

**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**

May 29 – 30, 2008

The National Advisory Environmental Health Sciences Council was convened for its one hundred twenty-fourth regular meeting on May 29, 2008 at 8:30 a.m. in the Rall Building, Rodbell Auditorium, National Institute of Environmental Health Sciences, Research Triangle Park, NC. Dr. Samuel Wilson presided as Chair.

The meeting was open to the public on May 29, 2008 from 8.30 a.m. to 5:00 p.m. In accordance with the provisions of Public Law 92-63 the meeting was closed to the public on May 30, 2008 from 2:30 p.m. to 4:00 p.m. for consideration of grant applications. Notice of the meeting was published in the *Federal Register*.

Members Present

Christopher Bradfield, PhD
Hillary Carpenter, PhD
David Christiani, MD
Richard Finnell, PhD
Bruce Freeman, PhD
Stefani Hines, MA, MS

George Leikauf, PhD
Daniel Liebler, PhD
Jerald Schnoor, PhD
Kevin Stephens, MD, JD
Altaf Wani, PhD
Nesdu Obot Witherspoon, MPH

Member Present by Teleconference

Kenneth Ramos, PhD

Ex Officio Officer

CPT Michael Macinski

NIEHS Staff

Kathy Ahlmark
Beth Anderson
Janice B. Allen, PhD
Ralph Ball, PhD
David Balshaw, PhD
Linda Bass, PhD
Martha Barnes
Sharon Beard
Perry Blackshear, PhD
Trisha Castranio
Gwen Collman, PhD
William Copeland, PhD
Caroline Dilworth
Christie Drew, PhD
Dorothy Duke
Sally Eckert-Tilotta, PhD
Kris Erwin
Benigno Encarnacion
Elliot Gilmer
Kimberly Gray, PhD

Jerrold Heindel, PhD
Heather Henry, PhD
Marc Hollander
Sharon Hrynkow, PhD
Michael Humble, PhD
Laurie Johnson
Marian Johnson-Thompson, PhD
Annette Kirshner, PhD
Dennis Lang, PhD
Cindy Lawler, PhD
Robin Mackar
Carolyn Mason
J. Patrick Mastin, PhD
Elizabeth Maull, PhD
Rose Anne McGee
Elizabeth McNair
Srikanth Nadadur, PhD
Teresa Nesbitt, PhD
Shelia Newton, PhD
Liam O'Fallon
Theodore Outwater

Michelle Owens
Jerry Phelps
Leslie Reinlib, PhD
Margarita Roque
John Schlep
Barbara Shane, PhD
Daniel Shaughnessy, PhD

Carol Shreffler, PhD
William Suk, PhD
Claudia Thompson, PhD
Samuel Wilson, MD.
Marva Wood
Leroy Worth, PhD

Other Federal Staff

Timothy Hays, PhD, NIH, OD, OPASI

Members of the Public Present

Kevin Beverly, Social and Scientific Systems, Inc.
Lara Bono, SafeMinds
Stanley M. Finger, PhD, American Autoimmune Related Disease Association, Inc.
John Hildebrandt, PhD, Medical University of South Carolina
Shana C. Leake, Court Reporting Services
Gerri Wolfe, Consultant, NIEHS

OPEN PORTION OF THE MEETING

May 29, 2008 – 8:30 a.m.

I. CALL TO ORDER AND OPENING REMARKS

Dr. Samuel Wilson called the one hundred twenty-fourth regular meeting of the National Advisory Environmental Health Sciences Council to order. He opened the meeting by welcoming those in attendance and turned the meeting over to Dr. Dennis Lang to discuss administrative matters.

Dr. Lang informed Council the meeting was being videotaped. Dr. Lang introduced the new Ex Officio Officer, Captain Michael Macinski, Director of the Public Health Office, US Navy and Marine Cops Public Health Center, Portsmouth, Virginia. He also introduced Dr. Jerald Schnoor, a new member to the Council. He asked Council members and those individuals at the table to introduce themselves, and National Institute of Environmental Health Sciences (NIEHS) staff and guests to continue with the introductions.

II. REVIEW OF CONFIDENTIALITY AND CONFLICT OF INTEREST PROCEDURES

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

Dr. Lang reminded Council members to sign their conflict of interest forms and to complete their travel vouchers expeditiously. He noted that Michelle Owens was available to Council members to help with any administrative or logistic matters.

III. CONSIDERATION OF MEETING MINUTES

A motion was made by Council member, Stephani Hines, to accept the February 19, 2008 minutes with revisions. She pointed out that the revisions are to be included under "Section VI, Council Discussion Items - Council Members" which should reference the document titled "Sense of Council" and that the document was signed by the Council, except for members Drs. John Essigmann, Bruce Freeman, and Daniel Liebler who were absent at the time of the signing. Ms. Hines also requested that the document be appended to the minutes.

Dr. Lang noted that the suggested changes will be emailed to all members for approval. The suggested revision was made to the minutes, circulated to all council members by email, and was subsequently approved unanimously by council members. Thus the minutes from the February 19, 2008 minutes stand as approved.

IV. FUTURE COUNCIL MEETING DATES

The following dates were confirmed:

September 9–10, 2008	NIEHS	Tuesday – Wednesday
February 19–20, 2009	NIEHS	Tuesday – Wednesday
May 21–22, 2009	NIEHS	Thursday – Friday
September 14–16, 2009	NIEHS	Monday – Tuesday - Wednesday

Dr. Lang pointed out that the September 2009 Council meeting dates includes the Council retreat and therefore is three days.

V. REPORT OF THE ACTING DIRECTOR – Dr. Samuel Wilson

Dr. Wilson outlined the topics he would be addressing in his presentation: Highlights and Milestones; Comments on Noteworthy Publications; Appropriations; and Office of Management Assessment Review of National Institute of Environmental Health Sciences Management Practices. He informed Council that his presentation was designed to allow ample time for discussion and a detailed version of similar information is presented in the Council Book and the Report of the Acting Director. Dr. Wilson made note that Dr. Sheila Newton was instrumental in putting together the Acting Director's Report.

Dr. Wilson briefed Council on some of the NIEHS highlights and milestones since February 2008. Dr. Sharon Hrynkow, Associate Director, is spearheading the Institute's effort in Climate Change Outreach, and she and her associates recently held a workshop entitled "Framing the Climate Change Agenda at the National Institute of Environmental Health Sciences." The workshop was in April on the National Institutes of Health (NIH) campus in Bethesda, Maryland.

The NIEHS intramural program again was rated once again as one of the best places for postdoctoral fellows to work.

