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 19, 2009

The National Advisory Environmental Health Sciences Council was convened for its one hundred twenty-sixth regular meeting on February 19, 2009 at 8:30 a.m. in the Rall Building, Rodbell Auditorium, National Institute of Environmental Health Sciences, Research Triangle Park, NC. Dr. Linda Birnbaum presided as Chair.

The meeting was open to the public on February 19, 2009 from 8:30 a.m. to 2:40 p.m. In accordance with the provisions of Public Law 92–463 the meeting was closed to the public on September 9, 2008 from 3:00 p.m. to 4:45 p.m. for consideration of grant applications. Notice of the meeting was published in the *Federal Register*.

Members Present

Hillary Carpenter, PhD David Christiani, MD John Essigmann, PhD Richard Finnell, PhD Joseph Graziano, PhD Stefani Hines, MA, MS

Ad Hoc Members

Grace LeMasters, PhD R. Stephen Lloyd, PhD

Ex Officio Officer CPT Michael Macinski

NIEHS Staff

Kathy Ahlmark **Beth Anderson** Steven Akiyama, PhD David Balshaw, PhD Linda Bass. PhD Martha Barnes Sharon Beard Pamela Clark Jennifer Collins Gwen Collman, PhD Helena Davis Caroline Dilworth. PhD Christie Drew, PhD Dorothy Duke Sally Eckert-Tilotta, PhD Donald Ellis Kris Erwin

George Leikauf, PhD Daniel Liebler, PhD Kenneth Ramos, PhD Jerald Schnoor, PhD Kevin Stephen, MD Altaf Wani, PhD Nesdu Obot Witherspoon, MPH

Janet McCabe, JD Sem Phan, MD, PhD Palmer Taylor, PhD

Benigno Encarnacion Christine Flowers Elliot Gilmer Kimberly Gray, PhD Jerrold Heindel, PhD Heather Henry, PhD Marc Hollander Michael Humble, PhD Ethel Jackson, DDS Laurie Johnson Annette Kirshner, PhD Dennis Lang, PhD Cindy Lawler, PhD Christopher Long Robin Mackar Joyce Martin, JD Carolyn Mason J. Patrick Mastin, PhD

Elizabeth Maull, PhD Kimberly McAllister, PhD Rose Anne McGee Elizabeth McNair Srikanth Nadadur, PhD Teresa Nesbitt, PhD Shelia Newton, PhD Aaron Nicholas Liam O'Fallon Theodore Outwater Michelle Owens Jerry Phelps Leslie Reinlib, PhD Donna Roach Margarita Roque William Schrader Carol Shreffler, PhD Daniel Shaughnessy, PhD William Suk, PhD Hugh Tilson, PhD Sally Tinkle, PhD Claudia Thompson, PhD Frederick Tyson, PhD Myra Westmoreland Michelle Victalino James Williams Mary Wolfe Marva Wood Leroy Worth, PhD

Members of the Public Present

David Brown, SRA International James TerMaat, Social and Scientific Systems, Inc. Pamela Schwingl, Social and Scientific Systems, Inc.

OPEN PORTION OF THE MEETING

February 19, 2009 – 8:30 a.m.

I. CALL TO ORDER AND OPENING REMARKS

Dr. Linda Birnbaum called the one hundred twenty-sixth regular meeting of the National Advisory Environmental Health Sciences Council to order. She opened the meeting by welcoming those in attendance. She welcomed the new members Drs. Grace LeMasters, Stephen Lloyd, Sem Phan, Palmer Taylor, and Ms. Janet McCabe. Dr. Birnbaum thanked the retiring members for their service and dedication to the Council and NIEHS. She also recognized the contributions of three retiring member who were not preset at the meeting – Drs. Kathleen Dixon, Bruce Freeman, and Ms. Lisa Greenhill. The retiring members who were present received their certificates for service on the Council. She then invited Council members and those individuals at the table to introduce themselves, she also invited National Institute of Environmental Health Sciences (NIEHS) staff and guests to continue with the introductions. After the introductions she turned the meeting over to Dr. Gwen Collman to discuss administrative matters.

Dr. Collman reminded Council members to sign their conflict of interest forms and to complete their travel vouchers expeditiously. She noted that Michelle Owens was available to Council members to help with any administrative or logistic matters. She also mentioned that the Council meeting was being webcast and to use the microphones.

II. REVIEW OF CONFIDENTIALITY AND CONFLICT OF INTEREST PROCEDURES

Dr. Collman 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.

III. CONSIDERATION OF MEETING MINUTES

A motion was made by Council member, Kevin Stephen, to approve the September 9, 2009 minutes as written. The motion was seconded and approved unanimously by the members of Council.

IV. FUTURE COUNCIL MEETING DATES

The following dates were confirmed:	
May 21–22, 2009	NIEHS
September 14 –16, 2009	NIEHS
February 17–19, 2010	NIEHS
May 19 – 20, 2010	NIEHS

Thursday – Friday Monday – Tuesday – Wednesday Wednesday - Thursday Wednesday - Thursday

The September 2009 Council meeting dates include the Council retreat and therefore are three days.

V. REPORT OF THE ACTING DIRECTOR – Dr. Linda Birnbaum

Dr. Birnbaum introduced herself to Council and in her opening remarks, extended special thanks to Dr. Samuel Wilson who served as Acting Director for over a year when the Institute was going through some uncertain and demanding situations. Through his leadership he was able to direct the Institute into a positive and forward direction. She also thanked Dr. William Suk for serving as the Acting Deputy Director. She then informed Council that the intent of her presentation was to update Council on recent events, both at the Institute and at NIH. She outlined the areas she would be presenting, 1) her vision for the Institute, 2) actions in the past month, 3) NIEHS highlights and milestones; 4) recent scientific advances, 5) response to the Office of Management Assessment (OMA) Report, 6) Corrective Action Plan (CAP) implementation, status, and Director's actions to date, 7) Appropriations FY2009, 8) The American Recovery and Reinvestment Act (ARRA) of 2009, 9) Funds provided to NIH by ARRA, 10) Breast Cancer and Environmental Research Act, 11) NIH update, and 12) the role of the NAEHS Council.

