



UNIVERSITY OF MARYLAND  
SCHOOL OF MEDICINE

November 20, 2008

TO: All School of Medicine Faculty and Staff

FROM: Bruce E. Jarrell, MD., FACS *B Jarrell*  
Executive Vice Dean

CC: Fred Herman (UMMC), Hank Franey (UMMC), Melanie Mack (UPI), Jerry Carr (SOM), Dennis Paffrath (ORD), Mike Rollor (ORD), Gregory Handlir (SOM), Ellen Datena (SOM), Patrice Holtz (SOM)

RE: Clinical Research Administrative Review Program – Preliminary Medicare Coverage and Billing Analysis Review for All SOM Clinical Research

As you already know, the School of Medicine is committed to ensuring our affiliated healthcare provider organizations have the information they need to bill appropriate parties for clinical care provided in the context of a research study.

Beginning December 1, 2008, all clinical research regardless of funding source (including clinical research that does not have an external funding source) must be submitted to the Center for Clinical Trials for review prior to beginning a study.

Please see the attached for additional information.

Thank you for your cooperation.

BEJ:pad  
Attachment

**SOM CENTER FOR CLINICAL TRIALS  
CLINICAL RESEARCH ADMINISTRATIVE REVIEW**

**Preliminary Medicare Coverage and Billing Analysis**

**Clinical Research that Requires CCT Review**

- All clinical research that includes clinical care activity regardless of funding source including federal, state, foundation, external hospital or university funding
- All unfunded or internally funded clinical research that includes clinical care activity
- All commercially funded clinical research that includes clinical care activity (*no change*)

**Clinical Research that DOES NOT Require CCT Review**

- Retrospective studies that evaluate events that have already occurred including studies that rely exclusively on previously collected administrative records, medical data or other available data
- Survey studies that do not include clinical care activities
- Laboratory analysis studies utilizing human tissue samples obtained from another entity that do not include additional clinical care activity

**How and When To Send a Protocol for PMCA/Billing Analysis Review**

A CCT Clinical Research Review Request Form found at <http://medschool.umaryland.edu/cct> must be completed and sent to CCT for the types of clinical research studies described above that require review. This is the same form currently used for commercially funded clinical research review. The request form should be completed a few weeks prior to IRB submission or at the same time the IRB application is submitted in draft to the IRB.

**NEW CCT Support Services Offered to SOM Faculty Submitting Grant Proposals**

CCT has established a new service to assist faculty investigators determine clinical care cost estimates and potential Medicare coverage of protocol-driven clinical care. This SOM support service is offered to faculty to help ensure budgets submitted to funding agencies include a request for sufficient funds to cover the cost of non-billable clinical care. The development of the proposed grant budget will continue to be the responsibility of the investigator and department.

Faculty who would like this assistance may contact CCT at 410-706-2328 and ask for a financial feasibility review of the proposed clinical research. A CCT Clinical Trial Analyst will contact them within 10 working days.