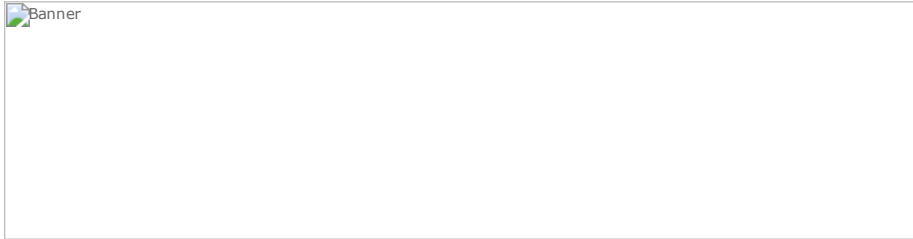




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Next Steps for ACTS

The Association for Clinical and Translational Science (ACTS) continues to develop new relationships with the Association for Patient-Oriented Research (APOR) and the Association for Clinical Research and Training (ACRT). Both organizations have agreed to dissolve and transfer their assets to ACTS, with an expected closing date of February 28, 2013.

At that time, the ACTS Board of Directors will be reorganized, with the following leadership positions: Anantha Shekhar, MD PhD, President; Michael Lichtenstein, MD, MSc, President-elect; Rebecca Jackson, MD, Secretary-Treasurer. Additionally, members will be: Jasjit Ahluwalia, MD, MPH; Barry Coller, MD; Marie Gelato, MD; Andrew Einstein, MD, PhD; Sonali Patel, MD PhD; Satish Raj MD MSCI; Ellie Schoenbaum, MD; Harry Selker, MD MPH ; and Roy Weiner, MD.

This new administrative structure will allow us to vigorously pursue our new purpose.

Additional details will be presented at Translational Science 2013.

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Be among science's best and brightest at **Translational Science 2013**. Join translational professionals and academics from all around the country for three-days of top-notch education and networking. Register by April 5 to benefit from early-bird registration discounts.

Translational Science will offer a discounted one-day registration rate for attendees who are unable to be present for all three days of the meeting. Please visit the [Translational Science 2013 registration site](#) for pricing details.

Activities during the meeting include the opportunities to participate in meetings with NIH program officers, and a tour of the NIH Clinical Center. All events are available on the [registration site](#) on a first-come, first serve basis. Availability is limited, so please don't delay.

Register today, and we'll see you in Washington, DC!

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Washington Update

Dale P. Dirks and Dane R. Christiansen

The early January fiscal cliff deal reached by Congress and the Administration postponed automatic across-the-board funding cuts (sequestration) to nearly all federal programs until March 1st. If some agreement on sequestration cannot be reached by lawmakers by March 1st, then federal agencies such as NIH, FDA, and HRSA face reductions of 5-8%, and the Medicare program is slated for a 2% cut.

Recently, Senate Democrats introduced the American Family Economic Protection Act. This bill seeks to delay sequestration until January 2nd, 2014 by generating \$120 billion in savings through a combination of increased revenue and spending cuts. The reduced spending is attributed to savings related to the troop draw down in Afghanistan. The revenue is achieved by closing tax "loopholes" related to oil extraction, outsourcing, and farm subsidies and by requiring that individuals making over \$1 million pay at least 30% in taxes (the "Buffet Rule"). House Democrats subsequently unveiled their own bill, the Stop the Sequester Job Loss Now Act, which is very similar to the proposal put forward by the Democrats in the Senate.

When legislators return from the President's Day recess the week of February 25th, there will only be a few days before sequestration kicks in on March 1st. Most observers believe that the March 1st deadline will pass before anything substantive can occur. Once sequestration becomes a reality and its impact becomes clear, then Congress and the president will face tough choices on how to deal with it. Some want sequestration to stick, while others hope to fashion a solution to avoid the indiscriminant cuts.

The next likely battleground for this debate will be the overarching spending bill for the federal government. Currently, federal agencies are operating under a continuing resolution (CR) until March 27th. Congress must pass legislation to keep the government running and avoid a shut-down after the March 27th expiration of the existing CR. If sequestration is not addressed before then, it is expected that there will be an effort to incorporate a sequestration solution into the legislation to keep the government operating. Similar to the fiscal cliff negotiations which occurred during the holiday season this will be a major debate about fiscal responsibility, deficit reduction, and tax fairness.