The release (April 15, 2008) of the National Toxicology Program Draft Brief on Bisphenol A attracted widespread attention in both the scientific community and the media; the development of the Draft Brief represents a significant contribution by the National Toxicology Program toward protection of human health and prevention of disease.

A town hall meeting on autism was held on May 3, 2008 at the University of California, Davis to obtain input on the strategic plan being developed for autism research by the, the Interagency Autism Coordinating Committee (IACC), under the Combating Autism Act of 2006. As noted in the past, this effort in autism research is a multi-institute NIH effort in which NIEHS participates. Dr. Wilson acknowledged Dr. Cindy Lawler's contribution to the recent autism town hall meeting and the various research planning activities of the IACC. He also mentioned contributions of community members, Ms. Laura Bono and Ms. Lynn Redwood, who have been interacting with NIEHS and are involved in the IACC's strategic planning effort.

A meeting of the United States–Japan Cooperative Medical Science Program–Gene Environment and Disease Panel was held March 27–28, 2008, in San Francisco, California. The United States–Japan Cooperative meeting has been ongoing for many years and is sponsored by a number of NIH institutes. National Institute of Allergy and Infectious Diseases has generally the lead IC for these activities, but the National Cancer Institute and NIEHS also have been major contributors. The successful meeting in March was organized and led by Dr. William Martin, Associate Director, NIEHS.

Council Member (Dr. Liebler) asked for clarification on whether this was a new standing panel and if NIH used to sponsor the environmental panel.

Dr. Wilson replied that the panel is long-standing and the environmental panel sponsored by NIH was part of the same program, but that this particular panel ("environmental") is no longer active. NIH continues to sponsor programs under the general aegis of the Cooperative. Other recent United States–Japan meetings have been in the area of DNA repair and genome stability, but these have not been associated with the Cooperative Program itself.

A joint NIEHS Superfund Basic Research Program–Worker Education and Training Program Technical Workshop and the Worker Education and Training Program Spring Awardees meeting was held April 3–4, 2008 on the NIH campus in Bethesda. The main theme for discussion was: "Reducing Risk and Protecting Public Health through Research and Training."

Under the topic of Noteworthy Publications, Dr. Wilson briefly highlighted four publications from the extramural community, as well as publications from the intramural program at NIEHS.

Dr. Wilson then commented on appropriations. He illustrated the FY2008 appropriation and the FY2009 President's Request through PowerPoint. The NIEHS budget is essentially flat across these years, and the overall NIH budget remains essentially the same. The Common Fund (NIH Director's Common Fund) from which the Roadmap programs and Trans–NIH activities are supported will increase by a small amount. The FY2009 President's Request for the Superfund Basic Research Support Program and the Worker Education and Training Program provides the same appropriations as for FY2008. The Department of Energy's interagency training agreement has not been specified for FY2009. Dr. Wilson noted that as the government moves into the next fiscal year, NIH would most likely be operating on a Continuing Resolution, which may extend well into the next calendar year.

Dr. Wilson updated Council on the NIH Office of Management Assessment (OMA) review. Background information on the OMA review, A United States House of Representatives Appropriations Subcommittee requested that NIH conduct a comprehensive management review of NIEHS, especially in the areas of personnel practices, contracting procedures, financial management, financial disclosures, and conflict of interest. The OMA created a team of federal and private-sector subject matter experts that included individuals from the National Academy of Public Administration. The review covered the period from October 1, 2004

through July 31, 2007. In addition, a senior-level review panel from inside and outside NIH provided oversight for the OMA review team. The OMA's final report was issued April 9, 2008. NIH and NIEHS have not released the report because NIH policy is to not to release OMA reports to the public. Nevertheless, the report is available through other sources.

The NIEHS has been charged with developing a draft Corrective Action Plan (CAP) in response to the findings in the OMA report. There were two categories of findings, termed overall and functional.

The four overall findings were; 1) the ethics program is not operating effectively; 2) decisions to fund grants out of rank order are not documented; 3) resource information on the use of service cores by the intramural research laboratories is not being provided to the Board of Scientific Counselors; and 4) negative perceptions of NIEHS leadership are prevalent among NIEHS employees.

The functional findings were, 1) personnel practices, including communication with the employee union; 2) contracting procedures; 3) property management and the use of government vehicles; 4) financial management and accounting practices; 5) integrity of NIEHS grant-making process; 6) governance structure and other management decisions; and equal employment opportunities and the overall morale at NIEHS.

Dr. Wilson explained the process used to develop the CAP; Mr. Marc Hollander, Executive Officer, and Dr. Wilson are coordinating the process. Subcommittees were formed composed of 8–12 senior-level NIEHS management staff from across the divisions of the Institute. These subcommittees were charged with addressing: 1) ethics; 2) organizational climate; 3) governance; 4) human resources; 5) contracting; 6) finance; and 7) grant-making. The subcommittees were asked to formulate proposed corrective actions.

Many of the deficiencies in the report were identified as problems with procedures, and/or the failure to adhere to established rules and guidelines. In addition, the Ethics Office was not reviewing and filing the necessary documents for conflict of interest and ethics compliance in a timely manner. Throughout the Institute, the report noted the need for NIEHS to enhance oversight, audits, communication, and training for staff.

The subcommittees analyzed the findings in the OMA report, gathered additional information in some cases and composed draft responses. Dr. Wilson is refining these draft responses in consultation with subject matter experts, senior leadership at NIEHS, the NIH deputy directors for internal management and functional areas and, Dr. Claude L'Enfant (former National Heart Lung Blood Institute Director). The draft CAP will be submitted by Dr. Wilson to the NIH deputy directors for review, and the final Plan will be sent to Dr. Zerhouni for approval.

Dr. Wilson opened the meeting for comments and discussion from the Council.

VI. DISCUSSION OF DIRECTOR'S REPORT

Council member (Dr. Liebler) requested more detail on the work of the Grant-Making Subcommittee to understand the major issues that needed to be addressed.

Dr. Wilson responded that the specific OMA finding was that the justifications for making funding decisions out of rank order, while done appropriately, were not recorded and attached to the

funding plans as part of the record. Dr. Lang indicated that procedures are now in place for including such justifications and that adequate check and balances also are in place.

Council member (Dr. Leikauf) expressed the opinion that many in the scientific community are disturbed about the “skips” and “raise to pay” process, because this skips an individual who would be funded, and the process appears to be unusual and not done at other Institutes. It would be helpful if Council is informed of how many other Institutes fund out of order.

Dr. Wilson agreed with Dr. Leikauf that we need to provide answers to the concerns that have been expressed in relation to out of rank order funding decisions and to clarify out of rank order at this Institute and across the NIH.

Council member (Dr. Liebler) mentioned that to allay the negative perception concerning the integrity of the grant funding process that Council should be informed on how the decisions are made.

