



EFFECTIVE OCTOBER 1, 2009, ALL PROTOCOLS SUBMITTED TO THE IRB MUST HAVE STAFF WITH CURRENT HUMAN SUBJECT PROTECTION (HSP) TRAINING

Any protocols submitted to the IRB that include staff with either expired HSP training or no HSP training will not be given to the IRB committee for review until the deficiency is resolved. All staff with deficient HSP training must either be removed from the study or complete the training through the CITI Program. For more information, please contact the IRB Office at 501-686-5667.

CITI INFORMATION

In order to do research with human subjects at UAMS, you must be up to date on the mandatory Human Subject Protection (HSP) training, also known as CITI training. **This training must be renewed every two years.**

Please go to www.citiprogram.org, register, affiliate with UAMS, and complete the Basic Human Subject Protection training course for either Biomedical or Social Behavioral Research (whichever applies to your area).

This self-guided online training takes approximately 2-4 hours to complete. You will need to complete all of the modules in the course, with a score of 100% on the quiz at the end of each module.

If you have already completed HSP training through an institution other than UAMS or ACH, please send a copy of your completion certificate to Kate Henning, Ph.D., manager of the Research Education Program at khenning2@uams.edu.

TWO NEW UAMS POLICIES INVOLVING RESEARCH

The following two new UAMS policies will impact the UAMS researchers conducting investigator-initiated research on both the UAMS and ACH campuses. The policies are:

- **Declaration of Sponsorship for Investigational New Drug Applications**
<http://www.uams.edu/AdminGuide/PDFs/12.1.10.pdf>
- **Declaration of Sponsorship for Investigational Device Exemption Applications**
<http://www.uams.edu/AdminGuide/PDFs/12.1.11.pdf>

For more information, please contact Carole Hamon, Regulatory Affairs Manager in the UAMS Research Support Center at 501-526-7437.

DOCUMENTING YOUR STUDY TEAM'S QUALIFICATIONS

Has everybody on your research staff completed their human subject protection (HSP) training as required? Can you confirm that all research staffers are qualified to carry out their study-related responsibilities? Keeping your study team qualifications documentation current will allow you to track whether everybody is up-to-date on the skills and training they need for their job. Such documentation is recommended in the International Conference on Harmonization guidelines for clinical trials. And while keeping such paperwork on hand isn't required by regulation for other types of studies, it's always a good idea to make sure these records are readily available. Examples of records to include are:



- A current CV for the PI, sub-investigators, and other study staff whose responsibilities require specialized education or training. Have staffers review, update, and sign and date their CVs each year to confirm that they are current.
- A copy of medical, nursing, and any other professional licenses.
- Certificates showing that all study staff have completed human subject protection training within the previous two years.
- A study staff signature and delegation of responsibility log. This record documents everybody's original signature and can be used to show which study responsibility each staffer is authorized to perform. Click on the "Self Assessment Tools and Templates" link at uams.edu/orc to navigate to a sample template.
- Sign-in sheets or other documentation of study-specific training, such as a site initiation visit or training on how to complete a study procedure or to use an investigational device.

A couple of recordkeeping hints:

- If staffers are involved in multiple studies, you can keep a single copy of some records, such as CVs, licenses, and human subject protection training certificates, in a central location. Just add a note to each study's records indicating where these items can be found.
- Rather than relying on ARIA to store your CVs and HSP training certificates, keep a paper copy on hand. The day you need to pull a copy quickly will be the day that, for some reason, you're unable to access ARIA.

Questions? Call the UAMS Research Compliance Office at 686-8062 or 526-6270. For questions related to human subject protection training, call Kate Henning, manager of the Research Education Program, at 526-6879.

Office of Research and Sponsored Programs (ORSP) Staff Changes

Suzanne Alstadt, M.P.A, CRA, Director of the Office of Research and Sponsored Programs (ORSP), recently announced two Grants Administrator staff changes:

Bettie Cook, a 20 year employee at UAMS, was promoted to Senior Grants Administrator after 2 years successfully working within ORSP. She previously worked for the Department of Family & Community Medicine, AHEC, and the Office of Scientific Publications. Bettie may be contacted by phone at (501) 686-8162, or by email at cookbettiej@uams.edu.

Rachel Phillips is the newest addition to ORSP as a Grants Administrator. She has been here at UAMS for over 10 years, working as a Research Assistant and Lab Manager in the Departments of Biochemistry, Geriatrics, and most recently, Pharmacology & Toxicology. Rachel may be reached by phone at (501) 686-5504, or by email at REPhillips@uams.edu.

The Grants Administrators' job responsibilities include the careful review of grant submissions for compliance to various funding agency guidelines, the completing of grant subcontracts, and generally assisting Researchers' pursuit for grant funding.

Bettie and Rachel work closely together to support UAMS success in research. The Office of ORSP is in the Biomedical Research I Building, room B 102. The fax number is (501) 686-8359.



Bettie Cook
Sr. ORSP Grants Administrator



Rachel Phillips
ORSP Grants Administrator