



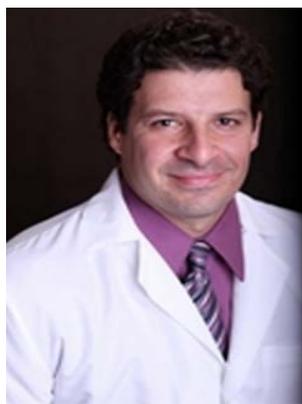
ACTS CONNECTION

ASSOCIATION FOR CLINICAL AND TRANSLATIONAL SCIENCE

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SC CTSI-Supported Researchers Develop First Fully-Implantable Micropacemaker Designed for Fetal Use

August 27, 2015



A team of investigators at Children's Hospital Los Angeles and the University of Southern California have developed the first fully implantable micropacemaker designed for use in a fetus with complete heart block. The team has done preclinical testing and optimization as reported in a recent issue of the journal *Heart Rhythm*, and the micropacemaker has been designated a Humanitarian Use Device by the US Food & Drug Administration (FDA). The investigators anticipate the first human use of the device in the near future. "Up until now, the pacemaker devices that have been used in an attempt to treat this condition in a fetus were designed for adults," said Yaniv Bar-Cohen, MD, pediatric cardiologist at CHLA and lead author on the paper. "We have lacked an effective treatment option for fetuses."

This article is written by Children's Hospital Los Angeles. For more information, please [click here](#) for details on this story.

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"Friends of AHRQ" Letters Lead JAMA to Write Online Piece

"Friends of AHRQ," consisting of more than 100 health groups signed letters in June and July urging the House and Senate to maintain AHRQ and the research it funds. To do otherwise "is pennywise and pound foolish," the groups wrote.

On August 19th, 2015, JAMA released an online piece about AHRQ. The piece includes an interview with AHRQ Director Dr. Richard Kronick, who answers questions about how AHRQ's work relates to that of NIH, how it is different than that of the Patient-Centered Outcomes Research Institute (PCORI) and the National Quality Forum, and how the Affordable Care Act has affected the mission of AHRQ.

To read the Friends of AHRQ Letter please [click here](#). To read the JAMA online piece, please [click here](#).

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ACTS Member Highlight Coming in September 24th Issue

Coming soon in the next issue of ACTS Connection:

Mark Walter, Ph.D., professor of microbiology in the University of Alabama at Birmingham School of Medicine, is seeking a way to detect at the level of individual immune cells — exactly which interferons and which cells provoke the disease. This ability would help develop blood tests to diagnose the disease and also measure the effectiveness of lupus treatments.

Share Your Exciting News Stories With Us! Does your institution have news you want to share with the *ACTS Connection* readership? Do you have an investigator

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News from ACTS

Save the Date Now for Translational Science 2016

Mark Your Calendars! Translational Science 2016 will take place April 13-15 at the Omni Shoreham Hotel in Washington, DC. Registration for Translational 2016 is expected to open in December 2015.

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Translational Science News

New FDA Guidance Addresses Common Issues in Orphan Drug Development

The Food and Drug Administration (FDA) has released draft guidance to help drugmakers address issues frequently seen in orphan drug development. Such issues include adequate description and understanding of the disease's natural history, reliable endpoints and outcome assessment, and manufacturing considerations during drug development. FDA says that such issues occur in other areas of drug development, but they are "more acute with increasing rarity of the disorder." Companies are encouraged to conduct research into disease pathophysiology, as this could lead to the identification of meaningful biomarkers and disease variations.

From "New FDA Guidance Addresses Common Issues in Orphan Drug Development"

Regulatory Affairs Professionals Society (08/17/2015) Mezher, Michael

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21st Century Cures Act Prompts Debate Over Patient Consent Rules

The Senate is developing its own version of the 21st Century Cures Act, but privacy advocates are concerned about the possible use of personal health data for biomedical research without patient consent. HIPAA currently allows certain entities, such as healthcare providers and health plans, to share information on healthcare operations without patients' authorization in some cases. A House version of the Cures Act, passed in July, also would allow research entities conducting biomedical research to access data without patients' consent. Supporters of the Cures Act say it will speed up treatment development and delivery, but privacy advocates fear that profits-focused research might use data from patients' electronic health records without their consent, undermining trust.

From "21st Century Cures Act Prompts Debate Over Patient Consent Rules"
iHealth Beat (08/13/15) Lewis, Nicole

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Grant Opportunities

Early-Stage Development of Informatics Technologies for Cancer Research and Management (U01)

The National Cancer Institute (NCI) has issued a funding opportunity announcement (FOA) calling for Cooperative Agreement applications to develop enabling informatics technologies to improve the acquisition, analysis, and dissemination of cancer-research data. This FOA is part of NCI's Informatics Technology for Cancer Research Program, and focuses on early-stage development from prototyping to hardening and adaptation. The application due date is Nov. 20, 2015. Award budgets are limited to \$300,000 in annual direct costs, excluding consortium F&A costs, and the maximum project period is three years.

From "Early-Stage Development of Informatics Technologies for Cancer Research and Management (U01)"
NIH Grants (08/18/15)

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Development of Innovative Informatics Methods and Algorithms for Cancer Research and Management (R21)

The National Cancer Institute (NCI) has issued a funding opportunity announcement (FOA) to invite exploratory/developmental research grant applications for the development of new methods and algorithms for cancer research. As part of NCI's Informatics Technology for Cancer Research Initiative, this FOA encourages applications focused on the development of innovative algorithms and methods that can improve acquisition, management, analysis, and dissemination of relevant data and knowledge. Grant amounts will depend on National Institutes of Health appropriations and the number of applications, but direct costs are limited to \$275,000 in a two-year period, and no more than \$200,000 may be requested in any single year. Applications are due by Nov. 20, 2015.

From "Development of Innovative Informatics Methods and Algorithms for Cancer Research and Management (R21)"
NIH Grants (08/18/15)

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Centers of Research Translation (P50)

The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) has issued a funding opportunity announcement to request applications for Centers of Research Translation. The research focus could be either a disease-targeted translational theme addressed by synergistic Research Projects with optional Research Cores, or a disease-related critical translational research question addressed through a single collaborative Research Project enabled by several highly interactive Research Cores. NIAMS will commit up to \$6 million in the 2016 fiscal year to fund a maximum of four awards. Application budgets are limited to \$1 million in direct costs annually. Applications are due by Dec. 11, 2015.

From "Centers of Research Translation (P50)"
NIH Grants (08/12/15)

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