

**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 16, 2006**

The National Advisory Environmental Health Sciences Council was convened for its one hundred seventeenth regular meeting on February 16, 2006 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 16, 2006 from 8:30 a.m. to 5:00 p.m. and on February 17, 2006 from 8:30 a.m. to 10:00 p.m. in accordance with the provisions of Public Law 92-463. The meeting was closed to the public on February 17, 2006 from 10:30 a.m. to 12:30 p.m. for consideration of grant applications. Notice of the meeting was published in the *Federal Register*.

**Members Present**

Teresa Bowers, Ph.D.  
Kathleen Dixon, Ph.D.  
Elaine Faustman, Ph.D.  
Bruce Freeman, Ph.D.  
Bernard Goldstein, M.D., Ph.D.  
Lisa Greenhill, MPA  
Daniel Liebler, Ph.D.

David Losee, J.D.  
Martin Philbert, Ph.D.  
Peter Spencer, Ph.D.  
Frank Talamantes, Ph.D.  
Peter Thorne, Ph.D.  
James, Townsel, Ph.D.

**Members Absent**

Douglas Benevento, J.D.

**Ex Officio Members Absent**

COL James S. Neville

**Liaison Members Present**

Olivia Harris – Alternate, National Center for Environmental Health, ATSDR, CDC  
Susan West Marmagas, Collaborative on Health and the Environment  
R. Julian Preston, Ph.D., USEPA  
David Ringer, Ph.D., American Cancer Society  
Kendall Wallace, Ph.D., Society of Toxicology

**Liaison Members Absent**

Michael Galvin, Ph.D., National Institute for Occupational Safety and Health

**NIEHS Staff**

Kathy Ahlmark  
Janice B. Allen, Ph.D.  
Beth Anderson  
David Balshaw, Ph.D.  
Martha Barnes  
Linda Bass, Ph.D.  
Sharon Beard  
Lutz Birnbaumer, Ph.D.  
Christine Bruske  
Gwen Collman, Ph.D.  
Dorothy Duke  
Sally Eckert-Tilotta, Ph.D.  
Richard Freed  
Kevin Gerrish  
Kimberly Gray, Ph.D.  
Vicki Grigston  
Jerrold Heindel, Ph.D.  
Michael Humble, Ph.D.  
Ethel Jackson, D.D.S.  
Laurie Johnson  
Marian Johnson-Thompson, Ph.D.  
Annette Kirshner, Ph.D.  
Dennis Lang, Ph.D.  
Cindy Lawler, Ph.D.  
Shelia Newton, Ph.D.  
Robin Mackar  
Elizabeth Maull, Ph.D.  
Carolyn Mason

J. Patrick Mastin, Ph.D.  
Kimberly McAllister, Ph.D.  
Rose Anne McGee  
Pamela Moore  
Teresa Nesbitt, DVM, Ph.D.  
Richard Paules, Ph.D.  
Sheila Newton, Ph.D.  
Liam O'Fallon  
Michelle Owens  
Theodore Outwater  
Jerry Phelps  
Leslie Reinlib, Ph.D.  
Margarita Roque  
Anne P. Sassaman, Ph.D.  
John Schelp  
Carol Shreffler, Ph.D.  
Barbara Shane, Ph.D.  
William Suk, Ph.D.  
Anne Thompson  
Claudia Thompson, Ph.D.  
Patricia Thompson  
Sally Tinkle, Ph.D.  
Frederick Tyson, Ph.D.  
Bennett Van Houten, Ph.D.  
Brenda Weis, Ph.D.  
Samuel Wilson, M.D.  
Leroy Worth Jr., Ph.D.

**Other Federal Staff**

Camina Davis, NIH

**Members of Public Present**

Daniel Baden, Ph.D., University of North Carolina, Wilmington  
Robert Berendt, Robert Berendt Associates  
Kevin Beverly, Social and Scientific Systems, Inc.  
David Brown, Constella Health Sciences  
William Martin, M.D., University of Cincinnati  
Edo Pellizzari, Ph.D., RTI International  
Beth Roy, Social and Scientific Systems, Inc.  
Pamela Schwingl, Social and Scientific Systems, Inc.  
Branica Sekis, Social and Scientific Systems, Inc.  
Gerald Wogan, Ph.D., Massachusetts Institute of Technology

**I. CALL TO ORDER AND OPENING REMARKS**

Dr. David Schwartz called the one hundred seventeenth regular meeting of the National Advisory Environmental Health Sciences Council to order. Dr. Schwartz, in his opening remarks, informed Council that their comments would be very beneficial in terms of the direction

the Institute is taking, the programs and scientific priorities and the scientific impact on the field. He acknowledged and welcomed the new liaison members to Council. He mentioned that the Council slate was at the Office of the Secretary, DHHS and was going through the approval process. He then had the Council members, NIEHS staff and guests introduce themselves.

