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NIH/FDA regulatory science initiative IRTAs get patient-care experience Gene mutations linked to stuttering

Clinical Center



Patient care and research continued at the Clinical Center through the twin blizzards of February 2010. CRTP fellow Zachary Dezman snapped the above as he skied to the hospital to work on some samples.

Patient care perseveres through snowstorms

It may have seemed that the Washington, DC, metropolitan area shut down for a week in early February as two snowstorms rendered roads impassable and left hundreds of thousands without power. The needs of Clinical Center patients remained constant, though, even as the weather patterns of the mid-Atlantic did not.

CC staff banded together to provide round-the-clock care for more than 170 patients over the federal government closure from noon Friday, February 5 through Thursday, Friday 11.

This area has faced storms before that have complicated operations, but the twin blizzards of 2010 posed a greater challenge. "It was worse for two reasons," said CC Director Dr. John I. Gallin. "One, the duration and severity of the storm. And two, we had more patients in the hospital than we've had in the past."

Staff stayed overnight and worked double shifts to keep patients safe and on track with their treatments. The CC provided beds for 304 employees, and The Children's Inn lent their few vacancies.

More than 54 staff with four-wheel drive vehicles, including Gallin, volunteered to transport those without between their homes and the hospital.

Administration eased the experience for the dedicated staff—distributing food vouchers, and opening patient entertainment (movies, board games, foosball) to employee use. Chief Operating Officer Maureen Gormley had a local print shop quickly turnaround "I Survived the 2010 Blizzard at the NIH Clinical Center" t-shirts for the CC staff who extended their services.

"I was just astounded by the level of energy, the commitment, and the cooperation. Even with a blizzard outside, there wasn't anything going on inside that would indicate people were doing anything but focusing on patients," Gormley said.

Clinical Research Training Program fellow Zachary Dezman skied to campus from his nearby home to support the other side of patient care—medical research. "I work

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Executive coaching program shines Clinical Center gems

Even the best can do better, and an innovative addition to the Clinical Center talent development strategy has shown as much with positive reports from clients and their co-workers, as well as concrete pay-offs.

The now award-winning CC Executive Coaching and Leadership Development Program reinforces current leaders and fosters the next generation through one-on-one coaching sessions to help staff create and implement achievable plans that will move them closer to their goals. Coaches observe an executive's behavior, recommend development plans and strategies, and evaluate progress.

Dr. Deborah Gardner, former chief of the Office of Organizational Development (OOD), spearheaded the program's integration into the CC leadership development model in 2005. "People are smart; people want to be respected," she said. "We need to see people on a learning curve—not that it isn't safe to make mistakes, but how do you learn from those mistakes? A coach really handles people differently."

Gardner accepted the International Coach Federation Metro DC Chapter's 2009 Prism Award for excellence in leadership coaching initiatives at a luncheon on February 12. The annual award highlights the impact of coaching on business results and employee performance. All eight of the coaches the CC program uses are certified by the International Coach Federation.

The leadership development program at the CC targets the 120 midto senior level managers—of which 35 percent have so far participated—and addresses workforce issues of succession planning, retention of high performers, and appreciation for the science of leadership.

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Art therapy products displayed in NIH Visitor Center





A new display in the NIH Visitor Center and Nobel Laureate Exhibit Hall in the Natcher Building spotlights Clinical Center partners in research the patients. Tiles from "The Art of Healing" art therapy project out of the CC Rehabilitation Medicine Department Recreation Therapy Section and the CC Art Program were installed in late February.

The project was conducted in the summer of 2008 and invited patients and their family members to decorate tiles to express their experiences through illness and treatment using mixed media like copper cut-out shapes, game pieces with letters, paint, and a texturized modeling paste. "The artwork demonstrates the CC's commitment to supporting our patients, by recognizing the integral role of our volunteer patients," said art therapist Megan Robb.

Some of the tiles are presented in the "Hope Flows from One to Another" display on the Hatfield Building's seventh floor. Another collection now in the Visitor Center and Nobel Laureate Exhibit Hall brings the art tiles to the other side of campus, injecting some color to the first stop for visiting tour groups and professionals. Next to the wall of NIH Nobel Prize laureates, the patient artwork completes a representation of translational research.

