

NIAAA NEWSLETTER

FEATURING INFORMATION FROM THE NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM

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Kathleen Grant To Receive Keller Award

Dr. Kathleen A. Grant, professor in the Department of Behavioral Neurosciences at the Oregon Health and Science University, was selected to receive NIAAA's 2008 Mark Keller Honorary Award and to deliver a lecture titled, "The Alcoholic Drinking Phenotype in Non Human Primates: Who Bellies Up to the Bar?"

The ceremony will take place on October 21, 2008, from 1:30 to 3:00 p.m., at the Lipsett Amphitheater in the NIH Clinical Center, Bethesda, Maryland. For details visit www.niaaa.nih.gov.

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Clinical Trials Must Now Be Registered in NIH Site

Some Studies Must Report Results Data; Penalties for Noncompliance

The National Institutes of Health (NIH) has long required registration of NIH-supported clinical studies in its free, public-access Web database, ClinicalTrials.gov (www.clinicaltrials.gov). Now a new law has expanded the registry to include study results for some trials. The law also mandates monetary fines or withholding of grant funds for noncompliance.

At a meeting of NIH officials in July, representatives from ClinicalTrials.gov described the changes being made to the registry as a result of the Food and Drug Administration Amendments Act (FDAAA, or Public Law 110-85).

Under the statute, the "applicable clinical trials" generally include:

- Trials of Drugs and Biologics: Controlled, clinical investigations, other than Phase 1 investigations, of a product subject to FDA regulation; and
- Trials of Devices: Controlled trials with health outcomes, other than small feasibility studies, and pediatric postmarket surveillance.

For applicable clinical trials, the law mandates registration as well as the submission of basic study results to ClinicalTrials.gov.

Online NIH Guidance

The NIH Office of Extramural Research (OER) has issued guidance on the new law: NOT-OD-08-014, available online at: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-014.html>.

http://grants.nih.gov/grants/policy/hs/faqs_aps_clinical_trials.htm) that addresses issues such as who is responsible for registering the trial (designated the "responsible party" in the law).

According to the OER site: "For NIH-funded clinical trials where there is an Investigational New Drug (IND) holder, consistent with FDA regulations, the IND holder is the sponsor, and will be considered the responsible party unless this obligation is delegated to the principal investigator. For NIH-funded clinical trials where there is no IND holder, the funding recipient will be considered the responsible party."

Other NIH information sites include:

- ClinicalTrials.gov Protocol Registration System (PRS) Information, available online at: <http://prsinfo.clinicaltrials.gov/> and
- PRS and U.S. Public Law 110-85, available online at: <http://prsinfo.clinicaltrials.gov/fdaaa.html>.

Contacts at NIH, NIAAA

NIAAA-funded investigators with questions about clinical trials registration can send e-mail to the ClinicalTrials.gov registrar at register@clinicaltrials.gov, or contact Gregory Roa in the NIAAA Office of Science Policy and Communications (301-443-0596, greg.roa@nih.gov).



Honors

Dr. Ralph Hingson, Director of the Division of Epidemiology and Prevention Research (DEPR), received the R. Brinkley Smithers Distinguished Scientist Award from the American Society of Addiction Medicine (ASAM). The citation notes Dr. Hingson's "innovative analytic and public policy strategies resulting in fundamental advances in prevention science and public policy concerning the use of alcohol and its harmful consequences in many dimensions of our society, especially in the pursuit to keep our youth and highways safer." The award was presented at the ASAM Annual Medical-Scientific Conference in Toronto, Canada, in April.

Dr. Robert Huebner, Deputy Director of the Division of Treatment and Recovery Research (DTRR), was selected to receive the 2008 American Psychological Association (APA) Meritorious Research Service Commendation. Dr. Huebner's award recognizes significant contributions in promoting and supporting important research at NIAAA and NIH in the areas of problem drinking, treatment and recovery, and the search for mechanisms of behavior change. Dr. Huebner will receive the award at the December meeting of APA's Board of Directors in Washington, D.C.

Dr. Kenneth Warren, NIAAA's Deputy Director, received the Excellence Award from the National Organization on Fetal Alcohol Syndrome (NOFAS) in May. The award cited Dr. Warren for pioneering research and distinguished contributions in addressing fetal alcohol spectrum disorders (FASD). Dr. Warren developed NIAAA's FAS research program more than 30 years ago and has been active in FASD research activities throughout his career, including serving as the current chair of the government-wide Interagency Coordinating Committee on FAS.

NIH Director's Awards were announced at a ceremony on July 21. Individual awards went to:

- Robin Kawazoe in recognition of administrative management excellence; and
- Dr. George Kunos for leadership of the intramural program and research on endocannabinoids.

