



ACTS ASSOCIATION FOR CLINICAL AND TRANSLATIONAL SCIENCE

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Dr. Francis Collins, NIH Director, to Speak at Translational Science 2015

We are proud to announce that **Dr. Francis Collins, Director of the National Institutes of Health (NIH)**, will be joining our opening plenary session at Translational Science 2015!

Dr. Collins' lecture, *NIH Efforts to Encourage Physician-Scientists*, will address the growing pressure on physician scientists, which is of increasing concern throughout the field of Translational Science. While the NIH is working to identify actions to help reduce pressure on this critical component of the biomedical workforce, funding challenges are still prevalent. Dr. Collins will discuss upcoming initiatives the NIH is planning to support physician scientists.

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There is Still Time to Register for Translational Science 2015

Translational Science 2015 is a week away, but it's not too late to register! Join us April 16 -18 at the Omni Shoreham for the meeting that brings together a multidisciplinary audience of clinical and translational researchers, for the unique benefit of networking and education with leaders.

Register Now!

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Don't Forget to Book Your Hotel Room!

Due to overwhelming demand, the discounted room rate at the Omni Shoreham is no longer available.

We have reserved additional rooms at the Washington Marriott Wardman Park, right across the street. Rooms are on a first-come, first-served basis. Please call 1-202-328-2000 or visit the [Marriott Wardman Park website](#) to book your room.

If you would like to book a room at the Omni Shoreham at the regular rate, please call (202) 234-0700.

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From the Hill--ACTS Advocacy News

Before adjourning at the end of March for the Easter/Passover Recess, Congress engaged in a flurry of legislative activity that included action on many issues impacting medical research and health policy. Legislators will return to Capitol Hill the week of April 13th and they are expected to pick up, and even finalize, some relevant efforts at that time. Below please find a brief summary of timely congressional action on relevant items.

April 2015

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The ACTS mission is to advance research and education in clinical and translational science to improve human health. For more information, visit actscience.org

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- The House of Representatives passed a bipartisan overhaul of the flawed Medicare Physician Reimbursement scheme, presently known as the Sustainable Growth Rate.
- The House and Senate each passed their own budget blueprints. Both the House and Senate proposals reduce funding for non-defense discretionary programs (below current sequestration levels) while seeking to increase spending on defense.
- The outgoing Commissioner of the Food and Drug Administration (FDA), Margaret Hamburg, called on the Senate to address potential serious issues in the House effort to streamline medical research and treatment development, known as the 21st Century Cures Initiative.

If you are interested in learning more about these issues or engaging the policy making process, consider [becoming an advocate](#).

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FDA/SOCRA Educational Conference: May 13-14, 2015

The Food and Drug Administration (FDA) is announcing an educational conference cosponsored with the Society of Clinical Research Associates (SOCRA). The public conference regarding FDA's clinical trial requirements is designed to aid the clinical research professional's understanding of the mission, responsibilities, and authority of FDA and to facilitate interaction with FDA representatives. The program will focus on the relationships among FDA and clinical trial staff, investigators, and institutional review boards (IRBs). Individual FDA representatives will discuss the informed consent process including informed consent documents, regulations relating to drugs, devices, and biologics, as well as inspections of clinical investigators, IRBs, and research sponsors.

The public conference will be held on May 13 and 14, 2015, from 8 a.m. to 5 p.m. at the Westin Cincinnati, Cincinnati, OH.

For more information, visit the [SOCRA website](#).

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News from ACTS

Share your exciting stories...Membership News!

Does your institution have news you want to share with the *ACTS Connection* readership? Do you have an investigator doing something innovative? Let us know! From innovative projects, star scholars and trainees, to award winning faculty, help us share the news that is important to you by submitting it through our [online form](#).

Your news may be shared on the ACTS website, and other ACTS social media sources!

