

**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**

September 19, 2006

The National Advisory Environmental Health Sciences Council was convened for its one hundred nineteenth regular meeting on September 19, 2006 at 8:00 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 September 19, 2006 from 8:00 a.m. to 8:15 am and reopened to the public 10:45 a.m. to 3:30 p.m. In accordance with the provisions of Public Law 92-463 the meeting was closed to the public from 8:15 a.m. to 10:30 a.m. for consideration of grant applications. Notice of the meeting was published in the *Federal Register*.

Members Present

Teresa Bowers, Ph.D.

David Christiani, M.D.

Kathleen Dixon, Ph.D.

John Essigmann, Ph.D.

Bruce Freeman, Ph.D.

Joseph Graziano, Ph.D.

Lisa Greenhill, MPA

Stefani Hines, MS

Daniel Liebler, Ph.D.

David Losee, J.D.

Martin Philbert, Ph.D.

Peter Spencer, Ph.D.

Peter Thorne, Ph.D.

Altaf Wani, Ph.D.

Ad Hoc Members Present

Kevin Stephens, M.D.

Members Absent

Douglas Benevento, J.D.

Elaine Faustman, Ph.D.

Frank Talamantes, Ph.D.

Ex Officio Members Present

COL James S. Neville

Liaison Members Present

Gina Mootrey, M.D. – Agency for Toxic Substances & Disease Registry, CDC

James Popp, Ph.D. – Society of Toxicology

NIEHS Staff

Kathy Ahlmark

Janice B. Allen, Ph.D.

Beth Anderson

David Balshaw, Ph.D.

Martha Barnes

Linda Bass, Ph.D.

Ebony Bookman, Ph.D.

John Bucher, Ph.D.

Gwen Collman, Ph.D.

Dorothy Duke

Sally Eckert-Tilotta, Ph.D.
Richard Freed
Kimberly Gray, 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.
Vanessa Knight
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

Teresa Nesbitt, DVM, Ph.D.
Sheila Newton, Ph.D.
Christine Bruske Flowers
Michelle Owens
Jerry Phelps
Christopher Portier, Ph.D.
Leslie Reinlib, Ph.D.
Anne P. Sassaman, Ph.D.
John Schelp
Carol Shreffler, Ph.D.
William Schrader, Ph.D.
William Suk, Ph.D.
Anne Thompson
Claudia Thompson, Ph.D.
Patricia Thompson
Sally Tinkle, Ph.D.
Bennett Van Houten, Ph.D.
Brenda Weis, Ph.D.
Samuel Wilson, M.D.
Mary Wolfe, Ph.D.

Members of Public Present

Bobbie Peterson, RTI International
Pamela Schwingl, Social and Scientific Systems, Inc.

OPEN PORTION OF THE MEETING

I. CALL TO ORDER AND OPENING REMARKS

Dr. David Schwartz called the one hundred nineteenth regular meeting of the National Advisory Environmental Health Sciences Council to order. Dr. Schwartz, in his opening remarks, commented on the Council Retreat and noted the positive dialogue. Dr. Schwartz mentioned those Council members who were not able to attend and acknowledged and welcomed the new members to Council. He presented Dr. Peter Thorne with a retirement plaque acknowledging his service on Council. He then had the Council members, NIEHS staff and guests introduce themselves.

Dr. Anne Sassaman 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 June 1, 2006 meeting were approved as written.

IV. FUTURE COUNCIL MEETING DATES

The following dates were confirmed:

February 15-16, 2007	NIEHS	Thursday – Friday
September 17-18, 2007	NIEHS	Monday – Tuesday
May 30-31, 2007	NIEHS	Wednesday – Thursday
February 19-20, 2008	NIEHS	Tuesday – Thursday

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 updated Council on the FY2007 budget. The President's budget for NIEHS is \$3.8 million below the FY2006 budget. The House Committee requests the same as the President, but the Senate Committee increased the budget by \$0.4 million. However, this level still remains \$3.2 million below FY2005. The decrease is likely to be 1%. This budget does not include the Genes and Environment Initiative (GEI) (\$16 million) or the Counter Act Budget (\$5 million). This is an aggregate increase of \$21 million. Additional funds will come from the Public–Private Partnership Initiative to support the project in New Orleans (\$1.65 million for 2 years) and the Minority Center Initiative which will also support projects in New Orleans (\$2 million for 2 years). He noted the importance of leveraging NIEHS' funds with other Institutes, Centers and Public–Private Partnerships.

