



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary  
Office of Public Health and Science

Office for Human Research Protections  
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April 30, 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 April 12, 2009 report in response to our March 23, 2009 request that Weizmann Institute of Science (WIS) provide documentation for our evaluation of compliance with Department of Health and Human Services (HHS) regulations for the protection of human research subjects (45 CFR part 46). Based on review of your response, we make the following determination:

We determine 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 specific, we note that, according to the table provided in your response the "Wider Project" had initial IRB approval on November 22, 2006 (although we note that Carmel IRB did not provide us with this date of an IRB meeting related to this protocol and did not provide meeting minutes for this date), continuing review by the IRB on October 21, 2007 (approved October 21, 2007) and November 10, 2008 (approved November 12, 2008). Your response stated that the Hospital Director's approval is a pre-condition to the conduct of human subjects research, in addition to the IRB approval, and you appear to set continuing review

dates based on the date of the Hospital Director's approval. However, HHS regulations at 45 CFR 46.109(e) require that continuing review **by the IRB** must occur at least annually, which did not occur for the "Wider Project" between 2007 and 2008. In addition, the list you provided us of subjects (code numbers only) enrolled at the Weizmann Institute for this study and dates of enrollment indicated that at least 9 subjects were enrolled during the lapse in IRB approval between October 21, 2008 and November 12, 2008.

**Required Action:** By June 12, 2009 please provide a corrective action to ensure that IRBs which review HHS-supported research on behalf of WIS conduct continuing review of research at least annually, and 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 occurs. Feel free to contact me if you would like guidance in developing a corrective action plan.

OHRP appreciates 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. Joshua M. Sharfstein, Acting 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