Ph.D.
Daniel Shaughnessy, Ph.D.
William Suk, Ph.D.
William Stokes, Ph.D.
Claudia Thompson, Ph.D.
Patricia Thompson
Sally Tinkle, Ph.D.
Bennett Van Houten, Ph.D.
James Williams
Samuel Wilson, M.D.
Mary Wolfe, Ph.D.
Leroy Worth, Ph.D.

Members of the Public Present

David Brown, Constella Group, LLC
Reshan Fernando, RTI International
Bobbie Peterson, RTI International
David Ringer, American Cancer Society
Beth Roy, Social and Scientific Systems, Inc.
Jennifer Sass, Public Interest Partners
Pamela Schwingl, Social and Scientific Systems, Inc.
Branka Sekis, Social and Scientific Systems, Inc.
Erich Staib, Duke University Press
James Ter Maat, Social and Scientific Systems, Inc.
Hunt Willard, Duke University

OPEN PORTION OF THE MEETING

I. CALL TO ORDER AND OPENING REMARKS

Dr. David Schwartz called the one hundred twentieth regular meeting of the National Advisory Environmental Health Sciences Council to order. Dr. Schwartz, in his opening remarks, commented. He then had the Council members, NIEHS staff and guests introduce themselves.

Dr. Dennis Lang reminded Council members to sign their Conflict of Interest forms and to complete their travel vouchers expeditiously.

II. REVIEW OF CONFIDENTIALITY AND CONFLICT OF INTEREST PROCEDURES

Dr. Schwartz discussed with Council confidentiality and conflict of interest procedures and then read the requirements of the Government in the Sunshine Act and the Federal Advisory Committee Acts. All aspects of the meeting were open to the public except those concerned with review, discussion and evaluation of grant applications and related information.

III. CONSIDERATION OF MEETING MINUTES

The minutes of the September 19, 2006 meeting were approved as written.

IV. FUTURE COUNCIL MEETING DATES

The following dates were confirmed:

May 30-31, 2007	NIEHS	Wednesday – Thursday
September 17-18, 2007	NIEHS	Monday – Tuesday
February 19-20, 2008	NIEHS	Tuesday – Wednesday
May 29-30, 2008	NIEHS	Thursday – Friday

CLOSED PORTION OF THE MEETING

This portion of the meeting was closed to the public in accordance with the determination that it was concerned with matters exempt from mandatory disclosure under Sections 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 regulations concerning conflict of interest were reviewed. Council members were reminded that materials furnished for review purposes and discussion during the closed portions of the meeting are considered privileged information. All Council members present signed a statement certifying that they did not participate in the discussion of, or vote on, an application from any organization, institution, or any part of a university system, of which they are an employee, consultant, officer, director or trustee, or in which they have a financial interest. Institutions or organizations which have multi-campus institution waivers, or are specifically designated as separate organizations under 18 U.S.C. 208(a), are exempt from this provision.

OPEN PORTION OF THE MEETING

V. REPORT OF THE DIRECTOR, NIEHS - Dr. Schwartz

Dr. Schwartz informed Council that NIH, at this time, was on a continuing resolution and the present budget for the Institute is the 2006 budget and not the President's 2007 budget which would increase the budget by 4.5 million dollars. The bill passed by the House and Senate allows NIH to receive another 620 million dollars, which would result in NIEHS receiving an additional 8 million dollars. Therefore, for 2007 the Institute would gain an additional 12.5 million dollars not including the Gene and Environment Initiative (GEI), the CounterACT funds, or the Superfund Basic Research appropriations.