Dr. Anne Sassaman brought to the attention of Council that Ms. Michelle Owens was available to assist them on any administrative matters. She also 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 13, 2005 meeting were approved as written.

## **FUTURE COUNCIL MEETING DATES**

The following dates were confirmed:

June 1-2, 2006	NIEHS	Thursday – Friday
September 18-19, 2006	NIEHS	Monday – Tuesday
February 15-16, 2007	NIEHS	Thursday – Friday

## **IV. REPORT OF THE DIRECTOR, NIEHS - Dr. Schwartz**

Dr. Schwartz began by informing Council that he would present the progress the Institute is making and the limitations encountered. He discussed the FY2006 Appropriations and the FY2007 President's budget. With the current budget and budget projections it was decided that the Institute would focus on prioritizing scientific allocations, the impact of the science and the development of scientists.

Current program development will prioritize investigator initiated research and try to achieve a success rate of approximately 20%. The Institute has developed an Integrative Research Program that focuses on complex human disease. This will emanate from the Office of Translational Research, the Discover Centers, Division of Intramural Research (DIR), Environmental Health Sciences Research Centers, and DIR Clinical Research. It will enhance the role of the physician scientist both intramurally and extramurally.

Dr. Schwartz mentioned that the Institute is in the process of restructuring the training programs to encourage more postdoctoral candidates to focus on integrative academic disciplines. New mechanisms are in place: the NIH Pathway to Independence Award (K99-R00) which moves trainees from mentored research to independent research, and the Outstanding New

Environmental Scientist (ONES) award which provides an R01 type award with dollars to set up a laboratory. An Enrichment Program has been provided to enhance the training and ongoing education for staff in the Division of Extramural Research and Training. This will be funded at \$100,000 yearly.

Dr. Schwartz reiterated the need to continue the Institute's commitment to community based research and his desire to expand the research globally. Due to budgetary constraints the Institute will look for partners to share in the funding. Nevertheless, this year one million dollars has been committed to focus on research on lung disease in individuals moving back to the Gulf Coast region, specifically, New Orleans.

In order to provide funds for new endeavors, the Institute is looking at ways to reallocate current funds. Therefore, the environmental genomics commitments are being re-evaluated. It was decided not to continue the Toxicogenomics and the Mouse Consortium programs. The National Center for Toxicogenomics will be streamlined and integrated with other programs. RFAs in epigenetics and environmental genomics have been developed. In addition, a training program in environment, genetics and genomics is being developed in collaboration with the National Human Genome Research Institute (NHGRI).

The Institute is evaluating our investments in various programs and asking several questions: First, do we have the right number of Environmental Health Sciences Research Centers? Second, do we need the current level of infrastructure support? Third, would the Superfund Program best serve the Institute as Center-based or investigator initiated research? Fourth, are the Program Project Grants meeting our scientific goals? Finally, we are evaluating our commitment to the Environmental Health Perspectives Journal. Three options are being considered: 1) to keep the journal at NIEHS with an independent editorial board; 2) to create a partnership with other Institutes or agencies; and 3) to let the private sector handle the publishing. The Institute hopes to make a decision within the next six months.

Dr. Schwartz updated Council on some of the scientific achievements from the intramural and extramural scientific communities. He highlighted several publications. These publications illustrate the broad breath of environmental sciences and the importance of scientific contributions to biomedical research.

Dr. Schwartz concluded his report with an overview of the Genes and Environment Initiative. He pointed out that forty million dollars of new monies has been allocated to this initiative which is in the FY2007 President's budget. Twenty-six million has been allocated to case control studies in genetics using the Hap Map as a template. Fourteen million has been allocated each year, for four years to focus on programs in environmental biology or environmental sciences. This is an NIH coordinated program, mainly with the NHGRI and will involve other Institutes.

Council was then given the opportunity to ask questions and to make comments concerning the report.

