



**December 2007**

### **TIME AND EFFORT REPORTING**

It's official! We now have ONE time and effort reporting system for all UAMS faculty members on the ACH and ACHRI campuses. A team of representatives from ACHRI, ACH and UAMS have worked tirelessly to consolidate their faculty effort reporting systems into one system that will eliminate the need for UAMS investigators working or conducting research on the ACHRI campus to certify their time on grants on a monthly basis at ACHRI and then semiannually at UAMS.

"I am very proud of the collaborative venture that captured a team effort from UAMS grants accounting, ACHRI accounting and staff, ACH accounting and staff, and the Department of Pediatrics management team," says Richard F. Jacobs, M.D., FAAP, president of ACHRI and chairman of the Department of Pediatrics at UAMS.

The U.S. Department of Health and Human Services approved our request to change our federal requirement of monthly effort reporting to semi-annual effort reporting. The substitute system we requested for the exemption was to utilize the UAMS semi-annual effort reports for all UAMS employees instead of monthly ACHRI reports via the Time Keeper system.

Effective immediately:

#### For ACHRI Activities

- Faculty and staff will no longer certify their research time and effort in the ACH Time Keeper system each month.
- Itemized personnel expense will still be available via the ACHRI PI Reporting system for PI review. If there are any concerns or corrections to UAMS personnel expenses, they should contact their responsible departmental administrator or business official for review.
- Time and Effort will be certified only through UAMS during the usual semiannual process. This now represents ONE TIME AND EFFORT reporting.

#### For ACH Activities

- All ACH-based clinicians will continue to get a monthly request for time reporting that is linked to teaching and administrative time (formerly referred to as "MD Time Keeper"). The documentation requirements for cost reimbursement still require more detail than the 6 month percentages. As a result, the number of hours spent in resident teaching and administrative activities on the ACH campus by physicians will be captured in a separate system. This system will be called the Teaching and Administration Documentation system (formerly referred to as "MD Time Keeper") No changes have been made to the system. This documentation is necessary for ACH to receive reimbursement on the Medicaid Cost Report.

[Click here](#) to view the list of Grants Life Cycle Committee members who played a major role accomplishing this change

If you have any questions about these changes, please contact Barry Brady at 364-6517.

### **NEW ROUTING PROCEDURES FOR LETTERS OF INTENT**

ACHRI's [Research Award Policy](#) has been revised. The policy now states that researchers submitting Letters of Intent must follow the same routing procedures that are followed for grant proposal submissions.

## **2007 SCIENTIFIC ADVISORY BOARD MEETING**

On November 8 and 9, ACHRI hosted the 2007 meeting of its Scientific Advisory Board. The purpose of the SAB is to assist and provide direction to ACHRI in its vision to become internationally recognized as a leader in pediatric biomedical research. Council members hold leadership positions in medicine, research, and industry. Members of the council seek to strengthen ties between ACHRI and federal agencies, agricultural businesses, and the research community. Together, under the direction of the ACHRI President, council members seek to identify opportunities, generate resources, and use their knowledge and experience to assist the ACHRI in developing scientific research efforts. The members of the council are advocates for ACHRI in the scientific community. The SAB provides guidance in evaluating ACHRI's research program. The SAB is currently completing their report for ACHRI administration. A summary of their report will be presented at the next investigator meeting scheduled for January 14th at 11:30am.

## **ACHRI'S 2007 ANNUAL REPORT HAS ARRIVED**

ACHRI has just released "Where Miracles Begin", its 2007 annual report. The report provides an overview of research revenue and milestones for ACHRI. It also presents the accomplishments of ACHRI researchers through features describing the impact of pediatric research on families and through highlights chronicling the achievements of ACHRI researchers over the past year. "[Where Miracles Begin](#)" (and a more exhaustive list of [research highlights](#)) is available at the ACHRI web site.

## **PRESIDENT'S CHOICE**

Stop by the bulletin board outside the research administration offices to see the poster featuring this month's President's Choice publications. The following articles were selected as this month's feature publications.

Forehand R, Armistead L, Long N, Wyckoff SC, Kotchick BA, Whitaker D, Shaffer A, Greenberg AE, Murry V, Jackson LC, Kelly A, McNair L, Dittus PJ, Lin CY, Miller KS. Efficacy of a Parent-Based Sexual-Risk Prevention Program for African American Preadolescents: A Randomized Controlled Trial. *Arch Pediatr Adolesc Med.* 2007;161(12):1123-1129.