Dr. Schwartz gave Council an update on activities related to the Strategic Plan. He informed Council that the Clinical Center Research Unit should be completed by late summer. The Heal Project in Louisiana has begun and individuals are being enrolled. The R01 portfolio (basic research) has a success rate of 20%. Superfund Basic Research now has an R01 component and over the next 5 years this will be 10% of the Superfund Basic Research budget. In terms of translational research there are two programs, the Discover Program for the extramural community and the Directors Challenge for the intramural community. Both bring basic and applied investigators together to focus on clinical and environmental health problems. In Global Environmental Health, training is an important component; therefore R01 supplements will enable scientists to train individuals outside the United States for 2 years. It is hoped that these individuals will return to their home country with the necessary research skills. Regarding the Exposure Biology portion of the Genes and Environment Health Initiative there are 5 requests for applications (RFAs) that have been issued to address this area. In the area of training and recruitment the Institute has developed the Short Term Educational Experiences for Research (STEER) is a supplement program which provides high school and undergraduates the opportunity to participate in grantee research projects during the summer. The T32 program has been changed to focus on interdisciplinary research. The Institute is still focusing on our partnerships with other ICs. The Institute currently has a strong partnership with the National Human Genome Research Institute in the Genes and Environment Health Initiative and with a T32 training program focused on genetics and the environment. We are exploring the possibility of developing a partnership with the National Institute on Aging and developing an initiative at the NIH on epigenetics which will be included under Roadmap 1.5.

Dr. Schwartz mentioned the NIEHS funding priorities and emphasis. He pointed out that investigator-initiated research still maintains the highest priority, with training and career development, integrated research, programmatic research, and infrastructure, in that order. In terms of success rate for the R01s for 2006 was just over 20% and for 2007 a success rate around 20% is anticipated.

Dr. Schwartz posed several issues to Council. He asked for solid answers, even though it might mean trade-offs in terms of what the Institute is able to fund:

The first issue concerns R01 applications and awards. 1) Should R01's continue to be a priority for NIEHS? What does this mean in relation to program project grants, Centers and other grant activities? 2) Should we maintain a constant number of new R01 awards each year? 3) How do we address the cost-per-grant issue? Should we cap R01's? If not, what should the review process be? 4) How do we address the need to have a diverse scientific balance of R01's?

The second issue concerns the NIEHS Centers. He pointed out that the Centers' budget line currently is \$95 million, which is approximately 25% of the Extramural budget in 2006. The current plan developed after discussion with the Center directors and extramural staff, is for the Core Centers to be reduced from 25 to 17 by 2012. The remaining Centers (Parkinson's, Children's, and Population Health and Health Disparities) will continue to be evaluated.

Dr. Schwartz then posed several questions to Council: 1) Should we be managing our Centers Program differently? What ideas do you have in terms of management, review, and where necessary, trade offs? 2) Should there be a fixed portion of the Extramural budget dedicated to Centers, and if so what percentage? 3) In what ways do we need to think differently about the Centers to fulfill the vision of the NIEHS Strategic Plan?

Dr. Schwartz updated Council on the Minority Career Development Program. Intramurally, Drs. Trevor Archer and Kenneth Olden have developed a program that will bring minority postdoctoral fellows to NIEHS. It is envisioned that three postdoctoral students will be funded in 2007 with an eventual goal of eight. Extramurally, NIH has a supplement program that allows R01 awardees to take on a minority postdoctoral candidate. At the previous Council meeting, remarks were made about the Meyerhoff Program at the University of Maryland and the significant accomplishments it has made in training of minority students. The Institute would like to expand this program so it is a nationally competitive program that is more focused on environmental health sciences.

Dr. Schwartz closed his presentation with the following questions to Council:

1) Should the Institute continue to support the Meyerhoff Program even if we cannot create a nationally competitive program? 2) What are the trade offs? 3) What should we be doing to develop career programs for minorities, especially in environmental health sciences?

Council Response and Discussion

Council discussion focused on the need to balance the R01 portfolio with other priorities at the Institute and the need for guidance from Council in the form of a working group or subcommittee.

VI. NIH Reform Act – Joyce Martin, JD

Attorney Martin informed Council that the NIH Reform Act of 2006 was signed by the President on January 15, 2007. She pointed out that this is the first reauthorization in 14 years for NIH. Under the Act, NIH will continue with the current Institute/Center (IC) structure; however, the ICs are capped at 27.

