

Tyi from the NHLBI

PIO Meeting Recap

The 13th annual NHLBI Public Interest Organization meeting was held Monday and Tuesday, June 11-12, 2012, in Bethesda, Maryland.

The keynote speaker Monday afternoon was Dr. Lawrence Tabak, Principal Deputy Director of the NIH. He gave an overview of the NIH mission, followed by information about the NIH budget. He noted that of the FY 2012 enacted budget of \$30.9 billion, 83% (or \$25.7 billion) went to fund extramural research programs. The combination of relatively flat budgets over recent years and inflation has left the NIH with about the same purchasing power as it had in 2002.

Dr. Tabak discussed the decrease in NIH grant application success rates: in 1978 about one-third of grant applications were funded, but in 2012 the success rate has only been 15 to 20%. He also discussed NIH efforts to increase diversity in the research workforce.

Dr. Gary Gibbons, the newly designated NHLBI Director (he subsequently assumed that position in mid August) addressed the PIO representatives. He said, "I feel some resonance with this group already. I'm not only a clinician-scientist, I'm a patient, the son of a patient, the brother of a patient, the father of a patient." He explained that his younger daughter was stricken with a neurological disorder in childhood, but thanks to research, she is now a junior in college and the diagnosis is a distant memory.

Tuesday's full-day schedule started with remarks by Dr. Carl Roth, Acting Deputy Director, NHLBI. He added to Dr. Tabak's earlier remarks about the overall NIH budget by discussing specific NHLBI concerns. He noted that during the budget doubling period of FY 1999 through FY 2003, using FY 1998 as the baseline, applications were funded up to the 32nd percentile, but that now they were only being funded to the 10th percentile, with funding extended up to the 20th percentile for Early Stage Investigators.

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NHLBI-funded Investigators Receive Honors

Five NHLBI-funded investigators were among the ten recipients chosen by the Clinical Research Forum in its inaugural competition to recognize outstanding clinical research accomplishments in the United States. The Forum is a non-profit organization founded in 1996 and dedicated to providing leadership in clinical research.

The NHLBI-supported awardees are Frank Accurso, M.D., University of Colorado, Aurora; Bonnie Ramsey, M.D., Seattle Children's Research Institute and University of Washington; Malcolm Brenner, M.D., Ph.D., Baylor College of Medicine, Houston; Stanley Hazen, M.D., Ph.D., Cleveland Clinic Lerner Research Institute; and Francis McCormack, M.D., University of Cincinnati.

Dr. Accurso and Dr. Ramsey were recognized for their clinical trials that assessed a new treatment called Ivacaftor (VX-770) for cystic fibrosis patients who have mutations in a gene called G551D. Ivacaftor was associated with improvement in lung function that began after 2 weeks of treatment and that was sustained throughout the 48-week study.

Dr. Brenner was honored for his work on improving bone marrow transplantation. His team created an enzyme "on/off switch" called iCasp9 to stop T cells in the immune system from attacking donor cells during the period immediately after transplants, when patients are most vulnerable.

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Upcoming NHLBI Workshops and Working Groups

No activities are scheduled for the period covering September 2012 through January 2013.

PIO Meeting Recap

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Dr. Roth also noted that the Institute will be required to increase funding of the Small Business Innovation Research (SBIR)/Small Business Technology Transfer (STTR) program over the next 6 years. The SBIR/STTR program accounted for 2.8% of the NHLBI's FY 2011 budget and will be 3.5% of its budget in FY 2013. He also noted that if sequestration (across-the-board budget cuts mandated by the Budget Control Act of 2011) occurs, the NIH budget, and consequently the NHLBI budget, will decrease by about 8%.

Dr. Eric Green, Director of the National Human Genome Research Institute (NHGRI), discussed the Human Genome Project, which began in October 1990 and was completed in April 2003, and also described some of its key findings. He described the NHGRI strategic plan, developed in 2011, that emphasizes understanding the structure and biology of genomes and the biology of disease, advancing the science of medicine, and improving the effectiveness of healthcare.

In addition, Dr. Green noted efforts being made to lower the cost of genome sequencing to as little as \$1,000 per genome, making it an affordable option to help clinicians make better diagnoses and determine best treatment.

Dr. Stanley Hazen, of the Cleveland Clinic Lerner Research Institute, gave a presentation about microbes inhabiting the intestinal tract - the "gut microbiome." He discussed a study in which his group transferred the gut bacteria from either obese or lean mice into germ-free mice, which lack bacteria in the gut. The germ-free mice that received bacteria from obese mice became obese, whereas those receiving bacteria from lean mice remained lean, suggesting that the gut flora play an important role in obesity.