Dr. Lang replied that the Council is informed every year at the February Council meeting on all funding decisions that were made for the previous year. The Institute would take under advisement whether Council should be provided details on those grants that were funded out of rank order.

Council member (Dr. Leikauf) clarified his request by stating he was not asking for names of principal investigators or grant titles, but general statistics; for example, three R01's were funded out of order because they met certain specific procedural criteria. He also mentioned that it would be helpful if Council is given the percentile level at which the Institute is funding.

Dr. Lang responded that the percentile changes every year.

Council member (Dr. Leikauf) asked if the Institute could provide Council with the percentiles that have been set in the past.

Dr. Lang answered that the Institute discusses the pay line in success rate terms rather than by percentile. While the Institute has attempted to consider all grants up to the twentieth percentile, this may vary over the funding cycles during the year.

Council member (Dr. Leikauf) pointed out that the success rate for NIEHS was reported at Council as being near the top relative to other NIH Institutes and Centers. The Albert Einstein College of Medicine of Yeshiva University's website, which compares the NIH pay lines and success rates, reports NIEHS as third from the bottom compared to the other NIH Institutes and Centers. Also, he noted that there is a perception in the environmental health community that NIEHS is not the best Institute for success with an R01 grant. If the Council could obtain the necessary data, they could assist the Institute in alleviating this type of rhetoric.

Dr. Wilson thanked Dr. Leikauf for his comments and recognized Dr. Christiani.

Council member (Dr. Christiani) commented on the remarks Dr. Leikauf made concerning success rate and the negative perception the environmental health community has regarding the chance of obtaining funding from NIEHS. Dr. Christiani pointed out that the problem may require some outreach and education to the scientific community. The NIEHS procedures in place for out of rank funding are in line with what other ICs are doing at NIH and non-NIH agencies like Centers for Disease Control and Environmental Protection Agency. The

procedures do not need to change; the question is how to give an explanation to the scientific community.

Dr. Wilson responded that every effort will be made to address the concerns and perceptions of the scientific community concerning funding opportunities at NIEHS.

Council member (Dr. Wani) asked if principal investigators are guided to another Institute when grants are skipped for program relevance and the grant has a high priority score or percentile ranking, or are investigator left to deal with the situation.

Dr. Mastin responded that program staff tries to help the investigators find an Institute that is interested in the science being proposed.

Council member (Dr. Freeman) also acknowledged that what might be a public relation weakness could be turned into an asset if the Institute communicated some data in more detail to the scientific community.

Dr. Wilson then called on Mr. Hollander to give comments on the process and status of the OMA CAP.

Mr. Hollander informed Council that a version of the draft CAP has been sent to NIH for review and, after all the comments are addressed, the Institute will send the final report to NIH. He then asked for questions.

Council member (Ms. Hines) asked for elaboration on the oversight, audit, and broader activities that have been planned.

Mr. Hollander responded that oversight and audit procedures will be strengthened in financial, grant-making, and ethics areas. Training of staff will be done to assist in areas of oversight and audit procedures.

Council member (Ms. Hines) asked if Council will have a role in the implementation of the CAP.

Dr. Wilson replied that Council would have a chance to review the CAP and to give feedback on the possible success of the Plan and areas that need to be emphasized in a more robust fashion.

Council member (Dr. Liebler) asked for information on the Organizational Climate Subcommittee as to what kinds of issues were discussed and if any of the outcomes emerging from the discussions were sent back in the report to Dr. Zerhouni.

Dr. Wilson responded that the organizational climate refers to the general attitude of the Institute staff, and the issues are a result of media coverage, congressional investigations, and communications with the union. Morale problems also extend from acute and chronic problems.

Dr. Suk mentioned that the proposed CAP deals with the Institute and the extramural community. Transparency, communication, empowerment, and accountability are areas of focus.

Dr. Blackshear commented that one of the criticisms of a previous survey cited in the OMA report was that it only captured 240 employees and it did not represent the total 800 plus employees. He believed that a survey should be taken again to be more inclusive. He also

suggested that the morale problem is related to the many “acting” positions at the Institute that have yet to be filled.

Dr. Wilson asked Dr. Sharon Hrynkow to update Council on the topic climate change. She summarized that a meeting was held on April 15, 2008 that included 25 experts, several grantees, and others to talk about how NIEHS can be involved in climate change as it relates to environmental health. A number of ideas surfaced that included outreach through web sites and articles and more health research. Discussion also focused on research gaps and opportunities. The Institute continues to work with the World Health Organization. Discussions on this topic are being pursued with potential new partners in the foundation sector.

Council member (Dr. Liebler) mentioned that in the past the scientific direction and priorities of the Institute have been criticized by the scientific community. However, the Council over the last several years has strongly supported the scientific vision as articulated in the strategic plan. At this point in time where does the Institute stand with respect to these priorities?

Dr. Wilson pointed out that the strategic plan is very broad and embraces environmental triggers in disease and in human health according to the mission of the Institute. The general theme that lies beneath program development and priority decisions is research excellence in pursuit of disease prevention and better health. This statement is important in the sense of focusing and emphasizing the theme of research excellence. The Institute continues to operate under the guidance of the strategic plan.

Dr. Wilson outlined some of the activities that are being pursued at this time; such as, enhancing exposure analysis, the exposure biology program, and ways to integrate exposure into various parts of our research approach. The Institute also is pursuing trans-NIH initiatives that include the exposure biology program, the epigenomics program and most recently an emerging mitochondrial program.

Council member (Dr. Leikauf) commented on the time frame concerning the acting positions.

Dr. Wilson replied that a vacancy announcement would appear shortly regarding the search for a permanent director for the Institute. It is hoped that the acting positions may be filled within a reasonable time frame after the selection of the new director has been made.

Council member (Dr. Leikauf) queried whether global warming will be considered for roadmap.

Dr. Wilson responded that global warming was not being considered as a roadmap initiative, but the Institute is enhancing its outreach and communications in the area under the aegis of Climate Change. It is hoped that environmental health will be put forward when the topic of climate change is discussed across the scientific community and in government agencies. NIEHS is not focusing on new research investments in Climate Change at this time.

Council member (Dr. Wani) wanted to know if the congressional inquiry continues to remain open.

Dr. Wilson commented that he is unsure about this, but to his knowledge the congressional inquiry does not remain open.

VII. ADVISING NIEHS: THE ROLE OF THE NAEHS COUNCIL – Ms. Jennifer Spaeth

Dr. Lang introduced Ms. Jennifer Spaeth, Director, Office of Federal Advisory Policy, Office of the Director, NIH.

