

# FYI from the NHLBI



Public Interest News from the National Heart, Lung, and Blood Institute

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## Message from the Director

The NHLBI staff are looking forward to the second annual meeting of NHLBI-related public interest organizations (PIOs). Invitations have been sent to over 70 organization leaders, and we have several dynamic presentations and breakout groups planned. I hope that all of your groups will be represented, since the meeting cannot be a success without you. Many members of the National Heart, Lung, and Blood Advisory Council will be at the PIO meeting to listen to your comments and learn how the Institute can better meet your needs, and everyone is welcome to attend the public session of the Council, which will be held on February 1, 2001.

In response to your suggestions from last year's meeting, the NHLBI has launched a new series of Web pages, called the *NHLBI Express*. This public liaison site is accessible through both our home page ([www.nhlbi.nih.gov](http://www.nhlbi.nih.gov)) and [www.nhlbi.nih.gov/public](http://www.nhlbi.nih.gov/public). This site was designed for you, and we are interested in hearing your comments. Please, let us know what you think by writing to us at [NHLBI.Listens@nih.gov](mailto:NHLBI.Listens@nih.gov).

In addition to our upcoming public interest organization and Council meetings, we have many other exciting events planned for this winter. To help you recover from any overindulging that you might do over the traditional Winter holidays and to help you stay healthy for your loved ones, we're working with the American Heart Association (AHA) to bring you American Heart Month in February. Watch your local news sources for information about AHA-sponsored programs in your area. Remember, though, that healthy habits should be practiced throughout the year. Visit our "Aim for a Healthy Weight" page for tips on ways to prevent extra pounds from creeping up on you. Also, remember to get plenty of sleep. The NHLBI has teamed up with Garfield the cat to spread that message to youngsters, and we need your help in setting a good example. And most important, remember that all of us at the NHLBI want you to have a safe and enjoyable holiday season.



Sincerely yours,

Claude Lenfant, M.D.  
Director

## All Aboard the *NHLBI Express*

Do you find yourself baffled by all of the health information available on the World Wide Web? Do you need information about NHLBI activities that you can't find on the home page? The *NHLBI Express* was designed with you in mind. Hop aboard at [www.nhlbi.nih.gov/public](http://www.nhlbi.nih.gov/public) and see where this new, user-friendly series of pages can take you.



The *Express* is divided into four main sections. Visit **Past, Present, and Future Research** to access literature search tools, to learn about clinical trials, and to identify research areas in which the NHLBI is investing today and is planning to develop programs in the future. Many of you asked us to provide information about congressional activities affecting the NHLBI; **Your Government, Your Institute** provides links to summaries of bills that have been passed recently or are under consideration as well as links to the home pages of congressional committees that determine the NHLBI's authorities and appropriations. If health information is what you need, **Informed People, Healthy Lives** is a good place to start. Want to find Web pages for organizations focusing on a specific disease? Looking for an earlier issue of *FYI from the NHLBI*? Then the stop you want is the **Public Involvement** page. And if you get lost, the navigational tools and information sources described in **About Express** should get you back on track.

Like the express train that doesn't stop at every station, the *NHLBI Express* doesn't link to all of the reliable information that is available. But, we hope this express site will give you a quick start to get you where you need to go.

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## NHLBI Staff Visit Gene Therapy Research Centers

As part of ongoing efforts to ensure patient protection in gene therapy trials, the Food and Drug Administration and the National Institutes of Health (NIH) are taking extra steps to protect individuals enrolled in gene therapy studies. One such action is the implementation of "not for cause" site visits to clinical centers conducting gene therapy trials. This year, the NHLBI visited all five of its centers and will continue to visit each site on an annual basis as long as the gene therapy protocols are in effect. Future trips also will include visits to the newly implemented Programs of Excellence in Gene Therapy and to the Specialized Centers of Research in Hematopoietic Stem Cell Biology.

The objectives of the visits are to ensure the safety of participants and to be certain that the highest clinical standards are being applied in NHLBI-supported gene therapy trials. NHLBI staff review documents associated with the trials, visit facilities where the trials take place, and, perhaps most important establish a dialogue with the trials' investigators, management, and administrative staff.

The site visits are not the only way that the NHLBI is enhancing its oversight of gene therapy trials. The Institute has increased its emphasis on training researchers about protection of research participants, identifying conflicts of interest, and establishing Data and Safety Monitoring Boards that are independent of other aspects of the trials.

Gene therapy is a recent, and still experimental, approach to treating, and possibly curing, diseases. The Institute is committed to holding gene transfer research to the highest ethical and scientific standards. Volunteers in clinical gene transfer trials should receive the greatest possible protection by investigators, institutions, and oversight agencies.

