November 2013 ACTS Connection

ACTS Leadership Profile: Roy Weiner, MD - Vice President of Patient Oriented Research

Dr. Roy Weiner is professor of medicine (hematology and medical oncology), pediatrics, and epidemiology, the associate dean for clinical research and training at Tulane University School of Medicine, and the associate director for clinical research at the Tulane Cancer Center and Louisiana Cancer Research Consortium. Dr. Weiner has been active in translational research throughout his career, focusing initially on methods for cryopreserving human mononuclear cells for preservation of function in the late 1960’s and subsequently studying the use of cryopreserved stem cells to reconstitute patients after ablative cytotoxic chemotherapy. He has sustained his clinical research activity in funded early drug development, as the director of Tulane’s K30 program, and now through the career development core of Tulane’s IDEA Grant with LSU and Pennington Biomedical Research Center. Dr. Weiner was a member and the president of the Association for Patient Oriented Research during the merger of APOR, ACRT, and SCTS to form ACTS and, as a vice-president, chairs the Patient Oriented Research (POR) Committee of ACTS. He also serves on the task force developing the bylaws and policies for ACTS.

With his leadership, the POR Committee promotes research conducted with human subjects spanning the spectrum, including elucidation of normal and altered physiology, pharmacokinetics, early clinical trials, comparative studies, and studies leading to improved standard of care. The POR Committee will be involved in identifying, fostering, and teaching best practices in human investigation and in the protection of human subjects. The committee will have close ties to the ACTS committees responsible for training and mentorship, as well as the committee responsible for adoption and outcomes. Placed as it is toward the research side of the translational continuum, the POR committee has enormous opportunity to interact productively with all subspecialty groups and with patient-based disease advocates, as well as with ‘pharma’ and all NIH administrative units. There is also great potential to develop a productive relationship with AAMC GRAND and bridge the common interests of American medical academia and clinical and translational research.

The POR Committee is actively seeking members from the broad spectrum of interested professionals from academia, government, and ‘pharma’. Independent investigators, members of multidisciplinary research teams, developing investigators, mentors, and administrators are all welcome to participate in the committee to promote and guide the course of research involving patients. Interested ACTS members should contact Dr. Weiner to express interest at this early stage, when each member can have a meaningful impact on the committee’s agenda.

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News from ACTS

Submit an Abstract for Translational Science 2014 Meeting

The Translational Science 2014 Program Committee encourages young investigators and their mentors from all over the country to join us for the Translational Science 2014 Meeting on April 9-11, 2014 at the Omni Shoreham Hotel in Washington, DC. Furthermore, we are seeking abstracts submissions of research to be presented in a poster session or in an oral presentation featuring the highest ranking abstracts. Translational Science programs, members Meeting as your most prestigious opportunity organizations.

Submit your abstract before January 29, 2014.

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Washington Update

In October, the federal government experienced a 16 day shut down after Congressional leaders failed to reach an agreement regarding proposals to delay, defund, or reform the Affordable Care Act (healthcare reform). These proposals were attached to must-pass legislation providing temporary funding to all federal programs and also raising the country’s debt ceiling. While the shutdown was short-lived, the disruption has resonated within our nation’s medical research infrastructure. Intramural research projects at the National Institutes of Health (NIH) were put on hold and NIH’s ability to provide extramural funding, including research training and career development grants, also ceased. NIH recently released guidance showing applicants how to "refresh" grant applications and attempting to reschedule many review group meetings for later in the year.

Ultimately, legislation was passed and signed by President Obama to re-open the government, including a funding resolution to keep federal programs operating at their FY 2013 levels through January and language to raise the federal debt ceiling until February. This package also calls for a bipartisan, bicameral Committee to work on reconciling the Republican House budget and the Democratic Senate budget into a final, compromise budget.

