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## June 2014 ACTS Connection



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### ACTS Leadership Profile: Harry Selker, MD, MSPH

Harry P. Selker, MD, MSPH is Dean of Tufts Clinical and Translational Science Institute (CTSI) and Principal Investigator of the Tufts Clinical and Translational Science Award (CTSA). In that role, he provides leadership for the programs and infrastructure that support clinical and translational research at the ten Tufts University Schools, ten Tufts teaching hospitals, three other CTSI academic partners, and community-based and industry CTSI partners. He is also the Executive Director of the Institute for Clinical Research and Health Policy Studies at Tufts Medical Center, and Director of its Center for Cardiovascular Health Services Research. Nationally, he is an active member of the National CTSA Consortium, including serving on its Steering Committee.



Dr. Selker's research has long focused on the development of treatment strategies, decision aids, methods, and systems aimed at improving medical care, especially emergency and cardiac care. He is particularly known for a series of studies of the factors influencing emergency cardiac care and for development of clinical predictive instruments as decision aids that provide emergency physicians and paramedics with predictions for their patients' likely cardiac diagnoses and outcomes for real-time use in clinical care. This has included larger multicenter clinical effectiveness trial of the impact of the predictive instruments on emergency cardiac care and their use to support emergency medical service treatment of acute coronary syndromes with intravenous glucose-insulin-potassium ("GIK") in the IMMEDIATE Trial. Concurrently, he is involved in research to advance clinical study design, data analysis, mathematical predictive modeling of medical outcomes, and comparative effectiveness research. These efforts have been continuously funded by RO1 and U awards for over 25 years.

He continues to mentor students, fellows, and junior faculty, and besides the T and K awards that are part of the Tufts CTSA grant, for over twenty years he was the PI on a disease-agnostic Clinical Care Research/Health Services Research T32 training grant. During this time he also founded the nation's first MS/PhD program in clinical research at a biomedical graduate school and academic medical center.

Dr. Selker also continues to see patients in his practice at Tufts Medical Center's Pratt Diagnostic Clinic.

To read more of Dr. Selker's profile, including his vision for ACTS and career highlights, click here.

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## News from ACTS

### New Section – Trainee Profiles

We would like to profile notable achievements of trainees and mentors of member institutions for a new regular feature in our newsletter. If you have suggestions for individuals you wish us to feature, please let us know by contacting Tristan Wood at [twood@acts-science.org](mailto:twood@acts-science.org) with information including name, institution, and email address of the trainee or mentor. We will seek permission from the individual and ask for a photograph to accompany the profile, which should be limited to 250 words.



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### Washington Update

The Senate has stuck to a previously outlined plan to mark up the chamber's twelve Fiscal Year 2015 (FY15) appropriations bills before the end of June. Thus far, the Senate has reported a number of appropriations bills with the Labor-Health and Human Services-Education (LHHS) and Department of Defense Appropriations (DoD) appropriations bills scheduled to move forward in mid to late June. In it is unclear how clinical and translational research programs will fare under tight FY15 spending caps, but there are indications that the Senate intends to provide modest increases for federal medical research activities.

The House of Representatives has been moving their twelve annual appropriations bills forward too, but not action has been scheduled on the FY15 LHHS appropriations bill. With the House still very focused on deficit reduction and reigning in federal spending, it is unclear if clinical and translational research and research training programs will receive additional funding in FY15. In this regard, some House appropriators have indicated an interest in eliminating evaluation tap funding for medical research activities to provide the National Institutes of Health with roughly \$800 million in discretionary resources. Currently, tap funding supports the Agency for Healthcare Research and Quality and critical programs at the Centers for Disease Control and Prevention and the Substance Abuse and Mental Health Services Administration. The patient and professional communities are currently mobilizing to educate lawmakers about the value and importance of tap-funded research activities.

In recognition of a pressing need to find innovative solutions to bolster medical research, the House and Senate are each advancing legislative proposals to accelerate scientific advancement. The Senate's American Cures Act (S. 2115) seeks to make federal research spending mandatory (instead of discretionary) and structured in such a way as to provide annual, predictable growth. The House is still working to craft a proposal under the working title of "21st Century Cures." So far, this effort has included listening sessions with NIH leadership and patient organizations. In June, the House Energy and Commerce Committee's Health Subcommittee will hold a hearing to gather additional input as they work to craft an effective bill.

The Administration is also working to improve and expand clinical and translational research activities. Most recently, NIH prepared a plan to implement the Institute of Medicine's recommendations for improving and advancing the Clinical and Translational Science Awards Program. The strategic goals outlined for this effort include translational science workforce development, increased stakeholder engagement and collaboration, translational science integration across phases and disciplines, and improvements to methodology and processes.