Dr. Birnbaum pointed out that health and the environment is one of the priorities of the new federal administration. She also noted that the environment is no longer just a local concern but also a global concern. Issues that impact us locally, such as climate change, pollution or environmental stresses, will also impact the rest of the world. To adequately address these complex diseases and complex environmental impacts, the best individuals and team scientists will be needed. She noted that improved integration across research disciplines and improvement in translation of basic science and human health also will be needed. Translation is not just bench to beside, but also encompasses bench to public health.

Dr. Birnbaum shared the actions she has taken during the past month. 1) She has been restoring interactions and visibility with the Institutes in Bethesda and the extramural communities. She is now a member of the Interagency Autism Coordinating Committee (IACC) and the Facilities Working Group (FWG). 2) She has opened the Clinical Research Unit (CRU)

which provides the Institute greater opportunities to direct clinical and field studies, and to better integrate basic scientists with actual human disease outcomes. The CRU will not perform invasive procedures or conduct inhalation exposures studies. Dr. Darryl Zeldin, acting chief of the CRU, will form an outside advisory panel for the conduct of the clinical studies. 3) The gates at US EPA have been opened week-ends and evenings to facilitate movement back and forth between NIEHS and US EPA. 4) Opportunities for facilities sharing with the US EPA have been initiated at the Research Triangle Park Campus and the Memorial Hospital Human Studies Facility of US EPA to allow cost savings for both institutions. 5) A continuous 10 minute shuttle will run between the main NIEHS campus and satellite buildings. 6) A national search will be conducted to fill the positions of Scientific Director, Deputy Director, and Director of Division of Extramural Research and Training. It is hoped that permanent staff will be in these positions within the year. At this time, positions in the area of ethics and diversity are being filled.

Dr. Birnbaum highlighted recent events and milestones at NIEHS. She noted that Drs. Samuel Wilson and Jerrel Yankel were named 2008 Fellows by the American Association for the Advancement of Science. In January, NIEHS organized and supported the Institutes of Medicine's Roundtable on Environmental Health, "A Research Agenda for Managing the Health Risks of Climate Change." The National Toxicology Program (NTP) established new evaluation criteria for reproductive, developmental, and immunotoxicology studies. These criteria are patterned after the cancer bioassay evaluation language and should be adopted universally. She noted the recent scientific advances in the areas of fine particulate air pollution and life expectancy in the United States; arsenic exposure and the prevalence of Type 2 diabetes in US adults research has found the disruption of transcription factor Nrf2 promotes pro-oxidative dendritic cells that stimulate Th2-like immunoresponsiveness upon activation by ambient particulate matter; and anti-cockroach and anti-mouse IgE are associated with early wheeze and atopy in an inner-city birth cohort.

Dr. Birnbaum updated Council on the response to the Office Management Assessment (OMA) report. The report contained recommendations to the NIEHS in areas of human resources, contracting, financial management, ethics, grant making, governance structure, and organizational climate. NIEHS staff worked to create the Corrective Action Plan (CAP) which was approved by Dr. Zerhouni on August 29, 2008. The CAP includes action steps for each of the recommendations in the OMA report. Dr. Wilson established the Implementation Review Committee (IRC), which included staff from all divisions of NIEHS to oversee the execution of the CAP. The Institute is required to fulfill the requirements of the CAP. Dr. Sally Tinkle was appointed as Chair of the IRC. Once the action steps are implemented the Trans-Institute Implementation Committee will review each response to determine if it is complete, responsive, and sustainable. The responses are then submitted to the NIEHS Director for review and signature. A hard copy is filed in the Office of the Director and an electronic copy will be on the Sharepoint website for access and review by NIH OMA. She informed Council that of 108 Action Steps, 92 were submitted for review and 56 have been signed by the Director, NIEHS and the timetable for CAP is on target.

Dr. Birnbaum then commented on Appropriations from Congress. She illustrated the FY2008 appropriation and the FY2009 President's, House subcommittee and the Senate subcommittee budgets through PowerPoint. The NIEHS budget shows a slight increase in the House and Senate appropriations for FY 2009 as does the overall NIH budget. The Common Fund (directed by the NIH director), from which the Roadmap programs and Trans-NIH activities are supported, will increase by a small amount. The FY2009 President's budget for the Superfund Basic Research Program and the Worker Education and Training Program provides the same appropriation as for FY2008. The Department of Energy's Interagency Training Agreement has not been specified for FY2009.

Dr. Birnbaum brought Council up to date on the American Recovery and Reinvestment Act of 2009, better known as the Stimulus Bill. This Act will provide NIH with ten billion dollars for two years: \$1 billion for extramural facility construction and renovation; \$300 billion for shared instrumentation, \$8.2 billion for research, of which \$7.4 billion will be allocated to the ICs and \$800 million, will remain in the Office of the Director, NIH; and \$500 million for intramural program building and facilities, including new construction on the NIH campus. In addition, NIH has received \$400 million for Comparative Effectiveness Research. This research will compare the effectiveness of one treatment/intervention to another treatment/intervention for the same disease.

Dr. Birnbaum described the funds provided to NIH by ARRA, which creates an expeditious, merit-based process for maximum economic, health, and scientific benefits. Funding is for two years, with maximum flexibility within the stimulus guidelines. The \$7.4 billion dollars will be allocated among the Institutes. A large percentage of the money will go to highly meritorious R01 applications that slightly missed the payline as well as new R01s with funding for only 2 years. There will be also opportunities for currently funded grants to add new supplements. Out of the \$800 million in the Office of the Director, NIH, \$300 million will be allocated to Challenge Grants that will be centrally funded. These grants will address a defined health and science problem.

Dr. Birnbaum commented on the Breast Cancer and Environmental Research Act which was passed in October, 2008. The Act establishes the Interagency Breast Cancer and Environmental Research Coordinating Committee, which sets April 8, 2009 as the date for the Committee to be operational. The Act authorizes (but does not appropriate) \$40 million to carry out research to evaluate environmental and genomic factors that may be related to the etiology of breast cancer. This committee will consist of seven federal officials, six scientists/physicians, and six individuals from advocacy groups. The objective of this coordinating committee is to coordinate information on existing research activities, make recommendations for new research, and develop a comprehensive strategy.