Ms Spaeth informed Council that she has the responsibility for setting policy across the NIH for the National Advisory Councils, Program Advisory Councils, The Boards of Scientific Counselors, and the Integrated Review Groups. She indicated that her presentation would be specifically about the NIEHS National Advisory Council and the role of Council members.

She commented on the different statutes that form the legal basis for having advisory councils. She noted that "...the Secretary shall appoint an advisory council for each national research institute which shall advise, assist, consult with, and make recommendations ...on matters related to the activities carried out by and through the Institute and the policies respecting such activities...."

Additional information on regulations and policy are as follows:

Federal Advisory Committee Management; Final Rule can be found in 41 CFR Parts 101–6 and 102–3;

HHS advisory committee policies can be found in the HHS General Administration Manual, Chapter 9-00;

Management and Procedures of National Advisory Councils and Boards in their Review of Extramural Activities can be found in NIH Policy Manual 54513.

Ms. Spaeth outlined the general guidelines for Council membership.

- Not more than 18 members
 - Two thirds from among leading representatives of the health and scientific disciplines
 - One third of the members must be from the general public
- Four-year terms for members
- Two-year terms for the chairperson
- Appointed as Special Government Employees
- Serves in either a scientific or public position
- Has the right and obligation to participate in all committee activities including making motions and voting
- Attendance counts toward a quorum
- Council to meet at least three times a year

Ms. Spaeth mentioned that the Department of Health and Human Services has no members on their Advisory Councils that serve as representatives of industry's point of view.

She reviewed the primary duties of the Council chairperson and the executive secretary.

The Council chairperson 1) presides and adheres to the agenda; 2) ensures that no member with a conflict of interest is present during specific discussions; and 3) signs the meeting minutes.

The executive secretary 1) is a federal employee who is the “designated federal official;” 2) approves the meeting agenda; 2) calls, attends, and adjourns committee meetings; 3) maintains records on cost and membership; 4) ensures efficient operations; and 5) maintains records for availability to the public and signs the meeting minutes.

Ms. Spaeth reviewed the functions as stated in the Council charter for NIEHS which are very broadly drawn. 1) Council, advises on matters relating to the conduct and support of research, training, health information dissemination, and other programs with respect to factors in the environment that affect human health. 2) Recommends the acceptance of conditional gifts for study, investigation, or research with respect to the development of knowledge basic to understanding the processes by which human health is adversely affected by the environment; for the acquisition of grounds, or for construction, equipping, or maintenance of facilities for the Institute. 3) Makes recommendations on applications for research grants and cooperative agreements for research and training and recommends approval of applications for projects which show promise of making valuable contributions to human knowledge. 4) Collects information as to studies with respect to understanding the processes by which human health is affected by the environment; and with the approval of the Director of NIEHS, makes available this information for the benefit of the general public.

Ms. Spaeth outlined the areas that are outside the Council’s domain. Council does not have the authority to, 1) implement final actions that follow from Council recommendations\approvals; 2) make decisions on internal personnel matters; 3) make final budget decisions; or 4) make official NIEHS communications. The NIEHS staff is responsible for the final product/actions in the above areas.

Ms. Spaeth then compared how a corporate board differs from an advisory council. A member of a corporate board, 1) exercises corporate powers, 2) is responsible for final decision-making, 3) has a fiduciary obligation to the corporation, and 4) assumes legal liability if it fails to discharge duties in accordance with officially authorized standards.

An advisory council, 1) has no corporate powers to exercise, 2) cannot make final decisions on behalf of the government, 3) has no fiduciary obligations to the Institute, and 4) does not assume legal liability if it fails to discharge duties in accordance with officially authorized standards.

Ms. Spaeth concluded her presentation by encouraging Council members to look closely at the contents of the Council Operating Procedures, to have discussions on the scope and purpose of the Council, and to have clear-cut communications with the Institute.

After concluding her presentation, she asked for questions.

Council Response and Discussion

Council member (Ms. Hines) cited the *Federal Register*, Vol.66, No. 39 Thursday, July 19, 2001; Part II; General Services Administration; 41CFR Parts 101–6 and 102–3; Federal Advisory Committee Management; Final Rule. She pointed out the statement on Page 37741, §102.395 (e) “Seek feedback.” Agencies continually should seek feedback from advisory committee members and the public regarding the effectiveness of the advisory committee’s activities. At

regular intervals, agencies should communicate to the members how their advice has affected agency programs and decision-making.” She asked for clarification between what the *Federal Register* states and the statement in the slide, “final actions that follow from Council’s recommendations/approvals are outside Council’s scope.”

Ms. Spaeth gave further details. She pointed out that the actual responsibility for final decisions is the responsibility of the Institute. It does not mean that Council cannot receive feedback on their recommendations.

Council member (Ms. Hines) wanted further clarification. Is there a reason if Council requests follow-up on an issue that information could not be provided? Is it within the law for information to be provided to Council?

Ms. Spaeth pointed out that the Institute is not obligated by law to provide information. Institutes normally provide feedback to their Councils concerning Council’s recommendations and approvals to keep them informed.

Council member (Dr. Schnoor) wanted to know whether or not Council could get feedback via letter when they put forward a recommendation as to whether or not the recommendation was adopted?

Dr. Lang replied that Council does not get a letter. Once a year, funding decisions for the fiscal year are reported back at a Council meeting.

Council member (Dr. Schnoor) gave an additional scenario; for example, suppose Council favors the climate change initiative and it is advertised as a request for applications, what happens after the recommendation?

Dr. Lang responded that the recommendation and details would be presented to Council in the form of a Concept Clearance. Council would vote on whether they would like the initiative to move forward.

Council member (Dr. Leikauf) queried if Council wished to speak as one voice outside of Council;(for example, send a letter to Dr. Zerhouni concerning an initiative) should this be done through the chairperson of the Council?

Ms. Spaeth responded if Council contacts each other without a formal meeting or without the Institute’s knowledge, then this is beyond the auspices of the Institute. If Council is meeting with the support of the Institute this should be done according to the FACA regulations, in a public forum, with a designated federal official.

Council member (Dr. Leikauf) asked for clarification on testifying before Congress. If a Council member testifies without the consensus or consent of the Council, and say I am a member of Council, is the individual representing him/herself or does that statement automatically convey that this individual represents the Council?

Ms. Spaeth replied that individuals may speak on behalf of themselves only; individual members may not speak on behalf of the entire Council.

Council member (Ms. Hines) asked Ms. Spaeth to follow-up on the issue of the public forum. It was her understanding of the law that Council members can meet prior to the Council to get together, discuss and prioritize issues in preparation for the meeting.

Ms. Spaeth remarked that there is an allowance for exchange of information, but it is NIH policy to have a designated federal official present at the meeting. The entire Council is not able to meet outside of the public forum as is clear in the Code of Federal Regulations.