### Two New Programs from the NHLBI

On September 30, the NHLBI issued grants to investigators at 35 research settings that will establish 11 programs for genomic applications (PGAs). After identifying human genes particularly relevant to heart, lung, blood, and sleep functions, PGA researchers will decipher the genes' functions. "The PGA initiative is one of the NHLBI's most ambitious, wide-ranging efforts to date," says NHLBI Director Dr. Lenfant. "Our challenge is to clearly identify the subsets of genes linked to heart, lung, blood, and sleep function, then to build upon this knowledge to develop better methods for prevention, diagnosis, and therapy."

In another effort, the NHLBI launched the Multi-Ethnic Study of Atherosclerosis (MESA). The objective is to find heart disease before symptoms develop. "The earlier the risk of heart disease can be detected, the sooner steps can be taken to prevent its development," said Dr. Lenfant. "Most of [our current] prevention effort has focused on the standard risk factors for heart disease. This study may give us better indicators of heart disease risk." The study also could yield more specific disease predictors; it will try to determine which factors best predict heart disease in men, women, and ethnic groups.



## News from Capitol Hill

The Congress has not passed an FY 2001 spending bill for the National Institutes of Health (NIH). The NIH has, therefore, been operating under a series of congressional resolutions that provide funding on a temporary basis. At the present time, it is unclear when an FY 2001 spending bill will be agreed upon, passed by the Congress, and signed into law by the President.

President Clinton recently signed into law three bills of interest to the NIH. The full text of these bills, as well as all others enacted during the 106<sup>th</sup> Congress, is available through the Library of Congress website at <http://thomas.loc.gov/bss/d106/d106laws.html>.

The **Public Health Improvement Act** (H.R. 2498, now P. L. 106-505) consists largely of previously free-standing bills such as the Public Health Threats and Emergencies Act, the Clinical Research Enhancement Act, the Twenty-First Century Research Laboratories Act, the Cardiac Arrest Survival Act, the Lupus Research Act, the Prostate Cancer Research and Protection Act, the Organ Procurement Organization Certification Act, and the Alzheimer's Clinical Research and Training Awards Act of 2000, as well as a new provision on sexually transmitted disease clinical research and training.

The **Children's Health Act of 2000** (H.R. 4365, now P.L. 106-310) contains provisions on federal research into autism, Fragile X, juvenile arthritis, diabetes, asthma, hearing loss in infants, epilepsy, traumatic brain injuries, muscular dystrophy, childhood malignancies, birth defects, and autoimmune diseases. It also creates a pediatric research initiative at the NIH, authorizes repayment of educational loans for qualified health professionals conducting pediatric research, and establishes protections for pediatric research subjects. It requires that federal asthma activities be coordinated through the Coordinating Committee of the NHLBI National Asthma Education and Prevention Program.

The **Minority Health and Health Disparities Research Act of 2000** (S. 1880, now P. L. 106-525) establishes in law a National Center for Minority Health and Health Disparities at the NIH to coordinate health disparities research performed or supported by NIH. It also will establish a grant program through the new Center to enhance biomedical and behavioral research training, an endowment program to facilitate minority and other health disparities research, and a loan repayment program to encourage members of minority or other health disparities populations to pursue careers as biomedical research professionals.

## New NHLBI Research Initiatives

From time to time, the NHLBI invites investigators to submit grant applications or contract proposals for specific research programs. We currently are soliciting applications for the following programs. Unless a due date is noted below, applications are accepted for February 1, June 1, and October 1 deadlines each year. For a full description of these and other research initiatives, visit [www.nhlbi.nih.gov/funding/inits/index.htm](http://www.nhlbi.nih.gov/funding/inits/index.htm).

### **Ancillary Studies in Heart, Lung, and Blood Disease Trials (RFA-HL-00-012)**

- Applications Due: see announcement.
- Objective: To conduct mechanistic studies using patients and patient materials from clinical trials related to heart, lung, and blood diseases.

### **Biobehavioral Research for Effective Sleep (PA-00-046)**

- Objective: To support research on sleep-related problems found in healthy and chronically ill individuals with acute and chronic sleep deprivation.

### **Cellular and Molecular Mechanisms of Primary Pulmonary Hypertension (PA-00-043)**

- Objective: To promote research in primary pulmonary hypertension with an emphasis on understanding disease mechanisms.

### **Functional Tissue Engineering for Heart, Vascular, Lung, Blood, and Sleep Disorders and Diseases (PAR-01-006)**

- Applications Due: see announcement.
- Objectives: To stimulate engineering of biological substitutes for damaged tissues and organs and to promote development of novel tissue regeneration and remodeling approaches.