Dr. Birnbaum updated Council on information from the Bethesda campus, NIH. There was a NIH peer review self study done from 2000 – 2008 which developed recommendations to improve the peer review system now in the process of being implemented.

Via the Roadmap Process there will be some centralized funding for high — risk, paradigm —shifting research. These will be funded under the Transformative R01 Program (T-R01). The areas included are: 1) Understanding and Facilitating Human Behavior Change, 2)Complex 3-D Tissue Models, 3) Functional Variation in Mitochondria in Human Disease, 5) Transition from acute to Chronic Pain, and 4) Formulation of Novel Protein Capture Reagents — Providing an Evidence Base for Pharmacogenomics.

Dr. Birnbaum illustrated the NIH web page. This web page, the product of the NIH Reform Act Reauthorization (2006) authorizes NIH to use major efforts to promote transparency. The link is report.nih.gov. From this site you can find information about NIH and funding issues. She illustrated the Biennial Report of the Director and the RePORT and RCDC as examples.

Dr. Birnbaum ended her presentation by emphasizing the importance of Council to the Institute. NIEHS values and appreciates Council's advice.

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

VII. DISCUSSION OF DIRECTOR'S REPORT

Dr. Essigmann (Council member) asked, with the guidelines provided in the American Recovery and Reinvest Act of 2009 (Stimulus Bill) how do you envision Council being involved. With the fast turnaround of these applications at what point will Council concur with the review of these applications.

Dr. Birnbaum remarked the time lines are very short for receipt, review, and funding of these applications; however, Council will be updated as the process evolves. Most likely many of the applications will be done by early concurrence procedures.

Dr. George Leikauf (Council member) queried if it is possible to spend the money allocated on such a fast timeline.

Dr. Birnbaum reiterated that these will be grants that were very close to the payline and those that were in the grey zone. Supplements will go to already funded applications. The new R01s will be on a super fast review cycle. These applications will be our greatest challenge in relationship to the time line.

Dr Jerald Schnoor (Council member) asked if there are special requirements for these grants.

Dr. Birnbaum commented that these grants will undergo a special and separate accounting process. Grants will be tracked on jobs created or preserved from the Stimulus Bill funds.

Dr. Liebler (Council member) asked for clarification on how the Institute plans to distribute the funds among the grants eligible for funding under this program.

Dr. Collman responded that the focus will be on the R01 mechanism. The grants will have to be identified and completed in a two- year time period. Remaining funds can be distributed across the other research program grants (RPGs).

Dr. Liebler (Council member) queried if existing funded grants would be able to reinstate budgets cuts if deemed meritorious.

Dr. Collman replied that NIEHS will not be able to reinstate budgets cuts, but if parts of the original proposal can be accomplished in two years, those parts can be submitted as a supplement. Guidance is still being sought in this area.

Dr. Essigmann (Council member) commented, given that this is a time of high unemployment this would be an ideal time to train postdoctoral students for a two- year time period. This would give these individuals employment for two years and will make them very eligible for employment in environmental science areas; for example, environmental engineering.

Dr. Essigmann (Council member) asked how allocations for equipment will be handled. Will it be across ICs or NIH wide?

Dr. Collman responded since the National Center for Research Resources (NCRR) already has existing programs for shared and high-end instrumentation and authority for construction and renovation all grants will be directed to NCRR for review and funding. These grants are usually in the \$100,000 range or higher. Guidance is forthcoming on whether small instrumentation grants can be administrative supplements through the individual ICs.

Dr. Leikauf (Council member) queried if all grants will be brought to Council for consideration.

Dr. Collman replied that there are several methods for funding grants: 1) the Council's early concurrence process, 2) the Council's delegated authority gives the Institute permission to go to \$150,000 awards without Council action, and 3) supplements can be handled administratively by the Diversity Supplement Program and the Emergency Needs Supplemental Program.

Dr. Ramos (Council member) suggested communicating with Council early so plans can be made accordingly as soon as the process is outlined for how things will proceed.

Dr. Finnell (Council member) mentioned that in this process we should not forget young investigators.

Dr. Carpenter (Council member) noted that in the early concurrence process three Council members appears to be a small committee in view of the number of applications that will have to be reviewed in a short time frame. Is it possible to expand the number of Council members?

Dr. Birnbaum informed Council their suggestions will be given consideration to see how Council can best be accommodated.

Dr. Liebler (Council member) reiterated Dr. Finnell's comment that young investigators should be given every opportunity to receive funding through mechanisms supported under the Stimulus Bill. He also pointed out that ES funded investigators should be notified by email once the guidance concerning the shared equipments grants are finalized.

Dr. Collman informed Council the plan is to send emails with key correspondence to the extramural community concerning all announcements and updates. She noted that the NIEHS website will be updated and information on the Stimulus Bill and funding opportunities can be found there.

Dr. Leikauf (Council member) asked if bridge funding could be considered for those investigators who did not get their grants renewed that were close to the pay line. Each investigator can lose several people in their laboratory when a grant is not renewed. He also wanted to know if time would be available before the conclusion of Council to spend some time contemplating ideas that would be covered under the Stimulus Bill.

Dr. Birnbaum informed Council that bridge funding is being considered because it is as important to conserve jobs as well as create new ones. Council would be provided time later in the meeting to discuss their ideas that may be covered under the Stimulus Bill.

Dr. Lloyd (Council member) noted he hoped the grants chosen for the two years of funding would be sustainable after the two years. Otherwise, laboratories will be closed and staff let go because of lack of funding after the two year period.

Dr. Birnbaum replied that we all hope that the grants that are funded will have scientific ideas that are sustainable for more than two years. However, after two years NIH will be back to a normal budget and these grants will have to compete within the budget allocated.

Dr. Essigmann (Council member) asked CPT Macinski to give his views on the opportunities for partnerships between the Department of Defense (DOD) and NIEHS, for example, in devices for monitoring.

CPT Macinski replied that interagency partnerships are beneficial for both sides.

Dr. Essigmann (Council member) commented that in the near future it is hoped that NIEHS and DOD will have progressed to the stage of announcing what type of funding will be feasible for an interagency partnership.

