



...where miracles begin



RESEARCH UPDATE

November 2008

Clinical Trials at ACH: Impacting treatment of Pediatric hypertension



Zach keeps his eye on the ball and on his blood pressure.

Zach was having recurring headaches about twice a week. Each lasted all day and made it hard for him to concentrate. His mom Traci took him to their doctor. "Our doctor noticed that Zach's blood pressure was a little high and that he was a little overweight," says Traci. The doctors sent the family to ACH to have then 14-year-old Zach examined further. A nephrologist at ACH determined that Zach had pediatric hypertension and suggested that Zach and his family consider having him participate in a clinical trial for pediatric hypertension.

They spoke to Research Nurse Lee Howard, RN, CCRC, about the trial. She explained that the trial was to compare two antihypertensive drugs, drugs approved for use in adults but that have not yet had adequate dosing and safety information determined for children. Dr. Tom Wells is the principal investigator of the study, and he has been treating and researching pediatric hypertension for over 20 years at Arkansas Children's Hospital.

Pediatric hypertension is found in 1% to 3% of children. The primary cause of pediatric hypertension is unknown though it is possibly related to genetics, obesity, or other factors. Secondary, underlying causes can include kidney disease or vascular problems. "Many of these children may have headaches or sleep disorders," says Dr. Wells. He adds, "They generally go to school and aren't ill

appearing."

Zach decided to join the trial to possibly improve his health and the health of other children. His participation included taking medication and 7 visits to ACH's Pediatric Clinical Research Unit over a 3- to 4-month period. The study procedures included physical examinations, blood draws, and an electrocardiogram. The research team provided Zach a home blood pressure monitor and taught him how to use it to monitor his blood pressure. Zach continued on the medication beyond his last visit after consulting with Dr. Wells. After a year, Zach says his headaches were gone.

Zach and his family adjusted his diet as well. The family has reduced salt in their meals; Zach has replaced soda with water and iced tea. In addition to reducing his blood pressure, Zach has also reduced his weight. Always athletic, Zach previously found it hard on occasion to run with the other players on his baseball team; now, the 16 year old easily keeps up with his teammates.

The study, which has already closed its enrollment, is an industry-sponsored, multi-center study being conducted by the Network of Pediatric Pharmacology Research Units (PPRUs), funded by the NIH. The PPRU at Arkansas Children's Hospital is one of 13 PPRUs in the nation established by the National Institute of Child Health and Human Development in response to the need for appropriate drug therapy for pediatric patients. Dr. Wells served as the principal investigator for the PPRU for 10 years; Dr. Laura James now leads the PPRU in this position.

The family speaks highly of the research team. "They were really nice and do what they need to do," says Zach. He adds, "Dr. Wells is a top doctor." With the work of physicians through the ACHRI PPRU and the participation of families throughout the region, physicians everywhere will have safer dosing information for children.

President's Choice

Stop by the bulletin board located in the first-floor lobby of the ACHRI building to see this month's President's Choice publications. The following articles were selected as this month's feature publications.

- Mosley BS, Cleves MA, Siega-Riz AM, Shaw GM, Canfield MA, Waller DK, Werler MM, Hobbs CA; for the National Birth Defects Prevention Study. Neural Tube Defects and Maternal Folate Intake Among Pregnancies Conceived After Folic Acid Fortification in the United States. *Am J Epidemiol.* 2008 Oct 25. [Epub ahead of print]
- Perry TT, Vargas PA, McCracken A, Jones SM. Underdiagnosed and uncontrolled asthma: findings in rural schoolchildren from the Delta region of Arkansas. *Ann Allergy Asthma Immunol.* 2008 Oct;101(4):375-81.

ACHRI would like to know about your published findings, as your articles are published, please email or mail a copy to [Phaedra Yount](#) (mail slot 842). The number of publications by our researchers is reported to the hospital and ACHRI boards, so it is important that we receive an accurate count of the publications your research produces. To see all recent publications by ACHRI researchers and their collaborators, please visit the [publications web page](#).

ACHRI Welcomes Three New Board Members

ACHRI is pleased to introduce three newly elected board members, Mark Millsap, Kathryn Bennett Perkins, and Dee Ann Landreth, who will bring a breadth of leadership experience to the Board.