The automatic, indiscriminate funding cuts known as sequestration are becoming increasingly unpopular on Capitol Hill as their impact is felt across the country. With another round of sequester cuts scheduled to take place in January, there is hope among medical research advocates that lawmakers will use the budget committee as an opportunity to mitigate or reverse sequestration. NIH and many other medical research programs will face a 2% sequester cut next year, but there is hope that such a cut can be cancelled and additional funding for clinical and translational research activities can be provided when lawmakers complete work on FY 2014 appropriations.

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Share Your Passion, Share Your Experience: Become Involved in ACTS!

Involvement in ACTS is an ideal way to advance your profession while continuing to expand the clinical and translational science field. ACTS volunteers provide the unique opportunity to influence the direction and future of our organization.

The ACTS Board of Directors is currently seeking qualified candidates to fill three Director-at-Large positions. All members in good standing are eligible to nominate themselves or others for this position. If you would like to serve as a Director-at-Large or recommend someone else for the position, please visit ACTS's Nomination webpage to fill out a nomination form by January 6, 2014.

ACTS is also seeking volunteers to serve on our many committees. Visit our volunteer webpage for more information on the committees and to indicate your interest in a committee position.

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The ACTS Connection Editors Want Your Feedback

ACTS Connection Editor, Dr. Satish R. Raj, MD, MSCi, and Associate Editor, Dr. Quinn Wells, MD, PharmD, MSCi, are interested in hearing about ways that ACTS Connection could provide even more value to our readers.

Please feel free to email Dr. Raj or Dr. Wells with your comments or suggestions
Translational Science News

NIH Announces 15 Clinical and Translational Science Awards to Help Translate Scientific Discoveries to Improved Health

The National Institutes of Health (NIH) has announced more than $79 million in fiscal year 2013 funding to support 15 Institutional Clinical and Translational Science Awards (CTSA). The CTSA program is led by the National Center for Advancing Translational Sciences (NCATS) and aims to accelerate improvements across the entire spectrum of translational research. “The CTSA Consortium is leading national efforts to enhance the efficiency, quality, and safety of translational research, no matter the disease or condition,” said NCATS Director Christopher P. Austin. “This aligns with the NCATS mission to create new technologies and methods that can be applied widely to streamline development and implementation of interventions that improve human health.” The 2013 awards broaden the network to 31 states and the District of Columbia. The institutions receiving five-year awards are the Albert Einstein College of Medicine, Dartmouth College, Duke University, Harvard Medical School, Indiana University, Johns Hopkins University, Ohio State University, Scripps Research Institute, Stanford University, Tufts University, University of Colorado, University of North Carolina at Chapel Hill, University of Texas Health Science Center, University of Texas Southwestern Medical Center, and University of Utah.

From "NIH Announces 15 Clinical and Translational Science Awards to Help Translate Scientific Discoveries to Improved Health" NIH News (10/22/13)

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FDA Awards More Than a Dozen Grants for Rare Disease Research

The Food and Drug Administration (FDA) recently awarded 15 grants totaling more than $14 million to encourage the development of products for patients with rare diseases. The grants include funding for research into potential drugs for Stargardt disease, Fanconi anemia, Wiskott-Aldrich syndrome, and sickle-cell anemia. “The FDA is committed to fostering and encouraging the development of products for rare diseases, most of which have no available or adequate treatments,” FDA Office of Orphan Product Development director Gayatri Rao said. “The grants awarded this year support studies in very vulnerable, difficult-to-treat populations who have no available options.”