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Translational Science News

NIH Forms Team of Experts to Chart Course for the President's Precision Medicine Initiative Research Network

The National Institutes of Health has formed a new team of experts that will seek input on the President's Precision Medicine Initiative, a study to encourage the development of precision medicine. The team will help define what can be learned from such a study, what issues must be considered and addressed in its design, and what a successful study would look like. The experts will deliver a preliminary report in September that will provide information meant to speed up the understanding of how individual differences affect health and how to tailor better prevention and treatment strategies.

From "NIH Forms Team of Experts to Chart Course for the President's Precision Medicine Initiative Research Network"

NIH News (03/30/15)

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Point-Person Project May Be More Successful With a National Infrastructure for Clinical Trials

Qualified investigators are more likely to respond to opportunities for clinical trials when they are contacted by an institution-specific point person, a study in Science Translational Medicine has found. A team led by Dr. Jonathan M. Davis of Tufts Clinical and Translational Science Institute launched the Point-Person Project, a pilot study that built a national network of navigators to find investigators for specific research opportunities. The project designated 84 navigators at institutions supported by the Clinical and Translational Science Awards program, funded through the National Center for Advancing Translational Sciences. The pilot project appeared to increase awareness of planned clinical trials, suggesting that the Point-Person model may be adopted nationally.

From "Point-Person Project May Be More Successful With a National Infrastructure for Clinical Trials"

News-Medical.Net (03/23/15)

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Grant Opportunities

NIBIB Research Education Programs for Residents and Clinical Fellows (R25)

The National Institutes of Health has issued a funding opportunity announcement for the NIBIB Research Education Programs for Residents and Clinical Fellows. The program aims to support research experiences for residents and/or clinical fellows in radiology or other National Institute of Biomedical Imaging and Bioengineering-relevant clinical programs to support their career development and further their careers as clinician-scientists. Applicants must be residents or clinical fellows in programs including cardiology, neurology, nuclear medicine, ophthalmology, orthopedics, radiology, or surgery. Awards will be for up to \$70,000 in direct costs annually, for a total of up to five years. Applications are due by June 9, 2015.

From "NIBIB Research Education Programs for Residents and Clinical Fellows (R25)"

NIH Grants (04/01/15)

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NIAMS Clinical Trial Implementation Cooperative Agreement (U01)

A new funding opportunity announcement from the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) seeks cooperative agreement applications for implementation of investigator-initiated interventional clinical trials. Although applications for clinical trials submitted to NIAMS usually must go through a two-part process, investigators who have completed the required pre-trial planning and preparation through other means may apply for a NIAMS U01 without having applied for a U34 planning phase. The trials should be hypothesis-driven, milestone-defined, related to NIAMS' research mission, and considered high-priority by the institute. Application budgets should reflect the actual needs of the proposed project, the length of which should not exceed five years. Applications are due by July 1, 2015.

From "NIAMS Clinical Trial Implementation Cooperative Agreement (U01)"
NIH Grants (03/31/15)

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Confirmatory Efficacy Clinical Trials of Non-Pharmacological Interventions for Mental Disorders (R01)

The National Institute of Mental Health has issued a funding opportunity announcement to support confirmatory efficacy testing of non-pharmacological therapeutic and preventive interventions for mental disorders in adults and children with an experimental therapeutics approach. Trials should be designed so that the results, whether positive or negative, provide information of high scientific utility and support "go/no-go" decisions about further development and effectiveness testing of the intervention. Interventions appropriate for efficacy testing must be based on a compelling scientific rationale, previous demonstration that the intervention engages and alters the hypothesized mechanism of action, a preliminary efficacy signal, and must address an unmet therapeutic need. Application budgets should reflect the actual needs of the project, which researchers are encouraged to limit to three or four years. Applications are due by June 15, 2015.

