

UNIVERSITY OF MARYLAND SCHOOL OF MEDICINE

June 3, 2009

TO: Faculty and staff involved in clinical research:

The University of Maryland School of Medicine, University of Maryland Medical System, and University Physicians Inc. continue our efforts to insure that items and services relating to clinical research are being billed correctly to either the study sponsor or the patient's third party insurance carrier.

A policy was developed to register research subjects for clinical research related services. We are changing to a web based registration which will replace the previous versions of the hard copy/paper research participant registration.

A copy of the policy, which goes into effect immediately, is attached.

If you have any questions regarding this policy, please contact either Bryan Soronson at 410-328-3855, Fred Herman from UMMS at 410-328-4391, or Elizabeth Belschner from UPI at 410-328-0951.

Thank you in advance for your cooperation regarding this important matter.

Sincerely,

Bruce E. Jarrell, MD, FACS

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Executive Vice Dean

Henry J. Franey

Senior Vice President & Chief Financial Officer

University of Maryland Medical System

William E. Tucker

Chief Corporate Officer

University Physicians, Inc.

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Attachment

UMMS AND UNIVERSITY PHYSICIANS (UPI) POLICY FOR REGISTERING CLINICAL TRIAL RESEARCH SUBJECTS FOR CLINICAL TRIAL RELATED SERVICES AT UMMC AND OTHER UMMS AFFILIATED FACILITIES AND UPI PHYSICIAN **PRACTICES**

Research Participant Registration must be submitted for ALL research subjects who will receive care at any UPI or UMMS facility (UMMC; Kernan Orthopedic and Rehabilitation Hospital; Maryland General Hospital; Baltimore Washington Medical Center; University Specialty Hospital, Mount Washington Pediatric Hospital; Shore Medical System; Chester River Hospital) and/or any other practice locations. This requirement applies regardless of whether the services will be paid by the clinical trial sponsor, 3rd party insurance (including Medicare) or other funding source.

Online registration with both UPI and UMMS is completed via a web site at http://medschool.umaryland.edu/CCT, or at https://bioinformatics.umaryland.edu/hospresSDATA home//

A login account must be established prior to signing in to the web page and it is suggested that you obtain a login before you are ready to register patients as it may take up to 24 hours to receive your account.

Registrations should be entered the same day the patient is consented/enrolled in the research study. Please retain a hard copy of the registration for future use.

The registration also must be updated when the research subject completes the trial or withdraws from the trial. Registration via the website is only completed upon enrollment and is not to be used to schedule services unless the enrollment and date of first service are on the same date.

Responsibility for compliance with this policy rests with the Principal Investigator. Also please note that Departments/PAs must continue to work with UMMS and UPI to insure that these services are billed to the proper entity.

[Failure to provide the required registration may delay services or result in cost for services provided being charged to the trial or principal investigator's department.

If you are unsure as to whether your patients should be registered with UMMS and UPI, please call Elizabeth Belschner with UPI at 410-328-0951 and/or Fred Herman with UMMS at 410-328-4391.

NOTE: The Research Patient Registration Form should not be completed for data analyses, questionnaires, surveys, interviews, chart reviews, database reviews, specimen/laboratory experiments that do not involve clinical care services as well as studies conducted solely at the VA Hospital.

Bruce E. Jarrell, MD, FACS

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