



July 27, 2007 Vol. 1 Issue 2

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## **IMPORTANT!**

**"SHIPPING OF INFECTIOUS SUBSTANCES" TRAINING CLASS WILL BE HELD ON TUESDAY, JULY 31  
10:00 AM - 11:30 AM AT VA FLOOR 7E (NO REGISTRATION NECESSARY)**

Anyone shipping biohazardous or infectious substances from ACH, UAMS, or VA is required to have this training.

The transportation of biohazardous substances is regulated by the U.S. Public Health Service (PHS), the U.S. Department of Transportation (DOT), and the International Air Transport Association (IATA). Infectious Substances according to the regulations include but are not limited to:

- Infectious Substances affecting humans
- Infectious Substances affecting animals
- Biological Substances (formerly Diagnostic or Clinic Specimens) and include human derived materials (e.g. human cell lines)
- Genetically modified organisms (GMO) and Genetically modified microorganisms (GMMO)

Both VA personnel and WOCs (Without Compensation) who ship any of the infectious substances listed above must complete this training program. This training is also accepted by UAMS OSHA. If you ship a substance listed above and no one in your lab has completed the training, the shipment will be confiscated and the lab will be reported to the VA R & D as per regulations.

Upon attending the 1.5 hour class and completing a short quiz, participants will receive credit for this training. Certificates will be issued and mailed to participants the following week. The certification will be valid for two years. Individuals who complete the training must retain

documentation confirming that they passed the final exam. Training certificates should be kept in the laboratory and must be able to be produced upon request.

For more information, please contact Dr. Sue Theus by phone at 501-257-4841 or by email at [theussuea@uams.edu](mailto:theussuea@uams.edu)

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## **AUGUST 2007 RESEARCH SUPPORT CLASSES**

### **Q & A class on INDs (Investigational New Drugs)**

**August 8 from 10 - 11 in Biomed 1 Building, Room 205/207**

How do you know if you need an IND? This class discusses the content and format for an investigational product that has not yet been previously marketed or investigated in humans, followed by an IND Q & A.

### **CRS class on Record Keeping and Regulatory Binders**

**August 22 9 – 11 in Biomed 1 Building, Room 205/207**

Researchers protect human subjects by having good paperwork. Organizing paperwork is as important as dispensing the right drug or the right dosage of a drug. The organization/maintenance of research binders and the documentation of data/activities surrounding research studies are required responsibilities of the investigator and the research staff. This class discusses the federal regulations regarding record keeping and the organization of investigator files.

For more information, see <http://www.uams.edu/rsc/>

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## **IRB POLICIES INFORMATION**

**Revision to IRB Policy 15.1 - Elements of Informed Consent Documents and Process (Addition of Options 1 – 3 regarding specific study situations on pages 3 & 4)**

For more information, see <http://www.uams.edu/irb/15%201%20June%207%202007.pdf>

**Addition of new IRB Policy 15.5 – The Informed Consent Process**

For more information, see <http://www.uams.edu/irb/Policy%2015%205%20-%20Documentation%20of%20Informed%20Consent%204%205%202007.pdf>

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## **NEW FDA GUIDANCE - COMPUTERIZED SYSTEMS USED IN CLINICAL INVESTIGATIONS**

This guidance provides recommendations to sponsors, data management centers, clinical investigators, and IRBs regarding the use of computerized systems in clinical investigations.

The computerized system applies to records in electronic form that are used to create, modify,

maintain, archive, retrieve, or transmit clinical data required to be maintained, or submitted to the FDA.”

The RSC staff can assist in summarizing the guidance for you. For more information, see <http://www.fda.gov/cder/guidance/7359fnl.htm>

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## **FDA REGULATED STUDIES ARTICLE**

In May 2007, the U.S. Food and Drug Administration (FDA) released a draft of its Guidance for Industry: Protecting the Rights, Safety and Welfare of Study Subjects—Supervisory Responsibilities of Investigators (the guidance). The guidance seeks to help investigators meet the FDA’s expectations with respect to protecting human subjects and ensuring the integrity of the data from clinical investigators.

For more information in FDA regulated studies see <http://www.mwe.com/info/news/ots0507m.htm>

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We invite your input. Please e-mail any items that you would like to share with the Clinical Research community to: [doanleslie@uams.edu](mailto:doanleslie@uams.edu)