Four major provisions are provided by the Act: 1) the Roadmap Initiative (trans-NIH research) will now be in the Common Fund; 2) dedicated funds (a lump sum appropriated by congress) will support the Common Fund and there will no longer be a tax on each IC for funds; 3) a scientific management review board (SMRB) will recommend organizational changes; and 4) a new coordinating division as been created at the NIH OD.

Attorney Martin expanded on the provisions provided by the Act. The Common Fund will receive a percent of the appropriation that may not be less than that provided to the Common Fund in the prior year. There may be a separate line item for the Common Fund; the amount is based on the overall NIH appropriation. All of the ICs are impacted by the Common

Fund in the same way. Therefore, the ICs will be motivated to explore and pursue trans-NIH initiatives of interest that could be funded through the Common Fund. The appropriation for the NIH budget FY07 is \$28.9 billion.

Under the Act there will be a SMRB. The HHS Secretary by mid-March 2007 will appoint 21 members to the SMRB. Nine will be IC directors and the remainder will be nongovernmental members from public and private institutions who historically and traditionally received NIH funding. Any recommended organizational change must begin in 100 days and must be fully implemented in three years, unless the Director of NIH objects. Public process is required for some reorganization.

Another part of the Act creates the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI). This is a new division that is in the NIH OD. This division has broad responsibilities, such as to prioritize, collect, evaluate and oversee Common Fund proposals. It is also responsible for electronic coding of grants and activities and must produce a strategic planning report by June 1, 2007.

Also, the Act provides for a Council of Councils to advise the NIH director on conduct and support of research identified through the Common Fund. There will be 27 members selected by the Director on NIH (of these there will be one representative for each of these Institutes, NCI, NHLBI, and NIAID).

Attorney Martin ended her presentation with the following quote by Dr. Elias A. Zerhouni (when the Act was passed): "This affirmation from Congress has come at a critical time, and we want to ensure that we take the best possible advantage of its promise. We will be communicating with the community regularly as we make progress in the process."

Council Response and Discussion

Council acknowledged that this is an important Act and will enhance trans-NIH research.

VII. Epigenetics – Dr. Hunt Willard

Dr. Schwartz introduced Dr. Willard. He enlightened Council that Dr. Willard is the Director of the Institute for Genome Science and Policy and is also a Professor in the Department of Microbiology and Genetics at Duke University. Dr. Willard has made major accomplishments in genetics and genomics and has received numerous awards. He served as past president of the American Society for Human Genetics and has made major accomplishments to our understanding of X-chromosome inactivation.

Dr. Willard began his presentation with an introduction to the field of epigenetics. He highlighted different areas in science and medicine that are relevant to move the field forward and then touched on some questions people in the field are exploring in general and in the environmental health sciences. Such as, what is the basis for the difference between active chromatin and inactive chromatin? The histone code is a standard answer, but the elements of the combinatorial histone code and what leads to the code are not clear. Therefore, we need to understand the different kinds of epigenetic phenomena around the genome. For example, how and when are copies distinguished and what actually happens in the germ line in the case of imprinting? What is occurring between spermatogenesis and oogenesis that treats the identical

DNA differentially? In somatic cells, for example cancer, what is happening to allow epigenetic silencing of a large number of genes once the cancer and tumor process begins to unfold. How are these copies being distinguished, what is the cause, and how can one reverse the process? Why do dosage differences matter on these genes and why do we need imprinting? Why is only one copy of the gene expressed as opposed to two? The same could be asked for x-inactivation and why do we need for that many genes to have males and females expressing only a single copy of that gene? What are the consequences of epigenetic silencing? Lastly, what are the effects in the environment that could accelerate, decelerate or reverse the kinds of epigenetic modifications that involved DNA methylation or chromatin effects?

In conclusion, Dr. Willard stated this is a new window on the genome, which is much more complex than previously thought. However, this will allow us to gain a different type of insight into biological processes both in health and disease. It will ultimately provide the medical community with a set of different tools to begin to understand, prevent, and treat diseases.

Council Response and Discussion

Council thanked Dr. Willard for an enlightening presentation on epigenetics and for making such a complex subject very clear.