### **Genetic Aspects of Tuberculosis in the Lung (RFA-HL-00-012)**

- Applications Due: 1/17/01
- Objective: To identify genes, or families of genes, that determine resistance and susceptibility to mycobacterial infection, virulence, latency, reactivation of disease, and resistance to antituberculous drugs.

### **Genetic Modifiers of Single Gene Defect Diseases (RFA-HL-01-001)**

- Applications Due: 2/20/01
- Objective: To identify and characterize genes responsible for differences in clinical progression and outcome for various diseases.

### **Mouse Models of Diabetic Complications Consortium (RFA-DK-01-009)**

- Applications Due: 3/28/01
- Objective: To assemble a cross-disciplinary consortium to develop mouse models that closely mimic the human complications of diabetes.

### **Non-mouse Models of Diabetes Complications in Cardiovascular and Microvascular Diseases (RFA-HL-01-010)**

- Applications Due: 3/21/01
- Objective: To accelerate the pace at which accurate and reproducible non-mouse animal models of diabetic vascular complications are developed.

### **Physical Activity and Obesity Across Chronic Diseases (PA-01-017)**

- Objectives: To examine relationships between physical activity and obesity, to improve methodologies for assessment of physical activity and energy balance, and to test interventions that incorporate physical activity for obesity prevention or treatment related to chronic diseases.

### **SCOR: Molecular Medicine and Atherosclerosis (RFA-HL-00-015)**

- Applications Due: 6/15/01
- Objective: To support molecular research on the etiology and pathophysiology of atherosclerosis.

### **Self-Management Strategies Across Chronic Diseases (PA-00-109)**

- Objectives: To expand research on self-management interventions, such as those used in treating blood disorders, and to understand their implications in treating other chronic diseases.

### **Stem Cell Plasticity in Hematopoietic and Non-hematopoietic Tissue (RFA-HL-01-007)**

- Applications Due: 3/21/01
- Objective: To encourage research to document the extent to which stem cells that have the potential to form blood cells also may be able to form other cells (e.g., neural cells).



## Spotlight on Our Web Site

### Clinical Cardiology Unit Develops Web Page for Children

The youngest patients of the NHLBI's 7 East Clinical Cardiology Unit now can get an online tour of what they can expect during their stay in Bethesda, Maryland. The colorful site, located at [www.nhlbi.nih.gov/labs/7east/kidspage.htm](http://www.nhlbi.nih.gov/labs/7east/kidspage.htm), introduces patients and their families to the admissions process, shows pictures of hospital rooms and the playroom, and accurately describes the medical procedures in a comforting, friendly way. Parents also will benefit from the Unit's general site ([www.nhlbi.nih.gov/labs/7east](http://www.nhlbi.nih.gov/labs/7east)), where they can get information on a variety of subjects including diagnostic tests, common cardiac medications, and services to make the patient's stay a little easier.

## The National Heart, Lung, and Blood Advisory Council's Fall Meetings

The National Heart, Lung, and Blood Advisory Council (NHLBAC) meets four times a year in Bethesda, MD. Full minutes of Council meetings are available at [www.nhlbi.nih.gov/meetings/nhlbac/index.htm](http://www.nhlbi.nih.gov/meetings/nhlbac/index.htm). The Council's next meeting is scheduled for February 1, 2001, at 8:30 AM. It is open to the public and will be held at the NIH in Building 31C, Conference Room 10.

The *FYI from the NHLBI* staff thanks Mrs. Judith Simpson, member of the NHLBAC and Vice President, Pulmonary Hypertension Association, for her efforts in preparing these summaries.

### September 8, 2000 Meeting

Following preliminary remarks by Dr. Claude Lenfant, Director of the NHLBI, the Council engaged in a discussion of patient safety during clinical trials. It is of paramount importance to the NIH that investigators conducting studies with human subjects ensure patient safety. Dr. Amy Patterson, Director of the NIH Office of Biotechnology Activities, described oversight of NIH-funded gene therapy trials. Dr. Sonia Skarlatos, NHLBI, described the roles of data and safety monitoring boards. A discussion ensued about patient education and informed consent. It is hoped that recommendations for improvements in ensuring patient safety will emerge from a NIH patient safety symposium and a cardiovascular safety symposium to be held this winter.

Dr. Susan Old, NHLBI, presented information on the NIH Biomedical Information Science and Technology Initiative and Consortium. Simply put, the data deluge has created informatic and computational challenges in areas including surgery, clinical practice, medical genetics, clinical trials, drug development, and cell biology.

