



RESEARCH update

May 2009

Mile High Research



Jackson's travels have included an Angel One flight during which he participated in a research study.

Getting your blood pressure measured generally happens in a clinical setting at a doctor's office or a hospital. Doctors and nurses are trained to perform this routine task with equipment approved and designed for use in such commonplace settings. What if you're being transported from one location to another during a medical emergency and your blood pressure needs monitoring...and you just happen to be high above the ground in a fast-moving helicopter?

"Using equipment normally used in the hospital in an aircraft can make taking blood pressure problematic," says Dr. Michael Stroud of the Section of Pediatric Critical Care Medicine in the Department of Pediatrics. He explains, "The noise and motion of the helicopter and the vibration of rotors can interfere getting an accurate reading."

Dr. Stroud investigated the difficulties of blood pressure monitoring during pediatric transport during his pediatric critical care medicine fellowship at ACH. He continues this research by examining issues related to many types of medical intervention during transport of children, many who are critically ill or have experienced trauma. "We know early intervention improves the outcomes for these children," Dr. Stroud says, "but delivering ICU-level care during transport is not always the same as delivering it in the ICU." Dr. Stroud's research aims to improve monitoring techniques, protocols, and therapeutic interventions during pediatric transport to in

turn improve early intervention.

Only 10% of emergency medical calls involve pediatric patients. One of these transport calls was for inter-facility transport of 3-year-old Jackson in July of 2006. Jackson had complications from a ruptured appendix and was in an adult intensive care unit at a northwest Arkansas medical center. "After 2 weeks," says his mother Amy, "he still had continuous infections and trouble with an IV." The decision was made to move Jackson for specialized care at the pediatric intensive care unit at Arkansas Children's Hospital.

The family allowed Jackson to participate in Dr. Stroud's blood pressure monitoring study during his hour-long flight by Angel One. Amy says her family understands the importance of research to children's health. "If I can help in any way, I feel part of the responsibility to go there," she adds. Jackson's stay at ACH was less than two weeks. With the help of a nurse at home, Jackson was able to start pre-school on time that fall.

With funds from the Children's University Medical Group, Dr. Stroud is continuing his research in the area of pediatric transport medicine. He is currently conducting a study of noninvasive measurement of tissue oxygenation during pediatric inter-facility. Monitoring tissue oxygenation, including cerebral oxygenation, is very important when caring for a child that is critically ill or experienced trauma. "You must ensure tissue oxygenation readings are correct," Dr. Stroud stresses, "otherwise you might as well not do them at all."

Dr. Stroud is using Near Infrared Spectroscopy (NIRS) to determine tissue oxygenation. NIRS technology reads the light reflected by tissue to determine the level of hemoglobin (the oxygen transporting substance in blood) in the targeted tissue. Dr. Stroud will determine if NIRS measurements change with altitude during transport to develop techniques to measure cerebral tissue oxygenation more accurately during flight.

"A more effective early intervention is important especially for children requiring transport," Dr. Stroud says, "and the result

is they need fewer procedures at the hospital and they get out of the hospital faster.” With the research of Dr. Stroud, ACHRI is dedicated to children’s well-being whether it is on the ground or up in the sky.

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.

- Helmkamp JC, Aitken ME, Lawrence LA. ATV and Bicycle Deaths and Associated Costs in the United States, 2000–2005. Public Health Reports; May–June 2009; 124:409-18.
- Langlois PH, Ramadhani TA, Royle MH, Robbins JM, Scheuerle AE, Wyszynski DF. Birth defects and military service since 1990. Mil Med. 2009 Feb;174(2):170-6.

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](#).