From "FDA Awards More Than a Dozen Grants for Rare Disease Research" Drug Store News (10/21/13) Dearment, Alaric

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Cancer Research Needs More Support

The American Association for Cancer Research (AACR) Cancer Progress Report 2013 addresses the need for funding for the National Institutes of Health (NIH) and the National Cancer Institute (NCI) as a national priority. The report examines how scientific discoveries enabled by federal investments in basic, translational, and clinical research are transforming cancer care. For instance, new therapies that leverage a patient’s immune system to treat cancer would not have been realized without basic research in immunology. The report also notes that drugs originally developed for cancer patients have led to treatments for such conditions as macular degeneration, atherosclerosis, psoriasis, rheumatoid arthritis, and hepatitis. Such relationships between certain diseases emphasize the need for scientists, patients, and advocates to call for sustainable research funding. Direct budget cuts in March 2013 due to sequestration caused the NCI to experience a cut of $293 million, while the NIH is funding the lowest number of research projects since 2001. Unless Congress intervenes, sequestration will result in an overall reduction to the NIH budget of $19 billion by 2021.

From "Cancer Research Needs More Support" Laboratory Equipment (10/13)

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Universities Stepping Up Efforts to Discover Drugs

Many pharmaceutical companies—including Merck, Pfizer, Lilly, and AstraZeneca—are downsizing their internal R&D operations amid decreasing sales due to patent expirations. These companies hope to curb costs through increased efficiencies and scaled down R&D programs, but they also need to bring in new drug candidates externally. This is prompting universities to broaden their drug discovery research efforts. To this end, more than 80 academic institutions are part of the Academic Drug Discovery Consortium (ADDC), which encourages the exchange of knowledge and expertise among centers as well as the partnering of service providers, biopharma companies, and the National Institutes of Health. One reason university presidents are focusing on drug discovery is the potential to secure royalty streams that emerge from collaborations between pharmaceutical companies and professors. The lung cancer drug Alimta, for example, came from the lab of Professor Edward C. Taylor at Princeton in collaboration with Lilly, allowing Princeton to receive $524 million in royalties from 2005 to 2012 from sales of the drug. Vanderbilt’s Center for Neuroscience Drug Discovery (VCNDD) comprises 100 scientists working in four areas: medicinal chemistry, molecular pharmacology, drug metabolism/pharmacokinetics, and behavioral pharmacology. The VCNDD has been able to attract funding from a variety of sources, including the National Institute of Mental Health, the National Institute of Drug Abuse, the Michael J. Fox Foundation, AstraZeneca, and Bristol-Myers Squibb.

From "Universities Stepping Up Efforts to Discover Drugs" Forbes (10/21/13) LaMattina, John

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U.S. Federal Government Shutdown Ends, Scientists Head Back to Work

The legislation President Obama signed in October to end the partial shutdown of the U.S. government sets spending at an annualized level of about $966 billion. The deal will allow the National Institutes of Health (NIH) and the National Science Foundation to resume processing grant applications that had been stalled during the 16-day layoff as well as accept new applications. Scientists will now be able to enroll patients in biomedical trials and studies at NIH’s clinical research center. However, National Cancer Institute (NCI) Director Harold Varmus warned in an Oct. 11 memo that the resumption of research could be challenging. "(A)vailing a major crisis in grant-
making and program development this year may be possible only if all members of the NCI communities are willing to help alleviate the consequences of the shutdown," he wrote. NCI has had to postpone "several site visits to evaluate re-competing centers and large grant applications, and it has postponed more than a dozen meetings to review grant applications. Thus, the NCI's grant review cycle could be significantly delayed, threatening a smooth restart of NCI's support of extramural research, even if the NIH reopens relatively soon." Meanwhile, research agencies might not know their final 2014 spending levels for many months, compelling them to spend conservatively.

From "U.S. Shutdown Ends, Scientists Head Back to Work" Science (10/17/13) Mataloff, David

'Researcher Speed Dating' at Tufts Helps Lab Scientists, Doctors, Academics Forge Partnerships

The Tufts Clinical and Translational Science Institute is encouraging greater interaction between physicians, academics, and lab scientists by hosting "researcher speed dating" events. During these events, participants look for ideal research partners. Some researchers display posters describing who they are, their project ideas, and the kind of collaborator they require. "We organized this event to foster collaborations that can help speed up the process of taking something from an idea for research to a pill or a medicine or something that can improve public health," says Amy West, a Tufts spokeswoman. Ivette Emery, a translational research scientist at Maine Medical Center, found a potential match in Graham B. Jones, professor and chair of the chemistry and chemical biology department at Northeastern. Emery and Jones work at different levels of a four-stage scale used to assess the varying phases of research. Tufts and other research institutions also have established Facebook-like online portals that researchers can search to see what other researchers are working on and contact one another. Tufts' Web-based portal, called Profiles, was launched in February, and officials hope it will eventually lead to new research and discoveries that might not have occurred otherwise.