As Members of Congress work to make key decisions on federal funding and deficit reduction, they need to understand the value of clinical and translational research and research training programs. The best way to get this message across is to ensure that they appreciate the positive effect these programs have locally while learning of the critical role they play in this country's biotech industry. Consider reaching out to your members of Congress, educating them about the value of clinical and translational research and research training activities, and asking them to support adequate funding for key federal programs. If you would like to conduct one of the following advocacy activities on this issue, please contact the Joint Advocacy Coalition's Washington Representative, Dane Christiansen, at <mailto:Christiansen@hmcw.org>

- Have a personal letter delivered to your members of Congress.
- Participate in the advocacy activities of Translational Science 2013 and meet with the offices of your members of Congress
- Host one of your members of Congress at your institution.

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NIH Cuts - Take Action and Tell Us Your Story

ACTS wants you to take action regarding the direct impact on your research by the sequestration-induced budget cuts.

First, share your personal examples of how sequestration-induced budget cuts would directly impact your research in our new [forum](#) on our website. The most effective stories will include very specific information whose importance is readily understood by someone without a scientific background. For example, what impact would loss or unavailability of funding have on your career? How would significant cuts affect your funded grants (e.g., reduction of specific aims)? What research would not be completed if you were unable to obtain funding? What would the impact of this lost research be on the research field?

The more specific your story is the better. Please include your state and institution in all posts. You may also share your name and position if comfortable doing so. We plan to use these discussions to enhance our advocacy related to NIH funding.

ACTS also invites you to attend our [Advocacy Training and Hill Day](#) visits on Wednesday, April 17.

Advocates from various societies involved in **Translational Science 2013** will descend on Capitol Hill in teams to meet legislators and advise them of legislative and policy priorities for translational science.

Participants for the events will receive materials prior to Hill Day in order to prepare for visits with legislators.

Seats for this event are limited and available on a first-come, first-served basis. A focused training session will be held in the morning on Wednesday, April 17, followed by constituent visits to the House and Senate offices in the afternoon. Both sessions

require separate registration. There is no fee to attend.

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Trainee Travel Awards Call for Nominations - Translational Science 2013

Members are invited to nominate one trainee for The Burroughs-Wellcome Fund Trainee Travel Award to attend the Translational Science 2013 Meeting in Washington, DC April 17-19, 2013. This includes complementary registration to the meeting, plus will defray up to \$600 of travel costs.

Trainees will benefit with special sessions designed for trainees such as "Meetings with Program Offices," poster sessions, and networking opportunities. Details of the full program are available on the meeting website at www.translationalsciencemeeting.org.

Nominations may be made by email to Angela Kite at <mailto:AKite@firstpointresources.com> by March 15, 2013

Please include:

- The nominee's CV
- The name, degree(s), and training status of the nominee (e.g., enrolled in clinical research Master's or K30 program, K12, K23, R25 or other career development award)
- A paragraph or two (no more than 1 page) about the current status and career development plans of the nominee
- A statement of their commitment to cover any remaining travel expenses for their trainee.

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Translational Science News

Cutting-Edge Science, Collaboration, and Sustained Funding Needed to Get New Medicines From Lab to Patient

At a recent Capitol Hill briefing hosted by FasterCures and the Friends of Cancer Research, National Institutes of Health Director Francis Collins discussed how limited fiscal resources threaten the ability of the research and development ecosystem to deliver science's full potential to better health and well-being. Collins and other participants described what it takes to turn a scientific discovery into a safe and effective treatment for patients. N. Anthony Coles, president and CEO of Onyx Pharmaceuticals, highlighted the role of public investment in basic research, noting that drug companies use this information to understand biology and disease origins. "Companies like Onyx then take these findings, advance the research, and move it toward delivery to patients," he said. Collins also reinforced the importance of supporting the next generation of investigators and innovation. "It is very tough right now to be a grad student, or a post-doc," he said. "As they look at the landscape of this country, they wonder if there's room for them."