VIII. Endocrine Disruptors (translational research and Battelle evaluation) – Dr. Heindel

Dr. Heindel began his presentation by giving a brief introduction to endocrine disruptors stating this is a subclass of environmental chemicals that are toxic because they disrupt endocrine function. He then focused on two chemicals in this class, phthalates and bisphenol A. He presented information on these environmental chemicals and the need for further research. He then talked about the RFAs that were used to stimulate the field of endocrine disruptors, and the meetings and work shops used to translate the activities. He then elaborated on the portfolio analysis being done by Battelle. He pointed out that a white paper, for the August meeting, will be prepared which will answer questions on the areas funded, the publication record, the comparison of the RFA versus investigator-initiated research, and what impact this has on policy. He concluded by discussing future directions for the field, indicating that we need to continue to work on translation of animal endpoints to those in humans, to improve exposure assessment and biomarkers of disease and to look closer at mixtures as they relate to these chemicals.

Council Response and Discussion

Council thanked Dr. Heindel for an informative presentation. Council discussion centered on the potential environmental influence and the impact the food chain may have on humans with regard to endocrine disruptors.

IX. Translational Research at NIEHS and Concept Clearance for K18 – Dr. W. Martin

Dr. Martin presented an update on the Office of Translational Research and presented a concept clearance for a K18 award.

Dr. Martin began his presentation with reference to the pyramid Dr. Zerhouni included in his presentation to Council last fall which included translational research. He gave the definition of

translational research for NIH as modified from the NCI Translational Research Working Group (2006). He noted the differences related to the outcomes from ICs such as, NCI, NIAID, and NHLBI which for these ICs are often new therapeutics or diagnostics. However, NIEHS will likely focus less on therapeutics and more on diagnostics and bio-monitoring that would impact public health, prevention, and policy related to human health and disease. He pointed out that this is a big challenge for NIH and offers unique challenges and opportunities for NIEHS. In doing translational research you need a specific focus with outcomes that can be measured. One example is developing outcome measures for critical components of translational research such as done for the Office of Technology Transfer. Dr. Martin mentioned that Division of Intramural Research and Division of Extramural Research and Training are involved in translational research through recruitment and development of physician scientists, new education and training programs, and new initiatives that involve translational research (DISCOVER, Director's Challenge). Dr. Martin noted that there needs to be better bi-directional communication between the Office of Translational Research and the public interests partners or NIEHS Office of communications to enhance communication of these concepts to the broader community. In his role as Director, Office of Translational Research, Dr. Martin is actively engaged in the NIH-wide initiative to promote translational research via the Clinical Translational Research Awards (CTSA's). Dr. Martin is Chair of the Translational Subcommittee for the CTSA's. He noted that there are no right answers to all the issues necessary to build successful translational research programs at NIH; however, everyone agrees translational research is critical to the future of NIH. NIEHS will be planning a small workshop for the summer of 2007 pending available funds that will identify opportunities/barriers, and partners, and provide recommendations.

Dr. Martin then presented the concept clearance for the K18 award. This mechanism will be for individuals who are established, well-funded mid-career investigators who wish to pursue short-term mentored career development from three months to one year. The targeted populations will be funded physician scientists with clinical training and minimal experience in research applicable to environmental health sciences as well as funded NIEHS basic science investigators who wish to gain experience in disease-oriented translational research.

Council Response and Discussion

Council asked for some clarification of the K18 award as it relates to a sabbatical and the type of individuals that would apply for this type of grant. They concluded that this was an excellent mechanism that should push the field of translational research forward. Council unanimously approved the Concept Clearance the K18 award.