"We so appreciate the addition of this patientfocused exhibit. It adds a wonderful dimension and balance to the other displays in the exhibit hall that focus on the importance of researchers as mentors," said Visitor Center and Nobel Laureate Exhibit Hall director Jennifer Gorman (at right in photo with coworker Tara Mowery). "The patient tiles bring the human story of research to the audience. They literally jump off the wall and say to the viewer that research and discovery is about life."

The art selection and arrangement of the work, with identifiable themes at eye-level, particularly appeals to middle-school age groups who participate in programs at the NIH, Gorman said, though any kid at heart should be drawn to the tiles.

The Visitor Center plans to continue enhancing the Nobel Laureate Hall's aesthetic with interactive consoles where visitors can hear stories of discoveries from the researchers who made them and experience virtual tours and science that highlight the NIH. To learn more or request a tour, visit http://www.nih.gov/icd/od/ocpl/VIC/index.htm.

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www.cc.nih.gov/about/news/newsletter.html

Maggie McGuire, editor

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photos are welcome.

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Volunteering gives future doctor IRTAs all-around experience

A certain breed of Clinical Center volunteers is getting more than they expected out of their time donated.

Post-baccalaureate Intramural Training Research Award fellows (post-bac IRTAs to NIH insiders) spend a year or two at NIH between their undergraduate studies and pursuit of an advanced degree. For those with plans to apply to medical school, the CC Volunteer Program offers patient care-experience—a great resume builder. The IRTAs gain more than a bullet point on an application, though, said program coordinator Courtney Duncan. Volunteering in patient-care areas supplements IRTAs laboratory or administrative assignments to humanize translational research and develop skills not found in a textbook.

"I think one of the most important parts of being a doctor, no matter your specialty, is knowing how to communicate," said Nizar Dowla, a fellow with the CC Rehabilitation Medicine Department (RMD) who plans to pursue a career in pediatrics. Dowla spends two hours a week in the Rehabilitation Medicine Department Recreation Therapy Section Main Playroom serving as a normalizing factor to kids who are suffering or have a loved one suffering. "They inherently know they're different," he said. "I act as a buffer, to let them know that it's ok to be different and that they can still be a kid."

Last year the volunteer program was restructured to focus more on the needs of the CC versus the needs of the potential volunteer. In the past, applicants would name their area of interest and the program would seek out positions. Now the program identifies areas of need, writes up specific position descriptions with the help of staff, and matches applicant skills and personality. "Volunteer programs are never successful if one need outweighs the other," Duncan said. "There has to be a balance in order for the individual and the organization to benefit.'

The two main areas of placement for IRTAs are recreation therapy jobs like supervised assistance in the playroom and patient ambassador roles, such as transporting patients to appointments. In radiology, volunteers may help patients navigate the CT scan process—drinking contrast, changing clothes, waiting for a technician—or wait with family members while tests are done. These efforts



IRTA fellow Nizar Dowla (second from right) supplements his training with patient interaction through Thomas and patient family members mom Reva and daughter Ariana Tagoloa.

tie into the CC's service excellence and customer service initiatives.

Fitting the required minimum (two hours a week for recreation therapy, four for patient ambassadors) of a volunteer position in with IRTA requirements takes the cooperation of a fellow's principal investigator (all of whom have been very amenable, Duncan said) and the dedication of the future doctor. Patient ambassador roles may be easier on an IRTA schedule, with early shifts before laboratory hours begin.

Jonathon Buggey managed two volunteer jobs—one in the playroom and one as a patient ambassador in the Department of Anesthesia and Surgical Services, where he learned the inner workings of a surgery department and saw "firsthand the teamwork aspect of medicine."

The volunteer experience offers direct contact with patients and their families helping to develop or enhance communication, compassion, and empathy. These acquired skills, often referred to as bedside manner, have been a particular focus of medical schools recently, said Recreation Therapy Section Chief Donna Gregory.

