



## Message from Chancellor I. Dodd Wilson

In order to provide continuing support for the responsible conduct of research and its associated activities, a new training course has been developed for research staff facing the challenges of conducting clinical studies. The program will be presented by Patient Billing Services, Medical College Physicians Group (MCPG) and the Office of Institutional Compliance. This training will focus on the operational aspects of clinical trials conducted at UAMS but will also provide insight into the regulatory and billing environment.

This training is mandatory for all study coordinators and other research staff whose duties are related to patient billing at UAMS. Principal Investigators who do not have dedicated coordinators should also attend. Please make time available for your research support staff to attend one of the following training sessions:

Tuesday, August 5<sup>th</sup> 12:00-1:30 pm (Meal Provided) Training Session will be held in Pauly Auditorium, COPH G219

Tuesday, August 19<sup>th</sup> 5:30-7:00 pm (Meal Provided ) Training Session will be held in ED II, G131 A/B

Monday, August 25<sup>th</sup> 7:30-9:00 am (Meal Provided) Training Session will be held in ED II, G131 A/B

Please contact Kristin Staggars at 501-614-2222 up to the day before to register for the course of your choice. This training counts as 1 1/2 contact hours toward the Certified Research Specialist (CRS) Program. If you have questions regarding the training or its applicability to your position, please contact Paula Alonso at 501-614-2182 or Jane Hohn at 501-603-1001.

## Compliance Tip from the UAMS Office of Research Compliance

The UAMS IRB requires that each page of an informed consent document be numbered and include a version number and date. Routinely adding a printed date and version number to each page of a protocol can also simplify your record-keeping. When the IRB approves a new or amended protocol, it will send you an approval letter referencing the protocol by the date you list in ARIA. It will be much easier for you to show that each version of your



protocol received IRB review and approval if the date in the approval letter matches the preprinted protocol date. In fact, dated protocols are required in clinical trials that are subject to the International Conference on Harmonization's Good Clinical Practice guideline. Even if your

study is not a clinical trial, dating each version of your protocol will make it much easier to link each IRB approval letter with a protocol. Also, whenever you get an IRB approval letter for a new informed consent form or protocol, make sure the letter has the correct document date listed. If not, ask the IRB for a corrected approval letter.

For more information, call the Research Compliance office at 686-8062 or 526-6270.

## In this issue:

Research Staff Training Course	Page 1
Compliance Tip from ORC	Page 1
Memorandum From Dr. L. D. Milne	Page 2
Six Revised IRB Policies	Page 2
August 2008 Education Calendar	Page 2
Farewell Reception for Dr. Tim Atkinson	Page 2
New and Revised IRB Policies	Page 3

## Memorandum From Dr. L.D. Milne, Ph.D.

On July 25, 2008, Dr. Larry Milne announced to the UAMS Research Community that Dr. Tim Atkinson, Director of the Office of Research and Sponsored Programs, resigned his position at UAMS to accept the Assistant Provost for Sponsored Programs and Research Compliance position at the University of Central Arkansas (UCA) in Conway.

Dr. Atkinson has a Doctor of Education in Higher Education Administration degree from UALR. His last day at UAMS is Friday, August 8, 2008.

## Six Revised IRB Policies

Tim Atkinson, Ed.D., Director, Office of Research and Sponsored Programs at UAMS announced this week the revision of six existing IRB Policies.

All of the revised policies are found on the [IRB website](#).

The revised policies are:

[7.5 Expedited Review](#)  
(Revised July 28, 2008);

[7.6 Continuing Review](#)  
(Revised July 28, 2008);

[9.1 Range of IRB Decisions](#)  
(Revised July 28, 2008);

[10.2 Unanticipated Problems Involving Risks to Participants or Others- Investigator Reporting](#)

[Requirements and IRB Actions](#)

(Revised July 28, 2008);

[15.1 Elements of Informed Consent Documents and Process](#)

(Revised July 28, 2008); and

[15.4 Non-English-Speaking Research Subjects](#)

(Revised July 28, 2008)

Contact the IRB office at 686-5667 if you have any questions.