Dr. Hazen also described how gut bacteria produce metabolites that promote cardiovascular disease. His group found that people with high levels of one metabolite, trimethylamine N-oxide, had about a four-fold increase in risk for a major cardiovascular event (myocardial infarction, stroke) or death compared with people lacking the metabolite.

The final presentation was a panel discussion of obesity, moderated by Ms. Barbara Cady, President of Take Off Pounds Sensibly, Inc. (TOPS) and with participation by Dr. Diane Bild, NHLBI; Dr. Jim Kiley, Director, Division of Lung Diseases, NHLBI; Dr. Cay Loria, NHLBI; and Ms. Heather Kirkwood, Vice President and Outreach Coordinator, Hermansky-Pudlak Syndrome Network, Inc.

Dr. Bild discussed epidemiological studies on obesity, noting

that in 1985, very few states in the United States had an obesity rate above 10% of the adult population, but now the rate is above 25% in most states, including about a dozen states that have an adult obesity rate above 30%.

Dr. Kiley discussed the data linking sleepiness and sleep apnea to obesity and cardiovascular disease (CVD) and the possibility that sleep may be an appropriate target for intervention to prevent obesity and CVD.

Dr. Loria discussed data indicating that there is no difference in weight loss results between people using low-fat versus low-carbohydrate diets; what really matters is the number of calories consumed.

Ms. Kirkwood discussed obesity-related difficulties confronting patients with chronic illness, such as taking medications that may promote weight gain. She noted how emotional issues and stress can prompt unhealthy eating habits.

Ms. Cady spoke about how TOPS seeks to work within an individual's eating and exercise limitations to provide support in weight loss.

The final portion of the meeting was an opportunity for each PIO representative to meet the NHLBI staff member whose expertise is most relevant to the organization's mission.

Mark Your Calendar . . .

September National Cholesterol Education Month
(<http://hp2010.nhlbihin.net/cholesterol-month/>)

National Sickle Cell Month
(<http://www.sicklecelldisease.org>)

National ITP Awareness Month
(<http://www.pdsa.org/resources/itp-awareness-month.html>)

30th Sport Purple For Platelets Day
(<http://www.pdsa.org>)

November COPD Awareness Month
(<http://www.lungusa.org>)

NHLBI Research Initiatives

From time to time, the NHLBI invites investigators to submit grant applications or contract proposals for specific research programs. We are soliciting applications for the following new programs. Please visit the URL listed with each program to obtain information about application dates and deadlines. For full descriptions of these and other current research initiatives, visit <http://www.nhlbi.nih.gov/funding/inits/index.htm>.

Ancillary Studies in Clinical Trials (R01)

(RFA-HL-13-003)

<http://grants.nih.gov/grants/guide/rfa-files/RFA-HL-13-003.html>

Objective: Conduct time-sensitive ancillary studies related to heart, lung, and blood diseases and sleep disorders in conjunction with ongoing clinical trials and other large clinical studies.

Cardiovascular Risk Reduction in Underserved Rural Communities (R01)

(RFA-HL-13-013)

<http://grants.nih.gov/grants/guide/rfa-files/RFA-HL-13-013.html>

Objective: Develop well-designed, controlled trials of approaches to reduce cardiovascular disease risk factors in rural communities.

NHLBI Systems Biology Collaborations (R01)

(PAR-12-138)

<http://grants.nih.gov/grants/guide/pa-files/PAR-12-138.html>

Objective: Develop collaborative, multi-disciplinary systems biology research projects to advance our understanding of normal physiology and perturbations associated with heart, lung, blood, and sleep diseases and disorders.

Mentored Career Award for Faculty at Institutions That Promote Diversity (K01)

(RFA-HL-13-018)

<http://grants.nih.gov/grants/guide/rfa-files/RFA-HL-13-018.html>

Objective: Provide support for faculty at institutions that train substantial numbers of students from disadvantaged backgrounds, receive modest research support from the NHLBI, and provide health-related services and education to minority and other health disparity populations.

Integrative Omics Data Analysis for Discovery in Lung Diseases (R01)

(PAR-12-155)

<http://grants.nih.gov/grants/guide/pa-files/PAR-12-155.html>

Objective: Generate systems-level models of pulmonary pathobiology through analyses of existing omics data and test the models using human tissues/cells and/or mammalian animal models.

