Supplementary Online Content


Letters
Hebrew SeniorLife
Washington University in St Louis
University of Maryland

This supplementary material has been provided by the institutions.
July 20, 2012

Dear [name of participant],

Several years ago, Hebrew Rehabilitation Center (HRC) served as the Massachusetts-area coordinating center for a national research study entitled “Trochanteric Padding to Prevent Hip Fractures” (the “HIP PRO Study”). The HIP PRO Study took place in three metropolitan areas. Washington University of St. Louis served as the St. Louis-area coordinating center and University of Maryland-Baltimore served as the Baltimore-area coordinating center. Between 2002 and 2006, nursing home residents from HRC, residents of other Massachusetts-area nursing homes, and residents from nursing homes in the Baltimore and St. Louis areas, were enrolled in the HIP PRO Study. You are receiving this letter because it is being sent to everyone who was enrolled in the HIP PRO Study on or after August 1, 2004 and our records indicate that you were enrolled as a research participant at [name of facility] during that time.

Falls among seniors are frequent. Despite significant efforts to prevent falls, in all environments in which seniors live, they still occur. Health care providers to nursing home residents, therefore, continue efforts to prevent falls, but also focus significantly on how to reduce the potential impact of falls, including hip fractures. The purpose of the HIP PRO Study was to understand whether external hip protectors (also known as hip pads) could be effective in decreasing hip fractures.

The HIP PRO Study was funded by the National Institutes on Aging, which is part of the federal government. During the HIP PRO Study, participants wore an external hip pad on either their left or right hip so that every participant had the opportunity to have one hip protected by the pad. This was a different approach from prior studies that assigned participants to either a group that did not wear the external hip pad at all or to a group that wore the hip pad on both sides.

The United States Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP) is responsible for providing oversight of research ethics for individuals who participate in research studies. Institutional Review Boards (IRBs) are committees that work to ensure that these ethics are followed. In late 2009, the OHRP contacted HRC and the other two coordinating centers regarding concerns that participants in
the HIP PRO Study might have experienced an increased chance of falling to the side that was assigned to wear the hip pad. From December 2009 until June 2011, HRC corresponded with the OHRP to review these concerns. On June 23, 2011, the OHRP notified HRC of its determination that, at some point after the Study began, some information emerged indicating the possibility that participants may have had an increased likelihood of falling to the side that was assigned to wear the external hip pad, and that this information should have been shared with study participants.

HRC, along with its parent, Hebrew SeniorLife (HSL) took this matter very seriously. HSL took the lead in conducting a rigorous fact-finding review. On the basis of the review, HSL concluded that as of August 2004, the investigator leadership of the HIP PRO Study was aware of preliminary data that suggested that there might be an increased chance of study participants falling to the padded side. Based on its review, HSL concluded that while the investigators disclosed some information about falls to the HSL IRB, there should have been fuller disclosure of this information to the IRB and a more robust discussion to determine the extent to which it was reliable and appropriate to share with participants.

Because the HIP PRO Study was designed to study hip fractures, but not falls, HSL was not able to determine during the course of its review whether or not wearing the external hip pad increased the risk of falling to the padded side. HSL is not aware of any participant that was harmed as a result of a fall attributable to his/her wearing of the external hip pad during the HIP PRO Study. Nonetheless, HSL cannot conclusively rule out the possibility of an increased risk of falling to the protected side. DHHS regulations require that research participants be notified of any new risks discovered during the course of the study so that each participant may evaluate their willingness to remain in the study. OHRP determined that this information should have been given to study participants when they consented to join the study in the Fall of 2004, or during the course of the study if they were still participating in the study in the Fall of 2004.

Although there is no way to know for certain how the IRB might have evaluated this information in the Fall of 2004, it is being shared with you now as a reflection of our commitment to transparency and research participant safety. We regret that this information was not provided to you earlier.

We, along with our colleagues at HSL, are committed to the safety and well-being of every individual who participates in a research study. We are grateful for your willingness to have participated in the HIP PRO Study and we hope your experience was a positive one. We are taking this opportunity to learn from this experience as we continue to improve and strengthen our research program to enhance the lives of seniors. You have our commitment that the members of the HSL IRB will take an active role in assisting in this effort.
If you are interested in learning more about the OHRP determination, you may find the official letter at the following link: [http://www.hhs.gov/ohrp/detrm_letrs/YR11/jun11a.pdf](http://www.hhs.gov/ohrp/detrm_letrs/YR11/jun11a.pdf). If you do not have a computer or access to the internet and wish us to send you a copy of this letter, or if you have any questions about your participation in the HIP PRO study, please contact Kathy Irvine Tasker, who is the institutional official at HSL in charge of our research program. You may reach Kathy by calling: 617.971.5351 or by email: KathyIrvine@hsl.harvard.edu.

Sincerely,

Madhuri Reddy, MD MSc, Chair, Institutional Review Board of Hebrew SeniorLife
On behalf of the Institutional Review Board of Hebrew SeniorLife

cc: Kathy Irvine Tasker, Institutional Official
Date

Dear Participant of the HIP PRO Study, Legally Authorized Representative of Participant, or next-of-kin:

This letter is being sent to all persons and/or their legally responsible representative or the next of kin of subjects who participated in the research study entitled “Trochanteric Padding to Prevent Hip Fractures (HIP PRO study)" which I conducted as a faculty member of the Washington University School of Medicine between 2002 and 2006 in several nursing homes in the St. Louis area.

The investigators have been instructed by the United States Department of Health and Human Services Office of Human Research Protection (OHRP; the federal office that is responsible for research ethics involving human subjects) to inform participants that, during the course of the study, information became available that should have been brought to the attention of the participants or their legally authorized representatives. You may find it useful to look at the following website for details of OHRP’s investigation: [http://www.hhs.gov/ohrp/detrm_lets/YR11/jun11a.pdf](http://www.hhs.gov/ohrp/detrm_lets/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 are to be notified of any new risk discovered during the course of the study so that each participant may evaluate their willingness to remain in the study. It has been determined that this information should have been given to study participants or their legally authorized representative when they joined the study (if after August, 2004), 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 address for the Human Research Protection Office listed below.

Please accept our apologies for this matter. Early in the study, there appeared to be a tendency to fall toward the protected hip (and participants should have been notified of this risk), however, the data at the conclusion of the study did not indicate an increased risk. If you have any questions, please contact Dr. Stanley Birge at the following address:

4488 Forest Park Blvd
St. Louis, MO 63108.

If you have questions, concerns, or complaints about your rights as a research participant, you may also contact the Human Research Protection Office at Washington University, 660 South Euclid Avenue, Campus Box 8089, St. Louis, MO 63110, (314) 633-7400, or 1-(800)-438-0445 or email hrpo@wusm.wustl.edu.

Sincerely,

Stanley Birge, M.D.
Associate Professor of Medicine
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](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