From "Cutting-Edge Science, Collaboration, and Sustained Funding Needed to Get New Medicines From Lab to Patient"
FasterCures (02/12/2013)

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Health Care's Good News

Ezekiel J. Emanuel, an oncologist, former White House adviser, and vice provost at the University of Pennsylvania, notes that although health care spending continues to rise, the rate at which it increases year to year has been declining. Premiums continue to rise, he suggests, because the big increases were in fairly small segments of the market, among individual and small-business policies, and because insurance companies are uncertain about what the future holds. The new exchanges opening in October should help to reduce this fear, however, and the rates should start to decline. Still, Emanuel asserts that we should not be complacent, and he notes there are several common sense reforms that can be taken. One area of reform is competitive bidding. A pilot project started two years ago tested competitive bidding in about 100 metropolitan areas and saw dramatic reductions in costs. Emanuel writes that instead of waiting for the Affordable Care Act to open competitive bidding for these products to the rest of the nation in 2016, "we should roll it out nationwide next year. And it shouldn't just be for medical equipment." He suggests that it could be used for lab procedures and "all medical commodities," which would "drive health care spending growth closer to the increase in G.D.P." Emanuel will be a speaker at Translational Science 2013.

From "Health Care's Good News"
New York Times (02/15/13) P. A27 Emanuel, Ezekiel J.

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The State of the FDA

FDA Matters' third annual "State of the FDA" report notes that 2013 appears promising. The Food and Drug Administration benefits from the dedication of its staff, growing self-confidence within the agency that it can solve problems, and continuity of leadership. Commissioner Margaret Hamburg has made improving the agency's scientific bench strength a priority, but the next step--integrating patients and human concerns into decisionmaking--is still a work in progress. The report states that "inadequate funding is the most pressing weakness of [the] FDA." Poor funding is a threat for both the agency and the public, the report concludes.

From "The State of the FDA"
FDA Matters (02/01/13) Grossman, Steven

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SBIR Thinks Smaller

New rules set to take effect on Jan. 28 should bring more small businesses in technologies such as biopharma into the U.S. Small Business Innovation Research (SBIR) program and its companion Small Business Technology Transfer (STTR). The changes are part of the National Defense Authorization Act for Fiscal Year 2012, which reauthorized SBIR and STTR for six years through the 2017 fiscal year. The Biotechnology Industry Organization predicted that SBIR "now will be an aggressively

competitive program that fulfills federal research and development goals of bringing breakthrough public health discoveries to the public." The U.S. Small Business Administration estimates that about 24,000 U.S. businesses could be "impacted" by the rule changes. The percentage that agencies must set aside for SBIR is being raised by 0.1 percent each fiscal year through the 2017 fiscal year, when it would be 3.2 percent. The extra funds and new rules will challenge SBIR and STTR to help biopharmas and other startups develop more technologies and increase jobs.

From "SBIR Thinks Smaller"
Genetic Engineering & Biotechnology News (01/24/13) Philippidis, Alex

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Translational Health Research Centres Form Global Alliance

Six translational health research entities are joining forces to create the new Global Alliance of Leading Drug Discovery and Development Centres. The goal is to foster the global academic and/or nonprofit drug development and commercialization network to accelerate the rate at which research is translated into new medicines. The alliance comprises the Centre for Drug Research and Development (Canada), Lead Discovery Center (Germany), Scripps Research Institute (United States), Centre for Drug Design and Discovery (Belgium), Medical Research Council Technology (United Kingdom), and Cancer Research Technology (United Kingdom). These members represent nearly 400 experienced drug developers collaborating with scientists worldwide on more than 165 therapeutic projects. Alliance members will collaborate on projects; share best practices, resources, and expertise; and develop common standards and performance measurements to enhance the conversion of early-stage technology into therapies.


From "Translational Health Research Centres Form Global Alliance"
Manufacturing Chemist (01/21/13)

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PCORI Aims to Help Patients Make Better Choices

Joe Selby, executive director of the Patient-Centered Outcomes Research Institute (PCORI), notes in a letter that PCORI funds comparative clinical effectiveness research to gauge what works best for different types of patients. PCORI includes patients and other healthcare community stakeholders in all stages of research, such as selecting study topics, sharing research findings, reviewing research applications, and taking part in the research. An example of PCORI research is a study funded in 2012 at Vanderbilt University Medical Center in Tennessee. Dr. Matthew Weinger and colleagues tested ways to identify potential safety risks in hospitals and clinics. They asked physicians and nurses to report "non-routine events" they observed during the day that could be indicative of safety risks. Now, patients have been requested to similarly report non-routine events they see in order to identify additional safety risks in hospitals and clinics. "This idea, that patients should be more involved, in research and in their care, is a hallmark of PCORI's approach," Selby explains, inviting patients, their caregivers, and health professionals to join them in their mission.