Mentored Career Development Award to Promote Faculty Diversity/Re-Entry in Biomedical Research (K01)

(RFA-HL-13-019)

<http://grants.nih.gov/grants/guide/rfa-files/RFA-HL-13-019.html>

Objective: Increase the number of highly trained investigators who come from backgrounds underrepresented in research areas of interest to the NHLBI or who wish to re-enter their research careers after a hiatus due to family responsibilities.

Short-Term Research Education Program to Increase Diversity in Health-Related Research (R25)

(RFA-HL-13-020)

<http://grants.nih.gov/grants/guide/rfa-files/RFA-HL-13-020.html>

Objective: Promote diversity in undergraduate and health professional participant populations by providing short-term research education support to stimulate career development in cardiovascular, pulmonary, hematologic, and sleep disorders research.

Comparison of Strategies to Study Pediatric Pulmonary Vascular Disease Outcomes Using Bioinformatics (U01)

(RFA-HL-14-005)

<http://grants.nih.gov/grants/guide/rfa-files/RFA-HL-14-005.html>

Objective: Compare the ability of two data sources, electronic health records and traditional prospective patient-based clinical and research data, to answer research questions regarding the natural history, longitudinal outcomes, and phenotypes of therapeutic response for pediatric pulmonary vascular disease.

NHLBI SBIR Phase IIB Bridge Awards to Accelerate the Commercialization of Technologies for Heart, Lung, Blood, and Sleep Disorders and Diseases (R44)

(RFA-HL-13-016)

<http://grants.nih.gov/grants/guide/rfa-files/RFA-HL-13-016.html>

Objective: Facilitate and accelerate the capital-intensive steps that are required to transition SBIR Phase II projects to the commercialization stage by promoting partnerships between SBIR Phase II awardees and third-party investors and/or strategic partners.

NHLBI-funded Investigators Honored

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The iCasp9 cell-suicide system may improve the safety of cellular therapies and expand their clinical applications.

Dr. Hazen was recognized for identifying digestion byproducts in the gut that predict risk for cardiovascular disease (CVD), including hardening of the arteries. His team identified three metabolites of the dietary lipid phosphatidylcholine – choline, trimethylamine N-oxide, and betaine – and found that elevated levels predicted CVD risk in a group of more than 1,800 adults who were undergoing elective cardiac evaluations. This discovery provides opportunities for

the development of new diagnostic tests and therapeutic approaches for atherosclerotic heart disease.

Dr. McCormack was recognized for testing a new treatment for the lung disease LAM (lymphangioleiomyomatosis) in women. He and his team found that sirolimus, which is typically used to prevent rejection after organ transplantation, stabilized lung function and was associated with a reduction in symptoms and improvement in quality of life. Sirolimus is the first drug to slow or halt the progression of LAM.

National Heart, Lung, and Blood Advisory Council Meeting

June 13, 2012

Dr. Shurin, Acting Director, NHLBI, welcomed members to the 246th meeting of the National Heart, Lung, and Blood Advisory Council.

Dr. Shurin updated the Council on several NHLBI and NIH leadership appointments: Dr. Gary H. Gibbons has been appointed the next NHLBI Director and is expected to start in early August; Ms. Sandy Gault, NHLBI Financial Management Officer, is retiring at the end of the month; Mr. Alex Hawkins is the new NHLBI Financial Management Officer; and Ms. Debra C. Chew has been appointed Director, NIH Office of Equal Opportunity and Diversity.

Dr. Shurin updated the Council on member news: Mr. Jonathan Alger has been named President of James Madison University in Harrisonburg, Virginia, and Dr. Lanetta Jordan joined the faculty of the Miller School of Medicine at the University of Miami.

Dr. Shurin discussed the FY 2013 President's Budget, which would increase the NHLBI budget by 0.02%, or approximately \$700 thousand. Despite the modest increase, the research project grant line would decrease slightly, in part due to a mandated increase in Small Business Innovation Research (SBIR)/Small Business Technology Transfer

Research (STTR) funding. The reauthorization of the SBIR/STTR programs requires increasing the set-aside percentages over the course of the next 6 years.

Dr. Shurin updated the Council on the new National Center for Advancing Translational Sciences (NCATS) and the proposed National Institute of Substance Use and Addiction Disorders that would encompass all substance use, abuse, and addiction-related research and supplant the current National Institute on Alcohol Abuse and Alcoholism and National Institute on Drug Abuse.

