

Research Update

Wishing You A Joyful Holiday Season And A Prosperous New Year



Lee Howard: IRB Service Benefitting Patients and Research



Experience as an IRB reviewer helps Lee Howard (right) as she and fellow Clinical Research Coordinator Suzanne Carlisle examine wording on a consent document in the PCRU.

The UAMS Institutional Review Board oversees all human subjects research on the campus of Arkansas Children's Hospital. Annually, the IRB has over 1,500 open studies at various locations including UAMS, ACH, and ACHRI. To review these studies, the UAMS IRB maintains 4 review committees that meet monthly to evaluate study protocols. Federal regulations require that the IRB's membership roster include men and women of varying professions and at least one scientist, one non-scientist, and a member unaffiliated with the institution. Additionally, the UAMS IRB ensures at least one representative from the Department of Pediatrics for each of its four committees.

All IRB members are all volunteers, and many members of the medical and scientific community of UAMS, ACH, and ACHRI are on its roster of members and potential members. While many of these volunteers generally serve 2 to 3 years, some IRB members serve longer. One of the IRB's long-standing volunteers is Lee Howard, RN, CCRC, in the Section of Clinical Pharmacology and Toxicology.

A Clinical Research Coordinator, Ms. Howard joined the IRB in July 2006 after another coordinator who was retiring from the IRB sent a recommendation to the IRB that she would fit the position well. Ms. Howard volunteered for IRB service she says because it was an obvious means to contribute to the safety of children and adults participating in research and because of her experience in ethical considerations involved with human subjects research.

Ms. Howard serves as a Department of Pediatrics representative on one of four committees that meet monthly. Her IRB service has also included work on the IRB's Audit Committee and Policy and Procedures Committee and as an alternate reviewer when needed. Ms. Howard is the primary reviewer on 4 to 6 protocols for her monthly IRB committee meetings. IRB members are also secondary reviewers of protocols, and she may review an additional 18 to 24 protocols for each monthly meeting. Ms. Howard spends about 20 hours reviewing her assigned protocols and uses time at work and outside of work to complete the reviews to prepare for a meeting that may last 3 to 4 hours.

"Lee is a very experienced pediatric clinical research coordinator and her talents and perspectives on research benefit many patients at ACH, as well as faculty members within the Department of Pediatrics that are involved in clinical research," says Dr. Laura James, Section Chief, Clinical Pharmacology and Toxicology, "She is also a great resource to the pharmaceutical industry about how to plan and conduct clinical trials in ways that are child friendly."

Though protection of human subjects is the foremost benefit of Ms. Howard's IRB participation, she also sees that IRB service provides a different perspective of what others do in research that can help her in her professional role as a Clinical Research Coordinator and nurse. "I learn better ways to write consent forms and better ways to reduce

pain in children that may occur during research procedures, such as obtain IVs," she says. In addition, Ms. Howard learns about policy changes, and combined with the other insight gained at IRB meetings, she is able to improve her submitted protocols.

To those considering IRB service, Ms. Howard says, "It's a great opportunity for personal growth and professional growth. You can never know it all, but this is another opportunity to learn as much as you can. Overall, it helps you see your subjects in a different manner. It also helps ACH help its patients."

ACHRI appreciates the years of dedication Ms. Howard and other pediatric representatives have given the UAMS IRB. The following is a list of current pediatric representatives on the UAMS IRB and their lengths of service: John Chelonis (5 years), Dale Dildy (2 months), Charles Field (2 years), Mark Heullitt (3 months), Lee Howard (7 years), Mohammad Ilyas (3 years), Gary Lowe (5 months), and Robert Saylor (11 years).



Ron Scott, retiring in February, has not called in sick in 20 years at ACH.

Ron Scott: 20 Years of Dedication and Loyalty

In February, Ron Scott will retire after 20 years at Arkansas Children's Hospital of which the last 15 years have been at ACHRI as an Environmental Technician. Ron is familiar to researchers and staff on the second floor of the research building and to many throughout ACHRI and ACNC.

Ron came to ACH in 1992. After 5 years at the hospital, he transferred to ACHRI in 1997. At that time the institute's Environmental Services staff consisted of three persons. Now Ron is part of an eight-member team that is responsible for over 160,000 square feet of space. He keeps the research buildings clean and sanitized and assists researchers and researcher staff members with other needs including storage and moving. Because his work is in a research environment, Ron is trained in regards to the proper disposal, storage, and cleanup of bio-hazardous and infectious agents, chemicals, and flammable liquids. His efforts are an essential part of sanitation of facilities which is critical when ACHRI is evaluated and accredited by outside agencies.