### **Council Response and Discussion**

As an information item Council wanted to know where the National Toxicology Program (NTP) fits into the overall strategic planning for the Institute. It was pointed out that the program is being evaluated and is one of the components that will aide in moving the intramural research forward. Questions centered on the flattening of the budget and scientific overlap with other ICs. Dr. Schwartz assured Council that the Institute was looking carefully at scientific overlap

and will leverage the budget with partnerships with other ICs and government agencies. Concern was expressed regarding the Physician Scientist trainee's release time to do research. The infrastructure problems within the biomedical research centers will be addressed through the Office of Translational Research. The Institute was commended on setting the goal of a 20% success rate for investigator-initiated research. Council mentioned that advocacy and policy communities do not readily use journals and websites to obtain information and the need for different forms of communication should be considered to keep these communities in the communication loop.

## **V. INTEGRATIVE SCIENCE INITIATIVES**

### **a. Intramural Initiatives – Dr. Birnbaumer**

Dr. Birnbaumer began his presentation with the elements for the integrated research program within Division of Intramural Research (DIR). This integration is an opportunity for the intramural investigators and fosters collaboration between intramural and extramural investigators. The structure for the DIR is now composed of the Environmental Toxicology Program, Environmental Biology Program, and Environmental Disease and Medicine Program which includes clinical research. The basic science laboratories and their investigators doing clinical research will have integration among different disciplines with good interface with the clinical program.

Dr. Birnbaumer pointed out a few of the different core laboratories like the cell sorting core, confocal core, microarray core, and pathology core. New hires are being recruited for these cores with the necessary scientific and clinical expertise. DIR investigators have been presented with the positive aspects of integrative research, since they have been primarily independent investigators.

He concluded his presentation with information on the DIR Program in Integrative Research, which is one of the initiatives of the Director's Challenge Program. The program administrator is Dr. Joan Packerham. An "Internal RFA" was released on January 6, 2006; letters of intent are due on March 1, 2006. Applications will be peer reviewed and the review is set for August 1, 2006.

### **Council Response and Discussion**

Council requested clarification on the Clinical Center. The Clinical Center is an outpatient facility, at NIEHS, where the investigators can have easy access to research patients. This will facilitate translating their basic research into clinical practice.

### **b. Extramural Initiatives – Dr. Sassaman**

Dr. Sassaman gave an update on the extramural initiatives. These initiatives will continue to develop integrative sciences within specific areas of focus on human disease, the integration of physician-scientists into the environmental health sciences, improved measures of exposures, and using exposures as tools to understand underlying biology.

The new extramural initiatives, Interdisciplinary Partnerships in Environmental Health Sciences and the Disease Investigation through Specialized Clinically-Oriented Ventures in Environmental Research (DISCOVER) were announced and discussed. First, the vision, the

charge, and the research were described for the Interdisciplinary Partnerships in Environmental Health Sciences initiative. Solicitation will be for three years by program announcement (PAR) and will be reviewed by a special emphasis panel within CSR using the R01 and R21 grant mechanisms. The Institute expects to fund 8–10 new awards per year for three years and 2.5 million dollars has been set aside for each year. Second, the vision, charge, leadership and scientific components of the DISCOVER program was described. This program will be solicited by a Request for Applications (RFA) using the P50 grant mechanism. The Institute expects to fund 4–6 new centers.

Dr. Sassaman concluded by giving the expectations of these two programs. They should, 1) help in determining the role of environmental exposures in the etiology and progression of disease; 2) accelerate the application of knowledge into clinical and public with the goal of improving human health; and 3) create opportunities to develop and apply novel approaches for the diagnosis, prognosis, prevention and treatment/intervention of environmentally-influenced disease or disorders. She thanked the Integrative Medicine Initiative Committee (IMIC), chaired by Dr. Claudia Thompson, for all their hard work for the development and promotion of the concepts.

### **Council Response and Discussion**

Discussion centered on such issues as the role of the epidemiologist in patient oriented research and the budget for the R01 mechanism for integrative research. It was noted that the epidemiologist would have a role in patient oriented research and there will be a cap on the budget for integrative research.