Velarde MC, Zeng Z, McQuown JR, Simmen FA, Simmen RC. Kruppel-Like Factor 9 Is a Negative Regulator of Ligand-Dependent Estrogen Receptor {alpha} Signaling in Ishikawa Endometrial Adenocarcinoma Cells. *Mol Endocrinol.* 2007 Dec;21(12):2988-3001. Epub 2007 Aug 23

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 hospital and ACHRI boards, so it is important that we receive an accurate count of the publications your research produces.

## **IN THE SPOTLIGHT**

### **Nutrition and Brain Function**

Research from the Arkansas Children's Nutrition Center is featured in the November/December 2007 issue of *Agricultural Research*. The article titled Nutrition and Brain Function: Boosting Our Knowledge of Brain Food describes how diet and nutrition might affect development of the central nervous system from birth. To read the article, please visit <http://www.ars.usda.gov/is/AR/archive/nov07/brain1107.htm>.

### **ACH the Focus of Anne Jansen's "25-Year Journal"**

Arkansas Children's Hospital was the subject of Anne Jansen's "25-Year Journal" that aired recently on Today's THV News. Anne shared the role ACH has played in her life throughout her career starting as an intern in 1978; hosting the Children's Miracle Network Telethon for 20 years; becoming a mom of a patient at ACH; and her role when Today's THV served as Central Arkansas media partner for the Folic Acid Coalition of Arkansas (ACH and ACHRI partnered with UAMS, March of Dimes and the Arkansas Department of Health to promote usage of folic acid helping to reduce the number of neural tube defects in Arkansas). [Click Here](#) to view the video.

## **Peanut Allergy Research In the News**

A publication this week in the *Charlotte Observer* acknowledges collaboration among peanut allergy researchers at Duke University and Arkansas Children's Hospital. To view the article, please visit <http://www.realcities.com/mld/charlotte/news/18073236.htm>

## **REGULATORY ALERT!!!! MANDATORY CHANGES IN CLINICAL TRIAL REGISTRATION**

The Food and Drug Administration Amendments Act of 2007 greatly expands the registration requirements for Clinical Trials. Enacted in September of this year, the Act ([Public Law 110-85](#)) requires that all ongoing drug and device trials that involve treatment or an intervention such as surgery or a procedure for a "serious or life threatening disease or condition" must be registered with [Clinicaltrials.gov](http://clinicaltrials.gov) before December 26, 2007! All trials that involve drugs and devices that do not involve a "serious or life threatening disease or condition", must be registered by 9/27/2008. However, if you have a new clinical trial and you wish to publish, the trial must be registered after IRB approval and prior to the enrollment of the first subject to be eligible for certain journal publication.

I. For Industry or Cooperative Group sponsored trials, check with your IND, IDE, or Cooperative Group sponsor to see if your trial is registered. II. For investigator-initiated trials:

A. If you have a **currently ongoing** clinical trial that:

- Is investigator initiated and;
- Involves a drug, device, interventional procedure, or combination thereof and;
- Is not a cooperative group study and;
- Is not under an industry IND or IDE.

**Your trial must be registered on [clinicaltrials.gov](http://clinicaltrials.gov) before December 26, 2007.**

B. If you have a **new** clinical trial that:

- Is intended for publication and/or;
- Is investigator initiated and;
- Involves a drug, device, interventional procedure, or combination thereof and;
- Is not a cooperative group study and;
- Is not under an industry IND or IDE.

**Your trial must be registered on [clinicaltrials.gov](http://clinicaltrials.gov) post-IRB approval and prior to enrolling your first subject.**

1. If your ongoing or completed trial was not registered as of September 2005, certain journals may not consider related manuscripts for publication. Refer to <http://prsinfo.clinicaltrials.gov/icmje.html> for more information and a link to the ICMJE website, which includes a list of participating journals.

2. Penalties for non-compliance include:

\$10,000 for the following:

- Non-registration
- Knowingly submitting false information

\$10,000 per DAY per incident for not correcting a problem within 30 days of notification

Lyndsey Avery, 686-5190 & Crystal Deville, 686-8098 with the Research Support Center are ready to assist you. Please contact Tanda Grisham at 364-3571 for research through ACHRI.

