



Compliance Tip from the UAMS Office of Research Compliance

The Health Information Portability and Accountability Act (HIPAA) applies to all research projects involving protected health information (PHI), even those deemed exempt by the IRB. This means one of the following must be present if a study is collecting or accessing PHI:

- i.) a valid authorization form or a consent form with all of the HIPAA authorization elements;
- ii) a waiver of authorization from the IRB/Privacy Board; or
- iii) a letter of agreement from your data source (Data Use Agreement or Letter stating only de-identified data will be provided).

Even if a study is granted a waiver of authorization, HIPAA still applies. A waiver only means you do not need a signed authorization from each subject. Additionally, HIPAA requires that you access or collect only the minimum necessary information required to conduct your research.

If you are conducting a research project such as a chart review and are accessing any of the UAMS medical records systems, you must make your data extract request through IT at the following link:

<http://intranet.uams.edu/itprojectrequest/> OR by requesting data from the Health Information Management (HIM) group by filling out the appropriate forms.

For more information regarding HIPAA, please go to: <http://hipaa.uams.edu>

Principal Investigator Responsibility and Informed Consent Presentation

- Speaker—Lyndi Lahl, RN, MS
Division of Education and Development
Office for Human Research Protections (OHRP)
- Date—Tuesday, September 30, 2008
- Time—8:00 am-9:00 am
- Location—Education West Building, Room 126 (Lecture Hall)

Register through UAMS Training Tracker as a RSC Q & A class

[Click here to register](#)

Counts as one CRS contact hour

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September 2008 Education Calendar

Wednesday, September 17, 2008

Developing a Clinical Research Protocol

CRS Course

Presented by Dr. Tom Wells
RSC Director

Biomedical 1 Building

Room 205/207

2:00 pm - 4:00 pm

Tuesday, September 30, 2008

Principal Investigator Responsibility and Informed Consent

Q & A Course

Presented by Lyndi Lahl
OHRP

ED West, Room 126 Lecture Hall

8:00 am - 9:00 am

[To register for any of these courses click here to go to Training Tracker](#)

Select RSC CRS course for the September 17 class, and select RSC Q&A for the September 30 class



ACHRI Fall Clinical Research Compliance Symposium

Tuesday, September 30, 2008
Arkansas Children's Hospital East Campus

- 7:30–8:00—Registration, Networking and Light Breakfast
 - 8:00–9:00—Special Topic Tracks
 - Case Studies and Discussions Featuring Janet Storment, RN
East Campus Room 60
 - Informed Consent Presentation Featuring Julia Washam, RN
East Campus Room 51
 - ARIA Tips and Tricks for New Submitters and Old Submitters Alike!
Featuring Jennifer Sharp, JD UAMS Office of Research Compliance
East Campus Lecture Hall
 - 9:10–10:00—Keynote Speaker: Lyndi Lahl, RN MS (OHRP)
“What Every Investigator Should Know: Research and Human Subject Protections”
East Campus Lecture Hall
 - 10:00–11:00—IRB, ACH, and ACHRI 2008 Policy Update Featuring Margie Brackeen, BS
East Campus Lecture Hall
 - 11:00—Dismissal: Pick up box lunches outside of Lecture Hall
- For more information, call Margie Brackeen at 501-364-3586 or [click here](#)**

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 Date: March 5, 2008)

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

[7.4 Standard or Full Committee Review](#) (Revised Date: 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 Date: 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 Date: 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 Date: March 13, 2008)

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

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

[17.1 Children in Research](#) (Revised Date: 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 Date: 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 Date: 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 main number at 501-686-5667.