### **VI. INTRAMURAL CLINICAL RESEARCH PROGRAM – Dr. Schwartz**

Dr. Schwartz presented for Dr. Perry Blackshear who is currently on sabbatical in England. He began his presentation with an update of the Office of Clinical Research. This is an office within DIR that focuses on the clinical research opportunities in environmental sciences. The proposed model is one of integration, allowing an investigator in the intramural clinical research program to also have an appointment in one of the intramural basic science laboratories. This arrangement allows an individual to focus on translational research (basic science from the laboratory to the patient's bedside or to the population) within a methodological discipline that is complementary to other investigators within the basic components of DIR. The Institute plans to recruit one to two clinically oriented investigators each year with a goal of achieving six to ten.

The clinical program will involve training at several levels: postdoctoral, predoctoral, medical students, undergraduates, and high school students. There are four outstanding universities in the area and over the next several years we plan to integrate the Institute into ongoing educational and training activities at the various institutions in the area.

Initially, the clinical research unit will be a temporary modular unit (9,000 square feet) located on the main campus of NIEHS. This location will facilitate the matrix organization. The facility will cost approximately \$3.5 million to be shared between DIR and the Office of the Director. Plans to open the temporary facility are slated for late fall or early winter 2006.

In the future, a permanent structure (29,000 square feet) adjacent to the F module is planned with expanded bed and equipment capacity.

## **Council Response and Discussion**

Council asked if the individuals on the research protocols in the clinical research program were classified as patients or research subjects. Clarification was given that these individuals will be research subjects and will be part of an IRB approved research protocol. Council posed concern about the social/ethical issues that will arise with this and other programs. They were informed that these issues are always a concern when data is generated on an individual; nonetheless, participating individuals are informed of the risks.

## **VII. GENES AND ENVIRONMENT INITIATIVE (GEI) – Dr. Weis**

Dr. Weis began her presentation by updating Council on the HHS Secretary's new initiative, the Gene and the Environment Initiative (GEI), which was announced to the public on February 8, 2006. The GEI is a Trans-NIH initiative led by NIEHS and NHGRI. The GEI is composed of two research components: the gene association studies (to look at genetic variants in individuals with diseases such as asthma and cancer) and the exposure science/technology studies (to develop new and novel approaches to more precisely measure exposures). NHGRI will be the lead institute for the gene association studies and NIEHS will be the lead institute for the exposure science and technology studies. Drs. David Schwartz and Francis Collins are co-chairing the NIH Coordinating Committee which consists of 12 members nominated from the Institutes and Centers.

Dr. Weis pointed out the need for better exposure data. This will help our understanding disease mechanisms, risk factors and better predict the risk of diseases. Currently, exposure data focuses on household air and dust, soil, water, and environmental air. In order to predict the impact of quantitative measurements of personal exposure (environmental sensors), biological indicators of personal exposure (biological sensors) and more precise measurements of dietary intake and physical activity to predict environmental exposure and genetic risk are needed.

NIEHS will lead in the development of new technologies for precise measures of personal exposures and NHGRI will be conducting genetic analysis on a variety of case control studies that they will identify from the NIH institutes.

Dr. Weis concluded her presentation by highlighting the FY06 – FY10 budget for the GEI. The exposure technology component has a budget of \$14 million each year totaling \$56 million, and the gene association studies have \$26 million each year totaling \$104 million. NIEHS has been allocated \$32 million above the allocated \$160 million.

## **Council Response and Discussion**

Council was pleased to see a focus on personal exposures. Discussion centered on developing new technology that would provide early markers of toxicity and light weight portable equipment that could easily be used by the study participants. Clarification was given for the choice of exposure sciences and exposure biology. The choices were seen as a good way of enhancing the initiative and providing tools that could be used by investigators in other studies. This also presented an opportunity to provide tools for investigators outside of NIEHS to apply environmental sciences to their research.

## **VIII. THE OFFICE OF PORTFOLIO ANALYSIS & STRATEGIC INITIATIVES (OPASI) – Dr. Schwartz**

Dr. Schwartz presented the overview of OPASI for Dr. Kington who was unable to attend Council meeting. He updated Council on how OPASI (a new office) will coordinate the management of the overall portfolio of NIH-funded research to address issues of duplication. It will be a transparent system to identify how NIH spends money on research related to specific diseases and conditions. It will also assess scientific opportunities and public health needs, and integrate them into NIH-wide funding priorities. In so doing, it will coordinate the funding of research areas that cut across or fall between the missions of any one Institute or Center. This should improve the evaluation and effectiveness of all the programs across the NIH and will allow the NIH to respond to various research opportunities with aggressive funding..