## NIH GUIDANCE FOR NEW LAW ENACTED TO EXPAND CLINICALTRIALS.GOV

Public Law 110-85, which was enacted on September 27, 2007 [[http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110\\_cong\\_public\\_laws&docid=f:publ085.110.pdf](http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_public_laws&docid=f:publ085.110.pdf)] amends the Public Health Service Act to expand the scope of clinical trials that must be registered in ClinicalTrials.gov. It also increases the number of registration fields that must be submitted, requires certain results information to be included and sets penalties for noncompliance. This notice provides information for NIH grantees and contractors on new responsibilities related to the first part of the law, the registration of clinical trials. Guidance on Public Law 110-85 has been issued and can be found at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-014.html>.

## COMING SOON!

ACHRI will conduct a Customer Opinion Survey for investigators and their staff in the spring of 2008. Specific dates and details will be announced soon.

## YOU'RE INVITED

You are cordially invited to attend the formal investiture of Angela Green, PhD, APN, as the recipient and steward of the John Boyd Family Endowed Chair in Pediatric Nursing, a program of Arkansas Children's Hospital and the University of Arkansas for Medical Sciences College of Nursing. Dr. Green is Director of Nursing Research at Arkansas Children's Hospital. The investiture will be held Thursday, December 13, 2007 at 4:00 p.m. in Chairman's Hall in the Sturgis Building. Congratulations Dr. Green.

## BEST WISHES

Please join us in wishing Kim Bobrosky, ACHRI Research Compliance Auditor, the best on her upcoming move to North Carolina to pursue a new career opportunity. We are sad that Kim is leaving us, and at the same time we are excited for her. She will be missed. Kim's last day at ACHRI will be Friday, December 21st. Join us in congratulating Kim on her new career opportunity.

## NEW RESEARCH FEE SCHEDULE FOR CLINICAL RESEARCH

ACH has issued a new Research Fee Schedule for Clinical Research. Please contact Janet Storment 364-2760 regarding any clinical pricing your project may need. All previously arranged pricing will not change.

## BUSINESS MILEAGE RATE FOR 2008

The IRS has announced that the business mileage rate for 2008 will be \$0.505. The current rate is \$0.485. For travel occurring after 12/31/07, the new rate should be used when requesting mileage reimbursement.

## NEW INDUSTRY-SPONSORED PROJECTS

| PI         | Agency       | Project Period | Total Cost |
|------------|--------------|----------------|------------|
| J Jaquiss  | Berlin Heart | 11/07 - 10/10  | \$38,250   |
| Kimo Stine | Baxter       | 11/07 - 7/10   | \$6,135    |

## RECENT GRANT AWARDS AND SUBMISSIONS

### Extramural Awards

| PI            | Agency                            | Project Title  | Project Period  | Total Funding for All Years |
|---------------|-----------------------------------|--|-----------------|-----------------------------|
| Mary Aitken   | Arkansas State Highway Commission | Arkansas Safe Routes to School Program                 | 12/1/07-4/2/09  | \$178,903                   |
| James Aronson | NIH                               | Bone Loss PPAR-g activity-Taledo Sub                   | 8/1/07-7/31/08  | \$8,897                     |
| Martin Ronis  | NIH                               | Lipid Aldehydes and Ethanol-Induced Liver Damage       | 8/10/07-7/31/08 | \$123,777                   |
| Judith Weber  | Robert Wood Johnson               | School Partnership for Obesity Research and Prevention | 11/1/07-2/31/08 | \$59,984                    |

Foundation (SPORT)