She has seen patients directly connect with IRTA volunteers, some children even rearranging their schedules to see their favorite buddy. For children and teens who have spent an extended period of time in

treatment away from others their age, Gregory said, the IRTAs serve as a peer or role model. "It's a real win-win—helping them with their career path and helping patients."

The international patient population of the CC exposes fellows to a unique constituency. Former IRTA Tess Crouss met patients and their families from around the world when volunteering at the popular Recreation Therapy Section's weekly bingo night.

"I took my access to quality medical treatment for granted. Knowing that so many families travel to the NIH with such optimism and grace has inspired me to use my education to serve people in other countries," wrote in her medical school application essay. She is now pursuing her doctorate in London.

"If you want to be a doctor, you can do the job. But, in order to be a good doctor, you need to understand the experience of being a patient" said Duncan.

The lessons extend to those getting a head start on their pursuit of a career in medicine. Volunteer opportunities are open to college students, as well. Anyone interested in applying to the program should visit www.cc.nih.gov/ volunteers.

Local music students play for Clinical Center audience

Students of Dr. Bella E. Oster (at left in photo), professor of piano performance at the European Academy of Music and Art, Inc., performed a concert on the CC's Steinway grand piano in the Hatfield Building's atrium on February 4.

The students ranged in age from 6 to 14 with anywhere from one to 10 years of experience—front row (from left): Kyra Du, Maggie Yin, Laura Meng, Olivia Wang, Grace Yetter; second row: Stacy Chen, Renee Tung, Kevin Huang, Alisa Yan, Ivy Liu; third row: Joe Wan, Eva Nesterenko.



Executive coaching program prepares and reinforces leaders

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"Executive coaching was invaluable for recognizing my managerial strengths and weaknesses and for developing a practical plan to improve in several important areas," said Critical Care Medicine Department Chief Dr. Henry Masur, who participated in the 2009 coaching cycle. "The coach had extensive experience in strengthening general areas and in solving very specific and concrete problems. I should have done this years ago!"

The CC executive team makes recommendations of coaching candidates to CC Director Dr. John I. Gallin, who chooses whom the coveted spots go to. Two years after the program began, coaching cycles were expanded to include mid-level managers, who must be nominated by their department heads and meet training criteria. The coaching program is a reward for those demonstrating consistent commitment, effective productivity, and capability for greater responsibilities. It is also used as a recruitment tool to attract new talent and ease the transition to the unique CC environment.

When chosen, staff interview coaches to find a good fit—someone with the same leadership philosophy and pace of change that the executive subscribes

to. OOD uses only coaches with an advanced degree, experience in an executive position, and knowledge of the federal government. All are educated on the CC mission and the CC's strategic plan in an orientation every coach attends each year to hear updates and new priorities.

A "360" interview for each client asks two subordinates, two peers, and one or two superiors about the participant's strengths and weaknesses. A manager or sponsor weighs in on goals and expected outcomes, and from there the coach meets with the employee over six months for at least four hours a month to explore thinking and behavior patterns, create strategies, and practice new behaviors.

The increase to eight from the original five coaches is evidence of the program's success. Another instrument of measurement is surveys of clients for quantitative and qualitative assessment and their manager/sponsor for coaching's impact and value on reports. "Staff experience the coaching program as a morale boost and a statement of investment in the person," one manager wrote in his evaluation.

Awards and promotions for those who have completed the CC Executive Coaching and Leadership Development Program—including two internal candidates chosen for department leadership roles after nation-wide searches—also speak to its power.

Coaches are also asked to provide feedback regarding the support offered at the CC for leadership development. To continue the work they've done, each coach sponsors a monthly roundtable inviting graduates of the program to check in and share lessons learned and best practices with their peers.

The Office of Organizational Development is planning a one-day on-the-spot coaching session offered to all managers and supervisors to spread the reach of the program. "We live in such a 'do' society with not enough reflection allowed. Good leadership also requires reflection," said Gardner.