The mission of OPASI is to provide the NIH Institutes and Centers (ICs) with methods and information necessary to improve the management of their large and complex scientific portfolios and to identify important areas of emerging scientific opportunities and public health challenges. The OPASI will also assist in the acceleration of funding in these areas, focusing on those involving multiple ICs. It will also coordinate and make more effective use of the NIH-wide evaluation process; this will help NIH identify areas that have the most scientific impact.

The organizational structure of OPASI is as follows: the OPASI Director will report to the NIH Director. The following divisions will report to the OPASI Director: Division of Research Development and Analysis, Division of Strategic Coordination, and Division of Evaluation and Systematic Assessments. Finally, there will be a Council of Councils that will be comprised of approximately 30 individuals. Representatives will be from ICs, the Office of the Director Program Office Advisory Council and NIH Council representatives. ICs and OD program offices will nominate 3 candidates, two will be scientists and one will be a lay member. The NIH director will make the final selection.

In summary, the OPASI is a new office created within NIH to facilitate the Roadmap initiative in hopes of alleviating ad hoc approaches to trans-NIH research and funding. This office will provide a common fund that will provide an opportunity for more trans-NIH dialogue, decision making and funding.

### **Council Response and Discussion**

Council was given additional information regarding the organizational structure of OPASI. Remarks were made that OPASI was a unique approach to deal with the large allocation of funds, and centralization should enhance the individual needs of Institutes and Centers across NIH.

## **IX. NIEHS STRATEGIC PLAN – Drs. Newton and Wogan**

Dr. Newton began her presentation by giving an update on the Strategic Planning Document. She noted the new title *New Frontiers in Environmental Sciences and Human Health, 2006-2011 Strategic Initiatives*. Dr. Christopher Portier was acknowledged for the redrafting of the document. She pointed out NIEHS is in a unique position to advance the understanding of disease processes. The Institute's science includes elements common to research programs in other Institutes, such as research in basic biology, molecular biology and genetics. The Institute also is interested in special populations which have special vulnerabilities to excess disease

burden. She pointed out that NIEHS has a unique strength in the study of environmental exposures that affect these aspects of biomedical science.

The process of developing the plan began in May 2005. After many meetings, comments, and drafts, and based on the feedback received, it was decided to build our strengths by implementing emerging scientific opportunities, enhancing our ability to respond to new challenges, improving collaboration and cooperation, and expanding the value and relevance of our science to understanding human disease and improving human health. The plan is based on seven interrelated goals which guide us in terms of clinical research, using the environment to understand human biology, integrated research models, linking research to communities, exposure biology and development of biological markers, training, and partnerships.

Dr. Newton concluded by pointing out that the plan will build on the strengths of the Institute and embrace new scientific opportunities in hopes of expanding our clinical research in such a way that it helps re-orient all our research disciplines towards the study of, and relevance to, human disease. The integrative research model will help position us to respond to new challenges in environmental health science. The goals identified in the plan represent a critical, new dimension for the overall efforts to help the Institute achieve this mission.

Dr. Newton introduced Dr. Gerald Wogan of the Massachusetts Institute of Technology (MIT) to give his perspective of the Institute's strategic plan. Dr. Wogan began by saying he would discuss not only the planning process, but the plan itself and point out what might be problematic in implementing the plan. He noted that he was supportive of the proposed plan and Dr. Newton and colleagues have done an outstanding job of assembling the information, getting input from the community-at-large and refining the information to form the current plan. Dr. Wogan expressed his reservations on the issue of identifying targets, disease targets or compound targets. Nevertheless, he felt the document was excellent and a blueprint for future progress.

He focused his presentation on three areas that needed to be addressed. The first is to improve collaboration and cooperation, and to stimulate interdisciplinary research. This is very important, but it needs to extend beyond the current investigators who are already interested in environmental health sciences. The second will be identifying individuals with a continual interest, vision, and awareness of where the technology is now and bringing them together in an effective way. The final point has to do with the plan itself. The statement, "the plan is a living document," erases the notion that the planning process has stopped with its publication, but will continue to evolve as new issues emerge. As it is now, there are 7 goals with many sub-goals, but the plan gives no sense of prioritization. The plan should reflect the priorities of the Institute and that would give the plan better direction.

### **Council Response and Discussion**

The discussion centered on elements of the Strategic Plan, such as clarity of the critical issues. Council thought the focus of the plan was appropriate, but the concept of the environment needs be clearly stated at the beginning of the document.