From "'Researcher Speed Dating' at Tufts Helps Lab Scientists, Doctors, Academics Forge Partnerships" Boston.com (10/10/2013) Rochelleau, Matt

U.S. Biopharma: 452 Drugs for Rare Diseases Now in R&D

More than 450 new drugs for the treatment of rare diseases are in development, according to new data from the Pharmaceutical Research and Manufacturers of America. The data shows that 452 medicines and vaccines are in human clinical trials or under review by the U.S. Food and Drug Administration (FDA). The total includes 105 drugs for cancer, 85 for genetic disorders, 65 for blood cancers, 32 for neurological disorders, 28 for infectious diseases, and 20 for respiratory conditions. The FDA says that about a third of all new drug approvals in the past five years have been for rare disease treatments.

From "U.S. Biopharma: 452 Drugs for Rare Diseases Now in R&D" Pharma Times (10/09/13) Taylor, Lynne

Drug Repurposing: A Path to Faster Cures?

The cost of translating a new basic science discovery into a new drug typically exceeds $1 billion and on average takes 13 years to achieve, largely due to the need for comprehensive safety testing. A different approach is to start with a drug that has already been approved for the treatment of a disease or condition, and to use it to treat another disease. Such drug repurposing can significantly reduce the time and cost needed to bring a new treatment to market. The National Institutes of Health is a key advocate of this approach. For instance, University of Rochester researcher Damian Krysan has identified off-patent drugs that can kill the lethal fungal pathogen Cryptococcus neoformans. This could potentially lead to a new and affordable cure for an infection that takes the lives of up to 500,000 people annually in developing countries. Similarly, stem cell researcher Mark Noble has identified an existing drug that can eliminate the toxic effects of tamsulosin on central nervous system progenitor cells. This may eventually help prevent "chemo-brain," or the cognitive impairment experienced by many cancer patients as they undergo treatment. The area of drug repurposing is promising because of its potential to enable faster cures.

From "Drug Repurposing: A Path to Faster Cures?" Rochester Democrat & Chronicle (NY) (10/04/13) Dewhurst, Stephen

How Can Translational Researchers Face Down Funding and Reproducible Result Challenges?

A worldwide survey of 608 translational researchers found that insufficient funding is a key hurdle to commercializing their work. The survey, conducted online by the American Association for the Advancement of Science, involved a random sample of researchers who are employed by academic and nonprofit institutions in North America, Europe, Asia-Pacific, and Australia. The researchers included graduate students (23 percent) followed by post-doc (19 percent), all levels of professors (17 percent), principal investigators (17 percent), and researchers and staff scientists (14 percent). Sixty-two percent of participants cited insufficient funding as the most significant barrier to progress in translational research, followed by lack of interdisciplinary training (33 percent) and an unclear path to creating successful commercial partnerships (33 percent). "Scientists may need to be more agile in the way they seek funding. This also presents new challenges as the demands for NIH grants and long-term pharmaceutical company interests are not the same," the report stated. To make sure their research was perceived as reproducible, the researchers said they were willing to have another lab reproduce findings, obtain outside expert statistical analysis, perform rigorous quality controls, including repeats, ensure thorough documentation, follow Good Laboratory Practices, use standardized or validated reagents, and increase sample size. "With increasing concern over reproducibility and budgets squandered on unverifiable science, the National Institutes of Health may soon require researchers to validate the results and protocols in grant applications," the report said.