Dr. Shurin discussed the proposed NIH policy for Special Council Review, i.e., extra consideration before awarding a grant to a PI with \$1.5 million or more annual NIH research support in total costs. *(Note: The policy has since been changed to \$1.0 million in direct costs. Please see <http://www.grants.nih.gov/grants/guide/notice-files/NOT-OD-12-140.html> for a full description.)*

Dr. Michael Lauer, Director, Division of Cardiovascular Sciences, NHLBI, presented an update of ongoing activities in the Institute's program divisions to assess impact and productivity of research investments. He also discussed developing results-based accountability as a part of the NHLBI culture.

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News from Capitol Hill

Appropriations

On June 14, 2012, the Senate Committee on Appropriations approved a bill, S.3295, that would fund the NIH in fiscal year (FY) 2013. The Senate bill includes \$30,731,459,000 for the NIH, an increase of \$100,000,000. The House Committee on Appropriations has not yet approved its version of a bill to fund the NIH.

The bill report (Senate Report 112-176) mentions numerous diseases, conditions, and other items of interest to the NHLBI, including asthma, basic behavioral research translation, cardiovascular disease, chronic obstructive pulmonary disease, the Jackson Heart Study, lymphangiomyomatosis, Marfan syndrome, pediatric cardiomyopathy, pulmonary fibrosis, scleroderma, sickle cell trait, sleep disorders, stem cell biology, lymphatic research and lymphatic disease, and cystic fibrosis.

NHLBI Acting Director Speaks at Sleep Disorders Congressional Briefing

On May 31, 2012, Dr. Shurin spoke at a congressional briefing highlighting the recent update of the NIH Sleep Disorders Research Plan. She discussed the role of the

NIH in advancing research on sleep and the development of the 2011 NIH Sleep Disorders Research Plan. Other speakers included Dr. Phyllis Zee, President of the Sleep Research Society, and Dr. David Dinges, Professor, University of Pennsylvania. The briefing was sponsored by the Sleep Research Society in conjunction with Representative Mike Honda (D-CA).

NHLBI Acting Director Discusses Link Between Heart Disease and Kidney Disease

On June 19, 2012, Dr. Shurin spoke at a congressional briefing on kidney disease research. Her remarks focused on the relationship between heart disease and kidney disease. Other speakers included Dr. Griffin Rodgers, Director, National Institute of Diabetes and Digestive and Kidney Disorders, Dr. William Schnapper, Northwestern University Fineberg School of Medicine, and Ms. LaVarne Burton, President and CEO of the American Kidney Fund. The briefing was sponsored by the American Society of Nephrology, the American Kidney Fund, and the American Society of Pediatric Nephrology. The Congressional Kidney Caucus was the honorary co-sponsor of the event.

Upcoming Events

Activity	Date/Location	More Information
Sudden Cardiac Arrest Association 2012 Annual Conference Program	September 13 – 15, 2012 Orlando, FL	http://www.suddencardiacarrest.org/aws/SCAA/pt/sp/annual_mtg
It's My Heart 4th Annual CHD Family Conference	September 14 – 16, 2012 Houston, TX	http://www.itsmyheart.org/
Vascular Disease Foundation Annual Meeting	September 21 – 23, 2012 Tysons Corner, VA	http://www.vdf.org/
Aplastic Anemia and MDS International Foundation, Inc. 2012 Patient and Family Conferences	September 22, 2012 Dallas, TX October 20, 2012 Chicago, IL	http://www.aamds.org/support-and-community/conferences
PXE (Pseudoxanthoma Elasticum) International 2012 Biennial Conference	September 22 – 23, 2012 Bethesda, MD	http://pxe.org/2012-biennial-conference
Sickle Cell Disease Association of America, Inc. 40th Annual Conference	September 25 – 28, 2012 Baltimore, MD	http://www.sicklecelldisease.org/
Fanconi Anemia Research Fund, Inc. 24th Annual Scientific Symposium	September 27 – 30, 2012 Denver, CO	http://www.fanconi.org/index.php/research/annual_symposium
First Candle / SIDS Alliance 2012 International Conference on Stillbirth, SIDS, and Infant Survival	October 4 – 7, 2012 Baltimore, MD	http://www.sidsalliance.org/
WomenHeart 2012 Science & Leadership Symposium	October 5 – 8, 2012 Rochester, MN	http://www.womenheart.org/programsEvents/events/index.cfm
Sudden Arrhythmia Death Syndromes (SADS) Foundation 6th International Conference	October 12 – 14, 2012 Salt Lake City, UT	http://www.sads.org/SADS-International-Conferences/Conference-Details
Narcolepsy Network 27th Annual Patient Conference	October 19 – 21, 2012 Cleveland, OH	http://www.narcolepsynetwork.org/
HHT (Hereditary Hemorrhagic Telangiectasia) Foundation International National Conference	October 26 – 28, 2012 Orlando, FL	http://hht.org/living-with-hht/patient-and-family-conferences/
National Heart, Lung, and Blood Advisory Council 248th Meeting	October 30, 2012 Bethesda, MD	http://www.nhlbi.nih.gov/meetings/nhlbac/index.htm
National Hemophilia Foundation 64th Annual Meeting	November 8 – 10, 2012 Orlando, FL	http://www.hemophilia.org/NHFWeb/MainPgs/MainNHF.aspx?menuid=23&contentid=17&rptname=annualmeeting
Tuberous Sclerosis Alliance Regional TSC Conference	November 11, 2012 Boston, MA November 17, 2012 Los Angeles, CA	http://www.tsalliance.org/pages.aspx?content=696
Parent Heart Watch 2013 National Conference	January 17 – 20, 2013 Seattle, WA	http://www.parentheartwatch.org/ActionAdvocacy/Events.aspx

