



August 10, 2007 Vol. 2 Issue 1

AUGUST 2007 RESEARCH SUPPORT CLASS

**CRS class on Record Keeping and Regulatory Binders
August 22, 9:00 – 11:00 in Biomed 1 Building, Room 205/207**

Researchers protect human subjects by having good paperwork. Organizing paperwork is as important as dispensing the right drug or the right dosage of a drug. The organization/ maintenance of research binders and the documentation of data/activities surrounding research studies are required responsibilities of the investigator and the research staff. This class discusses the federal regulations regarding record keeping and the organization of investigator files.

For more information and to register, see <http://www.uams.edu/rsc/>

NEW ARIA MODULE (CRMS) SUBMISSION HELP

Before you submit a protocol to the new CRMS module of ARIA, please take a moment to contact Julia Washam at 686-8572 or Cynthia Spinks at 526-4619 for some valuable and time saving training.

FOOD AND DRUG ADMINISTRATION (FDA) REGULATIONS CONCERNING DONOR ELIGIBILITY AND SCREENING INVOLVING HUMAN TISSUE

Guidance for Industry: Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)
Posted: 8/8/2007

The FDA issued a guidance to assist establishments making donor eligibility determinations with complying with the requirements in Title 21 Code of Federal

Regulations, part 1271, subpart C (21 CFR part 1271, subpart C) (Ref. 1). The regulations under 21 CFR part 1271, subpart C set out requirements for determining donor-eligibility, including donor screening and testing, for donors of human cells, tissues, and cellular and tissue-based products (HCT/Ps).

This guidance applies to cells and tissues procured on or after the effective date of the regulations contained in 21 CFR part 1271, subpart C (effective date May 25, 2005). This guidance replaces the guidance of the same title, dated February 27, 2007.

For more information, see <http://www.fda.gov/cber/gdlns/tissdonor.htm>

Human Cells, Tissues, and Cellular and Tissue-Based Products; Donor Screening and Testing, and Related Labeling; Final Rule

Effective June 19, 2007, the Food and Drug Administration (FDA) adopted as a final rule, without change, the provisions of the interim final rule that amended certain regulations

regarding the screening and testing of donors of human cells, tissues, and cellular and tissue-based products (HCT/Ps), and related labeling. FDA is taking this action to

complete the rulemaking initiated with the interim final rule.

For more information, see <http://www.fda.gov/cber/rules/hctdnr.htm>

ARKANSAS LION'S EYE BANK AND LABORATORY RECEIVES NEW ACCREDITATION

The Arkansas Lions' Eye Bank and Laboratory (ALEB&L) received a three year accreditation by the Eye Bank Association of America (EBAA) in June 2007. The EBAA accredits facilities that provide human eye tissue for surgical use, research and ophthalmic training. Results of the site visit are determined by a majority decision of the Accreditation Board following a thorough review of the information and materials submitted by the eye bank and the inspection team. Accreditation is awarded on a time-limited basis by vote of the Accreditation Board. An eye bank that receives no citations following inspection will be recommended to receive maximum accreditation status by motion and approval of the Accreditation Board. The accreditation comes after an EBAA inspection conducted in April 2007 and is the maximum accreditation term given by the association. Geoff Brown, BS, CEBT, is the Executive Director of the ALEB&L.

For more information about Good Tissue Practice (GTP) and Quality Assurance services provided by the Research Support Center, Quality Assurance Unit, please contact GTP Specialist, Beatrice Huey at 686-6286.

For more information on the Eye Bank Association of America, see <http://www.restoresight.org/>

May 2007 FDA Draft Guidance for Industry: Protecting the Rights, Safety, and Welfare of Study Subjects—Supervisory Responsibilities of Investigators

The U.S. Food and Drug Administration (FDA) released a draft in May 2007 of its Guidance for Industry: Protecting the Rights, Safety and Welfare of Study Subjects—Supervisory Responsibilities of Investigators (the guidance).

The guidance seeks to help investigators meet the FDA's expectations with respect to protecting human subjects and ensuring the integrity of the data from clinical investigators. The guidance pulls together investigator obligations currently listed in the Form 1572 or Investigator Agreement (as applicable), and 21 CFR Parts 812, 312, 50 and 56. The guidance focuses on "general responsibilities that are applicable to clinical trials of drugs, biologics and medical devices."

The following are among the main themes addressed in the guidance.

- **Form FDA-1572**
- **Supervision of Clinical Trials**
- **Protecting Human Subjects**

For more information, see <http://www.mwe.com/info/news/ots0507m.htm>

We invite your input. Please e-mail any items that you would like to share with the Clinical Research community to: doanleslie@uams.edu