From "PCORI Aims to Help Patients Make Better Choices"
Tennessean (01/21/13) Selby, Joe

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Top 10 Medical Research Trends to Watch in 2013

Federal funding will be a critical subject this year for scientific research, writes Margaret Anderson, Executive Director of FasterCures, in an article about medical-research trends to expect in 2013. Last year, a new "Patient-Focused Drug Development" initiative at the U.S. Food and Drug Administration (FDA) allowed the FDA to formally consult with some patients about their priorities and the tradeoffs they would accept. This could start a "paradigm shift" in treatment regulations. Other trends to watch this year include the "megafund" for risky research, including translational research, and the balance between quality and cost-cutting in medical innovation and reimbursement. FasterCures has been tracking the rise of venture philanthropy in medical research and notes that such funding is now in "the big leagues," with attention from large pharmaceutical companies. Other trends are the reproduction of positive results published in peer-reviewed journals, setting standards for collecting and analyzing data, and closing the gap between a treatment's approval and its widespread adoption to improve patient outcomes. This year could see changes in the linear R&D pipeline, with broader acceptance of the idea that collaboration among R&D stakeholders--such as government, academic institutes, industry, and nonprofits--will contribute vastly to progress in science and business. Researchers should conduct more systematic analysis of what is and is not effective in collaboration. Finally, 2013 is expected to see more "outside the box" thinking in medical research, with greater use of newer methods such as crowdfunding and crowdsourcing.

From "Top 10 Medical Research Trends to Watch in 2013"
FasterCures (01/14/2013) Anderson, Margaret

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Effectiveness and Variability of Patient Recruitment and Retention Practices; Tufts CSDD

A recent report from the Tufts Center for the Study of Drug Development (CSDD) found that globally, nine out of 10 clinical trials fulfill their patient enrollment goals. However, reaching those targets generally means drug developers must nearly double their original timelines. Tufts CSDD's analysis was based on more than 150 clinical studies involving nearly 16,000 sites, and is intended to help clinical research professionals improve how they plan and manage clinical trials. "Patient recruitment and retention are among the greatest challenges that the clinical research enterprise faces today, and they are a major cause of drug development delays," said Ken Getz, director of sponsored research at Tufts CSDD. The study also found that most drug sponsors and contract research organizations depend on a limited number of traditional recruitment and retention approaches, such as physician referrals and newspaper, television, and radio ads, and many have not yet turned to social media and other new strategies for enrollment.

From "Effectiveness and Variability of Patient Recruitment and Retention Practices; Tufts CSDD"
The Pharma Letter (01/17/13)

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TEDMED Innovation Panel: We're on the Verge of a Patient Engagement Explosion

A recent TEDMED discussion moderated by John Nosta at Ogilvy CommonHealth Worldwide examined the topic of "Achieving More Medical Innovation More Affordably." Participants said the chief obstacle in innovation in healthcare is coming up with ideas that can be adapted to systems for how providers are reimbursed and demonstrate they can improve patient outcomes. Innovation can be also be as low-key and inexpensive as providing small, achievable diet goals to improve a patient's health, similar to gamification, participants said. Another strategy could be providing mobile phones to pregnant women as part of a Medicaid program to ensure they can be contacted for follow-up care. Diego Miralles of Janssen noted that the pressure exerted by the HIV/AIDS community on the healthcare industry to develop a cure triggered the creation of new drugs. One panelist observed that much is at stake with adherence rates because if they were to be improved, pharmaceutical companies could generate more revenue, payer costs would decline, and healthcare would be more efficient.

