



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
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June 4, 2009

Haim Garty, Professor
Vice President
Weizmann Institute of Science
P.O. Box 26
Rehovot 76100
ISRAEL

RE: Human Research Subject Protections Under Federalwide Assurance (FWA)-8969

Research Project: DNA repair biomarkers for cancer risk assessment and early detection (UOI CA11219 - award to Weizmann Institute); + supplemental grant: Title: Collection and processing of blood samples for cellular enzymatic biomarkers (UO 1 CA084986-Weizmann is subcontracted to Johns Hopkins)

Principal Investigator: Prof. Zvi Livneh

Dear Dr. Garty:

Thank you for your May 28, 2009 report in response to our April 30, 2009 letter to Weizmann Institute of Science (WIS) regarding determinations of noncompliance with Department of Health and Human Services (HHS) regulations for the protection of human research subjects (45 CFR part 46). In our April 30, 2009 letter, we made the following determination:

We determined that the Carmel institutional review board (IRB), which reviewed this research on behalf of WIS, failed to conduct continuing review of research at least once per year for the above-referenced research as required by HHS regulations at 45 CFR 46.109(e). In addition, at least nine subjects were enrolled during the lapse in IRB approval between October 21, 2008 and November 12, 2008.

Corrective Action: OHRP acknowledges the following corrective actions to be taken by WIS:

(1) Each scientist who declares that s/he conducts human subjects research shall receive from the head of the Directorate for Research and Academic Affairs and the Human Protections Administrator a notification regarding human subjects protection compliance and shall be required to confirm compliance. This notification will address the researchers' responsibility to ensure that the IRB which reviews their HHS-supported research conducts continuing review of the research at

least annually; and that if a lapse in IRB approval occurs, the researcher is obliged to stop all human subjects research activities until IRB review and approval is obtained.

(2) The WIS Research Grants and Projects Office shall issue to investigators of ongoing projects periodic reminders as to the need for an annual continuing review and of the obligation to stop all human subjects research activities if a lapse in IRB approval occurs, until IRB review and approval is obtained.

We recommend that these policies and notifications be revised to indicate that if a lapse in IRB approval occurs, investigators are notified to stop all human subjects research activities, **unless it is in the best interests of the subjects to continue in the research**, until IRB review and approval is obtained.

We determine that these corrective actions adequately address the determination of noncompliance. At this time, there should be no need for further involvement by our office in this matter. Please notify us if you identify new information which might alter this determination.

We appreciate the continued commitment of your institution to the protection of human research subjects. Please feel free to contact me should you have any questions.

Sincerely,

Kristina C. Borrer, Ph.D.
Director
Division of Compliance Oversight

cc: Dr. Boaz Avron, Head, Directorate for Research and Academic Affairs, Weizmann
Institute of Science
Dr. Jacques Michel, Chair, Hadassah Medical Organization IRB#1
Dr. Ruth Kitzes-Cohen, Chair, Carmel Medical Center IRB#1
Dr. Lidia Arcavia, Chair, Kaplan Medical Center IRB#1
Dr. Margaret Hamburg, Commissioner, Food and Drug Administration
Dr. Joanne Less, Food and Drug Administration
Ms. Sherry Mills, National Institutes of Health, Office of Extramural Research
Mr. Joe Ellis, National Institutes of Health, Office of Extramural Research
Dr. John E. Niederhuber, Director, National Cancer Institute