



IRB Policy 15.1 Revised Elements of Informed Consent Documents and Processes

Tim Atkinson, Ed.D., Director, Office of Research and Sponsored Programs at UAMS recently announced that IRB Policy 15.1 was updated effective May 13, 2008.



He stated that in an effort to streamline processes for the IRB and for Clinical Trials

operations, policy 15.1 concerning written consent was modified to allow flexibility in the standard consent language. The language offered in the policy is now “suggested” instead of mandatory.

For example, on page 3 of the revised policy, this sentence was added after section 1.10 having to do with research involving **more than minimal risk**: “The following are suggested clauses to use. Any clause used must be consistent



with any sponsor or funding agreement and address the elements above.”

[IRB Policy 15.1 “Elements of Informed Consent Documents and Processes”](#) is found on the IRB website.

Contact Tim Atkinson tnatkinson@uams.edu or at 505-686-8845 if you have any questions.

Compliance Tips from the UAMS Office of Research Compliance

Help speed your proposed study’s trip through the IRB approval process. The IRB often requests changes to informed consent forms to add missing required elements or to make the consent forms match the protocol. Getting these

aspects of the IRB submission right the first time may help you avoid IRB requests for changes that can slow down approval. See Section 15 of the UAMS IRB policies for information about informed consent requirements. And make

sure that the procedures described in the protocol are accurately described in the informed consent document before you submit your study for IRB review.

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

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UAMS BLOOD DRIVE

American Red Cross

- Friday, May 16
- 10:00 am-5:00 pm
- COPH-First Floor
- 4301 W. Markham
- Donor Card or Photo ID required
- All blood donors will receive a free t-shirt and refreshments
- Call 1-800-448-3543 for more information

UAMS

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SPOTLIGHT ON...

Dr. Brooks Gentry is currently collaborating with Dr. Michael Owens in the development of new monoclonal antibody medications and vaccines for the treatment of methamphetamine and phencyclidine addiction and toxicity. They are developing plans for the first human testing of the medication, an antiphencyclidine antibody.

Dr. Gentry, a native of Arkadelphia, Arkansas, graduated from Hendrix College in Conway and received his medical degree from UAMS. He did an anesthesiology residency and clinical pharmacology fellowship at Northwestern University in Chicago, and has been with UAMS for over 14 years. In addition to spending family time with his wife, Shelley Clayton Gentry, and their two children, son Clayton, age 13 and daughter, Sterling, age 8, Dr. Gentry enjoys playing golf.



*W. Brooks Gentry, M.D.
Professor of Anesthesiology
and Pharmacology*

May/June Education Calendar

Tuesday, May 20, 2008

CRS Course

Developing Case Reporting Forms (CRFs)

Presented by Tracie Baker,
RSC Monitoring Manager

COPH, Room G226

2:00 pm – 4:00 pm

Thursday, June 5, 2008

IRB New Submitters Workshop

Jennifer Sharp, Esq. Of the UAMS
Office of Research Compliance will
guide you through a fictional
submission to the IRB step by step.
Brandon North A (ACHRI)

10:00 am – 12:00 pm

Contact Margie Backeen at
364-3586 for more information

Tuesday, June 17, 2008

ACHRI Intramural Grant Program: Focus on the CUMG Grant Program

Brandon North A and B (ACHRI)

2:00 pm – 3:00 pm

Contact John Gregan at
364-6296 for more information

Wednesday, June 4, 2008

CRS Course

Developing a Clinical Research Protocol

Presented by Dr. Tom Wells

COPH, Room G226

9:00 am – 11:00 am

Wednesday, June 11, 2008

CRS Course

Validation of Processes and Procedures

Presented by Dr. Ray Anderson

COPH, Room G226

9:00 am – 11:00 am



For more information about the UAMS CRS courses, contact Education Manager Crystal Hunnicutt, MEd at 501-526-6879 or chunnicutt@uams.edu.

New and Revised IRB Policies

Here are links to 2 new IRB Policies and 15 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)

[7.6 Continuing Review](#) (Revised Date March 5, 2008)

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

[9.1 Range of IRB Decisions](#) (Revised Date: March 5, 2008)

[10.2 Unanticipated Problems Involving Risks to Participants or Others—Investigator Reporting Requirements and IRB Actions](#) Revised Date: March 5, 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 Date: May 13, 2008)

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

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

[17.1 Children in Research](#) (Revised March 13, 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 686-5667 or Tim Atkinson at 686-8845.