From "TEDMED Innovation Panel: We're on the Verge of a Patient Engagement Explosion"

MedCity News (01/11/13) Baum, Stephanie

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NCATS' Austin Seeks to Tackle Big Bottlenecks in Biomedical Science

Chris Austin, the new director of the National Center for Advancing Translational Sciences (NCATS), says "high level people in every arena of the research ecosystem" want to find out about programs NCATS is planning and how they might participate. NCATS, launched at the end of 2011, now has three main sections: one focusing on clinical innovation, another on preclinical innovation, and an Office of the Director that oversees other remaining programs and tackles new ones. Austin feels that NCATS and the National Human Genome Research Institute both focus on how to remove bottlenecks that impede innovation in basic science data. He anticipates that NCATS will have a significant impact on a National Institutes of Health initiative launched in 2012 to develop a streamlined approach for target validation, identify targets more swiftly and efficiently, and develop a pre-competitive collaborative environment in which validation efforts can take place. "We're going to have a portfolio of metrics, some of which are going to be long term and some are going to be short term, and they're going to be across the translational spectrum," Austin explains. "NCATS is going to work in every area, from genome-based target discovery or target validation, through assay development, screening, chemical informatics, bioinformatics, medicinal chemistry, preclinical development, clinical pharmacology, clinical trials, and regulatory science ... a tremendously broad palette across the translational spectrum."

From "NCATS' Austin Seeks to Tackle Big Bottlenecks in Biomedical Science"

GenomeWeb Daily News (01/01/13) Jones, Matt

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Grant Opportunities

PCORI Announces Third Round of Research Funding

The Patient-Centered Outcomes Research Institute (PCORI) is accepting applications for funding for research to help patients and caregivers make more informed decisions about their health and health care. According to PCORI, up to \$96 million in funding, authorized by the Patient Protection and Affordable Care Act, will be used to support four the group's five research priorities: assessing prevention, diagnosis and treatment options; improving health care systems; communicating and disseminating research; and addressing disparities. The proposals must involve patients and caregivers. Hospitals and other groups must submit letters of intent by February 15, and applications will be accepted through April 15. More information is available at www.pcori.org/funding-opportunities/pfa.

From "PCORI Announces Third Round of Research Funding"

AHA News (01/17/13)

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International Traumatic Brain Injury Research Initiative: NIH Cooperative Program for Comparative Effectiveness of Clinical Tools and Therapies (U01)

A new funding opportunity announcement from the National Institute of Health aims to provide a competitive opportunity for a multicenter team in the United States to participate in the International Traumatic Brain Injury (InTBIR) Initiative to create a large, open source international patient registry. The team will conduct a prospective, observational, hypothesis-driven study on 3,000-4,000 children and adults with traumatic brain injury (TBI) and control subjects. The hypotheses or research question should aim to identify causal relationships between TBI treatments and patient outcomes. Research topics of interest include development and validation of surrogate markers of injury and recovery; development and validation of a patho-anatomical and biomarker-based patient classification system to enable targeted therapies; evaluating inheritable risk factors and/or co-morbidities as predictive or prognostic biomarkers; discriminating between TBI and PTSD or other psychological disorders; identifying age-dependent differences in the pathophysiology and outcomes following TBI; prediction and modulation of outcomes by patient, injury, and management across the continuum of care; and development of economical, potentially fieldable, continuous non-invasive methods for early detection of TBI and non-invasive to minimally-invasive monitoring/imaging of the sequelae of TBI with high sensitivity and specificity. A letter of intent is due on March 1, 2013, and the application is due on April 1, 2013.

From "International Traumatic Brain Injury Research Initiative: NIH Cooperative Program for Comparative Effectiveness of Clinical Tools and Therapies (U01)"

NIH Grants (01/10/13)

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The CDC's National Undergraduate Student Program: A Public Health Workplace Experience to Increase Student Interest in Public Health

The Centers for Disease Control and Prevention (CDC) has issued a funding opportunity announcement related to the creation of a national program for the exposure of undergraduate students, including those from underrepresented racial and ethnic minority populations, to public health and biomedical sciences. The CDC is seeking applications from organizations and institutions to serve as component sites for a 10-week national undergraduate student summer program. Each site will

demonstrate expertise in serving students, including those in underrepresented populations. The CDC will fund one successful application--a National Undergraduate Student Coordination Center--to be responsible for managing relationships and communications across grantees; to identify common objectives, processes, and performance outcome measures across the sites. In addition, the CDC fund one applicant to administer the eight-week James A. Ferguson Emerging Infectious Diseases Fellowship, which will target graduate and professional students, including those from underrepresented racial and ethnic minority populations, in medicine, public health, veterinary medicine, dentistry, and pharmacy. Eligible applicants may apply to conduct activities in one or more of the following three Program Areas: Recruitment, Orientation, Placement, Mentorship, and Follow-up Tracking of Undergraduate Students; National Undergraduate Student Coordination Center; and James A. Ferguson Emerging Infectious Diseases Fellowship -- Recruitment, Placement, Training and Mentorship of Graduate Students. This announcement is for non-research activities only. A letter of intent is due May 23, 2013.

