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January 2013 Connection

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ACTS Evolution

ACTS continues to evolve as we move into 2013. Our website has been modified to reflect organizational changes, and changes of social media channels will follow. The website still includes the robust advocacy information and tools that were initiated at SCTS. The annual meeting, Translational Science 2013, will also advance the newly expanded ACTS mission. One new feature is a grantsmanship course, being offered on Wednesday, April 17, from 1-4 PM; additionally, the NIH Clinical Center Tour, the traditional mock study sections (with participation of NIH Scientific Review Officers along with senior investigators) and the highly popular meetings with NIH Program Officers will be among the outstanding program offerings. For more information on ACTS, see our website at <http://www.ctssociety.org/> and for Translational Science 2013, see the meeting website.

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News from ACTS

Washington Update

Dale P. Dirks and Dane R. Christiansen

January 2013

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Society for Clinical and Translational Science
 2025 M Street NW
 Suite 800
 Washington, DC 20036
 (202) 367-1253
info@ctssociety.org

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The 112th Congress concluded with congressional leaders and the White House engaged in marathon negotiations to craft a legislative package to address scheduled tax increases and funding cuts to federal programs, collectively known as the "fiscal cliff." Ultimately, an agreement was reached that dealt with some of the most critical issues while delaying action on other important items. The fiscal cliff agreement, which is entitled The American Taxpayer Relief Act, passed both the Senate and House with bipartisan votes of 89 to 8 and 257 to 167 respectively. The president has signed the measure into law.

The American Taxpayer Relief Act includes a stop-gap measure that postpones the 8.2% funding cuts to most federal health and medical research programs and a 2% cut to some Medicare programs from taking effect by pushing sequestration back two months to March 2013. The fiscal cliff package also prevents a 27% cut to payments to physicians for the services they provide to Medicare program beneficiaries by patching the Sustainable Growth Rate reimbursement formula for twelve months. Lower tax rates for individuals making less than \$400,000 and couples making less than \$450,000 are made permanent through the measure, although American paychecks are set to shrink due to the expiration of the payroll tax holiday that temporarily lowered payroll tax rates from 6.2% to 4.2%.

The new and re-elected lawmakers comprising the 113th Congress were sworn into office on Thursday, January 3. As the 113th Congress convenes its members are already working to identify a comprehensive solution to avert or mitigate sequestration before the deep cuts occur in March. Meanwhile, lawmakers are also working on a March deadline to raise the debt ceiling before the U.S. defaults on its credit obligations. Considering the timing, it's possible that both of these issues could be tied up in a broad legislative package.

As the annual appropriations process begins on Capitol Hill, veteran legislators have taken new key leadership positions. Senator Barbara Mikulski (D-MD) has replaced the late Senator Daniel Inouye (D-HI) as Chair of the Senate Appropriations Committee and Congressman Jack Kingston (R-GA-1st) has replaced former Congressman Denny Rehberg (R-MT-At Large) as Chair of the House Appropriations Committee's Labor-HHS-Education Subcommittee. While the Fiscal Year 2014 (FY14) appropriations process is just starting, it is important to remember that lawmakers still have to complete work on FY13 appropriations, which are operating on a six month continuing resolution through March.

With all the budget activity currently taking place on Capitol Hill, now is the time to engage legislators and advocate for clinical and translational research and research training programs to ensure these programs have adequate support and are sufficiently funded moving forward.

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Translational Science 2013 Abstract Submission Deadline Extended to January 20, 2013

The deadline to submit abstracts for Translational Science 2013 has been extended to Sunday, January 20. Take advantage of nine extra days to compile your research and submit your work!

Don't miss out on this extraordinary opportunity to share your work at the only meeting addressing all translational science disciplines. The meeting will take place April 17-19 at the Omni Shoreham Hotel in Washington DC, and offers an outstanding meeting program with poster presentation opportunities.

Accepted abstracts will be published in Clinical and Translational Science (CTS), a publication that holds the prestige of being indexed in MEDLINE. Both researchers and trainees can submit abstracts. Additionally, trainee abstracts are eligible for awards based on review by senior investigators.