From "How Can Translational Researchers Face Down Funding and Reproducible Result Challenges?" MedCity News (10/02/13) Baum, Stephanie
Five CTSAs Enable NIH-Funded Research on Innovative Allergy Therapy

Peanut allergies affect roughly three in every 500 Americans and cause more than half of all deaths from food-related allergic reactions. The Consortium of Food Allergy Research (CoFAR), a group of scientists from five institutions that receive National Institutes of Health funding, hopes to find a feasible treatment approach. Hugh A. Sampson at Mount Sinai Hospital's Icahn School of Medicine is leading the consortium, which is working with Clinical and Translational Science Award (CTSA) program experts in multisite clinical trials. The researchers hope to strengthen evidence for sublingual immunotherapy, which is already widely used and approved in Europe to treat environmental allergies. "The dedicated clinical resources provided by the CTSA sites make it feasible for studies like ours to advance, reducing the difficulties and delays common to multisite trials," says Marshall Plaut, CoFAR scientific and medical officer and chief of the National Institute of Allergy and Infectious Diseases' Food Allergy, Atopic Dermatitis and Allergic Mechanisms Section. The CTSAs also accelerate institutional review board approval, says David M. Flescher, co-leader of the peanut allergy study and a member of the University of Colorado Denver CTSA. "In this trial, the CTSA provided nursing staff, food preparation, equipment, and medications across all sites," Sampson says. CoFAR published its first multicenter, randomized clinical trial of sublingual immunotherapy for peanut allergy in January 2013. The group continues to collect data from this trial and is now recruiting participants for two new trials that will test other therapies.

From "Five CTSAs Enable NIH-Funded Research on Innovative Allergy Therapy" National Center for Advancing Translational Sciences (10/01/2013)

Grant Opportunities

Patient-Centered Outcomes Research for Treatment Options in Uterine Fibroids: Dev. a Prospective Multi-Center Practice-Based Clinical Registry

The Agency for Healthcare Research and Quality (AHRQ), in partnership with the Patient-Centered Outcomes Research Institute (PCORI), is offering funding for research into the relative effectiveness of treatment options for women of childbearing age with uterine fibroids. AHRQ and PCORI will fund one application that will include a Research and Data Coordinating Center to build a registry infrastructure that involves six to ten separate and geographically diverse clinical centers. Topic areas of particular interest include: comparisons of interventions to evaluate the relative effectiveness of available procedural or nonprocedural treatments including medical and complementary therapies for uterine fibroids; the relative effectiveness of procedural treatments on durability of symptom relief and patient reported outcomes, as well as reproductive outcomes, harms, and other outcomes; promising strategies to identify and choose treatment options for fibroid management; evaluation of groups of reproductive-age women who differ by symptom severity, reproductive preferences, or other risk factors; factors that modify the clinical response to all treatments; and questions on innovative methods to investigate causal inference in non-randomized comparative studies and heterogeneity of treatment effects using data derived from large registries. Applications are due by Dec. 16, 2013.

From "Patient-Centered Outcomes Research for Treatment Options in Uterine Fibroids: Dev. a Prospective Multi-Center Practice-Based Clinical Registry" Patient-Centered Outcomes Research Institute (10/24/2013)

AACR-Aflac Inc. Career Development Award for Pediatric Cancer Research

The American Association for Cancer Research and Aflac are offering funding for pediatric cancer research. The AACR-Aflac Inc. Career Development Award for Pediatric Cancer Research is a joint effort to encourage junior faculty who are in the first five years of a faculty appointment (at the start of the grant term) to conduct pediatric cancer research and establish successful career paths in this field. The award provides $100,000 over two years for expenses related to the research project. Applications are due by Dec. 11, 2013.