X. GLOBAL ENVIRONMENTAL Health (workshop report and future plans) – Dr. W. Martin

Dr. Martin briefed Council on activities that took place at the NIEHS Global Environmental Health Conference held January 10-13, 2007 in San Francisco. He noted the make up of the participants, the purpose of the conference and the relevance to Goal 4 of the Strategic Plan. . He recognized the Global Environmental Health organizing committee who worked diligently to make the conference a success. He discussed about the conference format and why the Pellston Conference format was selected. The Pellston Conference was started by the Society of Environmental Toxicology and Chemistry (SETAC) who used a small number of attendees (30-40) divided into working groups to reach consensus on important topics and provide a written report. The organizing committee followed this format using only 44 participants in the workshop. Dr. Martin pointed out the five key tasks given to the conference participants:

identify diseases where environment plausibly constitutes a significant contributor to human disease; identify specific key methodological approaches for advancing research and interventions/therapies on this topic; identify methods for connecting NIEHS/NIH funded researcher with communities and researchers in the developing world; identify barriers and alternatives for breaking them down to achieve meaningful research in global environmental health; and identify partnership possibilities with NIH, across federal agencies, as well as public-private partnerships with academic institutions, private foundations or industries to support or conduct global environmental health research. The 44 participants were assigned to one of the three working groups: A) environmental components of maternal and perinatal health; B) environmental components of child health; and C) environmental components of adult health. Dr. Martin pointed out the expected product from the working groups and what the content of the report should contain. He noted the challenges of the workshop format and presented the results of the workshop which included a 35 page summary with a rank order of suggested next steps for NIEHS and a rank order of possible research topics. The committee is finalizing the edits of the summary and plan to post information on the NIEHS website for comment from the scientific community and the public. This will include specific recommendations for implementation of the short- and long-term strategies.

Council Response and Discussion

Participants from Council and NIEHS staff who participated in NIEHS Global Environmental Health Conference expressed how well the Pellston format enables a small diversified group to work together and fulfill the goals set forth by the conference. It was also noted that the conference brought out the need to develop focused research areas that are not being pursued by other groups that make a distinct difference and demonstrate a clear impact on morbidity and mortality. .

Council discussion centered on how research in developing countries could help to address some of the research questions and inform the American public of their risks to certain diseases. Comments focused on the pros and cons of doing research in developing countries. It was stressed that when working in a developing country we should be building technical capability and not just giving technical advice. Also, we should be building intellectual capability to answer questions that are valuable to both the developing and developed countries. It was noted that we should be training a cadre of individuals in those developing countries.

XI. Concept Clearance for Fusion Grants – Dr. D. Balshaw

Dr. Balshaw began his presentation by giving a brief history on the evolution of the concept for the Fusion Grant. He pointed out that the DERT Integrative Medicine Initiative Committee (IMIC) developed this concept. The concept for the fusion grant relies on transformative research that will go beyond the reductionist incremental work that NIH traditionally funds and which will lay the foundation for major scientific breakthroughs. He pointed out that because of the complexity of human disease we will need to conduct research in a different way if we want to see breakthroughs in understanding disease processes. The Fusion Grant mechanism will help push for these breakthroughs by focusing on a hard problem that will make a huge impact; bringing multiple disciplines together to attack the problem; and giving interdisciplinary teams the time, resources, and the flexibility to make an impact in the environmental health sciences.

Dr. Balshaw concluded his presentation by giving some examples of possible problems and sample disciplines that might be addressed by a Fusion application. One example would be looking at the metagenomic effects on xenobiotic metabolism, and how understanding the

influences of microbial flora in the gut alters disease susceptibility as has been shown recently in the prevalence of obesity and diabetes. Through understanding the complexity of the disease process we would understand the specifics of the disease; and therefore could guide the diagnosis and therapy of the individual's disease.

Council Response and Discussion

Council was very enthusiastic in support of this concept and the need for breakthroughs in the environmental health sciences. They recognized the need for careful oversight of the projects, an expectation that a significant portion of the funded applications would fail, and that a mechanism such as the phased innovations award may be an appropriate approach to enabling these goals. A motion was made and seconded for approval of the Concept. Council unanimously approved the Concept proposal.