Constituents' Corner

No constituents' submissions were received for this issue.

We invite you to use this space that we reserve for you to share your successes and opinions. You may submit your ideas and articles to nhlbi.listens@nih.gov or Public Interest News, Office of Science and Technology, Building 31, Room 5A07, 31 Center Drive, MSC-2482, Bethesda, MD 20892-2482.

June 13, 2012 Advisory Council Meeting

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Dr. Monica Shah, NHLBI AIDS Coordinator, discussed the NHLBI AIDS program, which has an independent budget (\$68 million in FY 2012), a separate payline that is approximately 10 percentile points higher than the regular payline, specific receipt dates, and specific review. Success rates of AIDS applications are much higher than those of non-AIDS applications - 42% versus 18% in FY 2011. The NHLBI hopes to encourage more submissions of AIDS projects and hopes to understand the barriers to submission.

Council member Dr. Lanetta Jordan reported on the 13th annual NHLBI PIO meeting held June 11-12, 2012. Four Council members attended the meeting in addition to representatives from PIOs and professional societies and NHLBI staff.

Dr. Joylene John-Sowah, Medical Officer, NHLBI, and Dr. George Buchanan, Professor of Pediatrics, University of Texas Southwestern Medical Center, and Co-Chair, Sickle Cell Guidelines Expert Panel, presented background and a summary of the Panel's report on the management of sickle cell disease. The Panel had been convened at the request of the Council to develop evidence-based sickle cell disease guidelines.

Dr. John-Sowah outlined the guideline development steps and the review and approval process. Release of the guidelines is expected in December 2012. Dr. Buchanan discussed the goals of the panel, which are to generate imple-

mentable evidence-based recommendations on managing sickle cell disease in clinical practice and to identify gaps in knowledge for additional research.

Dr. Pamela Douglas, Ursula Geller Professor for Research in Cardiovascular Diseases and Director, Cardiovascular Imaging Program, Duke University School of Medicine, and Council member, presented a report of the Council Working Group on Clinical Practice Guidelines. The working group had been asked to consider whether the NHLBI should create guidelines. She offered a snapshot of the cost of guideline creation and dissemination and presented pros and cons for creation of guidelines by the NHLBI.

Dr. Larry Tabak, Principal Deputy Director, NIH, and the Council recognized Dr. Shurin's outstanding service as Acting Director of the NHLBI for the past 2.5 years.

NHLBI staff presented 7 new initiatives and 5 renewals, all of which had been reviewed in May by the Board of External Experts. The Council was mostly supportive of the initiatives presented, but made a number of specific recommendations for consideration prior to their release.

Need More Information?

We are always interested in receiving comments and suggestions from the community. If you or your organization have questions for me or for the Institute, please contact me at gary.gibbons@nih.gov or Dr. Carl Roth at carl.roth@nih.gov.



Gary H. Gibbons, M.D.
Director, NHLBI

For information on specific issues, the following contacts may be helpful:

- For health-related questions, information about publications, or communications pertaining to NHLBI policies and priorities, please contact the trained information specialists of the NHLBI Information Center at 301-592-8573, or write to the Information Center at P.O. Box 30105, Bethesda, MD 20824-0105, or email inquiries to nhlbiinfo@nhlbi.nih.gov.
- For additional information regarding NHLBI events, consult the references provided or www.nhlbi.nih.gov/calendar/nhcal.htm. Most other NIH Institutes and Centers also maintain calendars on their Web sites. Links to their Web pages are at www.nih.gov/icd.