



Arkansas Research in Medicine (ARM) Video Website

Dr. Mark Smeltzer, Professor at the UAMS Department of Microbiology and Immunology, spoke at a video taping on July 28, 2009 in the Rayford Auditorium in the Biomedical II Building.

Linda D. Williams, M.S., Dean's Research Liaison in the College of Medicine, organized the presentation as part of a new UAMS video website titled *Arkansas Research in Medicine* (ARM) that will feature COM researchers describing their research in lay language.

The website will be similar to a current website called www.ted.com and will eventually include many faculty members describing their research and will also encourage donations and help with recruiting and foundation issues.

For more information, please contact Linda Williams at 501-686-7418 or at ldwilliams@uams.edu.



Mark Smeltzer, Ph.D. speaks to an audience of UAMS researchers on July 28, 2009.

COMPLIANCE CORNER TIP

New study self-assessment tools are available on the UAMS Office of Research Compliance (ORC) web site. Study staffers can use these tools to guide them as they review their study processes. Currently available are tools for reviewing the informed consent process, subject records and source documentation, and regulatory binders. Periodic self-assessments are recommended to help ensure that all study documentation and processes are in order. They can also help investigators be ready for an outside review, such as those done by the UAMS Office of Research Compliance or a federal oversight agency.

Click on the "Compliance Oversight and Tools" link on the UAMS ORC home page (www.uams.edu/orc) for more information and to access the self-assessment tools.

Questions? Call the Office of Research Compliance at 686-8062 or 526-6270.

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HIPAA PRIVACY FOR RESEARCHERS

The HIPAA Privacy Rule requires an individual to provide signed permission, known as an Authorization under section 164.508 of the Privacy Rule, before a covered entity can use or disclose the individual's Protected Health Information (PHI) for research purposes. PHI is a subset of what is termed any *individually identifiable* health information.

It is the responsibility of the Principal Investigator (PI) to ensure that the HIPAA requirements have been satisfied and that the Institutional Review Board (IRB) has been provided the proper documentation of the review. The PI is also responsible for making sure HIPAA Authorization is provided by the subject in the proper way prior to conducting the research. One of the consequences of not properly obtaining HIPAA Authorization from the subject prior to conducting the research includes the disallowance of the data. The Informed Consent Form and the HIPAA Authorization may be combined in order to reduce the paperwork and potential clerical errors as long as it is clear to the subject that they are signing for both consent to participate and permission to use their protected health information.

The role of the IRB as the Privacy Board is to ensure that every research protocol complies with the Privacy Rule. The IRB has the authority to approve a waiver or an alteration of the Privacy Rule's Authorization requirement under certain circumstances. De-identified data are not subject to the Privacy Rule, but the IRB will verify that data are truly de-identified. Unlike de-identified data, a Limited Data Set with Data Use Agreement is subject to the minimum necessary requirements of the Privacy Rule as it is considered PHI.

Investigators may request access to review medical records in preparation to submit a research protocol. Preparatory to research activities may include activities to identify prospective research subjects, but it does not include recruitment of subjects in any manner or contacting patients or potential subjects. For each review preparatory to a research protocol, there must be a current written certification on file with the IRB specific to that project signed by the PI.

For additional information regarding HIPAA Privacy for Researchers:

<http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/>

<http://www.hhs.gov/ocr/privacy/hipaa/understanding/special/research/index.html>

http://privacyruleandresearch.nih.gov/pr_02.asp

http://privacyruleandresearch.nih.gov/irb_default.asp

If you have questions, comments, or concerns, please contact Mo Valentine, Privacy Officer for Research, at 501-526-7559 or email valentinepamelam@uams.edu.

PROTOCOL REVIEW AND MONITORING COMMITTEE

The Protocol Review and Monitoring Committee (PRMC) continues to actively move towards developing an easier, quicker submission process. We are please to announce that we are now accepting all submissions to PRMC review electronically.

The new electronic submission email address is
PRMCsubmissions@uams.edu

The 3 PRMC forms needed for submission.

- PI Checklist
- PI & Sub-Investigator Signatures
- Protocol Summary

The purpose of the PRMC is to scientifically review all human subject cancer or cancer-related protocols and establish their priority. In addition, the PRMC is responsible for reviewing the appropriateness of the Data and Safety Monitoring Plans (DSMP), monitoring accrual, and patient safety for all cancer or cancer-related studies within the Cancer Institution.

For more information, contact Alice Beard, PRMC Administrator, at 501-296-1505, ext. 1818 or by email at beardalicea@uams.edu or visit the PRMC website at <http://cancer/uams.edu/PRMC>.

AUGUST 2009 RESEARCH EDUCATION CLASS SCHEDULE

Does My Study Need an IND/IDE?

Presented by Carole Hamon, Research Support Center Regulatory Manager
and Lyndsey Avery, Research Support Center Regulatory Specialist

Thursday, August 13, 10:00 am - 12:00 pm

College of Public Health Building (CPH) Room G232

Adverse Event Reporting

Presented by Tracie Baker, Research Support Center Monitoring Manager
Thursday, August 27, 9:00 am - 10:00 am

College of Public Health Building (CPH) Room G232

For more information, please contact Kate Henning, PhD by phone at 501-526-6879 or email at KHenning2@uams.edu.