

Education Calendar

- Monday**
March 17, 2008
10:00 am-11:00 am
Reporting Adverse Events Discussion
Featuring Tracie Baker,
Monitoring Manager of the
UAMS RSC
Brandon North A
ACH South Campus

ACH & UAMS employees
register through the
[ACH Training Site](#)

If you have questions, call
Margie Brackeen at
501-364-3586 or by email
brackeenmargie@uams.edu
- Friday**
March 21, 2008
2:00 pm-3:00 pm
Conflict of Interest Q&A
Presented by
Dr. Tim Atkinson
Biomedical I Building
Room 205/207
- Wednesday,**
March 26, 2008
10:00 am—11:00 am
Manufacturing Records Q&A
Presented by Larry Parker
Biomedical I Building
Room 205/207

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

UAMS IRB ADDS 2 NEW AND REVISES 11 IRB POLICIES

Tim Atkinson, Ed.D, Director, Research and Sponsored Programs, announced this week the addition of two new IRB Policies. The new policies are:
[12.5 \(Reports of Potential Non-compliance\)](#) and
[12.6 \(Findings of Non-compliance Under IRB Policy 12.5\)](#).

In addition, eleven other IRB policies have been revised. The revised policies are:

- [1.4 \(Studies Requiring Review\)](#)
- [2.6 \(Reporting to Appropriate Federal Oversight Bodies, Institutional Officials and Research Sponsors\)](#)
- [7.4 \(Standard or Full Committee Review\)](#)
- [7.6 \(Continuing Review\)](#)
- [8.1 \(Changing Study Protocol/Modifications to Previously Approved Research\)](#)
- [9.1 \(Range of IRB Decisions\)](#)
- [10.2 \(Unanticipated Problems Involving Risks to Participants or Others—Investigator Reporting Requirements and IRB Actions\)](#)
- [12.4 \(Non-compliance with Human Research Protection Program Requirements—Formal Audit Reports as Finding of Non-compliance\)](#)
- [15.5 \(The Informed Consent Process\)](#)
- [18.3 \(Emergency Use of a Drug or Biologic \(Source *FDA Information Sheets Guidance for Institutional Review Boards and Clinical Investigators 1998 Update*\)](#)
- [18.4 \(Emergency Use of an Unapproved Medical Device \(Source *FDA Information Sheets Guidance for Institutional Review Boards and Clinical Investigators 1998 Update*\)](#)

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 as well as IRB Tips/Tools/Research Links For more information, call the IRB main number at 501-686-5667.

COMPLIANCE TIPS

The federal Food and Drug Administration requires that all study data and documents pass what it calls the ALCOA test. That means all data should be Accurate, Legible, Contemporaneous, Original, and Attributable. Even if the FDA does not oversee your study, the ALCOA test is a good one to keep in mind for all studies' data. Be sure that all study activities are fully documented, and that study documents and notes to file are appropriately signed and dated, regardless of the kind of human subject research you do.

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

