DEPARTMENT OF HEALTH & HUMAN SERVICES

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July 5, 2012

Kathryn W. Irvine Tasker
Vice President for Research Administration
Hebrew Senior Life
1200 Centre Street
Roslindale, MA 02131

RE: Human Research Protections under Federalwide Assurances FWA-00000885

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

Dear Ms. Tasker:

Thank you for your response 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 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 Hebrew Senior Life (HSL) to provide a corrective action plan to address these areas of noncompliance.

Corrective Actions: In a letter dated November 4, 2011, HSL proposed corrective actions to address OHRP's determinations. We reviewed the proposed corrective action actions (summarized in our February 17, 2012 determination letter) and requested revisions to the subject notification plan.

Under HSL's revised subject notification plan:

HSL will send notification letters to 268 of the 282 subjects or LARs involved in the HIP PRO study. We note that HSL was unable to ascertain the contact information for the 14 remaining subjects, their LARs, health care proxy or next-of-kin. HSL's revised notification plan does not include a plan for contacting study subjects' next-of-kin because: (a) HSL did not collect next-of-kin information at the time that informed consent was obtained; and (b) the participating nursing homes do not maintain such next-of-kin information on site or update this information once a nursing home resident dies or is discharged from the nursing home facility. Specifically:

(1) One research subject, who is still alive and competent to make health care decisions, will receive the revised subject notification letter. This former subject will receive the letter directly at the facility where the former subject currently resides. A nursing home representative will be available to the former research subject should the former subject have questions regarding the letter.

(2) The remaining 267 subjects, who were enrolled using LARs, will be sent the revised notification letter directed to the LARs. The notification letters will be sent to the LARs by Certified, Restricted Delivery, and Return Receipt mail.

We note that the revised notification plan and proposed notification letters were reviewed and approved by your IRB, and are consistent with the requirements outlined in our February 12, 2012 letter. We have determined that the corrective actions noted above are 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 institution 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. Zakyia Watkins, Administrator, Hebrew Rehabilitation Center for Aged
Dr. Susan Kalish, IRB Chair, Hebrew Rehabilitation Center for Aged
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)
Mr. Joseph Ellis, NIH
Dr. Richard J. Hodes, Director, National Institute on Aging