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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.

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## Translational Science News

### FDA Pledges Funding for Clinical Trials Improvement Initiative

The Clinical Trials Transformation Initiative (CTTI) will receive up to \$37.5 million in funding from the Food and Drug Administration, according to a notice published in the Federal Register. The grant will be phased in over five years and will be awarded to the Duke Translational Medicine Institute at Duke University, where CTTI is based. The funding will be granted for activities such as developing administrative and scientific infrastructure for all CTTI projects, recruiting qualified staff for project management and other positions, developing conduct plans for projects, obtaining resources for the conduct of projects, and generating results and recommendations once projects are completed. The FDA will fund up to \$7.5 million per year for the five-year grant, depending on the availability of fiscal year funds. After the first year, funding will be noncompetitive and based on satisfactory performance in the previous year. CTTI's aim is to increase the quality and efficiency of clinical trials and address common problems that any one company could not afford to study.

From "FDA Pledges Funding for Clinical Trials Improvement Initiative"  
*Med Device Online (05/27/2014) Otto, Nick*

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### How to Succeed in Translational Science

A draft report from an advisory committee to the National Center for Advancing

Translational Sciences (NCATS) addresses how to develop "meaningful, measurable goals and outcomes" for its Clinical and Translational Science Awards (CTSA) program, which offers grants of between \$4 million and \$23 million a year to support translational research at academic medical centers. A panel from the Institute of Medicine (IOM) last year said that the CTSA's needed to be more focused and were doing too much, and it recommended that NCATS take a more active role in their oversight. NCATS has already implemented many of those recommendations, such as replacing the CTSA committee structure with a simpler 15-member steering committee, but it asked the advisory committee for advice on how to get the centers to focus on their individual strengths through measurable goals and outcomes. The advisory committee came up with four main goals: workforce development, collaboration/engagement, integration, and methods/processes. In addition, it lists many "measurable objectives" for reaching those goals, including defining core competencies for translational science workers, better engaging stakeholders such as patient groups and the Food and Drug Administration, developing treatments for special populations, and moving more quickly through clinical trials. No specific metrics were offered to evaluate CTSA's, however, and working group co-chair Mary Disis says the report is "a template for metrics and evaluation." NCATS Director Christopher Austin said he considers it "a translational step from the IOM report to what we now need to do."

From "How to Succeed in Translational Science"  
*Science (05/16/14) Kaiser, Jocelyn*

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#### Federal Pain Research Database Launched

Six federal agencies have unveiled the Interagency Pain Research Portfolio (IPRP), a database that provides information on pain research and training activities backed by the federal government. Users can search the database for information about federally funded pain research initiatives. "They can search for individual research projects or sets of projects grouped by themes uniquely relevant to pain," says Linda Porter, Policy Advisor for Pain at the National Institute of Neurological Disorders and Stroke (NINDS). "It also can be helpful in identifying potential collaborators by searching for topic areas of interest or for investigators." The database contains more than 1,200 research projects arranged in a multi-tiered system. Tier 1 indicates that grants are organized as basic, translational, or clinical research projects. In Tier 2, grants are sorted among 29 scientific topic areas related to pain, such as biobehavioral and psychosocial mechanisms, chronic overlapping conditions, and neurobiological mechanisms. The database is managed by the Office of Pain Policy at NINDS, and was developed by NIH staff and members of the Interagency Pain Research Coordinating Committee.

From "Federal Pain Research Database Launched"  
*NIH News (05/27/14)*

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#### Manufacturers Seek Badly-Needed Volunteers to Test Drugs and Other Therapies

Before a new drug can be sold to the public, it must be tested on possibly thousands of volunteers in a rigorous, randomized clinical trial. But the number of people suitable as research subjects and are willing to invest the time has declined considerably. Trials also are becoming more complex, and the Food and Drug Administration and other entities are calling for more data. More than 10 percent of trials in a 2011 sample were derailed because researchers could not enroll even a single test subject. Volunteer enrollment for the 2004-2007 period fell 16 percent when compared with enrollment in studies conducted between 2000-2003, according to the Center for Information and Study on Clinical Research Participation. The retention of individuals volunteering for studies declined 21 percent in the same time. "Part of it is that more [people] are being excluded than used to be," says Terri Hinkley, deputy executive director of the Association of Clinical Research Professionals. There is also low public awareness of clinical trials, in particular among minorities. Researchers depend on physician referrals and various forms of advertising to recruit subjects for the four phases of research; people who enroll in Phase Three studies cannot be paid to prevent the skewing of results, however. "We have to rebuild some trust and have to rebuild our network," Hinkley says, hoping primary care physicians will be more active in referring patients to clinical trials.