Council member (Ms. Hines) then stated it was her understanding that when they meet as Council they automatically become a designated federal employee.

Ms. Spaeth replied that is not the case. Council members are special government employees, but not designated federal officials.

According to FACA, a designated federal official, 1) calls, attends, and adjourns committee meetings; 2) approves agendas; 3) maintains required records on costs and membership; 4) ensures efficient operations; 4) maintains records for availability to the public; and 5) provides copies of committee minutes to the Committee Management Officer for forwarding to the Library of Congress.

Council member (Ms. Hines) queried who appoints the chairperson for Council and why the chairperson is the Institute Director and not one of the Council members.

Ms. Spaeth answered that the appointment of the chairperson for Council is done by the Secretary of the Department of Health and Human Services

Council member (Ms. Hines) stated, to the best of her knowledge, there are provisions within the law that allows Council to freely discuss information and come to a consensus among themselves as a group.

Ms. Spaeth replied that there are some meetings that can be done outside of the public forum. The meeting can be a working group of Council which does not have to be advertised, where there can be an exchange of ideas and information, and is done in the presence of a designated federal official before reporting to a full committee.

Council member (Dr. Liebler) then noted that there is a gray area surrounding the level of how Council members may communicate and organize information. The manner in which the Council exchanges and gathers information is what tips the method toward a formal or informal forum. He queried if Council members could exchange information on an informal and individual basis prior to the meeting in order to understand the thoughts and ideas of the other members.

Ms. Spaeth responded that individuals could communicate on an individual basis, but not come to any consensus.

Council member (Ms. Hines) asked for clarification of the bullet "official NIEHS communications." She mentioned that reports written and generated for Congress or information requested by Congress were usually not shared with the Council. Therefore, explain what is shared under "official NIEHS communications."

Ms. Spaeth replied that "official NIEHS communications" is the responsibility of the Institute and means only officials of the government prepare material for distribution and respond to outside inquires, such as Congressional inquiries. The Institute may use their discretion in deciding what internal documents are passed on to Council members.

Dr. Wilson asked Ms. Spaeth to summarize the requirements and general practices regarding FACA for further clarification.

Ms. Spaeth outlined the provisions provided under FACA, such as requirements for establishing advisory committees; appointing advisory committee members; and open access to council meetings.

Council member (Ms. Hines) queried if the Council is discretionary.

Ms. Spaeth replied no, because there is a statute that requires every Institute to have a Council.

Council member (Ms. Hines) wanted to know where the accountability lies if the Council is nondiscretionary. What is the overarching purpose of Council?

Ms. Spaeth responded that Council does not have a fiduciary responsibility. Council does not have a legal liability. The Institute is responsible for accountability. The purpose of this Council is to advise and make recommendations to government officials and to do the second level of grant review for Council.

Council member (Ms. Hines) asked if there are metrics that evaluate the functionality of Council.

Ms. Spaeth replied there are no metric measures used to evaluate each Council.

Council member (Ms. Hines) thanked Ms. Spaeth for helping her to understand the parameters under which Council functions and Dr. Wilson and Dr. Lang for acknowledging the many requests made over the past year and the positive directions in which they have taken Council.

Council member (Dr. Liebler) queried if there are plans to have retreats and other interactions in which Council and the Institute could have meaningful discussions. He also suggested posting documents on the Council web pages for access at a later date.

Council member (Dr. Carpenter) queried why the chairperson of the Council has always been the Institute Director and not one of the Council members.

Ms. Spaeth noted that the decision was made at some point by the Secretary of the Department of Health and Human Services and the practice remains in place.

Council member (Dr. Leikauf) mentioned, as a procedural issue, that many of the comments, questions, discussion and clarifications made by Council members are just viewpoints and not recommendations. He suggested that there could be a formal motion at the end of each discussion to decide whether or not consensus had been reached on a particular recommendation.

Dr. Wilson replied he thought the idea was a good one and encouraged Council members to raise the point when they think it is appropriate.

VIII. RESEARCH, CONDITION, AND DISEASE CATEGORIZATION (RCDC)

Drs. Timothy Hays and Sheila Newton

Dr. Wilson introduced Dr. Sheila Newton, Director of Policy, Planning, and Evaluation, NIEHS. She laid the foundation for the presentation given by Dr. Timothy Hays, Project Director of the RCDC; Chief, Portfolio Analysis and Scientific Opportunities Branch; Office of Portfolio Analysis and Strategic Initiatives; Office of the Director, NIH.

Dr. Hays indicated that one of the ways NIH communicates with its stakeholders is by reporting the level of its investments in the different research/disease areas. He indicated that there are approximately 240 different research/disease areas that are reported every year to the public and Congress. An estimation is done on how much will be spent in these areas for the next two years. This information allows Congress and the public to better understand NIH research spending and priorities.

NIH recently consolidated the various processes currently carried out by the NIH Institutes and Centers. This single approach was encouraged in the 1st and 2nd National Academy of Sciences Reports (1998 and 2003 respectively). The reports recommended that NIH provide a clear method of how the accountings of the research/disease categories are obtained. In 2004 the RCDC was established with a successful pilot of the proposed system. In the NIH 2006 Reauthorization Act, Congress requires that NIH "...shall establish an electronic system to uniformly code research grants and activities..."

RCDC is a system that gathers, each fiscal year, information from 27 Institutes, Centers, and Offices and electronically reports NIH spending to Congress and the public. This system allows for consistency, transparency, efficiency, and opportunities for further portfolio analysis. Dr Hays then charted the steps on how a project is assigned to a category.

Dr. Hays then presented the timetable for launching RCDC. He noted that in 2007 presentations began to inform the NIH Advisory Councils about the RCDC system. In 2008 NIH began communications with public stakeholders. NIH proposes to launch RCDC with FY2008 projects in the spring of 2009. He pointed out that side-by-side comparison of FY2007 categorization summary data using old and new methods will be available at launch.

Dr. Newton reported on the NIEHS Project and Disease Reporting (NPDR) system data. She pointed out that grants are imported from IMPAC 2; intramural projects are imported from the NIH Database (NIDB). Contracts are imported from the Division of Intramural Research contracts database; and Medical Subject Heading (MeSH) indexing for the intramural and contracts; and CRISP indexing for grants. For FY2008, these data will be used to supplement RCDC. The data is preliminary and subject to change; projects may be added or removed throughout the year until the final fingerprint or RCDC definition is approved that incorporates advances in science.

Council Response and Discussion

Council member (Ms. Hines) asked are the definitions going to be available as to how these categories are defined.