XII. Gray Zone Work Group (Procedures) – Dr. D. Liebler

Dr. Liebler gave the framework for the Gray Zone Work Group and the charge of discussing grant applications that scored in what is termed the “gray zone,” that is applications which have priority scores from 150-200 or in the 15th to 30th percentile. The working group asked the question, beyond voting concurrence en bloc, how could Council provide input to program staff and the Director of NIEHS concerning these grants? The group came up with three areas that Council could give input: 1) investigator status, 2) relevance to the NIEHS mission, and 3) scientific impact. He reiterated that Council would not be re-reviewing grant applications, but would flag applications deserving additional consideration. Dr. Liebler pointed out that this could be done through the Electronic Council Book; there is an e-mail option to communicate with program staff concerning grants in the gray zone.

Council Response and Discussion

Council discussed what steps would be taken to bring an application or applications to the attention of staff. It was suggested that the Electronic Council Book could be used to flag the applications and generate the gray zone list. Council was enthusiastic about the gray zone concept and their contributions to the process.

XIII. Report of the Interim Director, DERT – Dr. D. Lang

Dr. Lang began his presentation by outlining the topics he would discuss which included, 1) extramural funding trends in 2006; 2) extramural awards made in 2006; 3) outcomes of electronic submissions; 4) mapping the extramural portfolio against the strategic plan, 5) Spires II; 6) paperless council meetings; 7) council delegated authorities; and 8) inclusion guidelines.

On extramural funding trends in 2006 a number of charts were shown to give the distribution of funds. They showed that 70% of the budget goes to support research project grants, training, centers, SBIRs, Superfund, and other research. Dr. Lang then compared the NIH success rate to NIEHS. In FY04, FY05, and FY06 the success rate for NIH decreased while the success rate for NIEHS was slightly better. He then showed the six-year history of targeted (RFA) expenditures. The percent of targeted funding has remained around 32% of the total RPG budget.

Extramural awards made in 2006 were described next. Competing solicited awards, (RPGs, Center's, Careers and other Research totaled \$22.6 million. Competing unsolicited awards, (RPGs, Career and training) totaled \$53.9 million. He noted that the solicited versus unsolicited success rates are very similar, 21.5% for solicited and 23.1% for unsolicited.

He then informed Council on the outcome of the electronic submission of R01 applications. He pointed out that 4,000 applications were received and 70% were error free on the first submission and 94% on the second submission. The average size of an application was 5MB with largest at 70.6MB. The median time from submission to grants.gov to acceptance at NIH was 15 minutes, making this process a success so far.

Dr. Lang acknowledged the individuals that helped map the extramural grants portfolio against the strategic plan. The concept for the retreat came from the realization that if we are proposing new initiatives to address the strategic plan goals, we need to know how the work that we already fund addresses the plan. Therefore, at the DERT Science Retreat held in December 2006, progress in the attempt to map the portfolio against the strategic plan was presented. From this endeavor extramural staff saw the complexity, diversity and breadth of the extramural portfolio in one picture. However, the process was very time consuming; therefore, the recommendation was made that we need to develop a database that will allow extramural staff to gather data on their grant portfolio by linking new fields to what is currently in the IMPACII database. This could be a web-searchable interface, so one could sort and identify portfolio contents through queries. This way of looking at the portfolio would be dynamic, and allow us to determine in real time the content of the portfolio.

The next topic presented was that of SPIRES II. This is a database that can do a bibliometric analysis across all of the NIH funded grants. Dr. Lang also demonstrated how the SPIRES II data could be linked to OmniViz, a text mining tool that scans and analyzes the title and abstracts from each publication and visually displays the scientific language of the publications. Together these tools are useful in the bibliometric analysis of grants, and in evaluating programs within DERT.

Dr. Lang proposed that Council try a paperless Council Book at the May meeting. By doing this we would eliminate many hours of work by staff to collating information into the Council Books. Everything Council would need for the discussion at the meeting will be preloaded on a laptop computer provided to each council member and, if needed, could be projected onto a screen.

Dr. Lang informed Council that once a year the Council Delegated Authority is presented to them for information and their approval. The only change in the document is that item 11, "Award supplements to the Chairperson of the Council committees and to the Environmental Health Science Review Committees (Chartered or ad hoc) in an amount necessary to carry out the functions of the committees" be deleted. Council unanimously approved the change in the document.