Dr. Schwartz then updated Council on the Superfund budget. The House committee has recommended an increase of the President's budget from \$78.4 million to \$79.4 million. This increase is based on creating an R01 program within the Superfund Program. Approximately 10% of the Superfund budget would be allocated to R01s over a 3–5 year period. By the end of

this period, approximately \$5 million will be allocated to R01 activities within the Superfund Program. This plan would also increase the number of R01 applications funded by NIEHS. While the House Committee was very supportive of the plan and increase, the Senate Committee was not and recommended the President's budget. If this remains the case, there will be a decrease in the budget from FY2006 by approximately \$1 million.

Dr. Schwartz pointed out the NIEHS funding priorities. The highest priorities will be investigator-initiated research, training and career development, and integrated research. Lower priority will be given to programmatic research and infrastructure. He then updated Council on the Centers Program. He pointed out that the Centers have doubled in number over the past 10 years. There are now 26 Centers at a cost of approximately \$30 million/year. It was decided that only Centers with the strongest science should be funded. Therefore, in consultation with the Center Directors, over the next 5 years the number of Centers will be reduced to approximately 18. This would reduce the cost of the Centers to approximately \$23 million and would enable NIEHS to contain costs and allocate funds to more scientific programs.

Dr. Schwartz updated Council on what the Institute hopes to accomplish over the next 5 years in terms of programmatic, scientific development, and scientific impacts. He stressed three areas. The first, Exposure Science, proposes to develop sensors and biomarkers that allow some precision in the environmental measurements, which allows us to look at environmental exposures as they relate to the development and risk of developing diseases. The second, Integrative Research on Complex Human Diseases, will look at a number of factors, such as environmental exposures, relevant genes, novel mechanisms, treatments, and pathways for prevention. The third, Global Environmental Health (under the Office of Translational Research) will focus on major health problems in environmental health that are global in scope.

Dr. Schwartz spoke of innovative initiatives such as the Fusion Grant. This would be a partnership between two investigators in different disciplines conducting research that they could not effectively do alone.

He stressed the need to train the next generation of scientists to increase the pipeline of scientist who will focus their research on environmental science. He then informed Council that Drs. Trevor Archer and Kenneth Olden will chair a committee to look at a Minority Career Development Program, which will have an intramural and extramural component.

Council Response and Discussion

Council posed several questions about the Centers Program. Dr. Schwartz informed Council that the number of Centers will be reduced and the make-up of the Centers will be different than they are currently. He envisions Centers taking advantage of new technologies and scientific opportunities as they become available with more budget flexibility than they have had in the past.

Council also wanted to know if the Core Centers were eligible to apply for supplements. They were informed that Centers that have research projects are eligible to submit supplements.

A discussion ensued on increasing the pipeline of minorities who would want to do research in environmental sciences. There was concern that NIEHS was competing with the Myerhoff Program for the same students. Council suggested, where possible, that NIEHS duplicate the approaches of the Myerhoff program.

VI. Genes and Environment Initiative (GEI) – Dr. Weis

Dr. Weis presented to Council an update on the Genes and Environment Initiative (GEI). Dr. Weis informed Council that the GEI Program has two complementary and integrated programs. The Exposure Biology Program, which is being developed by NIEHS, will develop technology in biomarkers. The Genetics Program, which is being developed by NHGRI, will identify genetic variants for common diseases. She highlighted the purpose of the program and discussed the budget, and expected outcomes. She informed Council that the following mechanisms will be used: environmental sensors U01; biological response biomarkers U01; and, biomarkers/biosensors U54.