CPT Macinski remarked DOD is just in the beginning stages of discussions concerning partnerships with other agencies. A lot of groundwork needs to be done before NIEHS and DOD actually formulate ideas concerning funding partnerships.

Dr. Essigmann (Council member) mentioned that DOD has funded large and successful breast cancer programs and its research base could be incorporated in environmental areas.

CPT Macinski pointed out that DOD believes partnerships with federal agencies are important and are paramount to what this federal administration is advocating in terms of future endeavors.

Ms. Witherspoon (Council member) asked for details concerning the Climate Change and Health Proposal and whether there will be an increase in funding for that proposal.

Dr. Birnbaum replied that at this time the proposal only has been discussed at the IOM Round Table and NIEHS has taken the lead to develop a strategy on how to deal with the health effects of climate change. As a result, the Institute will be able to respond to requests from the Office of Science and Technology.

VIII. REPORT OF THE DEPUTY SCIENTIFIC DIRECTOR, NIEHS – Dr. Steven Akiyama

The purpose of Dr. Akiyama's presentation was to update Council on recent activities within the Division of Intramural Research (DIR). The areas addressed were, 1) the Sixth Annual NIEHS/DIR Science Awards Day, 2) New Appointments, 3) DIR Recruitments, 4) Top DIR Papers from 2008, 5) DIR Awards and Honors, and 6) Training and Mentoring Highlights.

The Annual Science Awards day is organized each year by Dr. Joel Abramowitz with help from a DIR Steering Committee. The program is designed to acquaint the NIEHS with the research being developed at the Institute and to honor the postdoctoral fellows and senior scientist for their scientific achievements. Each of the honored postdoctoral fellows receives a \$1,000 travel award to a meeting of their choice.

The following individuals received awards: Scientist of the Year, Michael Resnick, PhD; Early Career Award, Michael Fessler, MD; Outstanding Staff Scientist, Freya Kamel, PhD; Mentor of the Year, Ronald Mason, PhD; Best Oral Presentation, Daniel Gilchrist, PhD; Paper of the Year (RNA-templated DNA Repair) F. Storici, K. Bebenek, T.A. Kunkel, D.A, Gordenin, and M.A. Resnick; and Best Poster Presentations, Stephanie McElhinny, PhD, Paivi Salo PhD, and Marcelo Bonini, PhD.

The following scientists were appointed to the Division of Intramural Research after open national searches: Dr Raymond Tice, Chief, Bimolecular Screening Branch, NTP; Dr. Mark Hoenerhoff, Staff Scientist, Cellular and Molecular Pathology Branch; and Drs. Weichun Huang and Keith Shockley, Staff Scientists, Biostatistics Branch.

DIR is in the process of appointing two tenure-track investigators in bioinformatics. Searches are also in process for tenure-track investigators in the fields of reproductive epidemiology, x-ray crystallography, embryonic stem cell biology, neurobiology, and a developmental biology

Dr. Akiyama highlighted the ten top DIR papers for the year 2008 and awards and honors received by DIR staff. Drs. Samuel Wilson and Jerrel Yankel were selected Fellows of the American Association for the Advancement of Science, Dr. John Cidlowski received the Edwin B. Astwood Award from the Endocrine Society in 2008, and Dr. Allen Wilcox received an honorary doctorate from the University of Bergen, Norway. He also highlighted the awards obtained by the postdoctoral fellows under the excellent guidance by their mentors. Dr. Arno Siraki received a K99/R00 grant; Cindy Visness and Michelle Sever, both received STAR Awards from the American Academy of Allergy, Asthma, Immunology; Dr. Erik Tokar was the first place winner of the North Carolina Society of Toxicology President's Postdoctoral Award for Research; and Dr. Scott Auerbach was the second place winner of the North Carolina Society of Toxicology President's Postdoctoral Award for Roxicology President's Postdoctoral Award for Research.

Dr, Akiyama extended thanks from the DIR staff to Drs. Samuel Wilson and Perry Blacksheer for their leadership through challenging times at the Institute. He then solicited discussion and questions from the Council

Council Response and Discussion

Dr. Leikauf (Council member) asked if there were plans to continue the program that enhanced collaborations among laboratories.

Dr. Akiyama responded DIR plans to continue the IRA Awards Program. The purpose of this program is to foster collaboration between scientists in different laboratories. Due to budget constraints of the past year, DIR was not able to solicit applications for this program.

Dr. Birnbaum emphasized that she is very supportive for continuing the IRA awards.

Dr. Leikauf (Council member) mentioned that the papers cited did not appear to have an environmental component. He suggested that papers cited in the future have more emphasis on environmental agents and translational research.

Dr. Akiyama replied that the papers cited were chosen keeping in mind relevance to environmental exposure or human health issues but this might not have been explained well in the written materials.

Dr. Birnbaum pointed out that the mission of DIR is to do high risk research that may not be able to be done elsewhere. Dr. Birnbaum also noted that sometimes the titles of papers do not always reflect their total scientific content.

Dr. Birnbaum introduced Dr. John Bucher, Associate Director of the National Toxicology Program (NTP), whose presentation will focus on the NTP updates.

X. REPORT OF ASSOCIATE DIRECTOR, NATIONAL TOXICOLOGY PROGRAM (NTP) – Dr. John Bucher

Dr. Bucher updated Council on the current activities for the National Toxicology Program (NTP). He began by highlighting the following meetings that took place: 1) High-Throughput Screening

Vendors meeting, September 11, 2008 [presentations by companies involved in developing high throughput screens for the pharmaceutical industry]; 2) NIH Research Festival, October 14 – 17, 2008 [Symposium topic "Genetic susceptibility – The Link between Environmental Exposure and Human Disease"]; 3) Reproductive Tract Pathology Workshop, October 29 – 30, 2008 [sponsored by the Pathology Branch]; 4) Peer Review of Draft Report of Carcinogens Substance Profiles, February 24, 2009; and 5) Peer Review of Draft Technical Reports, February 25, 2009.

Dr. Bucher informed Council of three program initiatives: 1) Evaluation Criteria for Non-Cancer Studies; 2) Herbals/Dietary Supplements; and 3) Bisphenol A.