From "The CDC's National Undergraduate Student Program: A Public Health Workplace Experience to Increase Student Interest in Public Health"
Grants.gov (01/10/13)

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Functional Epigenomics: Developing Tools and Technologies for Cell-type, Temporal, or Locus-specific Manipulation of the Epigenome (R01)

The National Institutes of Health (NIH) has issued a funding opportunity announcement (FOA) to stimulate research to develop novel technologies that enable one or more of the following: tissue or cell-specific manipulation of epigenetic modifications or their effector molecules, temporal manipulation of the epigenome, or locus-specific manipulation of the epigenome. This initiative is funded through the NIH Common Fund, which supports initiatives to develop innovative and often risky approaches to difficult problems. This Common Fund initiative is part of the NIH Roadmap. For this FOA, preliminary data are not required, but applicants should provide evidence that they can achieve their proposed goals. Total amount of funds available is approximately \$3.8 million per year for fiscal years 2013-2017. The letter of intent due date is Feb. 27, 2013, and the application is due on March 27, 2013.

From "Functional Epigenomics: Developing Tools and Technologies for Cell-type, Temporal, or Locus-specific Manipulation of the Epigenome (R01)"
NIH Grants (01/04/13)

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Exceptional Unconventional Research Enabling Knowledge Acceleration (EUREKA) for Neuroscience and Disorders of the Nervous System (R01)

The National Institutes of Health has announced a funding opportunity for the EUREKA (Exceptional Unconventional Research Enabling Knowledge Acceleration) initiative, seeking Research Project Grant (R01) applications addressing exceptionally novel hypotheses and/or remarkably difficult problems in neuroscience and disorders of the nervous system. The funding is for new rather than ongoing projects and is not intended for pilot research. The proposed research may have a high risk of failure, but it must promise results with especially high impact should it be successful. The research should be groundbreaking, innovative, original and/or unconventional, with the potential to solve important problems or open new areas for investigation. Applications are due by March 21, 2013.

From "Exceptional Unconventional Research Enabling Knowledge Acceleration (EUREKA) for Neuroscience and Disorders of the Nervous System (R01)"
NIH Grants (01/03/13)

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Opportunities for Collaborative Research at the NIH Clinical Center (U01)

A new funding opportunity announcement from the National Institutes of Health (NIH) aims to support collaborative translational research projects aligned with NIH efforts to enhance the translation of basic biological discoveries into clinical applications that improve health. This opportunity is specifically to promote partnerships between NIH intramural investigators and extramural investigators. It will provide support for extramural investigators to take advantage of the unique research opportunities available at the NIH Clinical Center by conducting research projects in collaboration with NIH intramural investigators. The application is due on March 20, 2013.

From "Opportunities for Collaborative Research at the NIH Clinical Center (U01)"
NIH Grants (12/20/12)

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Next-Generation National Nanotechnology Infrastructure Network

The National Science Foundation (NSF) has announced an open competition to establish a Next-Generation National Nanotechnology Infrastructure Network (NG NNIN) for fiscal years 2014-2018. A letter of intent is due by April 1, 2013, and a full proposal is due by May 13, 2013. The current National Nanotechnology Infrastructure Network (NNIN) will end its award life in fiscal year 2013. NNIN's core mission includes national-level education and outreach programs to develop a diverse science and engineering workforce and the study of societal implications of nanotechnology. The competition for the new NG NNIN will build on the concept of NNIN, with a wider scope. Support is provided by all NSF Directorates and the Office of International Science and Engineering as part of the NSF investment in Nanoscale Science and Engineering.

From "Next-Generation National Nanotechnology Infrastructure Network"
National Science Foundation (12/12/12)

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