From "Manufacturers Seek Badly-Needed Volunteers to Test Drugs and Other Therapies"  
*Washington Post (05/21/14) Bernstein, Lenny*

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#### Labs Are Told to Start Including a Neglected Variable: Females

Researchers have long used male laboratory animals in experiments out of concern that females' reproductive cycles and hormone fluctuations would alter results of carefully set-up experiments. That trend has resulted in researchers often knowing more about the effect of new drugs or treatments on men than on women. In a commentary published May 14 in the journal *Nature*, National Institutes of Health (NIH) Director Francis Collins and Janine A. Clayton, director of the NIH's Office of Research on Women's Health, warned that researchers must start to test their theories using female lab animals and in female tissues and cells. In the clinical research arena, women now comprise more than half the participants in clinical research funded by the NIH, but it has taken years to reach this point. Women continue to be widely underrepresented in clinical trials carried out by drug companies and medical device manufacturers. Women respond differently than men to a wide range of treatments, and they often do not experience the same benefits from them as men. NIH officials will start introducing new policies in October as the details continue to be finalized.

From "Labs Are Told to Start Including a Neglected Variable: Females"  
*New York Times (05/15/14) P. A1 Rabin, Roni Caryn*

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#### Translational Facilities Blend Research With Clinical Care

The concept of translational research is most popularly known in health sciences as "bench-to-bedside," or the effort to translate basic knowledge from research into new medical treatments or health outcomes. It has evolved to mean the transition from basic research to applied research, and is a process now used by researchers to solve patient care problems. This has led to closer integration within a single facility of traditional research, animal research, imaging facilities, and clinical labs in order to

better share ideas and potential gaps between researchers and doctors. Among the facilities taking this approach are the Albert Sherman Center at the University of Massachusetts Medical School, the Research Institute at Nationwide Children's Hospital, the Advanced Health Sciences Pavilion at Cedars-Sinai Medical Center, and the L.S. Skaggs, Jr. Pharmacy Research Building at the University of Utah School of Pharmacy, and the recently renovated Comprehensive Cancer Center/Wallace Tumor Institute at the University of Alabama at Birmingham. The latter brings researchers and clinicians from 19 different buildings together under one roof with research spaces for diagnostic and treatment groups, a floor plan that flows into a single zone around a central atrium, and an adaptable lab support core that support future research. Like-minded research is co-located on the same floor, such as cancer cell biologists, radiation biology, in vivo imaging experts, surgical neuro-oncologists and cancer pathology research. There is a vivarium on the top floor, three floors of research laboratories, one administrative level, access to adjoining hospitals, and a clinical imaging level adjacent to the oncology treatment center and radiopharmacy suite.

From "Translational Facilities Blend Research With Clinical Care"

*Laboratory Equipment (05/14) Studt, Tim*

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#### **Cluster of Five Major U.K. Universities Announces Agreement With Pfizer in Rare Disease Research**

The Global Medical Excellence Cluster (GMEC) has announced a five-year collaborative contract with Pfizer that provides a framework for the research and development of new and innovative medications for rare diseases. Through the agreement, researchers from GMEC partners Cambridge University, Imperial College London, King's College London, Queen Mary University London, University College London, and Oxford University will be able to collaborate with Pfizer scientists on joint drug discovery programs. The effort will build on progress in understanding the underlying molecular mechanisms of rare diseases as well as the U.K. government's momentum in genomics research. "We are looking forward to working with Pfizer on this project," says GMEC chairman and University of Oxford professor Sir John Bell. "It underlines the U.K.'s strengths in biomedical research and creates an important vehicle for academic and industrial scientists to work together with the goal to translate fundamental research into benefit for patients."

From "Cluster of Five Major U.K. Universities Announces Agreement With Pfizer in Rare Disease Research"

*Lab Manager (05/13/2014)*

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### **Grant Opportunities**

#### **NCATS Announces Funding Opportunities to Repurpose Drug Candidates From Industry**

The National Center for Advancing Translational Sciences (NCATS) has issued funding announcements for its Discovering New Therapeutic Uses for Existing Molecules (New Therapeutic Uses) program, which matches researchers with partially developed therapeutic candidates, or agents, to explore new treatments for patients. NCATS is working with AstraZeneca, Janssen Research & Development, Pfizer, and Sanofi to make 26 agents available for the funding opportunities, and for the first time, the companies will make available agents that are suitable for investigating for pediatric indications. An extra year of support will be provided for agents for pediatric indications, allowing time for additional studies of the safety, dosage, and side effects in healthy volunteers as well as juvenile toxicity studies. "New Therapeutic Uses addresses the common problem of failure in therapeutic development by turning it into an opportunity for the 'wisdom of the crowd' to suggest new conditions that candidate agents might treat," said NCATS Director Christopher P. Austin, M.D. "By working together with our industry and academic partners to further develop these agents, we can meet the goal of speeding treatments to patients in need." Interested researchers can submit a pre-application by July 15, 2014. A complete list of the funding announcements is available on NCATS' [New Therapeutics Funding Information Web page](#).