From "Confirmatory Efficacy Clinical Trials of Non-Pharmacological Interventions for Mental Disorders (R01)"
NIH Grants (03/30/15)

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Clinical Trials to Test the Effectiveness of Treatment, Preventive, and Services Interventions (R01)

A funding opportunity announcement from the National Institute of Mental Health (NIMH) aims to support investigator-initiated clinical trials to establish the effectiveness of interventions and to test hypotheses regarding moderators, mediators, and mechanisms of action of these interventions. The program supports clinical trials designed to test the therapeutic value of treatment and preventive interventions for which there is already evidence of efficacy, for use in community and practice settings. Applications may include research to evaluate the effectiveness or increase the clinical impact of pharmacologic, somatic, psychosocial, device-based, rehabilitative and combination interventions to prevent or treat mental illness. NIMH plans to commit \$6.5 million for the awards in fiscal year 2016, making 7-10 awards annually, with a maximum project period is five years. Applications are due by June 15, 2015.

From "Clinical Trials to Test the Effectiveness of Treatment, Preventive, and Services Interventions (R01)"
NIH Grants (03/30/15)

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Clinical Trials to Test the Effectiveness of Treatment, Preventive, and Services Interventions (Collaborative R01)

A new funding opportunity announcement from the National Institute of Mental Health is looking to support investigator-initiated clinical trials to establish the effectiveness of interventions and to test hypotheses regarding moderators, mediators, and mechanisms of action of these interventions. The program will support clinical trials designed to test the therapeutic value of treatment and preventive interventions for which there is already evidence of efficacy, for use in community and practice settings. The program also supports clinical trials to test patient-, provider-, organizational-, or systems -level services interventions to improve service access, engagement, quality, coordination, or delivery, with the

goal of improved outcomes at the individual and population level. Projects may last up to five years. Applications are due by June 15, 2015.

From "Clinical Trials to Test the Effectiveness of Treatment, Preventive, and Services Interventions (Collaborative R01)"
NIH Grants (03/30/15)

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Exploratory Clinical Trials of Novel Interventions for Mental Disorders (R33)

A funding opportunity announcement from the National Institute of Mental Health aims to support the efficient pilot testing of novel interventions for mental disorders in both adults and children through an experimental therapeutics approach. Proposed trials must be designed so that the results provide information of high scientific utility and will support "go/no-go" decisions about further development or testing of the intervention. Studies of novel interventions include behavioral, pharmacological, biologics-based, cognitive, device-based, interpersonal, physiological, or combined approaches. The program will provide support for testing and validating the intervention's ability to affect a specified target and for relating the change in target to functional or clinical effects. Application budgets should reflect the actual needs of the project, which should not exceed three years in length. Applications are due by June 15, 2015.

From "Exploratory Clinical Trials of Novel Interventions for Mental Disorders (R33)"
NIH Grants (03/30/15)

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Pilot and Feasibility Clinical Research Grants in Kidney Diseases (R21)

The National Institute of Diabetes and Digestive and Kidney Diseases has announced a funding opportunity announcement to support Exploratory/Developmental Research Grants (R21) that propose small-scale or pilot and feasibility clinical and translational research studies, including epidemiological studies or clinical trials related to kidney disease research. Projects should focus on key clinical and translational questions and are potentially of high clinical and public health impact. Some projects may lead to full-scale clinical studies including diagnostic strategies, epidemiological studies, or randomized clinical trials of diagnosis, prevention, or treatment of kidney diseases. Direct costs for the two-year project period may not exceed \$275,000. Applications are due by July 16, 2015.

From "Pilot and Feasibility Clinical Research Grants in Kidney Diseases (R21)"
NIH Grants (03/27/15)

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Pilot and Feasibility Clinical Research Grants in Urologic Disorders (R21)

A funding opportunity announcement from the National Institute of Diabetes and Digestive and Kidney Diseases is looking to support Exploratory/Developmental Research Grants (R21) that propose small scale or pilot and feasibility clinical and translational research studies, including epidemiological studies or clinical trials related to urologic disorders research. The proposed studies should focus on important clinical and translational questions that are potentially of high clinical and public health impact. Some projects supported by these grants could lead to full-scale clinical studies for the prevention, diagnosis or treatment of urologic disorders. Applicants may request up to \$275,000 in direct costs for a two-year project period. Applications are due by July 16, 2015.