Editor's note: The CC said goodbye to Gardner on February 19. After ten years at the CC, she left to accept a new position as a senior advisor at the Health Resources and Services Administration (HRSA), the primary federal agency for improving access to health-care services for people who are uninsured, isolated, or medically vulnerable. The HRSA grantees provide health care to uninsured people, people living with HIV/AIDS, and pregnant women, mothers, and children. They train health professionals and improve systems of care in rural communities.

Endometriosis survey data gives insight on co-occurring disease

A study in Fertility and Sterility co-authored by NIH clinician-scientists reported new findings on endometriosis. The paper "Cancers, infections, and endocrine diseases in women with endometriosis" has ramifications for care of this patient population and the advancement of related research, said co-author Dr. Ninet Sinaii of the Biostatistics and Clinical Epidemiology Service in the Clinical Center Office of the Deputy Director for Clinical Care.

Sinaii began analysis of an Endometriosis Association survey during her doctorate work with the National Institute of Child Health and Human Development and continued her series of papers when she transferred to the CC in 2006. The 1998 survey covered an array of topics to capture the broad scope of living with endometriosis, a condition where tissue that usually grows inside the uterus shows up elsewhere like the surface of organs in the pelvis or abdomen. Scientists believe the number of women living with endometriosis—said to be between 10 to 15 percent of reproductive-age females—may be underestimated, Sinaii said.

In addition to the symptoms of long-lasting chronic pain and high rates of infertility directly attributed to endometriosis, sufferers also have to deal with commonly co-occurring afflictions, the Endometriosis Association survey showed.

"Overall, 2,859 (66.0%) women selfreporting surgical diagnosis of endometriosis also reported physician diagnosis of at least one other condition," the authors of the Fertility and Sterility paper wrote. Most common among responders were infectious diseases—recurrent upper respiratory infections and recurrent vaginal infections—but melanoma and ovarian cancers were also noted as "more common in the study population than in similarly aged women in the general population."

"It's kind of like a chicken and the egg situation," Sinaii said. "While we believe that women with endometriosis may have an altered immune system, we don't know if a compromised immune system causes endometriosis or if endometriosis causes a compromised immune system."

The survey results will inform physicians and patients of possible coexisting conditions after diagnosis of endometriosis, Sinaii said. The findings may also stimulate further studies into the experience of the disease.

"This survey data related to other clinical observations is what helps shape translational research," said Dr. Pamela Stratton, chief of the Gynecology Consult Service in the NICHD Program in Reproductive and Adult Endocrinology and second author on the Fertility and Sterility paper.

While there is no cure for endometriosis, research into better treatments and strategies to prevent reoccurrence of symptoms and disease is strong. Stratton is examining the after effects of endometriosis, such as chronic fatigue and heightened sensitivity to pain, and exploring promising recent research involving endometrial stem cells for its possible link to the central nervous system.

Snowpocalypse slams the region

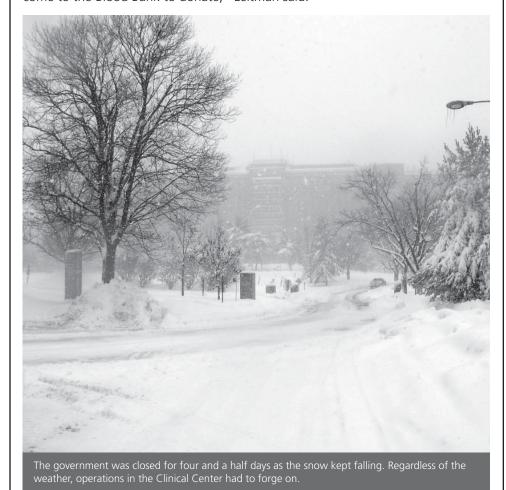
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in Dr. Robert Star's lab at the NIDDK, and I want to make the most of my limited time here. I couldn't afford to lose data from some of our ongoing experiments," Dezman said. "Besides, it was a fun excuse to break out my cross-country skis."

Another way staff showed commitment was by rising to the challenge of blood shortage. Without outside donors traveling to the NIH Blood Bank in the CC, the Department of Transfusion Medicine had a dire need for platelets and red cells.

