



## Disney Visits UAMS!

Mickey Mouse and Chris Caracci of Orlando, Florida address UAMS employees during a *Pathways to Excellence* session on Thursday, July 17, 2008. According to Melissa Johnston of UAMS Human Resources, approximately 2,000 employees involved in research, education, and clinical services attended one of the ten sessions offered July 14-18. This past May over 5,000 clinical employees attended the training sessions.

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## Compliance Tip from the UAMS Office of Research Compliance

Federal regulations and UAMS policies require investigators to follow their protocols exactly as approved. This requirement applies to **all** human subject and animal research studies, not just to those involving investigational drugs, devices, or treatments. In fact, federal oversight agencies for both animal and human subject research recently indicated that they will pay closer attention to this issue from now on. This means that

investigators carrying out any research study involving animals or human subjects, whether investigator-initiated, behavioral, or involving an investigational product, must follow their protocols exactly as written. If you find during the course of your research that you need to change something in the study, submit a protocol amendment to the IRB or IACUC and get it approved **before** you implement the change. Note to those

conducting human subject research: The only exception to this rule is a change that is implemented to eliminate an apparent immediate hazard to human subjects. That kind of change can be made immediately without prior IRB approval, but it must be reported to the UAMS IRB promptly after implementation. *All other changes must get IRB approval first.* Questions? Call the UAMS Research Compliance Office at 686-8062 or 526-6270.

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## Meet one of the New IRB Chairs...

**Jim Wohlleb  
MS, MDiv**



*James C. Wohlleb  
New IRB Chair  
Expedited and Exempt  
Protocols*

Starting July 1, Jim Wohlleb assumed the duties of reviewing all expedited and exempt protocols for the UAMS IRB. According to Beth Scanlan, Assistant Director of the IRB, this is the first time the IRB has an IRB Chair devoted exclusively to the expedited and exempt protocols.

Mr. Wohlleb, an employee of the Little Rock School district, has been with UAMS twelve years full-time, continuing as a volunteer IRB member after 2002, and now as a part-time employee.

He originally started with the UAMS in the late 1990's, coordinating students' capstone projects for Tulane University's MPH Program

for Arkansas, based at UAMS with a connected site in West Memphis, Arkansas. A native of Dayton, Ohio, Mr. Wohlleb graduated from college in Indiana and completed Graduate studies in Texas and Massachusetts. He has a MS degree in Human Ecology, Epidemiology and Statistics along with a Master of Divinity.

For the past four years he has worked in the School District's Planning, Research, and Evaluation Department (PRE).

Mr. Wohlleb's hobbies include biking, swimming, singing with his church choir, family travel and spending time with his five grandchildren ages 1 to 7.

## July and August 2008 Education Calendar

Monday, July 28, 2008

### **Essentials of Quality Human Subject Research Training for New Coordinators and Investigators**

Spine Center  
JTS Hamlen Board Room  
8:00 am – 5:00 pm

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

For more information about the UAMS courses, contact Education Manager Crystal Hunnicutt, M.Ed. at 501-526-6879 or [chunnicutt@uams.edu](mailto:chunnicutt@uams.edu).

Thursday, August 14, 2008

### **Part 11 Compliance Q & A Course**

Presented by Dr. Ray Anderson  
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

## Myeloma Dinner and Movie Night!

**Tuesday, July 22**

**6:30-Dinner—7:00-Movie**

***The Great Debaters  
with Denzel Washington***

**Walton Auditorium**

**10th Floor**

**Cancer Institute**

Free admission for all  
Myeloma patients, their  
families, and Myeloma Staff.



For more information call  
Annie Lincoln at 526-2873

# 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.