- **Mark Millsap**
Mark is co-owner of Foundation Resource Management, which is an SEC-registered investment advisory firm overseeing more than \$1.5 billion for institutional and private clients. He is a Chartered Financial Analyst and a Chartered Investment Counselor. Mark has spent his entire 25-year career as a value investment manager. He earned his Bachelor of Science degree from the University of Alabama in Corporate Finance and Investment Management. The Millsaps have been supporters of Arkansas Children's Hospital since moving to Little Rock from Birmingham, Alabama in 1989. Mark's daughter, Elizabeth, is a nurse at ACH.
- **Kathryn Bennett Perkins**
Kathy is a partner in the litigation section of Rose Law Firm with a practice emphasis in intellectual property. She has been with Rose Law Firm since 1992. Kathy currently serves on the Juvenile Diabetes Research Foundation Board and has been a member of the ACH Auxiliary since 1998. She was President of the Junior League of Arkansas for 2005-06 and formerly served on the board of directors of Ballet Arkansas, on the Arkansas Easter Seals Development Counsel, and as the Easter Seals VIP Fundraiser in 2000. Kathy received her B.S.B.A (high honors-accounting), M.S.A (Master of Science of Accounting) and J.D. (high honors) from the University of Arkansas. She is a native of Carlisle, Arkansas.
- **Dee Ann Landreth**
Dee Ann has worked for Mountaire Corporation for more than 29 years. She is currently the Executive Vice President and is responsible for legal activities including litigation. She assists in the overall management of corporate benefits, which includes health, vision, dental, life, and disability insurance; retirement plans; drug testing; and corporate policies for Mountaire's 6,000+ employees. She is also a Board Member of the Mountaire Corporation and a member of the Executive Committee. In addition, she has served, for over ten years, on the Arkansas State Plant Board, representing Arkansas Feed Manufacturers.

Charlotte Hobbs Named 2008 Dean's Distinguished Faculty Scholar

Each year, one faculty member from the UAMS College of Medicine is selected to receive the Dean's Distinguished Faculty Scholar Award, which recognizes outstanding faculty whose contributions to academic medicine have brought honor and prestige to the College of Medicine. The honored scholar presents as part of the Dean's Distinguished Faculty Lecture Series. Dr. Charlotte A. Hobbs, MD, PhD, was selected to receive the 2008 Dean's Distinguished Faculty Scholar Award.

Dr. Hobbs' lecture, "From the Bench to the Crib: Searching for Causes of Birth Defects", was presented on November 5 in Pauly Auditorium at the college of Public Health at UAMS and broadcast to Chairman's Hall at ACH. Dr. Hobbs is the Pamela D. Stephens Endowed Chair for Birth Defects Research and director of the Arkansas Center for Birth Defects Research and Prevention. She is a professor in the Department of Pediatrics and Section Chief of Birth Defects Research. Congratulations Dr. Hobbs! We are all very proud of you.

Meet ACHRI's Clinical Research Specialist

Join us in welcoming Rebecca Myrick as ACHRI's Clinical Research Specialist. She will work on post-award processes (including billing, reconciliation, and recruitment) for clinical research at ACHRI. Rebecca comes to ACHRI from UAMS where she worked for 7 years as a study coordinator and research compliance auditor. Prior to her tenure at UAMS, she worked as a research analyst for a state agency working on grant projects and study and statistical design. Rebecca has an M.S. in sociology with a focus on quantitative analysis from Auburn, and she is a Certified Clinical Research Professional (CCRP).

Sarah Blossom to Collaborate with ASU Scientists

Of 31 proposals submitted to the Arkansas Biosciences Institute in response to their institute-wide request for collaborative proposals, five projects were awarded funding. Congratulations goes to Sara Blossom, who in collaboration with Dr. Dolan and Dr. Buchanan of Arkansas State University, received \$60K to study maternal smoking and neuroimmune modulation involving altered expression of nicotine sensitive acetylcholine receptors in the developing brain and immune system. The three researchers will use a mouse model of maternal cigarette smoke exposure to study the hypothesis that alterations in nicotine-sensitive acetylcholine receptors (nAChR) in the developing brain and immune system represents a common mechanism for these effects. This research promises to provide a potential breakthrough in understanding the health consequences of maternal smoking in children.

The Compliance Hotline

Arkansas Children's Hospital has instituted a Compliance Hotline, for use by anyone who knows of, or suspects any illegal, unethical, or questionable activity such as research misconduct. The Office of Research Integrity defines research misconduct as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

The Compliance Hotline is intended to provide a private means to report issues that are considered to be of importance, especially if an appropriate means to report something is unknown. Callers to the Compliance Hotline will not be retaliated against by their managers or supervisors for making calls to the Compliance Hotline. All calls to the Compliance Hotline are confidential and private.

