



## **Contracts Module in CRIMSON**

On February 18, 2009, the Research Support Center launched the new “Contracts Module” within CRIMSON. The Contracts Module is a document management system that allows the Research Support Center, clinical investigators and study personnel to manage workflow and monitor the status of research contracts.

New research contracts and associated documents (original research contract, informed consent form, and any accompanying budget exhibits, where applicable) should be submitted, preferably in Microsoft Word format, to [researchcontracts@uams.edu](mailto:researchcontracts@uams.edu). Once submitted, the Research Support Center will upload the documents to the Contracts Module, and a contract review team will be assigned. The Contracts Module will maintain a record of work performed on each contract. The record of work will contain information regarding the type of work performed, the time it was performed and who was responsible for the work. The study coordinator and principal investigator will be notified via email of milestones as the contract progresses through the negotiation process. More importantly, principal investigators and study personnel will be able to access the Contracts Module and find up-to-date information regarding the status of their contracts.

If you have any questions, please contact Diana Barr at 668-8564 or [dlbarr@uams.edu](mailto:dlbarr@uams.edu).

## **Upcoming Grant Opportunities**

There are several upcoming grant opportunities available because of the Economic Stimulus. As part of the American Recovery/Reinvestment Act of 2009 (ARRA), NIH has designated at least \$200 million in FYs 2009-2010 for a new initiative called the *NIH Challenge Grants in Health and Science Research*, to fund 200 or more grants. Also, intended to stimulate the economy, NCCR will administer up to 1.3 billion in federal grants through several funding opportunities.

Check the [ORSP website](#) often for these and other new grant opportunities.

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## COMPLIANCE TIP



Whenever you get an IRB approval letter, make sure to check that it is correct. If you submitted several documents at one time for review, one might inadvertently not be listed on the approval letter, or the date or version number shown for a particular document might not be correct. If you notice that something is incorrect in an approval letter, get in touch with the IRB and ask for a corrected letter. That way you'll have documentation showing that you're using the correct, approved version of each study document.

For more information, call the Research Compliance office at 686-8062 or 526-6270.

## CLASS SCHEDULE

### **Conflict of Interest Q & A**

Wednesday, April 8, 2009  
9:00-10:00 am  
Room 204 in the I. Dodd Wilson Education Bldg.  
(1 Contact Hour)

### **Essentials of Quality Human Subject Research A Training Seminar for New Investigators, Coordinators, and Others Involved in Human Subject Research**

Thursday, April 23, 2009  
9:00 am-4:00 pm  
Room 214 A/B in the I. Dodd Wilson Education Bldg.  
(6 Contact Hours)

For more information or to register for any of these courses, visit the ORC website at <http://www.uams.edu/orc/ClassSchedule.htm>

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# **IRB NEWS**

## ***HOW TO GET ACCESS TO ARIA TO SUBMIT A PROTOCOL***

In order to submit a protocol for IRB review you will need to have an ARIA account with a Username and Password. Before you will be granted access to the system, you must complete the mandatory Human Subjects Protection (HSP) course in either Biomedical or Social/Behavioral Research (whichever is most applicable to your area) through the web-based CITI Program. Both of these courses also include the HIPAA for Research training. For your convenience, the IRB has created an ARIA Account Creation/ Modification Request form, which provides the IRB administrative staff all the information necessary to create a user profile in ARIA. Once this form is complete, it should be submitted to [IRB@UAMS.edu](mailto:IRB@UAMS.edu). An IRB staff member will create the user profile in ARIA. The Office of Research Compliance Education Coordinator will then verify that the CITI training or equivalent HSP training has been accomplished and create the Username and Password in ARIA. An automated email is sent to the user from ARIA. Be aware that in most cases the Username and Password are not activated until the next day. If this is a situation where the protocol needs to be submitted the same day that the user account is set up, please contact an IRB Administrator by calling the main IRB number 501-686-5667. All IRB forms as well as the CITI information is located on the IRB website at [http://www.uams.edu/irb/IRBsubmissions\\_ARIA.asp](http://www.uams.edu/irb/IRBsubmissions_ARIA.asp).

## ***HOW TO SUBMIT PERSONNEL CHANGES TO A PROTOCOL***

All personnel changes to a protocol require a modification to be submitted through ARIA. This is necessary to ensure the IRB has the proper documentation and authorization from the Investigator to add or retire personnel from a study. In order to be added to a protocol, the person must have an ARIA User Profile and have completed the Human Subjects Protection (HSP) training through the CITI Program. If the person you are trying to add to the study is not available from the search form in ARIA, you will need to complete the ARIA Account Creation/Modification Request form for this person and submit to [IRB@UAMS.edu](mailto:IRB@UAMS.edu). These individuals will not require access to ARIA. For more information, call the main IRB number at 501-686-5667.

# New and Revised IRB Policies

Here are links to 2 new IRB Policies and 17 revised IRB policies for your convenience

The new policies are:

[12.5 \(Reports of Potential Non-compliance\)](#) *(Effective Date: March 5, 2008)*

[12.6 \(Findings of Non-compliance Under IRB Policy 12.5\)](#). *(Effective Date: March 5, 2008)*

The revised policies are:

[1.4 Studies Requiring Review](#) *(Revised March 5, 2008)*

[2.6 Reporting to Appropriate Federal Oversight Bodies, Institutional Officials and Research Sponsors](#) *(Revised March 5, 2008)*

[7.4 Standard or Full Committee Review](#) *(Revised March 5, 2008)*

[7.5 Expedited Review](#) *(Revised July 28, 2008);*

[7.6 Continuing Review](#) *(Revised July 28, 2008);*

[8.1 Changing Study Protocol/Modifications to Previously Approved Research](#) *(Revised March 5, 2008)*

[9.1 Range of IRB Decisions](#) *(Revised July 28, 2008);*

[10.2 Unanticipated Problems Involving Risks to Participants or Others-Investigator Reporting Requirements and IRB Actions](#) *(Revised July 28, 2008);*

[12.4 Non-compliance with Human Research Protection Program Requirements—Formal Audit Reports as Finding of Non-compliance](#) *(Revised March 5, 2008)*

[15.1 Elements of Informed Consent Documents and Process](#) *(Revised July 28, 2008);*

[15.3 Waivers of Signed Informed Consent Documents and Waivers of Informed Consent Elements](#) *(Revised March 13, 2008)*

[15.4 Non-English-Speaking Research Subjects](#) *(Revised July 28, 2008)*

[15.5 The Informed Consent Process](#) *(Revised March 5, 2008)*

[17.1 Children in Research](#) *(Revised June 11, 2008)*

[17.8 Pregnant Women, Human Fetuses and Neonates Involved in Research](#) *(Revised March 13, 2008)*

[18.3 \(Emergency Use of a Drug or Biologic \(Source FDA Information Sheets Guidance for Institutional Review Boards and Clinical Investigators 1998 Update\)](#) *(Revised March 5, 2008)*

[18.4 \(Emergency Use of an Unapproved Medical Device \(Source FDA Information Sheets Guidance for Institutional Review Boards and Clinical Investigators 1998 Update\)](#) *(Revised March 5, 2008)*

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. For more information, call the IRB at 501-686-5667.