The patients of the CC are unique in that most are on scheduled treatments that can't take a break for the weather, such as chemotherapies and bone marrow transplants, said DTM Blood Services Section Chief Dr. Susan Leitman.

Staff filled the void made by appointment cancellations due to the snowstorm. "They will make the time, even though they're tired and not in the best mood to come to the Blood Bank to donate," Leitman said.



Researchers link gene mutations to stuttering

A trans-NIH study has identified three genes responsible for stuttering in its patient sample, a discovery that opens the door to new potential treatments for the speech disorder.

Led by the National Institute on Deafness and Other Communication Disorders with Clinical Center and National Human Genome Research Institute contributors, the study found that stut-

tering may be the result of a glitch in the process by which cellular components in key regions of the brain are broken down and recycled.

"For hundreds of years, the cause of stuttering has remained a mystery for researchers and practitioners alike," said Dr. James F. Battey, Jr., NIDCD director. "This is the first study to pinpoint specific gene mutations as the potential cause of stuttering, a disorder that affects three million Americans, and by doing so, could dramatically expand our options for treatment."

Stuttering is a speech disorder in which a person repeats or prolongs sounds, syllables, or words, disrupting the normal flow of speech. The condition tends to run in families, and researchers have long suspected a genetic component.

The NIDCD study grew from previous research by Dr. Dennis Drayna, a geneticist with the institute, which indicated a place on chromosome 12 that was likely to harbor a gene variant that caused stuttering in a group of families from Pakistan. Dr. Drayna and his team then refined the location of interest on chromosome 12 and identified mutations in a gene known as GNPTAB, which helps encode an enzyme that assists in breaking down and recycling cellular components, a process that takes place inside a cell structure called the lysosome.

GNPTAB encodes its enzyme with the help of another gene called GNPTG. In addition, a second enzyme, called NAGPA, acts at the next step in this process and together, these enzymes make up the signaling mechanism that cells use to steer a variety of enzymes to the lysosome to do their work. Because of the close relationship among the three genes in this process, the GNPTG and NAGPA genes were the next logical place for the researchers to look for

possible mutations in people who stutter. Indeed, when they examined these two genes, they found mutations in individuals who stutter, but not in control groups.

The new study involved patients from Pakistan, the United States, and England. Dr. Penelope Friedman of the CC Internal Medicine Consult Service and Dr. Donna Krasnewich, assistant clinical director of the NHGRI went through a medical his-

for This ... could dramatically expand our options for treatment.

- Dr. James F. Battey, Jr., NIDCD director

tory and physical examination with each patient seen in the CC to investigate if stuttering occurs in tandem with other abnormalities classically associated with severe mutations in these genes. They did not find evidence of such symptoms in the individuals who stutter. Their initial work is a fundamental step in identifying where to look in a patient's DNA and in maintaining the validity of the research, Friedman said.

The findings open new doors into possible treatments for stuttering. "Stuttering has been thought of as a behavioral

problem," Friedman said. Current therapies have focused reducing anxiety and regulating breathing and rate of speech. Drayna is interested in bringing the study and treatment of this condition into the world of medicine. An exciting future possibility may be offering enzyme replacement therapy as a potential treatment, as is used for some lysosomal storage disorders.

The researchers estimate that roughly 9 percent of people who stutter possess mutations in one of the three genes—a lot for such a complex disorder, Friedman said. Among the next steps, Drayna and his team are conducting a worldwide epidemiological study to better determine the percentage of people who carry one or more of these mutations. They are also conducting biochemical studies to determine specifically how the mutations affect the enzymes. A long-term goal is to use these findings to determine how this metabolic defect affects structures within the brain that are essential for fluent speech.

In addition to the NIH partners, researchers at the University of Punjab, Lahore, Pakistan and the Hollins Communications Research Institute, Roanoke, Va. contributed to this work.



CC earns CFC President's Award

Clinical Center Combined Federal Campaign (CFC) coordinators accepted the CFC President Award, denoting at least 75 percent employee participation or an average gift of \$275 or more, for the center's 2009 campaign. Celebrating with some whimsy eyewear were (from left) Angela Walker, Rebekah Geiger, Rachael Schacherer, Lisa Ruprecht, Maggie McGuire, and Debra Byram. CIT Acting Director Dr. Jack Jones (left) and NIH Director Dr. Francis Collins presented the team with the campaign's highest honor.