### New CUMG Awards

| PI               | Agency | Project Title   | Project Period   | Total Funding for All Years |
|------------------|--------|---|------------------|-----------------------------|
| Sarah Blossom    | CUMG   | Establishing a link between maternal immune dysfunction and congenital heart defects  | 12/1/07-11/30/09 | \$40,000                    |
| Steve Bowman     | CUMG   | An Assessment of Trauma Care in Arkansas: Resources, Capabilities and Quality of Care   | 12/1/07-11/30/09 | \$27,350                    |
| Marielle Engelen | CUMG   | Development and Applicability of new Stable Isotope Method to Determine Protein Requirements in Critically Ill Children   | 12/1/07-11/30/09 | \$39,955                    |
| Marie Lacy       | CUMG   | The Role of Polymorphonuclear Neutrophils in Regulating Adaptive Immune Responses in Chlamydial Infections  | 12/1/07-11/30/09 | \$39,814                    |
| Amiar Mian       | CUMG   | Outcome Prediction of Immune-Compromised Pediatric Patients with Fever and Neutropenia: A Risk-Stratified Predictive Model Based on inflammatory Markers, Acute Phase Reactants and Coagulation System. | 12/1/07-11/30/09 | \$39,377                    |
| Gal Shafirstein  | CUMG   | Personalized Interactive Laser Therapy of PWS (PILTP)   | 12/1/07-11/30/09 | \$31,612                    |
| Rosalia Simmen   | CUMG   | Diet, Stem Cells, and Prevention of Breast Cancer   | 12/1/07-11/30/09 | \$39,981                    |

### UPCOMING EDUCATION OPPORTUNITIES

For a complete listing of research education opportunities at ACHRI, please visit our [Research Education Calendar of Events](#) on the ACHRI Web page.

Topics for upcoming education opportunities include

- Coffee and Compliance Series: Recruitment Strategies (12/14/07) or New IRB and ACHRI Policies (1/10/08)
- Submitting Electronic Applications to NIH? (1/708)
- Intramural Grant Programs: Focus on the CUMG Grant Program (1/8/08)

Submitting a Grant Proposal in the Spring?

If you plan to submit a grant proposal in the spring and would like grant preparation assistance from an ACHRI science writer/editor, please contact us as soon as possible. Call or email [yountphaedra@uams.edu](mailto:yountphaedra@uams.edu) (364-2469) or [John Gregan](#) (364-6296).

### 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](http://achri.archildrens.org/resources/funding_opp.htm)). This file will be updated twice monthly. Bookmark the page! The listing of funding opportunities is located on the intranet; you must have access to ACH webapps to open the file.

## **GRANT PREPARATION TIP: NIH REDUCES TEMPORARY “ERROR CORRECTION WINDOW” TO TWO BUSINESS DAYS**

NIH has released a notice ([NOT-OD-08-018](#)) stating that it will reduce the “error correction window” (that is, the time allowed after the submission deadline to address NIH system identified errors/warnings) for all electronically submitted grant applications with submission deadlines on or after January 8, 2008. The reduction is from five business days to two business days.

The change means that electronic applications will be considered “on-time” if all of the following criteria are met:

- All required registrations must be complete prior to the initial submission.
- Initial successful submission to Grants.gov must have a timestamp on/before 5:00 p.m. local time of the applicant organization on the receipt date.
- Applicants must correct errors and/or warnings within the two business days following the receipt date (referred to as the “error correction window”).
- All application corrections must be in response to a system-identified error/warning (application submissions with additional changes may be refused).
- If final submission is sent after the receipt date, a cover letter attachment must be included identifying the system-identified errors/warnings that have been corrected.

The two business days provided to view the assembled application image in eRA Commons will remain unchanged.

It is NIH’s ultimate goal to define “on-time” submission as having an error-free application (that is, passes Grants.gov and eRA Commons system-enforced business rules without errors) with a Grants.gov timestamp on/before 5:00 p.m. local time of the applicant organization on the receipt date. NIH temporarily relaxed the definition of “on-time” submission by allowing a five business day “error correction window” for the first six electronic application receipt cycles following the initial transitions to electronic applications. The “error correction window” allowed applicants to adjust to the system-enforced business rules and ensured that Grants.gov and NIH system processing times did not interfere with successful submission. Progress on both fronts has allowed NIH to close this window to help speed up the process of getting the applications in to review and ultimately award.

NIH still remains committed to ensuring applicants are not penalized for Grants.gov or NIH system issues that are beyond their control and has contingency plans in place to handle those situations. The “error correction window” is a separate concept and has no effect on the contingency policies.

Summary of electronic application process:

- Find funding opportunity announcement of interest and download application package
- Prepare application
- Submit application to Grants.gov
- Wait for NIH to retrieve application
- Check submission status in eRA Commons
- Correct all errors and, at applicant's discretion, any warnings and resubmit through Grants.gov

Note: If corrections are made after the receipt date, the "Error correction window" applies

- Check assembled application image in eRA Commons within the two business day "application viewing window"
- Submission complete