The Compliance Hotline is operated by an outside vendor, located out of state. This company specializes in healthcare related compliance issues, and the telephone operators have been trained to receive Hotline calls. The Compliance Hotline is available 24 hours a day, seven days a week. All calls will be answered by a live person. Calls are not recorded and are not able to be traced. Callers have the option to remain anonymous. If the caller remains anonymous, they will be given a numeric code so they may call back and ask for follow up. Callers will be guided through the call and prompted by appropriate questions from the operator. It is important that the caller provide as much detail as possible. The caller will be given a date on which they can call back and receive a follow up report. Once the call is completed, a report will be generated and sent to the ACH Corporate Compliance Officer or Director of Corporate Compliance.

All reports will be investigated internally, and the findings will be reported back to the Compliance Hotline. Callers are urged to call back for follow up, because in the event more information is required, this will be an opportunity for the caller to provide those details.

The phone number to the Compliance Hotline is 1-877-384-4275. All calls are free.

CUMG Grant Application Workshop

The next deadline for CUMG grant applications is March 2, 2009. On November 18 (2:00 to 3:30 p.m., Brandon North A and B), ACHRI will hold a workshop on the CUMG grant program. The panel will include a researcher who has received CUMG funding and has served as a CUMG reviewer. For more information, contact [John Gregan](#) (364-6296) or [Amy Stalls](#) (364-3627).

Wanted: Researcher Profiles!

Last month there were almost 900 page visits to ACHRI's "Our Researchers" index page. These views were from many of the over 1,800 unique visitors to ACHRI's Web site. Would you like to add your researcher profile to our Web site? If so, send [John Gregan](#) the following information: your title, a paragraph about your research interests and accomplishments, a list of your current research funding, appropriate contact information, and a list of five key publications. Include a current digital photograph if you have one available. You can view the profiles we've developed here: <http://achri.archchildrens.org/researchers/faculty.htm>.

If you already have a profile at our web site, contact John if you need to revise it in regards to accomplishments, publications, and funding.

New Industry-Sponsored Projects

PI	Agency	Project Period	Total Funding
Shahid Hussain	Endo Pharma	10/08 - 10/09	\$70,475
Joe Elser	Abbott	10/08 - 11/09	\$17,000

Recent Awards and Submissions

Extramural Award

PI	Agency	Project Title	Project Period	Total Funding
Mary Aitken	Arkansas State Highway and Transportation Department	Mapping the Way to Success: Statewide Dissemination and Evaluation Planning for the Arkansas Safe Routes to School Program	10/27/08-3/8/10	\$155,245

Intramural Awards - Student and Clinical Staff Grant Program

PI	Agency	Project Title	Project Period	Total Funding
Tommy "Mac" Bird	ACHRI	Long-term Health Related Outcomes of Late Preterm Infants: A Propensity Score Matched Analysis	11/1/08-10/31/09	\$2,000
Chaoxuan Dong	ACHRI	bFGF Protects Neural Stem/Progenitor Cells from Ketamine-Induced Toxicity by Activating Akt	1/1/09-12/31/09	\$2,000
Della Fleming	ACHRI	The Efficacy of Standardized Exercise Protocol in Inpatient Care of the Patients with Cystic Fibrosis	1/1/09-12/1/11	\$1,250
Omar Rahal	ACHRI	Tumor Suppressor PTEN-Induced Signaling Pathways in Mammary Epithelium	1/1/09-12/1/11	\$2,000
Christian Simmons	ACHRI	Klf9-mediated Reproductive and Morphological Effects of Postnatal Estrogenic Exposure	11/1/08-10/31/09	\$2,000

Submissions

PI	Agency	Project Title	Project Period	Total Funding
Reza Hakkak	NIH	DHEA Obesity and Breast Cancer	7/1/09-6/30/11	\$404,250
Jill James	Autism Speaks	Biomarkers of Oxidative Stress in Autism	10/1/09-12/31/09	\$129,932
Marie Lacy	NIH	Neutrophil Elastase Mediates the Pathogenesis of Ocular Chlamydial Infection	6/1/09-5/31/11	\$362,500
Roger Rank	NIH	B. Guinea Pig Core	7/1/09-6/30/14	\$1,221,541
Roger Rank	NIH	Role of the Neurogenic Inflammatory Pathway in the Genital Tract Immune Response	7/1/09-6/30/11	\$404,250
Amy Scurlock	AAAI	Immunoregulatory Networks in Infection Induced Immunopathology	7/1/09-6/30/11	\$100,000
Mick Tilford	NIH	Measuring Caregiver Health Effects for Economic Evaluations of Autism Spectrum Disorders	4/1/09-3/31/11	\$404,250

Compliance Corner: Is Informed Consent for Clinical Research Over the Telephone Ever OK?

Unless you have prior authorization from the IRB, telephone consent is **NEVER** OK!