In addition, several staff received group awards for service:

- Ann Bradley and Drs. Mark Willenbring, Antonio Noronha, Sam Zakhari, Mark Egli, Raye Litten, and Bridget Grant for their work on the HBO Project;
- Dr. Lorraine Gunzerath as part of the Division of Extramural Activities Support (DEAS) Re-engineering Team;
- Drs. Patricia Powell and Vivian Faden for their efforts on *The Surgeon General's Call to Action*; and
- Dr. Brenda Weis as part of an NIH Roadmap Recognition Award.

New Appointments

Dr. Judith Arroyo was named Minority Health and Health Disparities Coordinator for NIAAA. As Coordinator, Dr. Arroyo provides leadership and guidance on all aspects of extramural activities related to minority health and health disparities. In addition to working in this capacity, she will continue serving as a Program Director in DEPR.

Dr. Patricia Powell was named Chief of the Science Policy Branch. She came to NIAAA in 2001 as an American Association for the Advancement of Science/NIH Science Policy Fellow and later became a health science administrator. She began working with the Leadership to Keep Children Alcohol Free in 2003; in 2007, she worked with the Office of the Surgeon General to develop *The Surgeon General's Call to Action*.

Dr. Brenda Weis joined NIAAA in July as a senior advisor to the NIAAA Director. Her duties include coordinating the Institute's activity in the NIH Roadmap initiatives and trans-NIH projects. She comes to NIAAA from the National Institute of Environmental Health Sciences where she worked for the past seven years in a variety of positions including Extramural Review Administrator, Program Director for the National Center for Toxicogenomics, and Senior Science Advisor to the Director. Dr. Weis has played a key role in the development and implementation of several trans-NIH programs, including the Pathways to Discovery-Metabolomics Technology Development Initiative; the Genes, Environment, and Health Initiative; and, most recently, the Roadmap Epigenomics Program.

Staff Departures

Dr. Ricardo Brown accepted a position with Howard University as Associate Vice President for Research and Professor of Physiology and Biophysics.

Dr. Vishnu Purohit accepted a position with the National Institute on Drug Abuse as a Program Director in the Division of Basic Neuroscience and Behavioral Research.

Dr. Jose Velazquez accepted a position as a Program Director in the Division of Aging Biology at the National Institute on Aging.

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NIH Announces Enhancements to Peer Review

In June, NIH Director Elias A. Zerhouni announced critical changes to enhance and improve the NIH peer review system. An important component of the new plan is an increased commitment to investigator-initiated, high-risk, high-impact research to prevent a slowdown of transformative research, despite difficult budgetary times.

The NIH Implementation Plan Report consists of four main priorities. Highlights include:

- Priority 1—engage the best reviewers: increase flexibility of service, formally acknowledge reviewer efforts, further compensate time and effort, and enhance and standardize training.
- Priority 2—improve quality and transparency of reviews: shorten and redesign applications to highlight the impact and to allow alignment of the application, review, and summary statement with five explicit review criteria, and modify the rating system.
- Priority 3—ensure balanced and fair reviews across scientific fields and career stages:
 - support a minimum number of early-stage investigators and investigators new to NIH and emphasize retrospective accomplishments of experienced investigators;
 - encourage and expand the Transformative Research Pathway;
 - create a new investigator-initiated Transformative R01 Award program funded within the NIH Roadmap with an intended commitment of a minimum of \$250 million over 5 years;
 - continue the commitment of—and possibly expand the use of—the Pioneer, EUREKA, and New Innovator Awards. NIH will invest at least \$750 million in these three programs over the next 5 years; and
 - reduce the burden of multiple

rounds of resubmission for the same application, especially for highly meritorious applications.

- Priority 4—develop a permanent process for continuous evaluation of peer review.

For more information about enhancing peer review at NIH and to learn about the Implementation Plan, please visit <http://enhancing-peer-review.nih.gov>.

NEW PUBLICATIONS

Alcohol Alert
#75: *Systems Biology: The Solution to Understanding Alcohol-Induced Disorders?*



Systems biology is a new field that uses advanced technologies to explore how the parts of the human body work together, in health and disease, as a synchronized whole. This *Alcohol Alert* describes how systems biology is providing tools to help researchers better understand how alcohol affects various body tissues and how the resulting changes lead to the development of addiction to alcohol and to organ damage. This new information also has the potential to help researchers develop better and more targeted medications for alcohol-induced disorders.

This NIAAA publication and other resources are available free for downloading as full-text documents. To order, visit www.niaaa.nih.gov, or write to:

NIAAA, Publications Distribution Center, P.O. Box 10686, Rockville, MD 20849-0686.

NIH Summit: The Science of Eliminating Health Disparities

In the United States and around the world, certain populations are more likely to experience health problems than others. Such health disparities may be traced to a range of causes, including differences in physiology, socioeconomic, environment, and culture, and inadequate access to health care. People who experience health disparities are more likely to suffer from diseases and conditions such as diabetes, stroke, heart disease, HIV/AIDS, and obesity.