The NTP has developed consistent evaluation criteria for several non-cancer endpoints in order to disseminate technical reports in the area of reproductive, developmental, and immunotoxicology studies. NTP is using the diagnostic criteria evaluations from the pathology workshops. The Board of Scientific Counselors (BSC) Criteria Work Group, which included academia, regulatory agencies, and industry, developed a language consistent with that currently used for their cancer studies that NTP will apply to these other endpoints. The work group reports were accepted by the BSC at its November 20, 2008. The criteria have been revised in response to some comments that were made at the BSC meeting. These criteria will be presented at the Society of Toxicology meeting being held in Baltimore, Maryland on March 15 - 19, 2008. Drs. Paul Foster and Dori Germolec were acknowledged for their work on this project.

Dr. Bucher noted that the herbal and dietary supplements are a major focus area for the NTP. Multiple compounds are under investigation which includes: multipurpose supplements, women's health supplements, cancer chemo-preventives, anti-aging supplements and weight loss aids/sports aids. The review of 2008 "Herbal Gram" indicates NTP activity on 16 of the 25 top-selling herbal dietary supplements. Androstenedione and goldenseal root are the first twoyear studies from the herbal initiative whose technical reports will be reviewed in February. Both of these show evidence of carcinogenicity in rat and mouse liver. The technical reports to be reviewed in October will be for ginseng, milk thistle extract, and pulegone (pennyroyal).

Dr. Bucher concluded his presentation on the current activities surrounding Bisphenol A which is a ubiquitous material in many types of plastics, thought to influence human development and/or adult onset of various diseases.

Council Response and Discussion

Dr. Essigmann (Council member) queried if the samples studied are archived for future "omic" type analysis.

Dr. Bucher responded that the chemical, slides, blocks, and the tissues from the studies are archived.

Dr. Essigmann (Council member) pointed out that NIEHS is looking for projects that can show impact in a short period of time. When the biological study is completed an investigator could analyze the data to retrieve more information.

Dr. Bucher noted that in the past the R03 mechanism was utilized to help fund that kind of activity and is something that may be done again.

Dr. Wani (Council member) asked if there is coordination between NCI and NTP on working on some of these carcinogenic properties.

Dr. Bucher stated that the NCI has a similar rodent testing program to develop cancer chemotherapeutics and acknowledged that there may be some overlap and some value in better coordination.

Dr. Taylor (Council member) asked if consideration had been give to international partnerships with Southeast Asia concerning the herbal initiative.

Dr. Bucher noted that partnerships have been established in the procurement of particular agents, but no partnerships exist in developing safety assessment with the Southeast Asian countries.

Dr. Taylor (Council member) suggested that partnering could be more of a global endeavor where agencies or governments were partnering in this area.

Dr. Bucher responded that coordination/partnerships for this type of endeavor might best be done through the World Health Organization.

Dr. Graziano (Council member) pointed out that the Center for Complementary and Alternative Medicine is funding some of the same studies that NTP is evaluating. Is there communication between the two programs?

Dr. Bucher replied there are representatives from the Center for Complementary and Alternative Medicine sitting on NTP's Nomination Committee and they are aware of NTP's studies. Most of the studies they fund are looking at efficacy and NTP is looking at the safety assessment aspects.

XI. REPORT OF THE EDITOR-IN-CHIEF – Dr. Hugh Tilson

Dr. Tilson divided his presentation into three parts: 1) historical perspective, 2) highlights for 2008, and 3) points of emphasis for 2009.

Dr. Tilson began his presentation with the history of the Environmental Health Perspectives Journal. Dr. Rall in 1972 created the journal to publish results from studies done at NIEHS. A decision was made in 2005 to privatize the Journal and the announcement was made in the Federal Register in March 2006. After public comments, a decision was made not to privatize the Journal at this time. In 2007 a roundtable discussion was held in Keystone, Colorado to provide insight on what would be best for the Journal. Based on the recommendations, Dr. Wilson testified at a Congressional hearing stating the Journal would remain at NIEHS and funding and support would be restored. In 2008 those actions were followed and a new editor-in-chief was hired.

The roundtable discussion developed a number of recommendations which would serve as the strategic objectives for the journal in terms of development in the coming years. The high priority themes from the roundtable discussion were, 1) increase the impact factor, 2) establish editorial independence, 3) restore functions that had been eliminated, 4) expand outreach efforts to market the Journal, 5) maintain open access, 6) continue to function as a bridge between evidence-based research and clinical practice, and 7) build a strong constituency for environmental health science and policy.

Highlights for 2008 involved the following: 1) ensure a continuity of production by extending the existing 5-year contract and in July 2008 a new 5-year contract was established, 2) restore personnel, and programmatic functions to the 2003 level; 3) increase the visibility of the journal by reorganizing the advisory, associate editor, and review boards; increasing the distribution of the journal; attending scientific meetings; and maintaining open access; and 5) deploy an on-line web-based manuscript processing software called Scholar One.

The impact factor has remained at its previous level and the Journal is first among environmental science journals and second among public, environmental and occupational health journals. There was a 5% increase in the submission of manuscripts.

Dr. Tilson closed his presentation by outlining areas that they plan to accomplished in 2009: 1) increase impact factor; 2) revise the website, 3) develop metrics for measuring the success of the programs, 4) establish due diligence process for potential conflict of interest, 5) fill the remaining staff positions, 6) expand the science education program, and 7) expand the international program by increasing foreign translation of news and science, identify additional partnerships, and establish regional editors.

Council Response and Discussion

Dr. Liebler (Council member) queried if 60% rejection of manuscripts without review appeared high and what was the cause?

Dr. Tilson responded many of the manuscripts do not meet the criteria and therefore are rejected without review. Each author receives two pages of guidelines that are used to see if the manuscript meets the criteria for publication.

Dr. Leikauf asked if the Institute is considering translating portions of the journal into Chinese.

Dr. Tilson responded the Institute translates news article from English into Chinese. We have begun to translate "seminal" papers into Chinese, French, and Spanish and to translate editorials that have been published in Chinese into English as part of the publication process.

Dr. Leikauf mentioned that Google and others internet service have had problems with censorship in China. How has the Institute handled that problem?

Dr. Tilson responded we are aware of those problems and try to avoid them whenever possible.