Dr. Lang concluded his presentation by informing Council that it is required by NIH policy to present to Council the NIEHS Biennial Advisory Report certifying compliance with the NIH Policy on inclusion guidelines. The guidelines outline all review, grants management, and program responsibilities and that no awards are made without compliance with NIH policy on the inclusion of women, minorities, and children in clinical research. Also, grants involving human subjects must comply with the inclusion and tracking of participants in clinical studies. Council unanimously approved the content of this NIEHS report.

Council Response and Discussion

Council thanked Dr. Lang for his informative presentation and said that they would be looking forward to having a paperless Council

XIV. Report of the Interim Director, DIR – Dr. P. Blackshear

Dr. Blackshear began with an update on the status of Division of Intramural Research (DIR) recruitments for the Director of Intramural Research, the Associate Director for the National Toxicology Program, Chief of the Laboratory Experimental Pathology, and tenure track clinical investigators.

He informed Council that the search committee for the Director of Intramural Research is headed by Dr. Samuel Wilson and the search will close March 15; the search committee for the Associate Director for the National Toxicology Program is also headed by Dr. Samuel Wilson. The committee has identified four candidates and these individuals will be interviewed and will present seminars over the next two months. A candidate for the position should be identified by late spring or early summer. The recruitment effort for the Chief of the Laboratory of Experimental Pathology is headed by Dr. Kenneth Korach. Two candidates are being interviewed and a selection should be finalized in the next few weeks. The search committee for the tenure track clinical investigators is headed by Dr. Darryl Zeldin, and the committee has selected three candidates. The selection should be announced within the week.

Dr. Blackshear pointed out the new appointments within DIR and updated Council on the current status of the Clinical Research Unit that should be ready for occupancy in mid August of this year. He also brought to the attention of Council the winners of the NIEHS Science Awards Day. Science of the Year, Ronald Mason; Early Career Award, Karen Adelman; Mentor of the Year, David Miller; and Paper of the Year, *Translation Regulatory Mechanisms Generate N-Terminal Glucocorticoid Receptor Isoforms with Unique Transcriptional Target Genes*, N.Z. Lu and J.A. Cidlowski.

He concluded his presentation with an update on the progress of training and mentoring within DIR. He noted that there were 22 individuals awarded the Fellows Award for Research Excellence (FARE). Regarding the Pathways to Independence Awards (K99/R00) three awards were made. Dr. Blackshear updated Council on the minority fellowship program directed by Drs. Trevor Archer and Kenneth Olden. This program should be implemented in the near future.

Council Response and Discussion

Council requested an update on the Directors Challenge Program awards. Council was informed that one application received a priority score that was in the funding range. Council thanked Dr. Blackshear for the informative update.

XV. CLOSING REMARKS – Dr. D. Schwartz

Dr. Schwartz recognized Dr. Jennifer Sass, Public Interest Partners. She informed Council that the Public Interest Partners were very supportive of the initiative to take the Parkinson Centers and broaden them towards neurodegenerative diseases and hoped that the Institute might consider similar initiatives in autism and other diseases that are multi-factorial and broaden the concept to developmental diseases with environmental etiologies. Dr. Schwartz assured her that if the Institute does something in the area of neurodevelopmental diseases, they would try to do something consistent with the suggestions she made. In closing, Dr. Schwartz thanked everyone for their contributions to the discussions and deliberations.

ADJOURNMENT OF THE NAEHS COUNCIL

The meeting was adjourned at 4:45 p.m. on September 15, 2007

CERTIFICATION

I hereby certify that, to the best of my knowledge, the foregoing minutes and attachments are accurate and complete.

David Schwartz, M.D.
Chairperson
National Advisory Environmental
Health Sciences Council

Dennis Lang, Ph.D.
Acting Executive Secretary
National Advisory Environmental
Health Sciences Council

Attachment:z
Council Roster