Dr. Carl Roth, NHLBI, presented information about the increase in the average cost of research grants. Dr. Lenfant noted that the primary concern is that as big dollar grants grow, the amount of funding for investigators with innovative research projects will decrease. On the other hand, genomics research and other new research areas that require big-ticket grants will change the way medicine is practiced. The Council began discussing possible ways of achieving a balance in funding to ensure continuation of both types of projects.

The Council awarded 115 grants for a total cost of \$72,730,466.

### October 19, 2000 Meeting

In his opening statement, Dr. Lenfant acknowledged and thanked five Council members whose terms are expiring and announced the appointment of five new members.

Dr. Teri Manolio, NHLBI, reported on activities pertaining to NHLBI training programs. Discussion focused on training in new disciplines to improve clinical and behavioral research, developing multidisciplinary programs to bridge areas of expertise, encouraging future research training programs and mentorships, and involving students early (for example, at the elementary school level) in exciting, interesting science. With rapidly emerging developments, it is the goal of the NHLBI to match research needs with appropriate training opportunities.

Dr. Robert Balaban, NHLBI, described how noninvasive imaging technologies have moved rapidly into clinical applications. Dr. George Sopko, NHLBI, discussed the surgical treatment of ischemic heart failure. Investigators are asking if the NHLBI, with cooperation and support from the Health Care Financing Administration, would be willing to receive a grant application to study the effectiveness of surgical anterior ventricle restoration (SAVR) in treating ischemic heart failure. SAVR, which has been performed for years in locations scattered throughout the country, reshapes the diseased heart from a watermelon shape to its original football shape. The Council recommended that the Institute agree to review the application.

Thirteen concepts for future NHLBI scientific initiatives were reviewed and supported by the Council. The recompetition for the ten Comprehensive Sickle Cell Centers that the NHLBI is required by law to support also was discussed. The Council concurred on the award of 152 grants for a total cost of \$59,558,494.

## Need More Information?

- For **health related questions and publications**, please contact the trained information specialists at the NHLBI Information Center (NHLBIinfo@rover.nhlbi.nih.gov) or write to the Information Center at P.O. Box 30105, Bethesda, MD 20824-0105.
- For communications pertaining to NHLBI **policies and priorities**, contact the NHLBI Office of Legislative and Public Liaison (SL34V@nih.gov).
- For **additional information regarding NHLBI events**, consult the references provided or [www.nhlbi.nih.gov/calendar/nhcal.htm](http://www.nhlbi.nih.gov/calendar/nhcal.htm). Most NIH Institutes also maintain calendars, accessible through their Web sites. Links to the Institutes' Web pages are at [www.nih.gov/icd](http://www.nih.gov/icd).

## Recent Advances from the NHLBI

**Ebola Vaccine in the Works:** Ebola virus is a rare but deadly microbe that kills up to 90 percent of the people whom it infects. Although outbreaks are not common or widespread, Ebola has received much publicity because of its horrifying symptoms, which include high fever and massive internal bleeding. To add to the mystery surrounding the cause and cure of this deadly disease, the virus strikes sporadically, often devastating a whole community before disappearing into the jungle, where it hides away in an as-yet-unknown host. Recently, scientists identified the viral gene thought to be responsible for the massive internal bleeding that leads to most of those deaths. Based on information about the gene and the protein it produces, researchers developed a vaccine that is being tested in animals. If the animal studies are successful, vaccine trials can be initiated in humans.

**Inhaled Steroids Safe and Effective for Children with Asthma:** Inhaled corticosteroids are safe and effective for the long-term treatment of children with mild to moderate asthma, according to the NHLBI's "Childhood Asthma Management Program (CAMP)." The 5-year study is the longest and largest controlled study of treatments for childhood asthma. It showed that inhaled corticosteroids provide superior asthma control. Their only side effect was a temporary one - a small reduction in the children's rate of growth observed just in the first year of treatment. NHLBI Director Dr. Claude Lenfant said "CAMP provides scientific evidence regarding the long-term effectiveness and safety of inhaled corticosteroids for children. Physicians, other health care professionals, and parents should feel comfortable using them to help children with mild to moderate asthma participate fully in childhood activities."

**Canine Narcolepsy Gene Provides Clues to Treatment of Human Narcolepsy:** People with narcolepsy suffer from excessive sleepiness, vivid hallucinatory dreams, and in extreme cases, episodes of sudden weakness (cataplexy). Narcolepsy is thought to affect as many as 1 in 2,000 people in the United States. The disorder is devastating to those affected and their families. Recent studies have identified a defective gene responsible for narcolepsy in dogs and discovered a related pathway that helps to maintain wakefulness. This clue led researchers to conduct clinical studies, which indicate that the same neural pathway is not functioning properly in most cases of human narcolepsy. Although a cure for narcolepsy is still far off, researchers are optimistic that these findings will lead to improved treatments for narcolepsy and other sleep disorders.