New corridor streamlines building transition

After more than a year of detours and construction, a new main corridor from the Clinical Center south entrance to the Hatfield Building makes navigating the hospital easier. Additionally, the updated Phlebotomy and EKG Heart Station units (two of the CC's most frequented patient-care areas) enjoy a larger, brighter waiting area.

Plans for the renovation began in 1996 and the construction company provided excellent quality control to bring the project to fruition, said project officer Gias Ahmad of the NIH Office of Research Facilities. "This has been a dream for a lot of people," he said.

NIH joins FDA to accelerate move from discovery to therapy

The announcement of an initiative to carry therapies from the "microscope to the marketplace" sooner and safer brought NIH Director Dr. Francis Collins, Department of Health and Human Services Secretary Kathleen Sebelius, and Food and Drug Administration Commissioner Dr. Margaret Hamburg to the Clinical Center on February 24.

"Today we're very excited to announce a new partnership with the goal of developing more lifesaving cures and getting them to Americans faster." Sebelius told the stakeholders and members of the press present gathered in Lipsett Amphitheater to hear details of the new initiative.

The new collaboration will unite NIH expertise in translational research bringing scientific breakthroughs from the bench to the bedside—and FDA focus on regulatory science—development of strategies to effectively and efficiently evaluate therapeutics. A Joint NIH-FDA Leadership Council will work to ensure that regulatory considerations

form an integral part of biomedical research planning, and that the latest science is integrated into the regulatory review process.

Six top scientists from each agency will serve on the council, but they have not been identified yet, nor has an agenda been set. First, Collins said, they must identify the problems to be addressed. A meeting to hear public comment is planned for the spring.

"The need for such enhanced collaboration has never been more pressing. The new scientific opportunities we see in front of us pose the possibilities of truly novel therapeutic developments but there are challenges to the way in which those are implemented," said Collins. Referenced areas of concern include the sample size of rare disease trials and the review process of combination trials (such as varied treatment for cancer).

A request for applications was posted in conjunction with the initiative announcement for research that hopefully will provide new methods, models, and technologies to inform the scientific and regulatory community about better approaches to evaluating safety and efficacy in medical product development.

The first direct investment in regulatory science will issue \$6.75 million in three or four (depending on size) threeyear grants.

An advocate stakeholder in the audience inquired about the potential benefit from NIH training mechanisms. With no current charted pathway to a career in regulatory science, the leadership council may seek to encourage one in the next generation, Collins said. He also answered in response to a question on continued public involvement that the public meeting is "not a one-shot deal."

To view a videocast of the announcement and learn more about regulatory science, visit www.fda.gov/ScienceResearch/SpecialTopics/RegulatoryScience/ default.htm.

Upcoming Lectures

All will be videocast at http://videocast.nih.gov.

CC Grand Rounds

Lipsett Amphitheater, 12 noon

March 3, 2010

How to Publish Without Perishing: Navigating the Biomedical Publication Process

Cynthia E. Dunbar, MD Head, Molecular Hematopoiesis Section, Hematology Branch, NHLBI

Pathogen Inactivation of Blood Components

Harvey G. Klein, MD, Chief, Department of Transfusion Medicine, CC

March 10, 2010

Contemporary Clinical Medicine: Great Teachers Vitamin D, Cardiovascular Disease, and Cancer: Emerging Evidence

JoAnn E. Manson, MD, DrPH Chief, Division of Preventive Medicine, and Co-Director, Connors Center for Women's Health and Gender Biology, Brigham and Women's Hospital Professor of Medicine and Elizabeth Fay Brigham Professor of Women's Health, Harvard Medical School

March 17, 2010

Therapeutic Gene Delivery Using Hematopoietic Stem Cells in Sickle Cell Disease

John F. Tisdale, MD Senior Investigator, Molecular and Clinical Hematology Branch, NHLBI

