

Office of Academic Affairs Research Compliance 800 West Baltimore Street, Suite 100 Baltimore, MD 21201 410-706-5037 Phone / 410-706-4189 Fax <u>hrpo@som.umaryland.edu</u> www.hrpo.umaryland.edu

Dear Participant:

Between the period of June 21, 2002 and August 31, 2006, you participated in a research study conducted by scientists at the University of Maryland School of Medicine and sponsored by the National Institute on Aging. The name of the study was "Hip Impact Protection Program (HIP PRO)." Dr. Jay Magaziner was one of the investigators conducting the study.

We have been instructed by the United States Department of Health and Human Services Office for Human Research Protection (OHRP)(the office that is responsible for research ethics involving human subjects) to inform subjects that, during the course of the study, information became available that should have been brought to the attention of the subjects or their legally authorized representatives. You may find it useful to look at the following website for details regarding OHRP's investigation: http://www.hhs.gov/ohrp/detrm_letrs/YR11/jun11a.pdf.

Specifically, individuals who participated in the study which required them to wear an undergarment with padding on one hip may have had an increased likelihood of falling to the side of the body that was meant to be protected. U.S. Department of Health and Human Services regulations require that subjects be notified of any new risks discovered during the course of the study so that each subject may evaluate their willingness to remain in the study. It has been determined that this information should have been given to study subjects or their legally authorized representatives when they joined the study (if that took place in the Fall of 2004 or later), or during the course of the study if they were still participating in the study in the Fall of 2004.

If you do not have access to the internet and wish us to send you a copy of OHRP's letter, please contact us at the University of Maryland's Human Research Protections Office at 800 West Baltimore Street, Suite 100, Baltimore Maryland, 21201. The office telephone number is (410) 707-5037. The office electronic mail address is HRPO@som.umaryland.edu.

If you have questions about this situation, you can contact the University of Maryland's Human Research Protections at 410-706-5037 and ask to speak with Mary MacFadden, research subject advocate.

Sincerely,

Robert Rosenthal, MD University of Maryland

Chair, Institutional Review Board