Dr. Leikauf pointed out that many journals are online because of the cost of printing. Does the Institute plan to follow this trend in the near future?

Dr. Tilson responded that the results of the recent reader survey points to continuing the printing of the hard copy; however, we do have the Journal on line.

Dr. Birnbaum introduced Dr. Gwen Collman who would be giving an update on the Extramural Program.

XII. REPORT OF INTERIM DIRECTOR, DERT – Dr. Gwen W. Collman

Dr. Collman outlined the topics she would discuss in her report to Council: 1) FY2008 Budget report, 2) Peer Review Enhancement, 3) RePort.gov, 4) Biennial Report on Minority and Gender Population Tracking, and 5) Council Delegated Authorities.

The extramural funding trends for FY2008 were presented in two different pie charts. These charts laid out the Institute's extramural grants distribution and expenditures excluding Superfund. The first pie chart showed the expenditure breakdown of extramural grants. Research Project Grants (RPGs) comprise the largest segment of the budget at 73%. Additional distributions are Centers 13%, Training 6%, Other Research 4%, and the Small Business Initiative Program (SBIR) 4%. The SBIR is an identified percentage of monies to be devoted to supporting small business that are universally applied across the government agencies that award research grants. The Superfund Basic Research Program is a separate appropriation. The second pie chart gave a breakdown of how RPGs were distributed by mechanism. The majority of funds are dispersed through the R01 mechanism 71%, followed by P01s 12.4%, U01s 6.2%, R21s 4.7%, NIH TAPs (extramural assessments) 2.3%, R37s 1.3%, R15s 0.7%, R03s 0.6%, R00 0.4%, R56 0.2%, and U19 0.1%.

Dr. Collman informed Council about the number and total costs of competing awards made in FY2008. She presented funding statistics describing the payline and the number of applications that were raised to pay. She noted that the payline is not set in advance.

Dr. Collman presented a graph of the success rate for the RPGs for NIH and NIEHS. The number of applications for competing RPGs awards increased during the NIH budget "doubling period" (FY1998 through FY2002) and this trend has continued. A number of charts were presented showing the RPGs, R01s, Unsolicited R01s, Solicited R01s, and the average cost of RPGs to other Institutes. NIEHS falls within the success rate of Institutes of similar size.

Dr. Collman updated Council on Peer Review Enhancement. With consultation from the extramural community and Center for Scientific Review (CSR) four priority areas were developed: 1) engage the best reviewer; 2) improve the quality and transparency of review; 3) ensure balanced and fair review reviews across scientific fields and career stages, and 4) continuous review of Peer Review System. She noted the peer review changes that will occur in 2009 and 2010. New review criteria, a new scoring system, and different components of the summary statement begin with the May 2009 review cycle. Scoring and critique changes will begin at the May 2009 review meetings. There will be a 9-point scoring system, enhanced review criteria, formatted reviewer critiques using templates, scoring of individual review criteria, and clustering of new investigator applications at the review. Other changes, beginning January 2010, applications are to be shorter and are to be organized with the review criteria. The rating system will put less emphasis on methodological details and more emphasis on potential scientific impact. She informed Council that there is an Enhanced Peer Review Website that can be accessed from the NIH or NIEHS websites for more information and further detail.

As an informational item she updated Council of the Research Portfolio Online Reporting Tool (RePORT) which consists of reports, data and analyses of NIH research activities, including information on NIH expenditures and the results of NIH-supported research. This website makes information available to outside investigators, advocacy groups, the public and interested parties. This information can be obtained from the NIH website.

Dr. Collman concluded her presentation with two DERT action items. The first item, the Biennial Report on Minority and Gender Population Tracking, is required by NIH policy to be presented

to Council certifying compliance with the NIH policy on inclusion guidelines. The guidelines outline all review, grants management, and program responsibilities and no awards are made without compliance with the NIH policy on the inclusion of women, minorities, and children in clinical research. Also, grants involving human subjects must comply with the inclusion and tracking of participants in clinical studies. Council unanimously approved the report.

The second DERT action item, Council Delegated Authorities is presented to Council once a year for information and their approval. Items number 2, 5, 6, 10, 11, 12, 13, and 14 had changes that needed approval.

Council asked for clarification and intent concerning the changes in item 5 and 13 which provide supplemental funds provided under the ARRA. After considerable discussion Council concurred with the amendment of item 5 and want to add "and/or" to the language. Now item 5 reads as follows: "Authorize supplemental direct costs to a Center in an amount not to exceed 15% of the direct costs (excluding consortium F&A costs) recommended for a current annual budget period **and/or** \$500,000 direct costs (excluding consortium F&A costs) to supplements awarded under the American Recovery and Reinvest Act. This provision will apply only in those circumstances where, 1) the Center director can show adequate justification that such funds are required to cover unanticipated costs or are needed to respond to newly identified problems of urgent program priority or 2) the supplement is in response to special programmatic or budgetary needs or opportunities identified by the Director, NIEHS." Council unanimously approved item 5 with the suggested change. All items were approved except item 13. Item13 will be redrafted after the guidelines for ARRA implementation are received. Approval from Council will be done by e-mail ballot.

Dr. Birnbaum assured Council that they would be kept informed throughout the ARRA process.

XIII. UPDATE on the EXPOSURE BIOLOGY PROGRAM – Dr. David Balshaw

In response to a request from Council at the October 2008 Council meeting Dr. Balshaw presented an update on recent activities within the Exposure Biology Program. The update included an overview of the Genes, Environment, and Health Initiative Exposure Biology Program goals; an overview of the awards, progress to date, and thoughts on future directions for the Exposure Biology Program.

In 2006 the NIH was authorized by the Secretary, HHS to create the Gene Environment Initiative (GEI.) in order to create a foundation for understanding the interactions between genetic and environmental factors that underlay most human disease. Two programs were established: the Exposure Biology Program with the National Institute of Environmental Health Sciences (NIEHS) as the lead Institute and the Genetics Program with the National Human Genome Research Institute (NHGRI) as the lead Institute. Both programs are overseen by coordinating committees with representation from several NIH Institutes.