Sunny Anand Awarded Nils Rosén von Rosenstein Medal

In April, Dr. Kanwaljeet J.S. “Sunny” Anand received one of the most prestigious awards in the field of Pediatrics, the Nils Rosén von Rosenstein Medal. The Swedish Society of Medicine presents this award, based on recommendations from the Swedish Pediatric Society. The award, named after the 18th century physician considered to be the founder of modern pediatrics, is presented to three pediatricians every five years. Dr. Anand was presented with a silver medal, a copy of Rosén von Rosenstein’s book (published 1771), and a citation at a ceremony at Uppsala University, among the oldest medical schools in Europe. The citation stated that his research on neonatal pain had changed the paradigm on how we view pain and stress in children and ushered in a new era of compassionate and more humane care in the field of pediatrics. Dr. Anand presented a prize memorial lecture entitled “Love, Pain, and Intensive Care in Pediatrics”. Awardees are scrutinized through an extensive 2-year selection process. The other recipients this year included Professor Ed Mitchell of the University of Auckland (New Zealand) cited for uncovering SIDS risks and Professor Ingemar Kjellmer of the University of Göteborg (Sweden) noted for his research of the mechanisms of neonatal brain damage.



Todd Nick Appointed to NIH Study Section

Todd G. Nick, Ph.D., the new director of the biostatistics program in the UAMS Department of Pediatrics, has been appointed to a four-year term on the Kidney, Nutrition, Obesity and Diabetes Study Section of the Center for Scientific Review. This panel reviews and makes recommendations on National Institutes of Health grant applications, and surveys the status of research in these fields.

Angela Green Named to Editorial Board

The Journal of Pediatric Nursing has named Dr. Angela Green, Director of Nursing Research at ACH, to its editorial board. It is the official journal of both the Society of Pediatric Nurses and the Pediatric Endocrinology Nursing Society. The journal provides original, peer-reviewed research that is based on the philosophy that pediatric nursing incorporates a family-centered approach and serves as a forum for the dissemination of current information in the field of pediatric nursing. Her appointment is for two years. Congratulations to Dr. Green!

Contact ACH Public Relations with All Media Requests

It is a policy of Arkansas Children’s Hospital that all employees (both ACH and UAMS who work on ACH campus) contact the ACH Public Relations department after any media request. Employees who are contacted by media for interviews regarding their work on the ACH campus, in connection with an outside organization, for their personal opinion on a particular topic, or any other reason should contact the ACH Public Relations department. Media are not allowed on the ACH campus unless they are escorted by a Public Relations representative. Employees who wish to conduct an interview with the media on matters not relating to Arkansas Children’s Hospital must conduct those interviews off-site from the hospital campus. Please direct any questions or concerns to the Public Relations office at 364-6444. [ACH Policy J02 – Press Relations Policies and Release of Patient Information](#) (available in the ACH Vault) addresses this issue.

Accounts Payable Holiday Schedule

For the Memorial Day holiday on May 25th, check requests will be due to Accounting by **noon on Monday, May 18th** instead of the regular deadline of 2:00 on Tuesday, May 19th. This will allow checks to be ready on the normal schedule of Tuesday, May 26th.

Reminder to All Who Conduct Human Research

Off label use of drugs or devices for the purpose of research activities is not the same as off label use for clinical purposes. The FDA has very specific regulations that apply to the research setting.

If you or someone you mentor is conducting an investigator-initiated research project that uses a drug or device, UAMS is requiring you to submit your protocol to the UAMS Research Support Center's Regulatory Affairs Unit for review prior to submission to the IRB. They will help you determine whether the project falls under the FDA regulations for IND/IDE (Investigational New Drug or Investigational Device) applications.

Note: If you have an Industry-Sponsored project, the Industry will already hold the IND/IDE if they are providing full support and have given you the protocol. If they are only partially supplying funds or just providing the device or drug free of charge but offer no additional support, you should still contact UAMS.

UAMS Research Support Center Contact Information: <http://www.uams.edu/rsc/>; Carole Hamon: 526-7437

ACHRI Research Affiliation with Arkansas School for Mathematics, Sciences, and the Arts

ACHRI has finalized a research affiliation with the Arkansas School for Mathematics, Sciences, and the Arts in Hot Springs. The agreement guides the two institutes in a working relationship to provide high quality learning experiences for students. Currently, ACHRI is calling for researchers to become mentors for mathematics and science high school students this summer. If you are interested, please contact Sandy Burrow at Volunteer Services (364-1812). These are volunteer positions. Please note that ACHRI is still looking for mentors for college students this summer.