Comments were made regarding improvement of integration of science in environmental health, the need for advocacy groups to be included in shaping the document, and the need for a workshop to focus on areas important in environmental health.

## **X. BENCHMARKING PROJECT REPORT – Drs. Dixon and Van Houten**

Dr. Dixon presented the NAEHS Council subcommittee report on the DERT Portfolio Analysis. The committee was provided with the following information: *Portfolio Benchmark Analysis*, historical comparisons of NIEHS with NHLBI, NICHD, NIA, NIAMS, NIAAA and NIH as a whole. The committee was charged to provide opinions on a series of questions related to the NIEHS/DERT portfolio. The report provided the following conclusions and recommendations. The portfolio appears to be appropriate to address the broad NIEHS mission. The expansion of Centers and targeted-initiatives will need to at a lower level to improve the support of investigator initiated research. It was recommended that there be a sun-setting of Center-like programs, and new and renewal Center applications of borderline quality. These funds should be redirected towards unsolicited RPGs and young investigators. The strategic plan should outline the investment needed in the areas of basic biology, disease and organ related research. Environmental health science information disseminated to the public and to other agencies needs safeguards to ensure that the information is scientifically sound and accurate. A training and professional development program should be implemented in environmental health science laboratories.

Dr. Van Houten highlighted the different data bases, new and existing, that can be used to obtain information concerning the DERT portfolio. The newest, the Extramural Research Portfolio allows one to track a scientific area, obtain the title of the grant, principal investigator, institution, city, award code, and publications associated with the grant. Also, Batelle is developing additional metrics for scientific productivity and impact.

### **Council Response and Discussion**

Discussion centered on whether the Center mechanism is the most efficient/economical way of sustaining a particular effort or would the R01 mechanism be better. To further address this issue, evaluation by DERT is required. Council regarded the use of benchmark comparison with other ICs informative, but is not necessarily the best way to determine how decisions are made on how NIEHS allocates its dollars. Council commented on the impact of a Core facility on the productivity of the investigator. Questions elicited from the discussion are: 1) is there any disparity among investigators in the application of technologies that are supported by facility cores, and 2) what impact do the Centers have on the NIEHS research portfolio? At this time there are no available data to answer these questions. Concerns were expressed regarding the collection, use, and meaning of the publication analysis and the need to have sufficient information on how the data are collected.

## **XI. REPORT OF THE DIRECTOR, DERT – Dr. Sassaman**

Dr. Sassaman informed Council she would be updating them on the following: NIH New Pathways to Independence Award, NIEHS Training Initiatives, Changes and News from NIH, New Challenges in Peer Review, Report from the Breast Cancer and the Environment Working Group, and Council Delegated Authorities.

The Pathway to Independence Award will utilize the K99/R00 mechanism. There will be five years of support consisting of two phases. The first phase will provide one-to-two years of mentored support and a total cost of \$90,000 per award per year. Phase two provides up to three years of independent research support contingent upon securing an independent research position and administrative review. The annual cost per award will be \$249,000.

The NIEHS training initiatives have been restructured. The scope of the restructuring includes emphasis on multidisciplinary and interdisciplinary training with basic, clinical, computational, public health research within the programs. Training programs consisting only of predoctoral trainees are no longer available. Due to the NIH changes in the NRSA program guidelines, T35 Short term training programs for Underrepresented Minority Students have been discontinued.

Dr. Sassaman mentioned the NIH Extramural Nexus which is published electronically every other month and is a valuable tool to keep Council informed on what is happening at NIH. She also updated Council on the electronic submission process.

Due to the large increase in the number of grant applications, Peer Review is being confronted with many challenges. Some possible approaches would be to enlarge study section membership, decrease frequency of participation, two reviewers instead of three, shorten applications and eliminate appendices. At NIEHS we have increased the use of Internet-assisted Review, and the P30 applications are reviewed by the Environmental Health Sciences Review Committee with appropriate ad hoc reviewers when necessary.

As an informational item Dr. Sassaman directed Council to the Breast Cancer Environment Working Group Report.

In conclusion, Dr. Sassaman informed Council that there were no changes to the existing Council- Delegated Authority. Council unanimously approved the Council-Delegated Authority.

### **Council Response and Discussion**

Council expressed concern about the requirements and restrictions within the K99/R00 mechanism, such as dollars available to investigators and the need to have a tenure track position. It was noted that there is flexibility in terms of the tenure track requirements. On a positive note, the K99/R00 mechanism could possibly encourage scientists to enter the field of environmental science.