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Translational Science 2013 Awards for Career Achievement and Contributions - Nominations are Now Being Accepted

In the fourth year of the Translational Science meeting, the sponsoring and partnering organizations will continue to acknowledge the outstanding contributions of investigators and educators in the field. Awardees will be recognized during Translational Science 2013 and will have the opportunity to make a brief presentation at a plenary session. Nominations are now being accepted for the following awards:

- ACTS Distinguished Educator Award
- ACTS Distinguished Investigator Awards
- AFMR Outstanding Investigator Award
- Team Science Award

Submit your nomination by February 8, 2013.

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Translational Science News

Catalyzing Drug Development for the Team Sport of Translational Science

At the 2012 Partnering for Cures meeting, held recently in New York City, experts discussed the drug development tools involved in translational science. Panelists in one session agreed that the drug development process should be more efficient, and this could be aided by reforming the system so the rules are standardized for all parties involved. Carolyn Compton, president and CEO of Critical Path Institute, noted that one of her group's main goals is to establish consortia around standards creation to streamline the rules, so they apply to all sponsors submitting new drug applications to the Food and Drug Administration (FDA). Both the sponsors and the FDA will see increased workflow efficiency with the creation of such standards, she said. The FDA's Eric Perakslis agreed that this type of streamlining is necessary, as the current system in which submitted applications are checked for completion can take months. The development of thoughtful and meaningful data standards would make a difference in streamlining the review process, he said. Meanwhile, Dana Ball of T1D Exchange stressed the importance of asking the right questions of the data that we have. "Data for the sake of having data is not helpful," Ball said. "We have to think ... down the line to ask what problems we are trying to solve with this information; all of this will [determine] the tools that we will need to build solutions to these problems and the

rules [of using] the data pools." The handling and interpreting of the data is the main limitation, panelists said, and that will require a significant investment in infrastructure.

From "Catalyzing Drug Development for the Team Sport of Translational Science"
FasterCures (12/13/2012)

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NIH Proposes Critical Initiatives to Sustain Future of U.S. Biomedical Research

In an effort to strengthen biomedical research in the United States, the National Institutes of Health (NIH) is planning to launch several initiatives, focusing on diversity in the biomedical research workforce, the future of the biomedical research workforce, and data and informatics. NIH Director Francis S. Collins tasked the Advisory Committee to the Director (ACD) to develop recommendations, which were presented to Collins earlier this year, and an implementation plan was discussed at the 105th meeting of the ACD in early December. "The future of biomedical research depends upon our ability to support a research ecosystem that leverages the flood of biomedical data, strengthens the research workforce through diversity, and attracts the next generation of researchers," said Collins. "I'm grateful to the experts, both inside NIH and from the broader biomedical research community, who have given these matters extensive thought and made it possible for NIH to put forward actions designed to benefit our entire research community for years to come."

From "NIH Proposes Critical Initiatives to Sustain Future of U.S. Biomedical Research"
NIH News (12/07/12)

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NIH Builds BrIDGs

As part of its Bridging Interventional Development Gaps (BrIDGs) program, the National Institutes of Health (NIH) has chosen three drug development projects that demonstrate efficacy in disease models for no-cost access to preclinical expertise. BrIDGs is led by the National Center for Advancing Translational Sciences (NCATS). NIH does not fund successful applicants directly; however, the projects can access providers of toxicology studies and other preclinical services that serve under NIH contracts. The three latest BrIDGs projects focus on developing potential new treatments for peritoneal cancers, spinal cord injury, and a rare disease that can lead to kidney failure. Most projects in the eight-year-old program, formerly called NIH Rapid Access to Interventional Development, are geared to enable submission of an IND application to the Food and Drug Administration. So far, the projects have led to 12 INDs and a clinical trial application to Health Canada.

From "NIH Builds BrIDGs"
Genetic Engineering & Biotechnology News (12/05/12)

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Health Care Community Helps PCORI Take the Next Step

The Patient-Centered Outcomes Research Institute (PCORI) is working with patients and the health care community to determine specific research topics for targeted funding announcements. Dr. Joe Selby, the executive director of PCORI, notes that "including patients and those who care for them in the process of generating and prioritizing research topics is a unique approach with a very clear intention." He explains that "if patients, their clinicians, and other stakeholders are partners in conducting research, the results will be better tailored to their needs and more likely to become adopted quickly into everyday practice." PCORI earlier this year set national research priorities to guide the organization's work and support its goal of improving health by generating trustworthy data that can help patients make informed decisions regarding their care. The priorities are being implemented through an ambitious research agenda, and PCORI expects to commit up to \$96 million in contracts by the end of 2012. PCORI also announced \$31 million in funding for its Pilot Projects Program this past spring.