Understanding health disparities is vital to overcoming them. The National Center on Minority Health and Health Disparities (NCMHD), with the support of its NIH Institute/Center partners, will host the first NIH Research Summit on *The Science of Eliminating Health Disparities*.

Participants from across the United States are expected to attend the

meeting, including scientists, health care professionals, health policy leaders, health educators, community advocates, media, and others who are interested in eliminating health disparities.

The summit will be held from December 16 to 18 at the Gaylord National Resort and Convention Center in National Harbor, Maryland. For more information or to register online, visit <http://www.blsmmeetings.net/2008healthdisparitiessummit/>.

"NIAAA is joining with the other NIH Institutes to strongly endorse this event. We encourage NIAAA investigators, both those who are currently conducting health disparities-related research and those who would like to move in this direction, to attend this important summit," said Dr. Judith A. Arroyo, Minority Health and Health Disparities Coordinator.

Reaching Teens Through Science

Tell a group of teenagers you study alcohol for a living and they will ask you lots of interesting questions. Just ask Dr. Dennis Twombly, one of several NIAAA scientists who volunteer in outreach programs for students visiting the Institute.

Twombly, who developed the Drunken Brain, an exhibit that illustrates alcohol's effects, said, "The brain model sparks a natural curiosity that young people have about how our bodies work and how to keep them healthy." Twombly regularly receives requests to display the model at events such as Brain Awareness Week and Take Your Child to Work Day.

Earlier this spring, Twombly and other NIAAA scientists hosted Jeter's Leaders, a youth group from New York City sponsored by baseball star Derek Jeter. The program fosters leadership, peer education, a healthy lifestyle, and preparation for college and beyond.

This year marked the organization's third and largest contingent to visit the NIH campus. Some new members of the youth group toured an NIAAA laboratory with Steve Lindell. Veterans



Dr. Heilig with Jeter's Leaders.

of previous trips met with NIAAA Clinical Director Dr. Markus Heilig for a question-and-answer session. They also heard presentations by scientists from other parts of NIH and discussed careers with former presidential management interns originally from New York City.

"The feedback from the group has been great every year," said NIAAA Public Liaison Officer Fred Donodeo,

who initiated the outreach to Jeter's Leaders. "The students appreciate the science-based messages about alcohol and say the trip's a positive experience." So positive, in fact, that Jeter organization officials invited Twombly and other NIH presenters to take their presentation "on the road" to Arlington, Texas, to exhibit at a substance abuse education fair for teen leaders in August.

Calendar of Events

NIAAA will participate in or exhibit at meetings and conferences listed below. For additional information or updates on these events, consult the sponsoring organization.

SEPTEMBER

- ▶ **September 17–21**
American Academy of Family Physicians (AAFP) Annual Scientific Assembly
San Diego Convention Center
111 West Harbor Drive, San Diego, CA
Contact: <http://www.aafp.org/online/en/home/cme/aafpcourses/conferences/assembly.html?FeaturePage=/content/en/home&FeatureLocation=FeatureAds2> or contactcenter@aafp.org

- ▶ **September 18**
National Advisory Council on Alcohol Abuse and Alcoholism
5635 Fishers Lane, Conference Center (Terrace Level), Rockville, MD
Contact: Melvin Carter, 301/443-9788; carterm@mail.nih.gov

- ▶ **September 23–24**
Preventing Alcohol, Tobacco, and Other Substance-exposed Pregnancies: A Community Affair
5635 Fishers Lane, Conference Center (Terrace Level), Rockville, MD
Contact: http://www.niaaa.nih.gov/NewsEvents/Conferences/Symposium9_08.htm or e-mail sharley@lclmlc.com

OCTOBER

- ▶ **October 1–3**
National Hispanic Science Network on Drug Abuse Community, Behavioral and Molecular Sciences in Addictive Disorders
Hyatt Regency
7400 Wisconsin Avenue, Bethesda, MD
Contact: <http://www.nhsn.med.miami.edu/>

- ▶ **October 30–November 1**
National Middle School Administration (NMSA) 35th Annual Conference & Exhibit
Colorado Convention Center
700 14th Street, Denver, CO
Contact: <http://nmsa.org/annual/>
- ▶ **October 31–November 5**
Association of American Medical Colleges (AAMC) Annual Meeting
Henry B. Gonzalez Convention Center
200 E. Market Street, San Antonio, TX
Contact: <http://aamc.org/meetings/annual/2008/start.htm>

Mark Keller Honorary Lecture **October 21, 2008, 1:30 p.m.**

Presented by Dr. Kathleen A. Grant, Department of Behavioral Neurosciences, Oregon Health and Science University, at the NIH Clinical Center, Bethesda, MD
Contact: Nancy Collada, NIAAA, 301/443-4733; ncollada@mail.nih.gov