## **XII. CONCEPT CLERANCE, COMPARATIVE BIOLOGY INITIATIVE – Dr. McAllister (Attachment B)**

Dr. McAllister presented to Council the Concept Clearance for the Comparative Biology Studies to Elucidate Susceptibility and Mechanisms for Pathways and Networks in Environmentally-Influenced Disease. She discussed the purpose and expected outcomes and highlighted the pathways/networks relevant to environmentally-influenced diseases. Examples of recent comparative genomics approaches with direct human disease applications were given, such as rheumatoid arthritis and Parkinson's (genomic convergence); hypertension, multiple sclerosis, and diabetes (intergenomic consensus, rodent quantitative trait loci (QTL)/Orthologs); cancers (mouse models); and chromosomal abnormality disorders and cancers (discovery and characterization of regulatory regions, promoters, breakpoints, and deletions).

Dr. McAllister shared the recommendations from the Environmental Genomics Workshop. They recommended: 1) an in-depth study of pathways; 2) pathway analysis using cross-species comparisons; and 3) the use of model systems in environmental health studies. Examples were given of appropriate studies, like biological pathways perturbed by environmental factors through comparative approaches; high-throughput predictive organism model systems; and a

panel of inbred mouse strains and/or crosses to screen for susceptibility genes to environmental agents. The grant mechanism to be used for this initiative is the R01. Applications will be received in September 2006 and will go to May Council 2007. Expected funding will be in the summer of 2007.

Council unanimously approved the Concept Clearance for this initiative.

### **Council Response and Discussion**

Council expressed support for this initiative and commented that the idea is terrific and use of model organisms is a validation for this model. They pointed out that due to the scientific area, the response for this initiative is going to be large.

## **XII. COUNCIL DISCUSSION – BUILDING ON THE MOMENTUM**

Dr. Schwartz initiated the discussion by asking Council to address the following questions: 1) what is the next step in moving the strategic plan forward and 2) how can Council participate?

Council discussion began by pointing out the lack of visibility in the strategic plan for community-based research. It was mentioned that the community-based research should not be a separate entity, but should be integrated into the research portfolio. It was decided that an action item would be to meet with the advocacy and public policy communities to have a dialogue on what is needed. Drs. Teresa Bowers, Elaine Faustman, and Ms. Lisa Greenhill agreed to assist Dr. Schwartz with this activity.

Council queried whether they could still participate in meetings and workshops sponsored by NIEHS to keep them fully engaged in aspects of the strategic plan. It was noted that participation has not been rescinded.

Dr. Schwarz discussed the Expanded Community Linked Research Portfolio (global environmental health). Global childhood respiratory illnesses are areas where little is being done, but could have a tremendous impact on morbidity and mortality around the world. This would take an enormous amount of planning, public and private partnerships to develop this program beyond our borders. Council proposed that with the decreasing budget, they could help leverage the dollars to incorporate this idea into the strategic plan. One way is to partner with industry that is privately funding this type of research. Rules of engagement and codes of ethics need to be addressed in this type of partnership. Dr. Elaine Faustman agreed to assist Dr. Schwartz with this activity.

Council suggested that they be clustered into subgroups to help guide the implementation of the strategic plan and work with program staff as a sounding board for new initiatives. This could be done outside of the regular council meetings and responsibilities. Mr. David Losee agreed to assist Dr. Schwartz with this activity.

On the global environmental health issue, Council suggested that Fogarty International Center and NIEHS supported investigators who are actively engaged in international research might be resources to pursue.

Dr. Wilson highlighted areas in analysis and website development that could involve Council and requested their involvement and assistance.

Council reiterated the need to have metrics broad enough to capture sufficient and essential data.

Dr. Schwartz closed the discussion by encouraging Council to notify him with additional ideas that would aide in moving the strategic plan forward

## **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.

## **XI. CONSIDERATION OF APPLICATIONS**

The Council considered 387 applications requesting \$140,844,766 direct cost. The Council recommended 208 applications with the total direct cost of \$78,625,965.

## **ADJOURNMENT OF THE NAEHS COUNCIL**

The meeting was adjourned at 12:30 p.m. on February 17, 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

### **Attachments:**

- A. NAEHS Council Roster
- B. Concept Clearance – Comparative Biology