Security Camera Installation

Recently ACH Security Services performed an assessment of ACHRI resulting in the installation of 31 interior and exterior security cameras. The cameras assist with watching the entry and exit points and elevator lobbies of ACHRI. The ACH Security Dispatch Center will monitor the motion-activated cameras. ACH Security will record and store images for a limited time.

Compliance Corner: When you make a change to your protocol do you need to re-consent your subjects

IRB Policy 8.1 has guidance on protocol changes and re-consenting. Policy 8.1 states:

Upon notification of any new information or change which might affect the willingness of a participant to continue in the study or changes the risk-benefit balance for those already enrolled, the Investigator will be directed (by the IRB) to notify participants. Depending upon the seriousness, the Investigator may be directed to contact the participants by letter, consent at next opportunity, or phone participants to schedule a visit for immediate re-consent process.

In situations where changes are to address administrative type changes and do not impact the participant or their ability to contact those associated with the study, the IRB typically will not required re-consenting of previously enrolled subjects.

Always check with your sponsor for their specific requirements as well. If you have any compliance questions with regard to human subject research, feel free to contact the ACHRI Regulatory Compliance Specialist; Margie Brackeen at brackeenmargiei@uams.edu or 364-3586.

New Video Clips of the Continuing Review Process in ARIA

On February 19, 2009 Jennifer Sharp Esq., the director of the Office of Research Compliance at the University of Arkansas for Medical Sciences (UAMS) presented "Submitting Your Continuing Review in ARIA". This presentation described the 13 steps of the Continuing Review submission process to the UAMS Institutional Review Board (IRB) via their software system ARIA. In order to make this program available to the researchers and staff on the ACH/ACHRI/UAMS campuses, the presentation was video-taped. This videotape was then broken down into smaller more "user-friendly" clips of no more than 10 minutes each.

See these video clips on our new webpage at: <http://achri.archildrens.org/guidebook/ARIACRR.html>

New Industry-Sponsored Projects

Clinical Trials	Agency	Project Period	Total Cost
Robert Saylor	Eisai/INC	1/09 - 1/10	\$41,799.00
Joe Elser	GSK	12/08 - 2/10	99,061.60
M. Siddiqui	ENDO	4/09 - 3/10	25,242.00
M. Siddiqui	ENDO	4/09 - 3/10	21,230.00
Laura James	GSK	4/09 - 6/09	2,750.00

Recent Grant Submissions

PI	Agency	Project Title	Project Period	Total Funding
Tom Badger	NIH	Center for Developmental Obesity	7/1/10-6/30/15	\$10,611,699.00
Lisa Buckmiller	NIH sub Children's Hospitals and Clinics of Minnesota	Measuring Outcomes of Cleft Palate Surgery	9/30/09-9/29/11	\$91,911.00
John Carroll	NIH	Postnatal Resetting of Carotid Chemoreceptor Sensitivity	7/1/09-6/30/11	\$186,330.00
Nicolaas Deutz	NIH	Determination of Minimal Protein Requirements in Critically Ill Children	9/30/10-9/29/12	\$1,000,000.00
Nicolaas Deutz	NIH	Eicosapentaenoic Acid and Amino Modulation to Induce Muscle Gain and Improve Overall Outcome in Pediatrics Patients with Cystic Fibrosis	9/30/10-9/29/12	\$988,743.00
John Fowlkes	NIH	Skeletal Modeling in Type 1 and Type 2 Diabetes	9/30/09-9/29/11	\$814,760.65
Kathleen Gilbert	NIH	Epigenetic Control of Autoimmune Response to TCE-containing Binary Mixtures	10/1/09-9/30/11	\$993,899.00
James Graham	NIH	Trial of an Intervention to Reduce Rural Disparities in Pediatric Emergency Health	10/1/09-9/30/11	\$973,722.00
Reza Hakkak	NIH	Anti-obesity Dietary Supplement and Breast Cancer	12/1/09- 11/30/11	\$528,948.00
Charlotte Hobbs	NIH	Administrative Supplement Providing Summer Research Experiences for Students and Science Educators	6/1/09-5/31/11	\$28,418.00
Jill James	NIH	Autism, Oxidative Stress, Epigenetic Dysfunction	10/1/09-9/30/11	\$832,051.00
Laura James	Case Western Reserve University/ NIH	Case Western Reserve University Cleveland Clinic CTSA - Supplement	10/1/09-9/30/10	\$81,425.00
Laura James	NIH	HIF-1alpha and VEGF in Acetaminophen Toxicity and Repair - Administrative Supplement	6/1/09-5/31/10	\$81,720.00

