



October 19, 2007 Vol. 4 Issue 2

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### **FDA ISSUES NEW DRAFT GUIDANCE FOR PHARMACOGENOMIC STUDIES**

The FDA has issued a 25-page draft guidance to be used as a companion to the guidance *Pharmacogenomic Data Submissions* issued in March 2005. This new guidance includes updated information gathered in the past two years along with FDA reviews of numerous protocols and data submitted under investigational new drug (IND) applications, new drug application (NDAs), and biologics license applications (BLAs). For more information, see <http://www.fda.gov/cder/guidance/7735dft.pdf>.

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### **CMS REGULATIONS**

CMS (Centers for Medicare & Medicaid Services) issued its expected "Final" Decision Memo for Clinical Trial Policy October 17, 2007. To view the Decision Memo for Clinical Trial Policy (CAG-00071R2), click <http://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?id=210>. CMS also released a Q&A document that provides more information. It is attached to this newsletter.

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### **UAMS BREAST CANCER RESEARCHERS CONDUCTING RESEARCH STUDY TARGETING "SUSAN G. KOMEN RACE FOR THE CURE" EVENTS**

UAMS Researchers Dr. Susan Kadlubar, Dr. V. Suzanne Klimberg, and Dr. Kristy Bondurant are leading a research team that hopes to collect saliva samples from over 40,000 women. Titled "Spit for the Cure", the saliva samples will be used to create a DNA database for future studies related to breast cancer risk and treatment. Everyone assisting with this study had to be trained and certified in Human Subject Protection. For more information, see the UAMS Press Release [http://www.uams.edu/update/absolutenm/templates/news\\_release\\_andrea.asp?articleid=6982&zoneid=35](http://www.uams.edu/update/absolutenm/templates/news_release_andrea.asp?articleid=6982&zoneid=35).

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## **UPCOMING EDUCATIONAL CLASSES**

**November 14th - CRS: Writing Informed Consent Documents**

**Presented by Jennifer Sharp, JD**

**Biomedical 1 Building, 205/207**

**9:00 - 11:00 AM**

**This course covers the essential elements of a well written informed consent document. Participants will be given an informed consent document to review. They will also learn about the ongoing process of maintaining consent throughout the study.**

**November 28th - CRS: Advanced Research Ethics**

**Presented by Dr. Chris Hackler and Dr. Micah Hester**

**ACH East Campus-CLASSROOM-EC Training 103**

**1:00 - 4:30 PM**

**This course discusses intellectual honesty in proposing, performing, and reporting research. Other topics covered in this course include data acquisition, management, sharing and ownership; protecting human subjects; research misconduct; conflict of interest; peer review and responsible authorship. Attendees will be given a case scenario to review in groups and present recommendations.**

**Register by clicking**

**<https://secure.uams.edu/TrainingTracker/frmEnrollInClass.aspx> and select RSRA CRS.**

**For more information, contact RSC Education Manager at 526-6879 or**

**[chunnicutt@uams.edu](mailto:chunnicutt@uams.edu).**

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

**Final Decision for Clinical Trial Policy  
Q's and A's**

**Q1. What changes are being made to the Clinical Trial Policy by the final National Coverage Determination issued on October 17, 2007?**

**A1.** We are making no changes at this time to the existing July 9, 2007 policy, which amended the prior policy issued in 2000. We are not eliminating any existing coverage. The changes made by the July 9<sup>th</sup> policy, which continue in effect, expanded coverage for items and services in certain clinical trials in two respects. First, it permits payment for the investigational item, if the item is otherwise covered outside of a clinical trial. Second, the investigational item could also be covered if CMS makes a separate National Coverage Determination (NCD) using Coverage with Evidence Development. CMS will continue to cover items and services in some trials that did not meet the standards of the 2000 policy but have been paid by some contractors.

**Q2. Why are there no changes to the policy?**

**A2.** The decision to make no changes at this time was based on a thorough review and consideration of comments from the public, and the recent enactment of the Food and Drug Administration Amendments Act of 2007 (FDA AA 2007). Public commenters conveyed continued confusion about how the most recent proposed changes would meet the intended goals of the Executive Memorandum of June 2000 and about the legal authority for the policy. In addition, several commenters requested that CMS engage in notice and comment rulemaking, in order to provide additional time to transition to meeting any new standards. We are working to develop clearer standards for Medicare-covered trials that will be consistent with the FDA AA 2007, which was enacted after the NCD public comment period expired. CMS is reviewing this legislation to ensure that we are not imposing duplicative or inconsistent standards .

**Q3. Does this decision (making no changes to the July 9, 2007 policy) limit Medicare coverage for beneficiaries and providers who participate in clinical research?**

**A3.** Maintaining the July 9, 2007 policy retains the status quo coverage for items and services that were covered under the 2000 clinical trial policy for deemed trials. It also continues to cover items and services in some other trials that did not meet the standards of the 2000 policy but have been paid by some contractors.

**Q4. How does CMS address the perception among the public and some Medicare contractors that privately funded studies were not subject to the deeming process established by the 2000 policy?**

**A4.** We understand that the current clinical trial policy has led to some confusion on this point. Trials that do not meet the existing criteria for deemed trials should contact their local Medicare contractors to determine whether items and services will be covered in that geographic area. CMS is not implementing a self-certification approval process as

described in the July 19<sup>th</sup> proposed decision memorandum at this time. Rather, we are retaining the deeming process for trials that meet the deeming standards described in the 2000 policy.

**Q5. What items and services will Medicare pay for when a beneficiary is in a clinical trial?**

**A5.** We are not eliminating or changing the existing coverage. Consistent with the July 9, 2007 policy, Medicare will pay for the item or service under investigation to the extent that the item or service would be covered outside of a clinical trial. In addition, Medicare will continue to pay for routine costs as described in the July 9<sup>th</sup> policy. The existing coverage exclusions set forth in the 2000 policy and retained in the July 9<sup>th</sup> policy (e.g., items and services customarily provided by the research sponsor free of charge, and items and services provided solely to satisfy data collection needs) continue in effect.

**Q6. What conditions or requirements must a trial meet in order to be covered under the July 9, 2007 policy?**

**A6.** Some trials may be “deemed” to meet the standards established in the 2000 policy and retained in the July 9<sup>th</sup> policy. Other trials may be covered if the treatments are considered reasonable and necessary by the local contractor.

**Q7. Why didn’t CMS adopt any of the standards recommended by the Medicare Evidence Development and Coverage Advisory Committee (MedCAC)?**

**A7.** CMS is not adopting the proposed standards recommended by the MedCAC at its December 13, 2006 meeting at this time. In addition to further consideration of the public comments on our July 19, 2007 proposal, we need additional time to examine the requirements of the FDA AA of 2007. We will continue to work with other HHS components on resolving these issues.