Council Response and Discussion

Council expressed support for this initiative and commented that for the future, funds could be leveraged by involving industry as a partner. It was felt that there needs to be, as much as possible, coordination with the National Cancer Institute on some of these initiatives.

VII. Report from the Working Group on P01s – Drs. Van Houten and Freeman

Dr. Van Houten began his presentation by acknowledging the Council subcommittee who formulated the report on the P01 investment by NIEHS to present to Council. Those on the committee included Drs. David Christiani, Kathleen Dixon, John Essigman, and Bruce Freeman. Dr. Van Houten discussed the process and the data supplied to the subcommittee members. Dr. Freeman spoke to the questions and data presented to the subcommittee for their analysis of the P01 program. The subcommittee, after looking at all the materials came up with the following recommendations: 1) solicit P01 applications from a pool of highly ranked, highly successful R01s in areas of priority to the Institute; 2) in the event the P01 mechanism is de-emphasized or eliminated, NIEHS will need to find alternative mechanisms to support translation research and core services; and 3) mini-core grants could be developed to hybridize Centers and P01s. A small number (2-4) of R01 funded investigators could collaborate to apply for a specific core service or supplements to augment related investigator teams. Additional recommendations are 4) the Glue grant model as one way to bring the best investigators together, regardless of geography; and 5) more stringent and fair review criteria. A P01 proposal should be evaluated on its current merits, regardless of review history.

The information provided by this report will be utilized to formulate the final report.

Council Response and Discussion

Council thanked Dr. Van Houten for providing the information on the P01 program to the subcommittee and to the subcommittee for putting the information together to present to Council, thereby, making the presentation very useful and informative.

Dr. Schwartz and Council had a discussion on the following: 1) does the publication rate represent a true level of impact and how important is this criterion for making a recommendation; 2) a more stringent review of the P01s needs to be implemented; 3) the components of the P01 need to be assessed and if weak, need to be removed; and 4) some P01 applications would better fit other mechanisms and would benefit from being converted/redesigned.

In the discussion it was stated that the publication rate is not a true impact factor and can often be misleading. A more stringent review would eliminate the weak P01s and the weak components. Some P01 applications could move to the Discover Program, and Fusion grants may also be an option.

VIII. Clinical Research Unit (CRU) – Dr. Blackshear

Dr. Blackshear began his presentation by acknowledging Mr. Richard Freed and colleagues who have put forth a tremendous effort in getting approval from NIH, HHS, OMB, and Congress, and finalizing the contract for the Clinical Research Unit (CRU). Dr. Blackshear informed Council that he would present the concepts behind the CRU and give an update on the building and personnel.

He stated that the underlying concept (the vision for NIEHS) is to use environmental science to understand human disease and improve human health. The Institute has a long history of accomplishments, particularly in basic biomedical science and public health, but little in integrative, clinical and translation science. The Institute has a very low percentage of physician scientists on staff. It is hoped that the CRU will provide the solution.

The rationale for the CRU is, 1) to enhance the impact of the intramural research on understanding human health and disease; 2) to apply basic science to problems in clinical environmental health; and 3) to serve as a role model for extramural scientists.

He informed Council that the clinical programs in environmental health would include, host defense/autoimmunity, environmental lung, neurodevelopment/neurodegenerative, and reproductive/epigenetic diseases. Initially the CRU will focus on pulmonary exposures and diseases and only outpatient research subjects. The technical capabilities initially will include routine subject evaluation, sample collection and processing, pulmonary function testing, fluoroscopy and portable x-rays, inhalation exposure chamber, and bronchoscopy and bronchial sampling capabilities.

It is anticipated that the CRU will open in 2007 and a permanent structure, with inpatient capabilities, around 2012. An update was given on the recruitment of clinical investigators.

In conclusion, Dr. Blackshear asked for feedback from Council.

Council Response and Discussion

Council discussion centered on the following issues: formal interactions between the intramural and the extramural programs, a visible linkage of basic and clinical researchers to the CRU. It was noted that the pool of pediatricians in the area of environmental sciences is very small; however a pediatrician is included in the recruitment and space plans for the CRU. Linkages are being developed between intramural and extramural programs, and between basic and clinical researchers to enhance the research within the Institute and the CRU.