The Exposure Biology Program proposes to develop new technology and biomarkers to strengthen the assessment of personal exposures. In looking at just the standard chemical exposures other factors, such as diet, physical activity, environmental exposures, psychosocial stresses, and addictive substances as well as biomarkers of response to these factors will also be observed; thus creating a broader definition of exposure which includes not only chemical concentrations but also measures of context and response. The goal in four years is to have more direct measures of personal exposure to multiple analytes in real-time and to be minimally intrusive.

In 2007 thirty-two awards were made. There are four programs: 1) Chemical Sensor, 2) Diet and Physical Activity, 3) Psychosocial Stress and Addictive Substances, and 4) Biologic Response Indicators. Dr. Balshaw gave an overview of each of the programs and progress being made by the grantees.

Dr. Balshaw concluded his presentation by stating the four-year mission of the program is to focus on the creation of a suite of tools which will lay the foundation to do large cohort studies that can test hypotheses which have not been possible in the areas of exposure and genetics. Possible future directions could include continued development of tools for gene-environment interaction studies, a shift from discovery and development to validation, and initial pilot studies in population-based studies.

Council Response and Discussion

Dr. Liebler Council member) asked for clarification of analytic capabilities or methods to population- based study groups.

Dr. Balshaw responded there have been discussions on what type of analytical capabilities there might be. It could be regional with Centers doing biomarker assessments, investigators with population-based studies using "omic" technologies and prototype sensors.

Dr. Lloyd (Council member) asked if any data had been captured on individuals who were in the Katrina trailers containing formaldehyde.

Dr. Balshaw mentioned that within the chemical sensor program, three of the grantees have formaldehyde as a stated analyte of interest. But to date the sensors have not been validated, so the program is not yet sufficiently mature to provide information from the trailers at this time.

Dr. Ramos (Council member) wanted to know if there are sufficient interactions between the Exposure Biology Program and the Genetic Program.

Dr. Balshaw responded, a Core Leadership group for both programs meets regularly, and there have been joint meetings of grantees. However, little scientific overlap exists between the funded studies which have complicated collaborations between these investigators.

CPT Macinski queried if NIEHS is interfacing with the Department of Defense (DOD) on these programs. He noted that the Defense Advance Research Project Agency (DARPA), Special Warfare Development Command is doing work with environmental stressors and are addressing similar issues. He noted this would be a great opportunity for NIEHS to partner with DOD.

Dr. Balshaw replied that there has been some communication with the army in relation to the Chemical Sensor Program. He thanked CPT Macinski for the information.

XIV. SUPERFUND PROGRAM – Dr. Claudia Thompson and Mr. Joseph Hughes Jr.

Mr. Hughes acknowledged the staff of the NIEHS Superfund Programs (William Suk, Beth Anderson, Claudia Thompson, Heather Henry, Kathy Ahlmark, Theodore Outwater, and James Remington).

Mr. Hughes pointed out that the NIEHS Superfund Program was created in 1986 by the Superfund Amendments and Reauthorization Act (SARA) of 1986. The program consists of two parts: The Superfund Basic Research Program (SBRP) and the Worker Education Training Program (WETP).

SBRP is mandated to, 1) detect and assess hazardous substances in the environment; 2) evaluate the risks and effects of hazardous exposures on human health; and 3) develop basic biological, chemical, and physical methods to reduce the toxicity of hazardous substances.

The WETP mandate included creation of state-of-the-art training programs for hazardous materials handlers, chemical emergency responders, and waste cleanup workers; and integration of its training with the National Response Plan.

The WETP Spring Awardees Meeting, "Reducing Risk and Protecting Public Health through Research and Training" was held April 3 - 4, 2008 in Bethesda, MD. The objectives of the meeting were to, 1) present Best Practices and Lessons Learned from the last two decades of research and training; 2) bring together all the principal investigators and consortia member to foster program collaboration; and 3) using science to inform safety, protect workers and communities, and support effective environmental remediation.

After giving an overview of the Superfund Program, Mr. Hughes presented slides illustrating the program components of WETP which are, hazardous waste worker training; minority worker training; HAZMAT disaster preparedness training; and DOE-Nuclear weapons HAZMAT training (DOE – WETP). He also presented a list of current grantees.

Mr. Hughes highlighted some of the WETP's activities: 1) maintain program quality; 2) NIEHS 9/11 worker response; 3) Katrina field training; 4) how the phases of response impact on safety; 5) preparedness training; 6) NIEHS initiatives; October 15 – 17, 2008 "Implications for Safety and Health Training in a Green Economy" — Chapel Hill, NC; 7) updated WETP's Strategic Plan; and 8) in the spring, April 30 – May 1, 2009, NIEHS Chemical Preparedness Workshop, Cincinnati, OH

Mr. Hughes ended his talk with a slide showing the future challenges for WETP. They include, 1) building model training programs to protect workers in identified high risk occupations; 2) supporting and integrating with the overall NIEHS mission; 3) creating effective consortia and organizational relationships to support innovative training delivery and be a national resource; 4) fostering close collaboration among grantee organizations to build a national safety culture and integrate WETP program areas; 5) maintaining interagency working partnerships to support innovative program development at national, state, and local levels; 6) developing WETP's capacity for utilizing and sharing technology tools to support worker-centered learning; and 7) sharing WETP's model training programs through information dissemination, networking, and communications.

Mr. Hughes turned the presentation over to Dr. Thompson

Dr. Thompson presented an update on recent activities within the Superfund Basic Research Program (SBRP). The update included an overview of the Program Goals; Historical Perspective; Research Translation; and the future direction of SBRP.

The overarching program goals are to, 1) look at the relationships between exposure and disease; 2) develop efficient and cost-effective cleanup strategies; 3) contribute to the decision-making process; 4) reduce the risk of exposure; and 5) improve public health.

The SBRP has been in existence for 22 years. Within that time-frame the program has grown from its original \$3 million and 4 programs, to current program that consist of 14 multi-project programs, 6 SBIRS and 15 R01s at the cost of \$46 million. The SBRP has evolved over the years and starting in 2005 it escalated its emphasis on research translation, redefined community outreach. In addition it added expanded research mechanisms to include individual research project grants (R01s)

Dr. Thompson redefined research translation is the process whereby research findings are effectively communicated to and used by the most appropriate stakeholder with the goal of achieving the greatest environmental and/or health benefit. Within each program there is a Research Translation Core. The SBRP research translation core must include partnerships with government agencies, a focus on technology transfer as well as communicating to broad audiences. Research translation is not just what the grantees do, but it is how NIEHS facilitates what they do in interaction with different groups. Dr. Thompson gave examples of research translation.