From "Health Care Community Helps PCORI Take the Next Step"
Health Affairs Blog (12/04/12) Selby, Joe

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NIDA Refocuses on Translational, Genetic Medicine

The National Institute on Drug Abuse (NIDA) has reworked its Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) grant program, emphasizing projects that further translational and genetic medicine related to the discovery of substance abuse treatments. According to Jonathan D. Pollock, chief of the Genetics and Molecular Neurobiology Research Branch at NIDA's Division of Basic Neuroscience and Behavioral Research, "We're interested in areas of genetics, in terms of smoking cessation, pharmacogenomics, treatment of substance abuse, and particularly right now, issues related to prescription substance abuse." Pollock also said they are interested in supporting the commercialization and development of products, resources, and services through SBIR/STTR related to brain research. "What we're really looking for is products that you could basically commercialize coming out of research," he said. "These can be things that are either products or services. I think that there are opportunities, particularly for groups of individuals that have an idea, IP, and want to have a startup company."

From "NIDA Refocuses on Translational, Genetic Medicine"
Genetic Engineering & Biotechnology News (12/06/12)

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FDA Announces Public-Private Partnership to Develop Regulatory Science That Will Speed Patient Access to New Medical Device Technologies

A new partnership aims to promote medical device regulatory science, particularly accelerating the development, assessment, and review of new products. The Medical Device Innovation Consortium (MDIC), the first public-private partnership of its sort, will work to prioritize the regulatory science needs of those in the medical device arena and finance projects to help facilitate the process of medical device design and marketing. MDIC, which was formed by the biomedical trade association LifeScience Alley2, will use input from industry, government, and other nonprofit groups. "By sharing and leveraging resources, MDIC may help industry to be better equipped to bring safe and effective medical devices to market more quickly and at a lower cost," said Jeffrey Shuren, M.D., J.D., director of the Food and Drug Administration's Center

for Devices and Radiological Health.

From "FDA Announces Public-Private Partnership to Develop Regulatory Science That Will Speed Patient Access to New Medical Device Technologies"
Food and Drug Administration (12/03/12)

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IT Tools Help Turn Research Into Clinical Practice

A new report shows that an initiative has developed open-source applications to encourage the use of electronic health records (EHRs) in research conducted by medical practice-based research networks (PBRNs). The electronic Primary Care Research Network (ePCRN), funded by the National Institutes of Health (NIH), created the software model working with 11 PBRNs in the United States and United Kingdom. In their report, the leaders of the ePCRN effort say the goal was to "enhance the growth and to expand the reach of PBRN research." According to Dr. Kevin Peterson, lead author of the paper and director of the center for Primary Care Research at the University of Minnesota Medical School, "The best research is done in the setting where the findings are going to be applied. So what this [software model] does is allow us to get the clinical practice engaged in research." While the EHRs used by doctors are not designed for research, ePCRN features a "practice clinical desktop" that can be used to extract the necessary data for PBRN studies. It also includes the PBRN director workbench, for data governance and business rules; the research workbench, which tracks data collection and passes study information to PBRNs and practices; and the administrative services package.

From "IT Tools Help Turn Research Into Clinical Practice"
InformationWeek (12/03/12) Terry, Ken

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Grant Opportunities

Robert Wood Johnson Foundation Investigator Awards in Health Policy Research

The Robert Wood Johnson Foundation has issued a call for applications for its Investigator Awards in Health Policy Research program, which supports educational and other nonprofit institutions where highly qualified individuals propose to undertake broad studies of the nation's most challenging policy issues in health and health care. Under the program, grants of up to \$335,000 each are awarded to institutions to support investigators from a variety of disciplines for innovative research projects that have national policy relevance. Letters of intent are due by Jan. 16, 2013, and, for those selected to submit a full proposal, the deadline is June 12, 2013.