From "Pilot and Feasibility Clinical Research Grants in Urologic Disorders (R21)"
NIH Grants (03/27/15)

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Planning Grant for Global Infectious Disease Research Training Program (D71)

The National Institutes of Health's Fogarty International Center has issued a funding opportunity announcement seeking new planning grant applications for the Global Infectious Disease Research Training Program from applicants at low- and middle-income research institutions (LMICs). Applicants should propose plans to develop a collaborative research training program with a U.S. institution that will

strengthen the capacity of the applicant institution to conduct infectious disease (excluding HIV/AIDS and select agents) research. The planning grants should describe the planning process and detailed vision for developing a research-training program that focuses on major endemic or life-threatening emerging infectious diseases, neglected tropical diseases, infections that frequently occur as co-infections in HIV-infected individuals, or infections associated with non-communicable disease conditions in LMICs. Application budgets are limited to \$28,000 in direct costs, with a maximum project period of one year. Applications are due by July 29, 2015.

From "Planning Grant for Global Infectious Disease Research Training Program (D71)"

NIH Grants (03/27/15)

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Exploratory/Developmental Clinical Research Grants in Obesity (R21)

The National Institutes of Health (NIH) has issued a funding opportunity announcement for Exploratory/Developmental Clinical Research Grants in Obesity (R21). NIH is seeking research grant applications from institutions and organizations that plan to conduct exploratory or development clinical studies to accelerate the development of effective interventions for the prevention or treatment of obesity in children and adults. The program also supports exploratory epidemiological research with a goal of informing translational and clinical research. Studies of interest include those on the prevention or treatment of overweight or obesity in children and/or adults, including dietary, physical activity, behavioral, psychosocial, neurocognitive and neuro-modulatory, pharmacologic, and surgical, approaches. The maximum project period is two years, with direct costs limited to \$275,000 over the study period. Applications are due by July 16, 2015.

From "Exploratory/Developmental Clinical Research Grants in Obesity (R21)"

NIH Grants (03/27/15)

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Philanthropies Announce New Program to Support Early-Career Scientists

The Howard Hughes Medical Institute, the Bill & Melinda Gates Foundation, and the Simons Foundation have formed a new partnership to provide research support for early-career scientists. As part of the new Faculty Scholars Program, the three philanthropies will provide a total of \$148 million in research support over the first five years. As many as 70 grants will be awarded every 2.5 years to promising scientists with potential to make unique contributions in their field. Successful applicants will receive a five-year, non-renewable grant, with amounts ranging from \$100,000 to \$400,000 annually for direct costs. The recipient's institution will also receive an additional 20 percent of the yearly grant for indirect costs. The program is open to basic researchers and physician scientists at more than 220 eligible institutions, and scholars will apply molecular, genetic, computational, and theoretical approaches to fundamental problems in diverse areas of biology. Applications for this award are due by July 28, 2015.

From "Philanthropies Announce New Program to Support Early-Career Scientists"

Howard Hughes Medical Institute News (03/23/15)

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AHRQ Small Research Grant Program (R03)

The Agency for Healthcare Research and Quality (AHRQ) has issued a funding opportunity announcement for the Small Research Grant Program. The announcement notes that the R03 grant mechanism supports various types of health services research projects, including pilot and feasibility studies; secondary analysis of existing data; small, self-contained research projects; development of research methodology; and development of new research technology. The funding aims to support a discrete health services research project that is related to the mission and research interests of AHRQ. Priority areas of focus include improving health care quality by accelerating implementation of patient-centered outcomes research; making health care safer; increasing accessibility by evaluating expansions of insurance coverage; and improving health care affordability, efficiency, and cost transparency. Institutions and organizations can apply for up to \$100,000 in total costs for the entire project period, which cannot exceed two years. Applications are due by July 5, 2015.

From "AHRQ Small Research Grant Program (R03)"

NIH Grants (03/19/15)

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