In addition to caring for the second floor of the research building, Ron is also the lead assistant to Sarah Jones, Environmental Services Supervisor. She knows Ron will see that the needs of the building occupants will be met and that the rest of the Environmental Services staff can turn to him for assistance and leadership when she is not at ACHRI. "Ron has tremendous experience and excellent morals, ethics, and values...traits that cannot be taught—you're gifted with them," says Blake Harrison, Director of Animal Research and ACHRI Facility Operations. Blake and Sarah note that Ron leads by example from arriving on time and dressing neatly to being a self-starter and independent worker.

ACHRI will definitely miss Ron's presence, loyalty, and hard work. Ron will not become idle during retirement. He plans to travel and visit family.

President's Choice Publications of the Month

The following articles were selected as this month's feature publications.

- Ronis MJ, Chen Y, Shankar K, Gomez-Acevedo H, Cleves MA, Badeaux J, Blackburn ML, Badger TM. Formula feeding alters hepatic gene expression signature, iron and cholesterol homeostasis in the neonatal pig. *Physiol Genomics*. 2011 Dec 5;43(23):1281-93. Epub 2011 Sep 27.
- Brann M, Mullins SH, Miller BK, Eoff S, Graham J, Aitken ME. Making the message meaningful: a qualitative assessment of media promoting all-terrain vehicle safety. *Inj Prev*. 2011 Nov 19. [Epub ahead of print]

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.

ACHRI Research Nurses Pass Clinical Research Professional Certification Examination

Pat Brady and Robin Gibson passed the recent Clinical Research Professional Certification Examination given by the Society of Clinical Research Associates. By passing the examination, they are now designated a Certified Clinical Research Professional (CCRP). We congratulate them on this noteworthy professional accomplishment.



2011 ACHRI Annual Report

ACHRI has just released its 2011 Annual Report, *We Believe*. The report reviews the successes of the last year and considers the exciting future of pediatric biomedical research. These stories are representative of the achievements of all of ACHRI's investigators and show the promise of research to improve the health, development, and well-being of children everywhere. The recent accomplishments by ACHRI's various research areas reflect our diverse research expertise, ranging from basic science to clinical and community-based research.

You can view the report online at <http://achri.archildrens.org/about/ACHRIAnnualReport2011.pdf>.

Clinical Systems Analyst Moving to ACH Systems Development Group

Beginning December 26 Jennie Stern, a clinical systems analyst on campus, will move from the UAMS Department of Pediatrics Biostatistics division to the ACH Systems Development Group. Jennie will continue offering database development and data retrieval support for ACHRI researchers.

Change in ACH Check Request Deadline

Effective Tuesday, December 13, 2011, all check requests must be **RECEIVED** by ACH Accounting no later than 11:30 a.m. for check distribution the following Tuesday. Currently, the requests must be received by 2:00 p.m. An earlier deadline will allow for concerns (if any) to be addressed and prevent delay in distribution for the following week.

Accounting asked that you put this into practice with the next deadline but will continue to accept requests until 2:00 p.m. for the next three weeks. Requests received after 11:30 a.m. on December 13th will not be available until December 27th.

Checks submitted by the deadline will be available for pickup at 8:00 a.m. the following Tuesday.

UPDATE - Elevator Upgrade

Due to delays in the elevator upgrades, completion is expected by the first week in January.

Employees may take the stairs or they may enter ACHRI via the skywalk located on the 4th floor of the South Campus Medical Arts Building. From that point, stairs may be taken to access ACHRI's 2nd or 4th floors. The freight

elevator is designated for animal and materials management purposes. Employees with handicaps that prevent them from using the stairs may receive authorization to use the freight elevator only after receipt of animal certification.

If you have questions or concerns regarding this matter, please contact Blake Harrison at 364-2710 or Al Martin at 364-7519 (pager 405-0272).

Focus Group Research Training

ACHRI and the UAMS Translational Research Institute (TRI) are offering focus group research training. Are you interested in acquiring qualitative data? Learn how to conduct a focus group and analyze the data through the methods of Richard A. Krueger. Topics include planning, recruiting, moderating, asking questions, analysis, and reporting.

The 2-day class is free but only 25 spaces are available – first come, first served. Lunch and snacks provided. If you would like to participate, registration must be completed and returned by January 27, 2012. Registration is free. Contact Hope Mullins, MPH, Program Manager, for more information: p. 501-364-4932, f. 501-364-3112, e-mail mullinssamanthah@uams.edu.

