



Office for Human Research Protections
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September 4, 2002

Paul Levy
President
Beth Israel Deaconess Medical Center
330 Brookline Avenue
Boston, MA 02215

**RE: Human Research Subject Protections Under the Multiple Project Assurance (MPA)
M-1544**

**Research Project: A Phase I Study T Cells Modified with Chimeric antiCEA
Immunoglobulin-T Cell Receptors (IgTCR) in Adenocarcinoma
Project Number: 94-1101-148
Principal Investigator: R.P. Junghans, M.D., Ph.D.**

**Research Project: A Phase I Study T Cells Modified with Chimeric antiGD3
Immunoglobulin-T Cell Receptors (IgTCR) in Metastatic Malignant Melanoma
Project Number: 94-1101-147
Principal Investigator: R.P. Junghans, M.D., Ph.D.**

Dear Mr. Levy:

The Office for Human Research Protections (OHRP) has reviewed the Beth Israel Deaconess Medical Center (BIDMC) August 7, 2002 report regarding the above referenced matter.

Based upon its review of your report, OHRP has determined that BIDMC has adequately addressed the additional concern raised by OHRP in its May 9, 2002 letter.

As a result, there should be no need for further involvement of OHRP in this matter. Of course, OHRP must be notified should new information be identified which might alter this determination.

OHRP appreciates the commitment of your institution to the protection of human subjects. Please do not hesitate to contact me should you have any questions.

Sincerely,

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

cc Dr. Alan Lisbon, Chair, BIDMC IRBs
Ms. Mary M. Williams, Vice Chair, BIDMC IRBs
Dr. Richard Junghans, BIDMC
Dr. Greg Koski, OHRP
Dr. Melody Lin, OHRP
Dr. Michael Carome, OHRP
Mr. George Gasparis, OHRP
Ms. Yvonne Higgins, OHRP
Mr. Barry Bowman, OHRP
Commissioner, FDA
Dr. David Lepay, FDA