Mr. Hays replied the project listing will reflect the definition, rather than providing a list of concepts. This will be done in the beginning to decrease confusion until there is a better understanding as to how the system works.

Council member (Dr. Leikauf) queried if this information could be used to see how the portfolio dollars are being distributed.

Dr. Hays replied that the system will not reflect the dollars that are planned to be spent, but only the way they are spent during the previous year.

Dr. Newton mentioned that once the system is up and running a research/disease area can be compared from one year to the next. You will be able to see how, for example, asthma expands or decreases versus how other research/disease area expands or decreases.

Council member (Dr. Leikauf) queried will this rationale be applied to Centers for Disease Control classifications or other death or disease classifications.

Dr. Hays responded this is not being done at this time, but the CDC has requested more information about the system.

Council member (Dr. Leikauf) pointed out that the classification of death is often used in epidemiological studies. If the epidemiologist could see how their portfolio links to common diseases that individuals are dying from rather than rare diseases, one could adjust the portfolio in that direction. Therefore, disease classification would be very useful.

Dr. Hayes replied that the Office of Portfolio Analysis Strategic Initiative (OPASI) is looking at ways to expand portfolio analysis at NIH. NIH will be looking at public health related, as well as other metrics in comparison to NIH and other funded research.

Council Member (Dr. Liebler) noted that when RCDC is “googled” Rose City Discussion Council appears.

Dr. Hays responded that the NIH has been working with Google to keep RCDC off their hit list until June 11th when the website will be up and running.

Council member (Ms. Witherspoon) asked is the lay public an intended audience for this tool.

Mr. Hays responded that only the internal NIH will be able to use this tool. However, the output of the tool will be available to any NIH stakeholder (members of the public, Congress, researchers, and scientific societies) to look at.

Council member (Ms. Hines) asked if NIEHS is still planning to do analyses in regard to chemicals and searches.

Dr. Lang responded that the Program Analysis Branch, DERT is doing analysis on the portfolios that are different from the RCDC. DERT will continue their analysis parallel to this effort.

Dr. Wilson inquired how are cross cutting topics like oxidative stress handled when they involve multiple topics.

Dr. Hays responded that the definition is left to the ICs to define each area. The definitions are not centralized. Only the tool and coordination is centralized.

Dr. Wilson inquired if there will be a process for refining definitions as new scientific information or best practices are identified.

Dr. Hays responded in any given year half of the categories will be revisited for changes in the science.

Council member (Dr. Freeman) asked that the scientific community be given an opportunity to give their input, and information should be available to the public.

Dr. Newton cautioned that the underlying aim is not primarily to see how any given research project has been categorized, but what is the overall level of investment for this type of research.

Dr. Wilson thanked Drs. Hays and Newton for their informative presentation and the answers to the questions surrounding this endeavor.

IX. REPORT OF THE CHAIR, BOARD OF SCIENTIFIC COUNSELORS

Dr. John Hildebrandt

Dr. Wilson introduced Dr. John Hildebrandt, Chairperson of the Board of Scientific Counselors for the Intramural Research Program. He noted that the Board of Scientific Counselors reviews the Intramural Programs at NIEHS. The Board is composed of both permanent and ad hoc members specific to the scientific area of the scientist being reviewed.

Dr. Hildebrandt noted the Division of Intramural Research (DIR) laboratories that have been reviewed and those that will be reviewed this year, 1) March 25–27, 2007 the Laboratory of Molecular Carcinogenesis and Laboratory of Molecular Toxicology, 2) December 2–4, 2007 the Laboratory of Respiratory Biology, 3) February 22–24, 2008 the Laboratory of Neurobiology, and 4) July 20–22, 2008 the Laboratory of Structural Biology.

He then concluded his presentation with a list of the current Board members.

Steven Belinsky (PhD), Lovelace Institute, New Mexico

Samuel Cohen (MD, PhD), University of Nebraska, Nebraska

Jay Goodman (PhD), Michigan State University, Michigan

Jack Keene (PhD), Duke University, North Carolina

Andrew Liu (MD), National Jewish Medical and Research Center, Colorado

Thomas Louis, (PhD), John Hopkins University, Maryland

Jeffrey Thorne (PhD), North Carolina State University, North Carolina

Council Response and Discussion

Council member (Dr. Liebler) queried if programs have been recommended to be discontinued.

Dr. Hildebrandt responded that approximately four DIR laboratories have been discontinued and in each review recommendations made for adjustments in the resources of laboratories.

Council member (Dr. Liebler) asked if the Board's recommendations have been implemented to the Board's satisfaction and what is the role of the Board in tenure decisions?

Dr. Hildebrandt responded the Board's role is advisory, and NIEHS has the final decision. Yet, most of the recommendations have been taken and when not, there has been a strong justification. The Board has a specific role in tenure decisions. The Board's review does not focus on tenure but on the accomplishments of the individual's research both during the time of

pre-tenure, future accomplishments they may make in the field, and establishing recognition in the field.

Council member (Dr. Leikauf) commented those scientists who participate in the Director's Challenge award need to be recognized for working across disciplines and not be penalized at the time of tenure.

Dr. Hildebrandt responded that the driving force for tenure is accomplishments from one's own research program. Once a scientist has tenure, those interactions within the Director's Challenge become important to the future development of the scientist.

X. SCIENTIFIC SEMINAR - Dr. William Copeland

In introducing Dr. William Copeland, Dr. Wilson described the speaker's findings as "seminal scientific information that is incredibly exciting."

Dr. Copeland explained how DNA polymerase gamma (pol γ) functions to replicate mitochondrial DNA (mtDNA). MtDNA encodes essential enzymes that function in the mitochondria, which is responsible for the body's energy production. Defects in mtDNA can lead to a long list of disease that can affect anyone during a lifetime and impact a variety of tissues, especially the heart, brain, liver, and kidneys, which are organs that utilize substantial amounts of energy. About 1 in every 2000 births will develop an inherited form of mitochondrial disease in their lifetime, where half will present with symptoms during childhood.

Mitochondrial defects have a secondary role in many other diseases, such as Parkinson's, Alzheimer's, Huntington's, diabetes, psychiatric disorders, cancer, aging, and autism. About ten percent of autistic children show biomarkers of mitochondrial disease.

Antiviral nucleoside analogs cause mitochondrial toxicity and associated side effects, such as peripheral neuropathy, skeletal muscle myopathy, depletion of mtDNA. One cause of this toxicity is the inhibition of DNA pol γ by these antiviral nucleoside analogs.

Like nuclear DNA, mtDNA is sensitive to mutagens and carcinogens, including some anti-cancer and anti-viral drugs. Because it is the only known DNA polymerase in mammalian mitochondria and a gene frequently found mutated in mitochondrial disease, understanding the role of pol γ dysfunction by mutations in the polymerase gamma (POLG) gene may be useful in discovering ways to intervene in mitochondrial disease and other diseases where mtDNA depletion and mutation play a role.