From "Robert Wood Johnson Foundation Investigator Awards in Health Policy Research"
Robert Wood Johnson Foundation (12/13/12)

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NP/PA Clinical Hepatology Fellowship Program

The American Association for the Study of Liver Diseases is seeking applications for its NP/PA Clinical Hepatology Fellowship program. The program offers salary and benefit support for certified and licensed Nurse Practitioners or Physician Assistants pursuing a full-year of training focused on clinical care in hepatology. The program is geared to increase the number of associate practitioners in clinical hepatology, facilitate the transition into clinical hepatology for associate practitioners, and increase access for liver disease patients to adequately trained clinicians. Successful applicants will receive an award of \$78,000 for one year, to be used for both salary and benefit support. The submission deadline is Feb. 13, 2013.

From "NP/PA Clinical Hepatology Fellowship Program"
American Association for the Study of Liver Diseases (12/13/12)

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American Diabetes Association and Merck Clinical/Translational Science Postdoctoral Fellowship Award

The American Diabetes Association is now accepting applications for the American Diabetes Association-Merck Clinical/Translational Science Postdoctoral Fellowship Award. The award supports the training of clinical diabetes investigators in the area of clinical/translational research. The award will be given to an established and active clinical diabetes investigator (Mentor/PI) in diabetes research for the annual stipend support of a postdoctoral fellow to work closely with the mentor. The focus on outcomes research will help to further outcomes research as an important area and spur more to see it as a viable career path. Under the program, the awards will provide up to \$75,000 per year for two years. The funds should be used for the stipend support of a single clinical/translational postdoctoral fellow in a given year as well as laboratory supplies and travel costs. The application is due on Jan. 15, 2013.

From "American Diabetes Association and Merck Clinical/Translational Science Postdoctoral Fellowship Award"
American Diabetes Association (12/13/12)

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Collaborative Network for Clinical Research on Immune Tolerance (UM1)

The National Institute of Allergy and Infectious Diseases has issued a funding opportunity announcement (FOA) seeking applications for the Collaborative Network for Clinical Research on Immune Tolerance. The Network aims to develop new tolerogenic approaches for the treatment and prevention of disease in three clinical areas: asthma and allergic diseases; autoimmune diseases; and immune-mediated rejection of transplanted solid organs, tissues and cells. The scope of research to be carried out includes: the design and conduct of clinical trials at all phases to evaluate the safety and efficacy of investigational products and approaches for the induction and maintenance of immune tolerance in humans; the design and conduct of mechanistic studies and the development of tolerance assays as integral components of the clinical trials undertaken, including establishing and directing a consortium of laboratories; and the provision of bioinformatics, data collection, validation, and analysis resources. The Network may also support, on a limited basis, focused product development and nonclinical studies necessary for the subsequent evaluation of promising tolerance induction approaches in humans. A letter of intent is due on Feb. 7, 2013, and the application is due on March 7, 2013.

From "Collaborative Network for Clinical Research on Immune Tolerance (UM1)"
NIH Grants (12/05/12)

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PhRMA Foundation Announces New Grant Program in Translational Medicine and Therapeutics

The PhRMA Foundation is offering funding for scientists in the field of Translational Medicine and Therapeutics (TMT). The program, which includes the distribution of up to \$350,000 annually through Research Starter Grants and Postdoctoral Fellowships, seeks to build a team of highly trained and qualified TMT investigators. Postdoctoral awards will be offered for a period of two years, with the second year contingent on progress in the first-year activities. Research Starter Grants--which will provide \$100,000 for a one-year period--will support the work of academic scientists as they begin careers in TMT. Postdoctoral Fellowships--which included a \$60,000 annual stipend--will support graduates with doctoral degrees who seek to expand and refine their TMT training. Applications are due by Feb. 1, 2013.

From "PhRMA Foundation Announces New Grant Program in Translational Medicine and Therapeutics"
PhRMA Foundation (11/20/12)

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Association for Clinical and Translational Science | 2025 M Street, NW, Suite 800 | Washington, DC 20036
Phone: (202) 367-1119 | Fax: (202) 367-2119 | email:info@actscience.org

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