



ORSP and IRB DIRECTORS ANNOUNCED

The Office of Research and Sponsored Programs and the Institutional Review Board are proud to welcome two new directors – Suzanne Alstadt and Mo Valentine.

Suzanne Alstadt is now serving as Director of the Office of Research and Sponsored Programs. Suzanne joined UAMS in 2003 as a Sr. Grants Administrator in ORSP. In 2006 she was promoted to ORSP Assistant Director, then to Executive Financial Analyst with the College of Medicine Dean’s Office.

Suzanne holds a Master’s in Public Administration Degree from the University of Arkansas at Little Rock and is a Certified Research Administrator through the national Research Administrators Certification Council. She is currently enrolled in UAMS’ College of Public Health in the Doctorate in Public Health Leadership Program.

Suzanne is thrilled to be back with the ORSP and is looking forward to all sorts of challenges in providing administration for researchers on campus.

Mo Valentine is the new Director of the Institutional Review Board. Mo came to UAMS in 2003 as Associate Director of Grants and Cost Accounting. Since that time she has made amazing strides in improving research administration on our campus. Among her other accomplishments, she was responsible for initiating the UAMS Grants Management Certification Program.

Mo is a Certified Research Administrator through the national Research Administrators Certification Council. This year she completed her Master’s in Public Administration Degree from the University of Arkansas at Little Rock.

Mo is looking forward to the opportunity to provide her expertise to the complex environment of the IRB.



Mo Valentine (left) new IRB Director and Suzanne Alstadt (right) new ORSP Director

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Research News

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November 2008 Education Calendar

Wednesday, November 12

Informed Consent Document and Process

CRS Course

Presented by Jennifer Sharp, JD
Office of Research Compliance
Biomedical 1 Building
Room 205/207

9:00 am - 11:00 am

Thursday, November 18

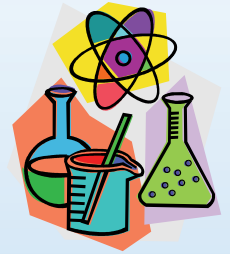
Advanced Research Ethics

CRS Course

Presented by Dr. Micah Hester
COM Medical Humanities
Stephens Spine Center
12th Floor Auditorium
1:00 pm - 5:00 pm

[To register for any of these courses click
here to go to Training Tracker](#)

Select RSC CRS course for the November
12th and 18th classes.



COMPLIANCE TIP

No need to wait for an Office of Research Compliance review to check your study records.

Researchers are encouraged to undertake their own internal quality improvement checks. Because the informed consent process is so important, it is an excellent place to start doing your own reviews.

Check all consent forms to ensure that the correct version was used; all required signatures, dates, and times are present; a qualified person obtained consent; the process is documented in a note to file, and that the consent process occurred prior to any study-specific activities. If you identify any problems, make the necessary improvements to ensure that your informed consent process is thorough, appropriate, and documented as required.

The Office of Research Compliance can provide you with a worksheet that will assist you with your own informed consent review.

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

NIH Grant Proposals Transition from PureEdge to Adobe Format

Over the next year most NIH grant proposals will move away from using the PureEdge forms to using the Adobe format. The overall electronic submission process of finding opportunities, downloading application packages, preparing forms, preparing the PDF attachment sections and submitting applications remains the same.

The new Adobe forms look and feel very similar to the PureEdge forms. The changes are mainly cosmetic, with the most significant difference being the budget pages.

Click here <http://grants.nih.gov/grants/funding/424/index.htm> for a link to the instructions for Adobe forms.

The major advantage of the Adobe forms is platform independence (works with both Mac and PC operating systems). Our Mac users on campus should find these forms much easier to open and complete than the PureEdge documents.

The table below shows final submission dates for PureEdge documents as well as the first submission date for Adobe forms.

Grant type	FINAL PureEdge Submission Date	First Adobe Submission Date
C06/UC6, R18/U18, R25, Gs, S11, S21, S22, SC1, SC2, SC3	9/25/2008	1/7/2009 (AIDS)
R15	10/25/2008	1/7/2009 (AIDS)
R01	11/5/2008	1/7/2009 (AIDS)
R03, R21, R33,	11/16/2008	1/7/2009 (AIDS)
R13/U13	1/7/2009	4/12/2009
R41, R42, R43, R44	1/7/2009 (AIDS)	4/5/2009

Please note:

Grants.gov requires the use of very specific Adobe Reader versions in order to open, download and save the application forms. Currently, applicants are advised to use **Adobe Reader 8.1.2 or 9.0**. In most circumstances, a pop-up warns users if they are using the wrong Adobe Reader version. Using the wrong version could corrupt your application.

Stay tuned for more information as we get further along in the transition process. If you have questions, please contact Suzanne Alstadt, Director of the Office of Research and Sponsored Programs at 686-8845 or by email at sealstadt@uams.edu.

New and Revised IRB Policies

Here are links to 2 new IRB Policies and 17 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 March 5, 2008)*

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

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

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

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

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

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

[15.1 Elements of Informed Consent Documents and Process](#) *(Revised July 28, 2008);*

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

[15.4 Non-English-Speaking Research Subjects](#) *(Revised July 28, 2008)*

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

[17.1 Children in Research](#) *(Revised 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 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 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 at 501-686-5667.