Arkansas Children's Hospital, East Campus, Room 103
February 8-9, 2012
Day one - 8:30 AM to 4:00 PM, Day two - 8:30 AM to 3:00 PM

NIH Funded Investigators

All publications that result from work funded by NIH are to be deposited to PubMed Central as specified in NIH's Public Access Policy within three months of ACCEPTANCE. Please contact [Phaedra Yount](#) AS SOON AS YOUR ARTICLE IS ACCEPTED by the journal. Phaedra will identify the party (the publisher or the author/PI) responsible for uploading the article to PubMed Central. If the publisher is responsible, she will follow up with the publisher to make sure that the article is deposited in a timely manner. If the author/PI is responsible, she can deposit the article on behalf of the author/PI or assist in the process.

Upcoming Intramural Grant Program Workshop

ACHRI intramural grant programs provide an opportunity for beginning and established investigators to obtain funding for their research projects and programs. ACHRI is providing a workshop on its Student/Clinical Staff research grant program on Tuesday, January 10, 10:00 am to 11:30 am, in Brandon Auditorium.

Upcoming Intramural Grant Program Deadlines

The upcoming application deadlines for ACHRI's intramural grant programs are as follows:

- March 1 - CUMG grant application deadline
- March 15 - Student/Clinical Staff grant application deadline
- February 1 - Marion B. Lyon New Scientist Development Award grant application deadline

More information on these programs is available at the ACHRI Web site:
http://achri.archildrens.org/resources/intramural_grant_programs.htm.

If you are interested in applying please contact Amy Stalls stallsamy@uams.edu.

New Industry-Sponsored Projects

PI	Sponsor	Project Period	Total Funding
Laura James	Duke University	8/11 - 8/14	\$67,000
Laura James	Duke University	11/11 - 11/12	\$84,000

Recent Grant Award

PI	Agency	Project Title	Project Period	Total Funding
Maya Lopez	HRSA/sub Massachusetts General Hospital	AIR-P Improvement/Guideline/Dissemination	9/1/2011- 8/31/2014	\$153,020.00

Recent Grant Submissions

PI	Agency	Project Title	Project Period	Total Funding
Richard Frye	DOD	Defining Subgroups of Mitochondrial Disease and Dysfunction in Autism Spectrum Disorder	10/1/2012- 9/30/2015	\$555,000.00
Dennis Kuo	Patient-Centered Outcomes Research Institute	Co-Management for Complex Neonates: Partnering Families and the Medical Home	7/1/2012- 6/30/2014	\$605,901.00
Dennis Kuo	Patient-Centered Outcomes Research Institute /sub Univ. of Pittsburgh	Developing a Dynamic Instrument to Identify Children with Health Complexity	7/1/2012- 6/30/2014	\$74,933.00

Grant Writing Tip: Don't Let a Parent Announcement Orphan You

Before you begin your investigator-initiated application in response to a Parent Announcement, be sure your target Institute or Center participates in the funding mechanism you've chosen. Institutes and Centers do periodically change their participation in these programs. For example, within the past six months both NHLBI and NIDDK have stopped accepting investigator-initiated R21 applications. Review announcements and notices to ensure your institute will accept your application.

First, find the current Parent Announcement at http://grants.nih.gov/grants/guide/parent_announcements.htm. Examine "Components of Participating Organizations" at the beginning of the announcement to see which Institutes and Centers participate in the program. Also review "Related Notices" for updated information that may apply to your planned submission. If your institute or center no longer is accepting applications through a Parent Announcement, review the funding section of the group's web site for other funding opportunities that may apply to your proposal.

Attention Grant Seekers!

Each week we will post NIH's Weekly Funding Opportunities and Notices and NACHRI's Funding Finds and Grants Alerts. You can receive immediate notification of additions of postings by using "Alert Me" under Actions at the new [Weekly Funding Opportunities](#) page at ACHRI's Sharepoint site.

Registering Your Clinical Trial with Clinicaltrials.gov

The link below is a great resource regarding your recent questions about Clinicaltrials.gov. This site will help you determine when and at what institution a research project should be registered.

http://grants.nih.gov/clinicaltrials_fdaaa/

If you will click on the link "Steps to Compliance for NIH Grantees" you will find 2 flow charts that will help you identify an applicable Clinical Trial and Identify the Responsible Party for which the clinical trial should be registered.

It is always important to remember, before the study is started, to know the plans for publications so the registration requirements can be determined. Keep in mind that while retrospective chart reviews and lab studies do not meet the general requirements for registration, the publisher can refuse to publish if it is not registered.

For more information, contact Janet Storment, RN, CCRC, ACHRI Clinical Trials Administrator at 364-2760.