



Compliance Tips from the UAMS Office of Research Compliance

06-24-08: The International Conference on Harmonization Good Clinical Practice (ICH GCP) guidelines were designed as a standard for clinical trials that involve human subjects. These guidelines should be followed for studies that generate data that are intended to be submitted to regulatory authorities such as the Food and



Drug Administration. However, the ICH GCP guidelines can be a useful reference for any type of human subject research, including behavioral studies and other research that may not involve drugs or devices. The guidelines contain useful information about study conduct and documentation

that is applicable to all human subject research. The guidelines can be accessed at <http://www.ich.org>. Click on the links for "Guidelines," then "Efficacy Topics" and then "E6" under Good Clinical Practice. For more information, call the Research Compliance office at 686-8062 or 526-6270.

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July/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
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
Presented by Dr. Ray Anderson,
Quality Assurance Manager, RSC
Biomedical 1 Building
Room 205/207
10:00 am – 11:00 am

Thursday, August 21, 2008

Reporting Adverse Events
Presented by Tracie Baker,
Monitoring Manager, RSC
Biomedical 1 Building
Room 205/207
2:00 pm - 3:00 pm

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

How To Sign The Following Forms Electronically:

- Health Insurance Portability and Accountability Act (HIPPA)
- Outside Employment Form
- Conflict of Interest (COI) and Commitment Disclosure Form

Click on this link:

[How to Sign the Clinical Salary Report Packet Electronically](#)

For more information, contact Troy Wells at 501-686-7875.

Meet one of the New IRB Chairs...

**William J. Evans
Ph.D., FACSM, FACN**



*Dr. William Evans
New IRB Chair
1st Week Committee*

Dr. William J. Evans is one of five new UAMS IRB Chairs replacing Dr. Jimmie Valentine, who recently retired from UAMS.

Dr. Evans, director of the Nutrition, Metabolism and Exercise Laboratory at UAMS' Donald W. Reynolds Institute on Aging, is also a College of Medicine Professor of geriatrics, physiology and nutrition, and has been with UAMS for 11 years, serving on the UAMS IRB for the past six years.

In October 2005, Dr. Evans was named the first recipient of the Jane and Ed Warmack Chair in Nutritional Longevity. In addition, he is a researcher at the Geriatric Research Education and Clinical Center at the Central Arkansas Veterans Healthcare System (CAVHS).

Prior to UAMS, Dr. Evans was a member of the Pennsylvania State University IRB for three years and the New England Medical Center at Tufts University IRB for seven years.

He is the author or co-author of more than 160 publications in scientific journals. His work has been featured on the CBS evening news, 20/20, Good Morning America, the New York Times, and the PBS series The Infinite Voyage.

Dr. Evans will serve as 1st week Chair of the UAMS IRB and started his new duties on July 1, 2008. The other chairs are Dr. Kathleen Eisenach (2nd week), Dr. Louanne Lawson (3rd week), Dr. Mahendran Mahadevan (4th week) and Mr. James Wohlleb (Expedited items).

Each chair will oversee the IRB meeting for that week and review the protocol studies that have been submitted for review.

Dr. Mahendran Mahadevan was recently named one of the five new UAMS IRB Chairs by Tim Atkinson, IRB Director.

Dr. Mahadevan, an Associate Professor for the College of Medicine Obstetrics and Gynecology, has been with UAMS for more than 16 years, serving as an IRB member for more than 12 years.

He is also co-course director for Medical genetics course for second year medical students. For more than 30 years, Dr. Mahadevan has worked with such OB/GYN issues as infertility, In Vitro fertilization and sperm banking. His current interests include stem cell biology, stem cell cryobiology and gene therapy in prostate cancer. He is currently collaborating with Dr. Paul Hermonat in

studying gene therapy and plans on collaborating with Dr. Graham Greene in researching prostate cancer.

Dr. Mahadevan's wife, Dhamayanthi, is an accountant with the Arkansas Public Employees Retirement System (APERS). Their daughter, Menaka, is a 2nd year pediatrics resident in Phoenix and their son, Ragavan, is a senior medical student at UAMS studying Psychiatry.

A native of Sri Lanka, an island south of Tamil Nadu, India, Dr. Mahadevan has also lived in Australia for seven years, in Canada for four years, and in Phoenix, Arizona for 4 years before moving to Little Rock in December 1991.

Meet one of the New IRB Chairs...

**Mahendran Mahadevan
D.V.M., Ph.D., M.B.A.**



*Dr. Mahendran Mahadevan
New IRB Chair
4th Week Committee*

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 Date: 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 686-5667 or Tim Atkinson at 686-8845.



ORSP UPDATES

The UAMS Office of Research and Sponsored Programs (ORSP) is the facilitator of the pre-award grants, contracts, subcontracts and industry-sponsored agreements process. Funding is often contingent on approval of research protocols overseen by the [UAMS Institutional Review Board](#), a division of ORSP.

Grants.gov is currently transiting from the PureEdge forms to the Adobe Forms. The PureEdge System is set to terminate on 12/31/2008. New Federal Program Announcements will require the Adobe Forms. Please make sure that you have Adobe **Reader** 8.1.2 downloaded on your computer in order to open the Adobe Forms. The transition schedule is posted at <http://www.grants.gov/assets/AgencyTransitionSchedule.pdf>. It is highly recommended as we transition from the PureEdge to the Adobe Forms that you carefully review the package requirements included in the proposal guidelines.

For more information, contact Rebecca Nickleson, Senior Grants Administrator at 501-686-8782 or by email at NicklesonRebeccaA@uams.edu.

GRANTS MANAGEMENT PROGRAM WORKSHOP SCHEDULE

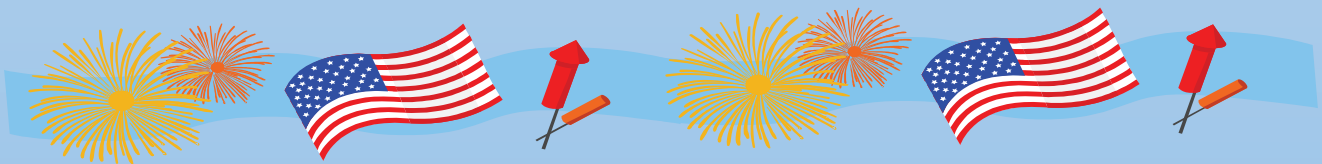
General Provisions for Selected Items of Cost and Budget Management
Tuesday, July 8, 2008 9:00a.m. - 9:50a.m.
CPH Room G226

Petty Cash Custodian Training
Tuesday, July 8, 2008 10:00a.m. - 10:50a.m.
ED2 Room G108A/B

Grants Management Orientation ~4 Core Credits~
Thursday, July 17, 2008 8:00a.m. - 11:50a.m.
CPH Room G218

Certified Research Administrator Study Group
Friday, July 11, 2008, 1:00 p.m. - 2:50 p.m.
Friday, July 18, 2008, 1:00 p.m. - 2:50 p.m.
Friday, July 25, 2008, 1:00 p.m. - 2:50 p.m.
CPH Room G218

The Grants Management classes can be found on the [Finance Department website](#).



Comments and suggestions are always welcome. If you have a great idea for an article or a suggestion, let us know! Send your suggestion to Leslie Doan at doanleslied@uams.edu or call 501-526-4862.