December 22, 2009

All Faculty Engaged in Clinical Research
Washington University

Dear Colleagues:

Washington University (WU), the Faculty Practice Plan and our hospital partners have an obligation to bill correctly for the clinical items and services provided in the context of a clinical research project. It is our role, as faculty and investigators, to be responsible partners and provide the information necessary to help meet this compliance responsibility. In 2006, WU implemented the Billing Matrix, a database that houses information on clinical trials and participants that are enrolled in them to assist with this responsibility. The use of the Billing Matrix is required for all clinical studies involving Washington University clinics and/or the facilities or resources of our affiliated hospitals. (http://hrpohome.wustl.edu/misc/billing_matrix.pdf).

The Billing Matrix staff receives a copy of every IRB approved protocol and is responsible for entering the basic protocol information and the schedule of events for each study in the Billing Matrix. It is, however, the Principal Investigator’s (PI) responsibility to review and approve the designation of Research vs. Standard of Care (SOC) for each item and service for your particular study in the Billing Matrix. Many of you, however, have shared with us that the Billing Matrix has been difficult to use.

We are pleased to announce that the Center for Clinical Studies has implemented version 2 of the Matrix. Several enhancements now make the Matrix easier to use, including easier navigation and better search capability. Many enhancements are based on your comments, questions and suggestions. We appreciate your feedback and believe these changes will make it easier for those engaged in human subject research to enter the participants enrolled in their trials.

In addition to the changes to the Billing Matrix, we have also clarified the criteria for entering participant data. If the Billing Matrix staff determines that your study meets certain criteria, i.e., is a data collection, tissue banking or retrospective chart review study, you will not be required to enter participant enrollment data into the Matrix.

More information about the enhancements to the Billing Matrix system and these procedural changes will be provided to the clinical research coordinators and staff. In addition, FAQs regarding the Billing Matrix program are attached here and will soon be posted on the Center for Clinical Studies' website.

The PI of the investigation is responsible for ensuring that their studies are compliant with the Billing Matrix requirements. If you have not already done so, please designate a member of your research team to enter the study participant enrollment data into the Billing Matrix and ask them to attend the second educational session presenting the Billing Matrix improvements and changes. This next
session is scheduled for December 30, 2009 and additional sessions may be scheduled if the demand warrants it. We encourage the PI’s attendance at this session as well. By making this designation, you will help us meet our billing compliance obligations.

For further information about the Billing Matrix, please contact the Billing Matrix team via ccsbillingmatrix@msnotes.wustl.edu or contact Phyllis Klein at KLEINP@WUSTL.EDU. Research projects managed through the Siteman Cancer Center will continue to use the Siteman Cancer Center Database which is integrated with the Billing Matrix.

We appreciate your help with this important regulatory requirement.

Sincerely,

Larry J. Shapiro, M.D.
Executive Vice Chancellor for Medical Affairs and Dean

Evan D. Kharasch, M.D., Ph.D.
Interim Vice Chancellor for Research