From "NCATS Announces Funding Opportunities to Repurpose Drug Candidates From Industry"

*National Center for Advancing Translational Sciences (05/12/2014)*

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#### **Lupus Research Institute Novel Research Grants**

The Lupus Research Institute is offering funding for idea-driven, novel research projects that are relevant to basic, translational, or clinical investigation in lupus. The grants will provide early stage support for creative and innovative approaches to key challenges in lupus research. The goal of the program is to spur research into unexplored pathways and generate transformative discoveries in lupus that could lead to safer and more effective treatments. Of particular interest are projects based on novel explorations of human lupus biology. Approved projects will receive annual funding of up to \$100,000 annually for three years, starting in January 2015. Applications are due by Aug. 4, 2014.

From "Lupus Research Institute Novel Research Grants"

*Lupus Research Institute (05/29/14)*

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#### **Rheumatology Research Foundation Investigator Award**

The Rheumatology Research Foundation Investigator Award offers support for basic science, translational, and clinical investigators who are conducting rheumatic diseases research for the period between the completion of post-doctorate fellowship training and establishment as an independent investigator. The award, intended to support junior investigators while they are developing a project that will be competitive for National Institutes of Health funding, is for up to \$375,000 for up to three years. Applications are due by Aug. 1, 2014.

From "Rheumatology Research Foundation Investigator Award"

*Rheumatology Research Foundation (05/29/14)*

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#### **Two-Year Fellowship to Support ALS Clinical Research Training**

The ALS Association and American Brain Foundation are accepting applications for a two-year fellowship to support clinical research training for amyotrophic lateral sclerosis. For the purpose of this fellowship, they define clinical research as "patient-oriented research conducted with human subjects, or translational research specifically designed to develop treatments or enhance diagnosis of neurological disease. These areas of research include epidemiologic or behavioral studies, clinical trials, studies of disease mechanisms, the development of new technologies, biomarker discovery and molecular neuropathy, and health services and outcomes research." However, disease-related research not directly involving humans or human tissue is also encouraged if the primary objective is the development of treatments, diagnostic tests, or other tools to help prevent or mitigate neurological diseases. Successful candidates will receive \$55,000 annually for two years, as well as \$10,000 per year for two years of tuition to support formal education in clinical research methodology at the applicant's institution or elsewhere. Applications are due by Oct. 1, 2014.

From "Two-Year Fellowship to Support ALS Clinical Research Training"  
ALS Association/American Brain Foundation (05/29/14)

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#### American Nephrology Nurses' Association Evidence-Based Practice Project Grant

The American Nephrology Nurses' Association (ANNA) Evidence-Based Practice Project Grant aims to fund nephrology nurses' efforts to translate research into practice in support of developing evidence-based nephrology nursing practice and demonstrating the value of nephrology nursing in improving patient outcomes. Project types eligible for funding include primary research, evidence summary, research translation, integration, and evaluation. The ANNA will award three grants of up to \$5,000 per proposal each year. Final proposals are due by Nov. 15, 2014, with an optional Aug. 31 deadline for first proposal submission for review and research committee feedback.

From "American Nephrology Nurses' Association Evidence-Based Practice Project Grant"  
American Nephrology Nurses' Association (05/29/14)

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#### A-T Children's Project Grant Program

The A-T Children's Project Grant Program offers grant awards for basic and translational research related to ataxia-telangiectasia. The program--which funds one- and two-year projects with up to \$75,000 annually--is focusing its funding on translational research, clinical studies, and proposals that apply innovative and novel strategies for suggesting, developing, and evaluating specific disease-modifying and symptomatic interventions, so these types of applications will receive priority funding. Applications are due by Sept. 1, 2014.

From "A-T Children's Project Grant Program"  
A-T Children's Project (05/29/14)

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#### American Acne and Rosacea Society Clinical Research Grant

The American Acne and Rosacea Society (AARS) is funding a clinical research grant in an effort to nurture younger investigators in the field of acne and rosacea. The society will award up to four grants in 2015, with preference given to research projects that are clinical/translational in nature. The maximum value for each grant is \$10,000. Eligible candidates include dermatology residents and fellows and recent graduates of U.S. dermatology residency. Applications are due by Dec. 31, 2014, with the awards announced at the 2015 AARS Annual Meeting.

From "American Acne and Rosacea Society Clinical Research Grant"  
American Acne and Rosacea Society (05/29/14)

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