DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
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October 28, 2002

Nancy C. Martin, Ph.D.
Vice President for Research
Office of Graduate Programs and Research
University of Louisville
Jouett Hall, Room 202B
Louisville, Kentucky 40292

Carol Z. Garrison, Ph.D.
Provost
University of Louisville
209 Gawemeyer Hall, MS 05-07
Louisville, Kentucky 40292

RE: Human Research Subject Protections Under Multiple Project Assurance (MPA) M-1189 and FederalWide Assurance (FWA) 00002211

Research Project: Use of Photofrin® and Photodynamic Therapy (PDT) for Malignancies Which Have Either Failed Conventional Therapy or for Patients Who Have Refused Conventional Therapy [HSC 180-96]
Principal Investigators: T. Jeffery Wieman, M.D. and Scott W. Taber, M.D.
UL Protocol Number: HSC 180-96

Dear Drs. Martin and Garrison:

The Office for Human Research Protections (OHRP) has reviewed the University of Louisville's (UL's) report dated October 18, 2002. OHRP has determined that the actions summarized below appropriately address the remaining issue raised in OHRP's letter of September 24, 2002.

OHRP acknowledges that the UL has modified its institutional review board (IRB) policies and procedures by revising the informed consent checklist and the sample informed consent document template to stipulate that the informed consent document is required to include an adequate description of reasonably foreseeable risks and discomforts to the subject for any medical or surgical procedures required by the research project. OHRP further acknowledges that UL plans to develop and implement a training program for IRB members that will address the importance of this requirement in the UL IRB's initial and continuing review of research. OHRP finds these corrective actions to be satisfactory and appropriate under the UL's FWA.

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

Sincerely,

Robert J. Meyer
Compliance Oversight Coordinator
Division of Compliance Oversight

cc: Mr. W. Bruce Lunsford, Vencor, Inc.
Dr. Richard L. Miller, Chair, IRB 1-A, UL
Dr. Edward R. Leist, Chair, IRB 2-B, UL
Dr. Lynn L. Ogden, Chair, IRB 1-A, Jewish Hospital Healthcare Services
Dr. Frank T. Serratoni, IRB 2-B, Jewish Hospital Healthcare Services
Dr. T. Jeffery Wieman, UL
Dr. John Mather, Director, Office of Research Compliance and Assurance, Veterans Health Administration

Commissioner, FDA
Dr. David A. Lepay, FDA
Dr. Greg Koski, OHRP
Dr. Melody H. Lin, OHRP
Dr. Michael A. Carome, OHRP
Dr. Jeffrey M. Cohen, OHRP
Mr. George Gasparis, OHRP
Dr. Harold Blatt, OHRP
Mr. Barry Bowman, OHRP