## August 2008 Education Calendar

Thursday, August 7, 2008

### Record Keeping and Regulatory Binders

CRS Course

Presented by Sandy Annis, Regulatory Research Supervisor, CRDM

Biomedical 1 Building

Room 205/207

2:00 pm - 4:00 pm

Thursday, August 14, 2008

### Part 11 Compliance

Q & A Course

Presented by Dr. Ray Anderson, QA Unit Manager, RSC

Biomedical 1 Building

Room 205/207

10:00 am - 11:00 am

Thursday, August 21, 2008

### Reporting Adverse Events Q & A Course

Presented by Tracie Baker Monitoring Manager, RSC

Biomedical 1 Building

Room 205/207

2:00 pm - 3:00 pm

To register for any of these courses, go to Training Tracker at <https://secure.uams.edu/TrainingTracker/frnEnrollInClass.aspx>

Select RSC CRS course for the August 7th class, and select RSC Q&A for both the August 14th and August 21st classes, then complete the registration information.

## Farewell Reception for Tim Atkinson

Thursday

August 7, 2008

2:00 pm—4:00 pm

Biomedical 1 Building

2nd floor Atrium

Drop in to bid farewell to Tim as he leaves UAMS.

Light snacks and punch provided.



# New and Revised IRB Policies

Here are links to 2 new IRB Policies and 15 revised IRB policies for your convenience.

The new policies are:

[12.5 \(Reports of Potential Non-compliance\)](#) *(Effective Date: March 5, 2008)*

[12.6 \(Findings of Non-compliance Under IRB Policy 12.5\)](#). *(Effective Date: March 5, 2008)*

The revised policies are:

[1.4 Studies Requiring Review](#) *(Revised Date: March 5, 2008)*

[2.6 Reporting to Appropriate Federal Oversight Bodies, Institutional Officials and Research Sponsors](#) *(Revised Date: March 5, 2008)*

[7.4 Standard or Full Committee Review](#) *(Revised Date: March 5, 2008)*

[7.6 Continuing Review](#) *(Revised Date March 5, 2008)*

[8.1 Changing Study Protocol/Modifications to Previously Approved Research](#) *(Revised Date: March 5, 2008)*

[9.1 Range of IRB Decisions](#) *(Revised Date: March 5, 2008)*

[10.2 Unanticipated Problems Involving Risks to Participants or Others—Investigator Reporting Requirements and IRB Actions](#) *Revised Date: March 5, 2008)*

[12.4 Non-compliance with Human Research Protection Program Requirements—Formal Audit Reports as Finding of Non-compliance](#) *(Revised Date: March 5, 2008)*

[15.1 Elements of Informed Consent Documents and Process](#) *(Revised Date: May 13, 2008)*

[15.3 Waivers of Signed Informed Consent Documents and Waivers of Informed Consent Elements](#) *(Revised Date: March 13, 2008)*

[15.5 The Informed Consent Process](#) *(Revised Date: March 5, 2008)*

[17.1 Children in Research](#) *(Revised Date: June 11, 2008)*

[17.8 Pregnant Women, Human Fetuses and Neonates Involved in Research](#) *(Revised March 13, 2008)*

[18.3 \(Emergency Use of a Drug or Biologic \(Source FDA Information Sheets Guidance for Institutional Review Boards and Clinical Investigators 1998 Update\)](#) *(Revised Date: March 5, 2008)*

[18.4 \(Emergency Use of an Unapproved Medical Device \(Source FDA Information Sheets Guidance for Institutional Review Boards and Clinical Investigators 1998 Update\)](#) *(Revised Date: March 5, 2008)*

These IRB Policies can be found at the IRB website [IRB Standard Operating Policies and Procedures](#). The IRB Policies can be viewed individually or in a full version. Archived IRB Policies are also available online. For more information, call the IRB main number at 501-686-5667 or Tim Atkinson at 501-686-8845.