**Hostility May Be Associated with Early Atherosclerosis:** Hostility may be hazardous to your health in more ways than you thought. Researchers studying factors that may place young adults at risk for developing coronary artery disease found that hostility correlates strongly with the subsequent development of coronary calcification, a precursor to atherosclerosis. This association persisted even when lifestyle and physiological differences were considered, leading scientists to wonder whether hormone levels, blood pressure changes, or other conditions are responsible for the increased susceptibility to heart disease. In addition to providing insight as to potential causes of heart disease, the study indicates a potential preventive strategy. Since other studies have shown that behavioral therapies can reduce hostility levels, researchers hypothesize that interventions to reduce hostile attitudes and behaviors may also prevent atherosclerosis.

## Update on High Blood Pressure in Pregnancy Now Available

The NHLBI's National High Blood Pressure Education Program Coordinating Committee has issued new guidance for clinicians on high blood pressure in pregnancy. The "2000 Working Group Report on High Blood Pressure in Pregnancy" clarifies how to monitor and treat pregnant women who have hypertension before pregnancy and those who develop hypertension during gestation. It is available through the NHLBI Web site and the Information Center.



Hypertensive disorders occur in 6 to 8 percent of pregnancies and contribute significantly to serious complications for both mother and fetus. They account for nearly 15 percent of maternal deaths in the United States and can impair the mother's kidneys, liver, and central nervous system. Fetal complications are equally severe and include growth retardation and death (stillbirth).

## Spokescat for Sleep Program

The NHLBI named Garfield a "Star Sleeper" and asked the clever cat to help spread the word that, when it comes to doing your best, a good night's sleep is hard to beat. Garfield credits his ability to outwit dogs and humans to the fact that he's had enough sleep. "Sleep is the perfect exercise," according to the famous kitty. "I wouldn't be where I am today without it."

Garfield will help the NHLBI get the message to kids in grades 1-5 that a good night's sleep helps them feel and do their best. Over the next five years, the NHLBI will be working with Jim Davis and Paws, Inc., owners of Garfield, to develop and distribute contests, games, and activities promoting sleep. For starters, the NHLBI held a contest in which students were asked to complete the comic shown here.



## Constituents' Corner

We are reserving space for you, our readers, to share ideas and broadcast opinions. We invite you to submit your comments, thoughts, and suggestions via **email** (NHLBI.Listens@nih.gov) or **snail mail** (Public Interest News, c/o Office of Science and Technology, Building 31, Room 5A03, 31 Center Drive, MSC-2482 Bethesda, MD 20892-2482). We also are considering the addition of a separate "Bulletin Board" where organizations can announce upcoming activities. For now, those announcements also can be sent to the above addresses.

### NHLBI to Hold Second Annual Public Interest Organization Meeting

On January 31, 2001, the NHLBI will bring together representatives from nearly 70 public interest organizations, members of the National Heart, Lung, and Blood Advisory Council (NHLBAC), and senior Institute staff to discuss how the organizations and the Institute can better support research, get the message out, and promote high quality clinical studies. As it did for last year's meeting, the Institute is supporting travel for one representative selected by each invited organization.

Many of the representatives also are planning to attend the NHLBAC meeting the following day. The Council, which is composed of a diverse mix of scientific and public leaders, plays an essential role in establishing and implementing NHLBI objectives. They have been strong proponents of all of the Institute's public liaison activities, including the development of the *FYI from the NHLBI* and the *NHLBI Express* that arose from last year's meeting.

### February is American Heart Month



On December 20, 1963, President Lyndon B. Johnson approved a joint congressional resolution to designate February as American Heart Month. Since the tradition began, our nation has made enormous progress in its fight against heart disease. Scientists have identified risk factors (e.g., smoking, high blood pressure, high blood cholesterol, diabetes, obesity, and physical inactivity) and treatments to prevent and treat heart disease. The death rate from coronary heart disease has fallen dramatically in the United States, with a nearly 60-percent reduction since its peak in the mid-1960s. However, heart disease remains a serious health problem. More than 58 million Americans have one or more types of cardiovascular disease (CVD), and each year nearly 1 million Americans die from CVD. Many of the factors that increase a person's risk of CVD are at least partially controllable. Please, do your part and take care of your heart. Ask your physician to help you determine the best strategy for reducing your risk for heart disease. And help us spread the word by circulating this issue of *FYI from the NHLBI* to people who might be interested.