

Education Calendar

- **March 5**
Institutional Review Board (IRB)
Continuing Review Discussion
Featuring Connie Price and Allison Streepey of the UAMS IRB
Brandon Auditorium
ACH South Campus
10:00 am-11:00 am
- **March 5**
Writing Standard Operating Procedures
Presented by Dr. Ray Anderson
ED II Building
Room G112 A/B
9:00-11:00 am
- **March 26**
Manufacturing Records
Presented by Larry Parker
BioMed 1 Building
Room 205/207
10:00-11:00 am

For more information about any of these RSC courses, contact Education Manager Crystal Hunnicutt at 501-526-6879 or chunnicutt@uams.edu

REVISED CONTACT PHONE NUMBERS

- Clinical Research Data Management (CRDM)-
686-8274
- Protocol Review and Monitoring Committee (PRMC)-
296-1505 x1818

INVESTIGATIONAL DEVICES

Medical devices are products that do not achieve their primary effects by chemical means or by being metabolized. The FDA separates medical devices into 3 general classes for regulatory purposes. Examples of **Class I** devices are surgical gloves and tongue depressors. Examples of **Class II** devices are flexible laryngoscopes and surgical drills. Examples of **Class III** devices are artificial organs, replacement heart valves, pacemakers, and

bone orthopedic implants. An investigational device exemption (**IDE**) allows an investigational device to be studied in humans in order to collect safety and effectiveness data.. Investigational use also includes clinical evaluation of certain modifications or new intended uses of legally marketed devices. All clinical evaluations of investigational devices, unless exempt, must have an approved IDE before the study is initiated. For more information, contact Crystal Deville at 501-686-8098.



ClinicalTrials.gov Reminder

If your clinical trial involves a drug or device, or if you intend to publish your clinical trial, you will need to register at ClinicalTrials.gov. Please contact the following staff based on your institution:

At UAMS, contact Lyndsey Avery at LGAVery@uams.edu or Crystal Deville at CKDeville@uams.edu

AT VA, contact Robin Atkins at RAtkins@uams.edu

At ACHRI, contact Margie Brackeen at brackeenmargie@uams.edu

CITI Collaborative Institutional Training Initiative

As of February 29, 716 people have completed the CITI Program Human Subject Protection online courses, including 128 at ACH and 588 at UAMS.

The CITI Newsletter is published three times a year and will arrive via email. Each issue of the Newsletter covers a hot topic, introduces new modules, provides an update on new CITI developments, and responds to readers' questions via a "Ask the Founders" column.

CITI Newsletter's link:
http://www.citiprogram.org/citidocuments/CITINewsletter/CITI_Newsletter_V2_I1.pdf

COMPLIANCE CORNER

Federal regulations and IRB policy require that study protocols be followed exactly as they were approved by the IRB. This requirement applies to all types of research that the UAMS IRB reviews, including drug and device studies, investigator-initiated studies, and behavioral studies. If you need to make a change to an approved protocol, be sure to submit the change to the IRB for review and approval prior to implementing it.

There is one exception to this requirement – a change that eliminates an apparent immediate hazard to subjects can be implemented immediately. But the IRB must be notified about that kind of change as soon as possible.

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