IX. Global Environmental Health (GEH) – Dr. Martin

Dr. Martin informed the Council that Global Environmental Health (GEH) is a major focus of the Institute and part of the Strategic Plan. He pointed out the GEH is specifically mentioned under Goal 4 of the Strategic Plan (Improve and Expand Community Linked Research) and that the latter two bullets relate to developing a program in Global Environmental Health and building a capacity to pursue research in this area. He mentioned that we have been supporting research, capacity building and training with our partnership with the Fogarty International Center (ITREOH program) and the Superfund Program.

Dr. Martin spoke about new training opportunities through the R01 supplement initiative for 2006 and the Roadmap 2 initiative. He pointed out that the Roadmap initiative is a very competitive process and it is not likely, from a statistical standpoint, that the Institute's Roadmap 2 initiative will be accepted at this time, but the Institute looks at the process as a place holder.

He then described the GEH Workshop. This is a 3 day workshop whose purpose is to inform the Institute on where the opportunities are in GEH, to identify barriers and how they can best be resolved, and to identify effective and long standing partnerships. These partnerships would also include complex global partnerships which are new to the Institute. The workshop will have a small number of attendees (30-40). It is a working meeting that will develop a consensus over a three day period. The design will be the Pellston format developed by the Society of Environmental Toxicology and Chemistry (SETAC).

Dr. Martin mentioned the Disease Control Priorities Project (DCPP). This is an ongoing effort to assess disease control priorities and produce evidence-based analysis and resource material to inform health policymaker in developing countries. This document was developed by the Fogarty International Center with the World Health Organization, Centers for Disease Control, and the Gates Foundation. He pointed out that reference to the environment as a contributor to disease is virtually absent in the document.

He concluded his presentation by stating that it is important to be aware of what is happening throughout the world in GEH and to do that, NIEHS needs to have partners throughout the world in order to advance its mission in GEH within the next five to ten years.

Council Response and Discussion

Discussion centered on the role the EHP Journal would have in increasing world awareness with respect to environmental health and clarification concerning attendees as well as outcomes of the GEH workshop.

Council was informed that it is expected that EHP in the future will have more editorial independence from NIEHS; however, EHP will likely augment its interest in GEH as this topic is increasingly being recognized as scientifically important and relevant to environmental health sciences.

CLOSING REMARKS

Dr. Schwartz informed Council that Ms. Lisa Greenhill has agreed to Chair the first working group, Minority Recruitment Development and Career Enhancement. Dr. Schwartz and Ms. Greenhill will meet to develop the committee which will include individuals outside the Institute as well as one or two Council members.

He thanked Michelle Owens for her efforts with the Council retreat and Council for their time and effort.

Dr. Schwartz, at the Council retreat, acknowledged the leadership provided by Dr. Anne Sassaman in her more than 20 years with the Institute as the Director of the Division of Extramural Research and Training (DERT). Dr. Sassaman's retirement is effective November 3, 2006, therefore, this was her last council meeting as Executive Secretary. On behalf of the Council, Dr. Schwartz presented her with an inscribed crystal clock as a memento of her service. During her 20 years tenure as Director of DERT, the Division has grown significantly from a staff of 21 to more than 60. More importantly, the science supported by the extramural division has grown proportionately both in scope and amount. Council members gratefully acknowledged her leadership of the National Advisory Environmental Health Sciences Council during her tenure. Dr. Sassaman's few remarks focused on the growth of the Institute during the last twenty years, her belief in the great accomplishments of the research supported by the Institute, and the fond memories she will have of her interactions with the Council and its members.

ADJOURNMENT OF THE NAEHS COUNCIL

The meeting was adjourned at 3:30 p.m. on September 19, 2006.

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

Anne P. Sassaman, Ph.D.
Executive Secretary
National Advisory Environmental
Health Sciences Council

Attachment:
Council Roster