Multiple Myeloma and Its Precursor (MGUS): Looking into the Future

Ola Landgren, MD, PhD Investigator, Medical Oncology Branch, Center for Cancer Research, NCI

March 24, 2010 **Updates in Endocrinology 2010**

Monica C. Skarulis, MD Chief, Clinical Endocrine Section, Clinical Endocrinology Branch, NIDDK

Lynnette Nieman, MD Senior Investigator, Intramural Research Program on Reproductive and Adult Endocrinology, NICHD

March 31, 2010 **Ankylosing Spondylitis**

Robert A. Colbert, MD, PhD Chief, Pediatric Translational Research Branch, NIAMS

Treatment of Autoantibody-Receptor Disease: The Story of Type B Insulin Resistance

Rana Malek, MD Staff Clinician, Diabetes Branch, NIDDK

Wednesday Afternoon Lecture Series

Masur Auditorium, 3 pm

March 3, 2010 The Paradox of Immunity

Jeffery Ravetch, MD, PhD

Theresa and Eugene Lang Professor, The Rockefeller University; and Head, Leonard Wagner Laboratory of Molecular Genetics and Immunology

March 10, 2010 Dynamics of PKA Signaling

Susan Taylor, PhD

Professor of Chemistry and Biochemistry, and Pharmacology, University of California, San Diego; and **HHMI** Investigator

March 11, 2010: Special Thursday Lecture Mouse Models of Human Disease: From Cancer to Neuropsychiatric Disorders

Mario Capecchi, PhD Co-chairman, Department of Human Genetics, University of Utah School of Medicine

March 17, 2010 Memory and the Aging Brain

Carol Barnes, PhD

Regents' Professor of Psychology and Neurology, and Evelyn F. McKnight Chair for Learning and Memory in Aging, University of Arizona

March 18, 2010: Special Thursday Lecture Closing the Implementation Gap to Stop HIV/AIDS

Julio Montaner, MD

Director, British Columbia Centre for Excellence in **HIV/AIDS**

March 24. 2010

Role of Regulatory T Cells in Tolerance: Implication in Human Diseases

Maria Grazia Roncarolo, MD Scientific Director, San Raffaele Scientific Institute; and Professor of Pediatrics, School of Medicine and Surgery at San Raffaele Vita-Salute University

March 31, 2010

Genomic Variation and the Inherited Basis of Common Disease

David Altshuler, MD, PhD, Professor of Genetics and Medicine, Harvard Medical School and Massachusetts General Hospital; and Director, Program in Medical and Population Genetics, Broad Institute

Recruiting Trials

For more information on any of the following clinical trials or on possible others with the same condition focus, call 1-866-444-2214 (TTY: 1-866-411-1010) or visit www.clinicaltrials.gov and refer to the provided study code.

Autism 09-CH-0203

Does your child have an autistic disorder or Asperger syndrome? Physicians at the National Institute of Child Health and Human Development are conducting a study to learn more about the role cholesterol plays in autism spectrum disorders.

Children age 4 to 11 with a diagnosis of autistic disorder, Asperger syndrome, or pervasive developmental disorder not otherwise specified may qualify to participate in this study.

All study-related tests and treatments are provided at no cost. Compensation is provided. Parental permission is required.

Diet-Induced-Obesity in Human Phenotypes 09-DK-0238

Healthy volunteers are needed for a study investigating the reasons why some individuals maintain their weight. The study looks at the response to different diets in relation to the subject's metabolism.

Consider participating in this study if you are between 30 and 50 years of age, have a body mass index between 18.5 and 23.0, and have a stable weight (less than 2 percent change in the last six months).

All study-related tests and meals are provided at no cost. Compensation is provided.

Rituximab Plus Cyclosporine in **Idiopathic Membranous** Nephropathy 09-DK-0223

Individuals with idiopathic membranous nephropathy (a form of kidney disease) are needed for a National Institute of Diabetes and Digestive and Kidney Diseases clinical research study to evaluate the safety and effectiveness of a combination of rituximab and cyclosporine medications.

Applicants must be 18 years of age or older. There is no cost for study-related medications or tests, and transportation assistance may be provided.