Karen McNiece	Case Western Reserve University/ NIH	Case Western Reserve University Cleveand Clinic CTSA - Supplement	10/1/09-9/30/10	\$12,410.00
Karen McNiece	Case Western Reserve University/ NIH	Effect of BMI on Exposure Response Relationships to Lisinopril in Children - Supplement	10/1/09-9/30/10	\$24,628.00
Shanmugam Nagarajan	NIH	Soy Peptides and Anti-Inflammation	9/1/09-8/31/11	\$726,282.00
Ronald Prior	USDA	Structural Elucidation, Bioavailability, and Anti-Obesity Properties of Polymeric Pigments in Blackberry and Blueberry Juice	9/1/09-8/31/12	\$213,761.00
Roger Rank	NIH	Host Response to Chlamydia Genital Infection in the Male - NIH Supplement	5/1/09-11/30/09	\$51,056.00
Amy Scurlock	NIH	Immunoregulatory Networks in Chlamydia Genital Tract Infection	5/1/09-4/30/11	\$99,466.00
Rosalia Simmen	NIH	Bioactive Dietary Factors and Mammary Cell Lineage	10/1/09-9/30/11	\$660,407.70
Judith Weber	USDA	Increasing School Bonding through Gardening to Reduce Obesity and Other Risk Behaviors in Children in the Delta	10/1/09-9/30/13	\$1,799,900.00

Grant Writing Tip: New Sample R01s; 12-page Research Plans Coming

NIAID has new sample R01s with their summary statements [online](#). The Institute expects to upload more samples in the coming weeks. These R01s are complete submissions including forms and attachments. The files are large pdf files that you can save to your computer for reference or bookmark in your favorites to access quickly.

A request was made to several PIs to volunteer for this project after NIH switched to the electronic application. They declined because the information and new application process was too new. After a year and a half, NIAID sought a new group of volunteers. At that point, people were very generous about having their applications posted.

Soon NIAID will again make a similar request. When NIH switches to a 12-page R01 research plan, NIAID we will have another lag until they can post a new batch of shorter applications. During the interim, these new samples will be maintained at their Web site.

As NIH moves to shorter research plans, they will provide advice on how a 12-page R01 research plan should differ from the 25-page samples. No specific date has been set for this change, but it is currently anticipated to occur in 2010. ACHRI administrative staff will also keep you posted on the status of this change and provide guidance to adapting to it.

IRB Submission Deadline Guidance (excerpt from the UAMS ORSP *Research News*, Volume 3, Issue 3)

All IRB submissions (full-board, expedited, exempt, determinations, modifications, adverse events) have the same processing turn-around schedule. There are no rush categories and expedited does not mean faster turn-around. The deadline for submission is each Monday at 4:00 p.m. CST. The IRB Administrative staff has until Thursday at 4:00 p.m. CST to review the submission and issue a pre-review contingency letter if necessary. All pre-review contingencies must be addressed by the PI before the submission will be placed on an IRB agenda (lack of response to pre-review contingencies will delay turn-around time). Once the pre-review contingencies have been met or none exist, the submission will be assigned to an IRB reviewer and placed on the IRB agenda. The agenda is distributed to the IRB Committee on Monday and the reviewer will confirm their acceptance for the review by the next day. The reviewers have one week to review the submissions for the meeting to be prepared to discuss your submission on the following Tuesday. A letter from the IRB Chair or delegate will be sent to the PI and primary contact by the Friday following the meeting with one of the following decisions: approved, not yet approved major revisions required, not yet approved minor revisions required, Administrative Hold, or Declined.