Council Response and Discussion

Discussion following Dr. Copeland's research presentation centered on elucidating the underlying mechanisms of mitochondrial dysfunction, specifically examining POLG mutations and their role in disease. Moreover, the role of environmental agents and their role in mitochondrial diseases due to uncoupling of oxidative phosphorylation/electron transport are being investigated by this group. Considerable enthusiasm was noted in this area of study by Council with a great deal of interest in understanding the potential role of POLG mutations, as this is the replicative polymerase in mitochondria.

Council member (Dr. Liebler) asked about any post-translation modifications (e.g., phosphorylation, glycosylation) associated with POLG.

Dr. Copeland noted that they are beginning to answer these questions as there is evidence of active protein kinases in the mitochondria.

Continued questioning involved examining *in vitro* Y955 mutations, as this tyrosine when mutated to cysteine is autosomal dominant. Dr. Copeland's group has shown that this mutant has reduced fidelity and probably competes with wild-type in binding at DNA replication forks.

Council member (Dr. Christiani) inquired about potential implications/possible relevance of DNA copy number and mitochondria disease states or altered metabolism.

Dr. Copeland replied that is an interesting question, as the field is still young in this area. There are certainly opportunities to begin to evaluate polymorphisms in terms of mitochondrial health and predisposition to disease.

Overall, the discussion was that there exists a multitude of prospective avenues, specifically animal models that begin to recapitulate disease states as a function of examining mitochondrial mutations at the mechanistic level.

XI. PARTNERSHIPS FOR ENVIRONMENTAL PUBLIC HEALTH – Dr. Gwen Collman

Dr. Collman gave an update on activities related to environmental public health. She informed Council of a new program called Partnerships for Environmental Public Health (PEPH). The Institute envisions this as an umbrella program to coordinate a variety of research, outreach, and education activities that will lead to prevention, reduction, and elimination of environmental exposures and related diseases with active engagement of those communities that are most affected in all stages of the work. The Institute wants to build upon the strengths of past and current research programs, continue emphasis on the development of educational and outreach materials, support research theories and methods both related to community engagement and involvement, and the dissemination and communication of scientific findings that are in the field of environmental health sciences.

Dr. Collman displayed a list of programs the Institute has sponsored, and with a variety of partners at the NIH and other agencies. Many of the programs have activities related to community involvement and engagement. Some of the programs are research based which involve advocates or community-based organizations, and other programs are outreach and education.

Dr. Collman mentioned three activities that Division of Extramural Research and Training (DERT) have been engaged in during the month of April. The first activity was a request for information from a variety of stakeholder communities. This tool was chosen because it reaches a wide audience quickly. Input was sought from the lay public, environmental health researchers, healthcare professionals, educators, policy makers, and others with a vested interest in the effects of environmental exposures on public health. DERT received over a 120 responses which are being synthesized into an executive summary and will be used at the upcoming workshop. Also, the integrated responses will be posted on the NIEHS website.

The second activity provides 1.5 million dollars in administrative supplements. The administrative supplements will focus on five areas, 1) building new partnerships with community groups and stakeholders; 2) developing and/or disseminating educational and outreach materials; 3) enhancing communication with existing partners by using a variety of

methods [i.e., town meetings, forums on selected topics]; 4) evaluating [process and outcome evaluations] strategies to quantify public health impact; and 5) engaging community and researchers in environmental health science research projects.

The third activity is the preparation of a workshop to be held June 30–July 1, 2008 at NIEHS. Twenty individuals have been invited in areas related to the PEPH components. Some have been actively involved in the NIEHS grant program, and others are working in complimentary areas outside of the NIEHS grant program. This cadre of individuals will bring new perspectives into the work that has been going on, and will direct the program into new areas.

Dr. Collman closed her presentation by pointing out that this has been a trans-DERT activity. Mr. Liam O’Fallon has been the lead on this activity and every branch in DERT was involved. She also thanked council members Ms. Hines and Dr. Carpenter for their participation as Council liaisons.

She then asked for comments or questions.

Council Response and Discussion

Council member (Ms. Witherspoon) queried the level of funding for this program. She was interested in whether the funding for some of the past programs would be at the level they were several years ago.

Dr. Collman responded that some of the programs listed, such as the Children’s Environmental Health Centers Program will continue and be developed with partnerships and community based activities. As far as the Environmental Justice Program, it needs to be redeveloped, reinvigorated, decide which components are needed, and the appropriate level of funding. The workshop will clarify these issues and provide a message of sustainability and commitment to the stakeholders of that community.

Council member (Dr. Stephens) wanted to know how the media has been involved and will be involved in getting information to the public.

Dr. Collman replied that in the past the media has been involved at the local level through community organizations and at the Institute level through the Office of Communications. For future communication the Institute will think more broadly using 21st Century communication strategies, and not relying only on media contacts.

Council member (Dr. Leikauf) queried Dr. Collman as to whether the parameters of environmental public health be defined at the workshop.

Dr. Collman responded that at the workshop there will be a spectrum of definitions put forth and a set of definitions will be chosen that best defines what the Institute expects to accomplish with the program. Future announcement of the program will be clear on the expectations and goals of the program.

Dr. Wilson indicated the Institute has taken a leadership role and has an opportunity to define the field. This type of research can effectively and uniformly have a public health impact and the engagement of the community. Discussions at the workshop and after are critical toward enhancing and benefitting this type of research activity.

XII. REPORT OF THE ACTING DIRECTOR, DERT – Dr. Dennis Lang

Dr. Lang listed the topics he would discuss in his report to Council: 1) NIEHS success rates, 2) Breast Cancer and Environmental Research Centers (BCERC) Working Group Report, 3) the Interagency Autism Coordinating Committee (IACC) Town Hall Meeting, 4) Peer review enhancement, and 4) DERT staff changes.

Dr. Lang showed the NIEHS success rate for FY2007 was 18.5 percent and the NIH success rate for FY2007 was 21.3 percent. He pointed out that R01s, R03s, and R21s are all placed under the RPG number. Individually the success rates for unsolicited R01s, R03s, and R21s were 22.7 percent, 27.3 percent, and 12.2 percent respectively.

Dr. Lang mentioned that of those applications funded for the September and February Council rounds, only two applications were raised to pay out of order. He noted that this type of information can be brought to each Council with a full summary at the February council.