A verbal approval to participate in a research study does not satisfy federal regulations for the requirement for documented (signed copy of informed consent) informed consent.

In the rare occasions when telephone consent is to be used in a study, the investigator must state so in the IRB application and fully describe the process which will be used to obtain and document telephone informed consent.

Remember! When you pick up that phone, your first call should be to the IRB, not to your research participant!

Your Laptop Has a 1 in 14 Chance of Being Stolen!

Portable devices such as laptop computers, thumb drives, smart phones, and PDA's have a high risk of being lost or stolen. Try this: treat your portable devices as if they are a \$100 bill. If that thumb drive was cash...would you leave it where just anyone could pick it up? Qualcomm's CEO had his laptop stolen from him during a news conference while he was standing no more than 30 feet from it. As in this case, the information contained on your devices is far more valuable than the device itself.

If you must transport your research data use these options to keep it safe:

6. Send your information in a secure email then access it when you get to your destination.
7. Use password protection or encryption on your thumb drive.
8. Use encryption software and password protection on your laptop computer.
9. Password protect your smart phone or PDA.

The few moments it takes to enter a password could save you a whole lot of time if your device is ever lost or stolen.

ACHRI Investigator Meeting

The next ACHRI Investigators' meeting will be held February 11 in the Brandon Auditorium at 11:30 a.m. Lunch will be provided to the first 50 attendees.

The [October meeting PowerPoint presentation and 2009 PI Meeting Schedule](#) are available at the ACHRI web site.

Funding Opportunities

The National Association of Children's Hospitals (NACH) prepares and distributes upcoming funding opportunities every two weeks. Funding opportunities recently distributed by the NACH are available on the ACHRI web site (http://achri.archildrens.org/resources/funding_opp.htm). This file is updated monthly. Bookmark the page! The listing of funding opportunities is located on the intranet; you must have access to MyACH vault files to open the file.

Grant Writing Tip: Just One Resubmission

Starting with applications submitted for the first time for the January 25 receipt date, NIH will allow you to revise and resubmit your application just once if it did not get a fundable score. Until then, you can resubmit twice. The change applies to both new and renewal applications.

Not affected are applications already in the system slated for the January and May 2009 advisory Councils. NIH announced the policy change in an [October 8, 2008, Guide notice](#).

While NIH's goal is to fund applications earlier, they do not yet know the effect of this change on reviewer behavior. NIH's move to trim resubmissions stems from its revamp of initial peer review – see [NIH Recasts Peer Review](#) in the [October 1, 2008, NIAID Funding News](#).

Mathematical Modeling Services for Researchers

Have you measured (or plan to measure) a variable consistently over a period of time, say growth, cell counts, cell movement, disease severity, or protein levels? Would you like to predict the outcome when you change some variables in your experiment without a complete repetition? Do you need to add extra scientific value to your grant to increase your chances of funding? If so, you may need help to develop a mathematical model for your research project. Contact Horacio Gómez-Acevedo, PhD, of the Department of Pediatrics to learn more about the advantages of mathematical modeling. He can work with you to take factors that are consistently measurable at different time

points to build a model that can reinforce your conclusions and help you with some predictions on how any one of those factors can affect the outcome of your experiment. Model development is very open to various factors and applicable in many research scenarios. Contact Dr. Gómez-Acevedo at 364-4532 when you're planning your project. His early involvement can help you determine what you should measure and how to construct a model that provides support to your experimental work.

UAMS COM Research Web site and Calendar

Please take a minute or two to explore the UAMS COM Research and Web site:

<http://www.uams.edu/com/research/>. The site offers a host of announcements and resources to assist UAMS faculty researchers. Research conferences hosted by ACHRI are included on the research calendar. A link to the calendar can be found on the left-hand side of the UAMS homepage. Linda Williams and Larry Cornett have done a fabulous job in putting this together.

Who do you call when you need Statistical Services?

For questions and requests regarding statistical services and reviews, please e-mail achbiostat@uams.edu. If you are currently working on a project with an individual in the statistics group, please copy achbiostat@uams.edu on your email correspondence with that individual.

Children in Clinical Studies Web site

A link to a web site designed to offer information about participation of children in clinical studies has been added to the ACH web site's clinical trials page and will soon be available on the CareHub system. The site, which was developed by NIH's National Heart Lung and Blood Institute, features videos of children, parents, and health care providers discussing their experiences with clinical research. This is a truly remarkable web site and we hope that you share this with families considering participation in clinical research. .

<http://www.nhlbi.nih.gov/childrenandclinicalstudies/index.php>

Arkansas Children's Hospital Research Institute