



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

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July 5, 2012

Bruce E. Jarrell, M.D., FACS
Vice Dean for Research and Academic Affairs
University of Maryland Baltimore, School of Medicine
655 W. Baltimore Street
Room 14-031
Baltimore, MD 21201

RE: Human Research Protections under Federalwide Assurances FWA-00007145

Research Project: Trochanteric Padding to Prevent Hip Fractures (also known as the Hip Impact Protection Program (HIP PRO))
Principal Investigator: Jay Magaziner, Ph.D.
HHS Protocol Number: 5R01AG018461

Dear Dr. Jarrell:

Thank you for your responses to the Office for Human Research Protection's (OHRP) February 17, 2012 letter that requested that your institution revise its proposed notification plan and accompanying letters for notifying former subjects or their legally authorized representatives (LARs) of information that the subjects or LARs should have received while enrolled in the research referenced above. As you are aware, the plan and letters are part of your institution's corrective action plan to address noncompliance with Department of Health and Human Services (HHS) regulations for the protection of human research subjects (45 CFR part 46) regarding the above-referenced research.

A. Determinations Regarding the Research Referenced Above:

- (1) In our June 23, 2011 letter, we made the following determinations specific to the research referenced above:
 - (a) When obtaining informed consent from subjects, the research team failed to disclose to subjects or their legally authorized representatives a description of reasonably

- foreseeable risks to the subjects, in contravention of the requirements of HHS regulations at 45 CFR 46.116(a)(2);
- (b) Investigators failed to provide subjects with significant new findings about these risks developed during the course of the research which may have related to the subject's willingness to continue participation, in contravention of the requirements of HHS regulations at 45 CFR 46.116(b)(5); and
 - (c) Investigators failed to report unanticipated problems, i.e., increased falling to the pocketed side and the associated risk of possible fractures, to their respective institutional review boards (IRBs), institutional officials, the funding agency and OHRP, in contravention of the requirements of HHS regulations at 45 CFR 46.103(a) and 46.103(b)(5).

As a result of these determinations, we asked University of Maryland (UMB) to provide a corrective action plan to address these areas of noncompliance.

Corrective Actions: In a letter dated August 5, 2011, UMB proposed corrective actions to address OHRP's determinations. We reviewed the proposed corrective actions (summarized in our February 17, 2012 determination letter) and requested revisions to the UMB notification plan. In a letters dated August 5, 2011 and April 30, 2012 and an email dated May 24, 2012, UMB notified us of the following revised notification plan:

- (1) The UMB investigator will visit each nursing home facility to ascertain which participants continue to live at the nursing home or obtain the participant's new address in the event that they no longer reside at the nursing home. During the indicated visits, the investigator will also obtain information regarding the subject's LAR, health care agent, administrator of the estate, or next-of-kin, as applicable. After the investigator has completed the dictated nursing home visits, he will search the national death registry to ascertain if any participants are now deceased. The investigator will be required to provide this information to the UMB IRB in spreadsheet format along with the mailing addresses for the living subjects, LARs, health care agents, administrators of the estate or next-of-kin, as applicable.
- (2) Notification letters will be sent as follows:
 - (a) A UMB subject notification letter will be sent to all living participants who are currently making their own medical decisions;
 - (b) A UMB LAR notification letter will be sent to all LARs who provided consent for subject participation, regardless of whether the former subject is living or deceased; and
 - (c) A UMB LAR Notification Letter, Next-of-Kin Notification letter, Responsible Healthcare Decision Maker Letter or an Administrator of the Estate of the Deceased Letter will be sent as follows:
 - (i) For living participants who enrolled themselves in the research, but are currently unable to make their own medical decisions, UMB will notify each participant's current LAR, which may be a person appointed by the participant

as a health care agent or surrogate or may be the next-of-kin determined in accordance with the surrogacy provisions of the Maryland Health Care Decisions Act; and

(ii) For participants who are now deceased, UMB will notify either the Administrator of the Estate of the deceased participant or the next of kin.

(c) All notification letters will be marked confidential and sent via certified mail with return receipts. The letters will contain the contact information for the UMB Human Research Protections Office (HRPO) Research Subject Advocate.

We note that the revised plan and proposed notification letters were reviewed and approved by your institutional IRB, and are consistent with the requirements outlined in our February 12, 2012 letter.

We determine that the revised notification plan noted above is appropriate under your institution's FWA. As a result, at this time, there should be no need for further involvement by our office in this matter.

We appreciate the continued commitment of your institutions to the protection of human research subjects. Please notify us if you identify new information which might alter this determination and do not hesitate to contact us should you have any questions.

Sincerely,

Lisa Buchanan, MAOM
Compliance Oversight Coordinator
Division of Compliance Oversight

Lisa A. Rooney, JD
Compliance Oversight Coordinator
Division of Compliance Oversight

cc:

Ms. Susan C. Buskirk, Executive Director, Human Research Protections Program,
University of Maryland Baltimore (UMB) School of Medicine

Dr. Robert Edelman, Associate Director, Clinical Research/Professor/IRB Chair, UMB,
School of Medicine

Dr. Margaret Hamburg, Commissioner, Food and Drug Administration (FDA)

Dr. Jeffrey Shuren, FDA

Dr. Joanne Less, FDA

Dr. Sherry Mills, National Institutes of Health (NIH)

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Mr. Joseph Ellis, NIH
Dr. Richard J. Hodes, Director, National Institute on Aging