



November 8, 2007 Vol. 5 Issue 1

ClinicalTrials.gov

On September 27, 2007, President Bush signed into law the Food and Drug Administration Amendments Act of 2007. Under this new law, all new and on-going drug and device trials are to be registered with ClinicalTrials.gov. This includes all trials expecting to receive Medicare/Medicaid funding, as well as all trials that are to be published in certain journals. The Research Support Center (RSC) is able to assist with registration of investigator-initiated trials. All industry sponsored and cooperative group studies should be registered by pharmaceutical firms or the cooperative group. In addition, RSC is creating a template for all investigators to complete in order to provide the applicable information for registering clinical trials.

For more information, please email RSC Regulatory Specialists Lyndsey Avery @ LG Avery@uams.edu or Crystal Deville @ CKDeville@uams.edu.

For more information on registering clinical trials go to <http://prsinfo.clinicaltrials.gov>
For additional information regarding the International Committee of Medical Journal Editors go to <http://www.icmje.org/jrnlist.html>

CRIMSON Update

The CRIMSON system was activated on July 16, 2007. Since that time, more than 100 research protocols have been entered into the system. Of these studies, approximately 40% are behavioral and 60% are biomedical. Approximately half of the biomedical protocols are industry-sponsored. The majority of the remaining biomedical studies are investigator-initiated. More than half of all of the studies submitted through CRIMSON have been fully approved in one day or less. The ARIA Programmers are currently working with the Protocol Review and Management Committee at the Winthrop P. Rockefeller Cancer Center to integrate the PRMC review into CRIMSON. If you need assistance with CRIMSON, please contact Julia Washam (686-8572) or Cynthia Spinks (526-4619).

CITI Update

As of November 7, 220 people have completed the CITI Program Human Subject Protection online courses, including 38 at ACHRI and 182 at UAMS. For more information see www.citiprogram.org.

Upcoming Educational Classes

November 14th - **CRS**: Writing Informed Consent Documents

Presented by Jennifer Sharp, JD

Biomedical 1 Building, 205/207

9:00 - 11:00 AM

This course covers the essential elements of a well written informed consent document. Participants will be given an informed consent document to review. They will also learn about the ongoing process of maintaining consent throughout the study.

November 15th - **Audio Conference**: Coping With the Centers for Medicare and Medicaid Services (CMS) Billing Rules for Clinical Research

Brandon South A&B

12:00 - 1:30 PM

Participants will be briefed on: The scope of clinical trials covered under the policy; the definition of “routine cost” and “usual patient care”; and the extent to which Medicare will go in paying for investigational clinical services.

To register:

ACH & UAMS Employees register through the **ACH Training Site**

Go to: <https://secure.archildrens.org/achtraining/myprofile/>

Department name: res human protections co

If you have any problems/questions contact Margie Brackeen at

brackeenmargiei@uams.edu or x43586

November 28th - **CRS**: Advanced Research Ethics

Presented by Dr. Chris Hackler and Dr. Micah Hester

ACH East Campus-CLASSROOM-EC Training 103

1:00 - 4:30 PM

This course discusses intellectual honesty in proposing, performing, and reporting research. Other topics covered in this course include data acquisition, management, sharing and ownership; protecting human subjects; research misconduct; conflict of interest; peer review and responsible authorship. Attendees will be given a case scenario to review in groups and present recommendations.

Register for the CRS courses by clicking <https://secure.uams.edu/TrainingTracker/frmEnrollInClass.aspx> and select RSRA CRS.

For more information, contact RSC Education Manager Crystal Hunnicutt by phone at 526-6879 or chunnicutt@uams.edu.

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