Dr. Lang presented the report on the BCERC Program. The annual meeting of this program was November 8–9, 2007 in Cincinnati, Ohio. The working group attends this meeting and every year creates a report on the progress of the program. The focal points of the report are summarized as follows: 1) progress has been made since the working Group Report of 2006; 2) communication within and among Centers has improved, and cross-disciplinary activities have increased. The design of new biology studies, for example, are being brought up to date by the exposure data obtained from the Epidemiology Bio-monitoring Pilot Study; 3) exciting novel findings have been reported by the biology and epidemiology projects (demonstrated by manuscripts, publications, and grant funding); 4) recruitment goals in the epidemiology project have been completed at all three Centers; and 5) the Community Outreach and Translation Cores have increased joint interactions within their groups and with the biology and epidemiology projects. The Cores continue to develop excellent educational activities, produce informative exposure facts sheets, and plan for dissemination of study findings.

The BCERC working group encouraged, 1) the creation of more opportunities for interactions between the biology and epidemiology projects; 2) a reflection on how mechanisms operating in animal models relate to human biology; and 3) the consideration of plans for renewable funding for longitudinal follow-up of the cohorts in the epidemiology studies.

Dr. Lang displayed the list of the members of the BCERC working group, chaired by Dr. Karen Miller, Huntington Breast Cancer Action Coalition.

Dr. Lang informed Council that IACC is comprised of representatives from all the ICs, agencies, and groups that have an interest in autism. He noted that Dr. Cindy Lawler was instrumental in organizing the Town Hall Meeting. He gave a brief report on the IACC Town Hall Meeting held May 3, 2008 in Sacramento, California. He outlined the goals and expected outcomes: 1) solicit public input on autism treatment research priorities for the Strategic Plan; 2) prepare a summary of recommendations to the IACC at the May 12, 2008 meeting; and 3) use the meeting summary to help plan further development and refinement of the Strategic Research Plan.

The panel themes and goals presented to the IACC at the May 12, 2008 meeting were as follows: Panel themes, 1) Panel I: ASD treatment in young children; 2) Panel II: ASD intervention, beyond the young child; and 3) Panel III: summary and open dialog with the public. Common goals were to stimulate discussion about the range of treatments being used, and develop recommendations about research priorities, including issues of efficacy and safety.

In summary, the May 12, 2008 meeting was a success, the attendance by the public was excellent (125–150 attendees), a wide range of opinions were expressed, and many attendees expressed their appreciation to the IACC for the opportunity to be heard. The next steps will be how to sustain the success of this meeting and continue an ongoing dialog of the IACC with the public.

Dr. Lang presented an update on the NIH Peer Review Enhancements. He noted that there were four core themes that developed in the planning process, 1) excellence of the reviewers; 2) fairness and clarity of the peer review; 3) support of scientist at different stages of their careers; and 4) continuous quality control and improvement of peer review.

The excellence of peer review is directly correlated to the ability to recruit, retain, and motivate the most accomplished, broadminded, and creative scientists to serve on study section. In order to accomplish this, the burden of review needs to be reduced, there needs to be flexibility in the meeting attendance, training of reviewers, and recognition and award for distinguished service of the reviewers.

The fairness and clarity of peer review depends on consistently identifying the application's relative merit, potential for scientific and/or public health impact, and feasibility. The applicants and the NIH program officers need clear and significant review feedback, including an informative summary statement. The rating system should be comparable across study sections and fields of science. To accomplish the above, the summary statement structure should be aligned with specific criteria. Pilot studies will be done to select the best method of achieving fairness and clarity in the peer review system.

To fairly fund scientists at different stages of their careers, proposals should be impartially evaluated regardless of career stage or discipline of the scientist. Bias should be avoided towards the more conservative and proven approaches at the expense of innovation and originality. To reduce the bias for early stage investigators, proposals should be fully discussed, not triaged, or the discussions of those proposals could be clustered and percentiled separately.

Continuous quality control and improvement of the peer review process is dependant on a rigorous and independent evaluation that favors, rather than discourages adaptive and innovative approaches to review and program management.

In summary, the project phases are as follows: Diagnostic (July 2007–February 2008); Design Implementation Plan (March 2008–April 2008); Begin Phased Implementation of Selected Actions (June 2008). After the project phases there will be an evaluation and development of new policies.

Dr. Lang closed his presentation by informing Council of recent staff changes. He mentioned that Dr. Carolyn Dilworth is a new member of the Susceptibility Population Health Branch and Dr. Benjamin Van Houten will be leaving NIEHS on August 1, 2008 to join the faculty at the University of Pittsburgh, Pittsburgh, Pennsylvania.

Council Response and Discussion

Council member (Dr. Libeler) queried if there has been any discussion on improving the quality of the study section composition and if investigators would be obligated to serve commensurate with their level of support.

Dr. Lang responded that discussions have centered on encouraging those investigators who have been successful in obtaining NIH support, and their service on study section would be an expectation as opposed to an obligation.

Council member (Dr. Leikauf) expressed concern about the level of the success rate achieved at NIEHS vs. other IC's.

Dr. Wilson assured Council that the level of the success rate is a priority of the Institute and the Institute would like to keep the number as high as possible. Additional information concerning the success rate will be updated at the September council.

Council member (Dr. Liebler) asked if the A1, A2 designation will be dropped from applications or will all applications be considered new applications.

Dr. Wilson replied that idea is no longer being considered.

There was a discussion about the morale of investigators, in particular the young investigators, during this period of limited budgets and reduced success rates. An idea was suggested to poll investigators about their level of satisfaction with the current situation but the Paperwork Reduction Act, prohibits surveys to about 10 people without OMB clearance. It was also suggested that an analysis of the NIEHS web site page that solicits comments from the community might be a source of information regarding grantee concerns and a way to take the pulse of that community.

Council member (Dr. Schnoor) suggested that we might think about instituting a nominal award for outstanding reviewers that NIEHS has used for institute reviews. This may serve to provide a "pat on the back" and boost morale amongst our reviewers. Dr. Lang agreed to look into this and suggested that the NIEHS Review Branch could identify such reviewers for recognition.

Dr. Wilson thanked the Council for a stimulating discussion and adjourned the open portion of the meeting.

The open portion of the meeting was adjourned at 2:30 p.m.

CLOSED PORTION OF THE MEETING

May 30, 2008 – 2:30 p.m.

XIII. Consideration of Grant Applications

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 FACA, 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.

XIV . ADJOURNMENT OF THE NAEHS COUNCIL

The meeting was adjourned at 4:00 p.m. on May 30, 2008.

CERTIFICATION

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

Samuel Wilson, MD
Acting Chairperson
National Advisory Environmental
Health Sciences Council

Dennis Lang, PhD
Acting Executive Secretary
National Advisory Environmental
Health Sciences Council

Attachment:
Council Roster