Dr. Thompson mentioned the Research Translation Committee (RTC) meeting. The meeting was held February 11 - 13, 2009. Action items from the meeting were: 1) understand and develop strategies to incorporate SBRP science into policy decisions; 2) develop effective strategies to work more closely with EPA/ATSDR; 4) develop databases and data-sharing; and 5) enhance collaborations with program elements.

In conclusion, Dr. Thompson noted that an External Advisory Panel has convened. Ms. Nesdu Obot Witherspoon is the Council representative for this committee. The goal of the committee is to provide input for the development of a framework for the future direction of the SBRP. The committee was asked to look at, 1) the balance between research needs and anticipated emerging issues; 2) how to keep the best scientist and best practices within the program; and 3) how to move laboratory research into practical applications. Recommendations from the report will be presented at the May 2009 NAEHS Council meeting.

Dr. Thompson asked for questions.

Council Response and Discussion

Dr. LeMasters (Council member) mentioned that firefighters have a high cancer rate. They come in contact with soot that is a known carcinogen; however, firefighters do not appear cognizant of this hazard.

Mr. Hughes responded that more can be done to bring this to the fore front as one of the hazards for firefighters. An International Association of Firefighters meeting will be held in Cincinnati. This would be an ideal forum to bring this hazard to their attention.

Dr. LeMasters (Council member) noted that the military has many Superfund sites and waste sites on military bases. Does NIEHS have collaboration with the military on what is being done on those sites?

Dr. Thompson responded that we have very little interaction in terms of the military Superfund sites, although NIEHS has developed interaction through an interagency working group with DOD and DOE where common issues among the programs are being looked at.

XV. CONCEPT CLEARANCE – VIRTUAL CONSORTIUM for TRANSDISCIPLINARY/ TRANSLATIONAL ENVIORNMENTAL RESEARCH (VICTER) – Dr. Jerrold Heindel

Dr. Heindel presented to Council the Virtual Consortium for Transdisciplinary/Translational Environmental Research (ViCTER) concept for their approval. He mentioned this program was developed by a group of scientist (Janice Allen, Caroline Dilworth, Jerrold Heindel, Annette Kirshner, Carolyn Mason, Elizabeth Maull, and Sri Nadadur) in the Division of Extramural Research and Training (DERT).

Dr. Heindel discussed the conceptual framework of ViCTER and why there is a need for this type of program. ViCTER is a new program designed to stimulate transdisciplinary and/or translational research which will be available to all funded ES grantees and will allow them to create a virtual consortium. This program will have a central focus on some aspect of environmental health and environmental agents in disease. At present, NIEHS has different types of Center programs which are large and expensive. The rationale for ViCTER is the need for a smaller less expense program which involves more investigators, develops collaborations, stimulates transdisciplinary and/or translational research, and expands research into new tissues, toxicants, and approaches. This will be a win-win situation for NIEHS and the investigators.

Dr. Heindel indicated the key objective of the ViCTER program is stimulating collaborations to improve human health. This goal will be under the umbrella of outstanding *in vitro*, animal, and epidemiology research. The ViCTER program will come under the R01 mechanism. The principal investigator will write a competitive supplement with 1-2 expanded aims with a specific ES focus that defines collaborations and integration/synergy. The collaboration will consist of three investigators.

The ViCTER will be announced in the *Federal Register* as a Program Announcement with Review (PAR) with a set aside budget for funding. This will be an open announcement to run for three years with one receipt date per year. Applications will have an expedited review with funding within 6 months of receipt. The length of award would depend on time remaining on the original application and is likely to be 2 or 3 years. It is anticipated to have 1 - 20 active consortia over a 3-year period. NIEHS can support 4 - 6 ViCTER consortia with a \$2 million budget each year; however, with the American Recovery and Reinvestment Act (ARRA) the budget may be higher.

Council Response and Discussion

The Concept was reviewed by Council members Drs. Kenneth Ramos and Richard Finnell. Dr. Ramos gave positive comments of the Concept. His only suggestion is to clearly state in the directions that there is no directionality to the examples provided and that there is more specificity to the actual monetary allocations with regards to the number of applications that will actually be funded. As calculated, the \$2 million dollars will not give you 15 – 20 grants over the 3-year period. Dr. Finnell agreed with Dr. Ramos, except he thought the anchoring to an ES investigator will leave many potential investigators out of this mechanism.

Dr. Heindel commented that an individual who does not have an ES grant could locate an investigator who has one and set up a consortium. He pointed out that only one investigator has to have an active ES grant and the other three individuals do not have to have any grants.

Ms. Hines (Council member) asked if there are a minimum/maximum number of investigators and if outreach is considered a collaborative area, and if so could this category be one of the examples in the announcement?

Dr. Heindel responded that the minimum number of collaborative investigators is two and the maximum number three. Outreach would be considered an area of collaboration and can be described in the announcement as one of the possibilities.

Council members suggested other types of collaborations and funding possibilities.

Council unanimously approved the Concept for ViCTER.

Dr. Collman announced that the open session of the meeting had ended and the next portion will be in closed session.

Dr. Birnbaum thanked the participants in the open session for their hard work and excellent presentations.

The open portion of the meeting was adjourned at 2:40 p.m.

CLOSED PORTION OF THE MEETING February 19, 2009 – 2:40 p.m.

XVI. 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.

The Feb 2009 Council considered 285 applications requesting \$119,227,742 in total cost and recommended 161 applications with the total cost of \$73,528,413.

XVII. ADJOURNMENT OF THE NAEHS COUNCIL

The meeting was adjourned at 5:00 p.m. on February 19, 2009

CERTIFICATION

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

Linda S. Birnbaum, PhD, DABT, ATS Chairperson National Advisory Environmental Health Sciences Council Gwen W. Collman, PhD Interim Executive Secretary National Advisory Environmental Health Sciences Council

Attachment: Council Roster