This processing schedule does not in any way guarantee an approval by the IRB committee within a certain time frame. All contingencies must be met and a final approval letter received before the research study can begin. In the event this is an emergency use exemption request, please follow the procedures outlined in IRB policy 18.3 for a drug or biologic and 18.4 for an unapproved medical device. These policies are located on the IRB website at http://www.uams.edu/irb/IRB_Policies.asp.

To find out the status of your IRB submission, please email irb@uams.edu and an IRB Administrator will respond to your request within one business day.

Advertise Your Clinical Trial on the ACH Website

Are all of your potential research subjects aware of your clinical trial? An excellent tool you can use to recruit participants for your studies is available at www.archildrens.org/research. This website lists currently enrolling studies, so interested parents can contact you about possible participation. To have your study included on the website, you must have received IRB approval for your study advertisement. Once you have done so, please email a copy of the approved material and a completed [Clinical Trial Website Form](#) to [Rebecca Myrick](mailto:Rebecca.Myrick) or call her at 364-3577.

Emails Bouncing Back or Not Received?

Please be aware that we have heard numerous reports of emails to individuals with UAMS addresses getting lost or bouncing back with messages "undeliverable." One of two things might be happening. #1) Your Microsoft Outlook may be operating in cache mode and is not pulling the most current email address/account information from the global address book. Changing the setting from cache mode takes only a minute and Techsource (phone: 364-5299) will be happy to walk you through making the change. #2) If you are using the autocomplete feature (you type a couple letters of a name in the address bar and a list pops up with a few names to select from), you may need to go to the global address book and select the person's name to ensure you are using the most recent email address since the most current address might not pop up with the autocomplete feature.

Several ACHRI staff members have had recent changes to their email accounts and have learned that emails to them have been returned or lost. If you have sent an email to one of them and you have not received a response in a reasonable amount of time, please verify that your email was received.

ACHRI Address Change

With the dedication of Children's Way (formerly Marshall Street), ACHRI has a new street address: 13 Children's Way. Use this address on grant applications submitted through ACHRI. Refer to the [sample SF 424](#) with ACHRI information at our Web site to view the change for NIH submissions.

Also, don't forget to update your study consent forms and other research-related documents (and any templates) that may contain the old address as you make new submissions to the IRB.

Administrative Supplements to Provide Summer Research Experiences for Students and Science Educators

NIH has \$21 million from the American Recovery and Reinvestment Act of 2009 available to facilitate educational opportunities for students and science educators in laboratories holding active NIH grants. These administrative supplements providing summer research experiences for students and science educators are now available on an expedited basis to those with active NIH research grants.

Consider working with one or more of these individuals in your laboratory this summer, as well as next summer. Salary support plus a modest amount of supplies would come from the administrative supplement to your research grant. You may apply for the supplement immediately without identifying these individuals. Follow the instructions in the NIH Guide Notice [NOT-OD-09-060](#) to apply for funds that will support these employment opportunities for students and science educators.

Be sure to consult with your NIH project officer to learn about your supporting Institute's participation in this program. Eligibility, priorities, and deadlines will vary across NIH. Contact [John Gregan](#) (364-6296) at ACHRI if you need to discuss your interest in applying for one of these administrative supplements. ACHRI staff can assist you with preparation of the supplement and with finding a student if an award is made.

Wanted: Researcher Profiles!

In April, there were 917 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.archildrens.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.

Upcoming Educational Opportunities There are several on-campus educational opportunities scheduled in the next couple months. To learn more about these opportunities, please visit <http://achri.archildrens.org/resources/calendar.htm>.

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.