From "AACR-Aflac Inc. Career Development Award for Pediatric Cancer Research" American Association for Cancer Research (10/24/13)

NIDCR Small Research Grants for Oral Health Data Analysis and Statistical Methodology Development (R03)

The National Institute of Dental and Craniofacial Research has issued a funding opportunity announcement for small research grants for oral health data analysis and statistical methodology development. The goal is to support worthy research projects that involve secondary data analyses of existing oral or craniofacial databases, or to develop needed statistical methodology for analyzing oral and craniofacial data using existing oral or craniofacial databases. The deadline for applications is Sept. 7, 2015.

From "NIDCR Small Research Grants for Oral Health Data Analysis and Statistical Methodology Development (R03)" NIH Grants (10/16/13)

Pfizer Ophthalmics Carl Camras Translational Research Awards

The ARVO Foundation for Eye Research is offering the Pfizer Ophthalmics Carl Camras Translational Research Awards, providing up to three awards of $10,000 each annually. The awards will recognize early career researchers who demonstrate excellence in research and their fundamental scientific discoveries, concepts, and novel technologies. Their discovery or observation must have led to, or have the promise of leading to, clinical applications. Nominations close on March 3, 2014.

From "Pfizer Ophthalmics Carl Camras Translational Research Awards" ARVO Foundation for Eye Research (10/24/13)
The National Institutes of Health (NIH) has issued a Funding Opportunity Announcement (FOA) seeking applications using community-engaged research methods to investigate the potential health risks of environmental exposures of concern to the community and to implement an environmental public health action plan based on research findings. The overall objective is to promote changes to prevent or reduce exposure to harmful environmental exposures and improve the health of a community. The FOA is part of the National Institute of Environmental Health Sciences’ Partnerships for Environmental Public Health program. However, it also highlights the National Institute of Nursing Research’s continued investment in clinical, biological, and translational research programs in a number of areas, such as chronic illness, symptom management, disease prevention, and patient-focused health programs that encourage and enable individuals to become guardians of their own well-being. The closing date for applications is Sept. 7, 2015.

From "Research to Action: Assessing and Addressing Community Exposures to Environmental Contaminants (R01)"

Centers Without Walls for Collaborative Research in the Epilepsies: Sudden Unexpected Death in Epilepsy (SUDEP) (U01)

A Funding Opportunity Announcement (FOA) from the National Institute of Neurological Disorders and Stroke (NINDS) aims to further research into sudden unexpected death in epilepsy (SUDEP), the most common epilepsy-related cause of death. The goal is to encourage linked cooperative agreement (U01) applications from multidisciplinary and multicenter PDS/PIs to further understand the underlying mechanisms that contribute to SUDEP, determine risk factors for SUDEP in individuals with epilepsy, and work toward interventions that prevent the condition. According to the NINDS, the Center Without Walls is a collaborative effort involving frequent interactions of awardees and with the National Institutes of Health. The group will include awardees under this FOA who submit linked U01 applications for either scientific projects or cores. A letter of intent is due on Feb. 10, 2014, with the full application due on March 10, 2014.

From "Centers Without Walls for Collaborative Research in the Epilepsies: Sudden Unexpected Death in Epilepsy (SUDEP) (U01)"

PCORI Launches Community-Building ‘Pipeline to Proposal’ Awards

The "Pipeline to Proposal" awards, a new initiative from the Patient-Centered Outcomes Research Institute (PCORI), aim to encourage the development of partnerships and health research project ideas among individuals and others not typically involved in such plans. PCORI will start with a pilot program offering individuals or small groups of patients, researchers, clinicians, and other healthcare stakeholders in 13 western states the opportunity to apply for "Tier I" awards of up to $15,000 each. A total of 25 awards will be made, providing seed money to support the recipients’ interests in joining together to develop patient-centered research ideas around shared interests. Proposals are being sought via a Request for Proposal process. Proposals are due by Dec. 2, 2013. More information about the awards can be found here.

From "PCORI Launches Community-Building ‘Pipeline to Proposal’ Awards"

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