



Office for Human Research Protections
The Tower Building
1101 Wootton Parkway, Suite 200
Rockville, Maryland 20852
Telephone: 301-435-0062
FAX: 301-402-2071

December 1, 2003

Dr. Harvey Colten
Vice President and Associate Dean
Columbia University Health Sciences
630 West 168th Street, P&S 2-2041
New York, NY 10032

**RE: Human Research Subject Protections Under Federalwide Assurance (FWA) 2636
and Multiple Project Assurance (MPA) 1356
Research Project: Daily versus thrice weekly interferon alpha-2b in combination
with ribavirin for patients with chronic hepatitis C infection who have relapsed or
failed prior interferon therapy
IRB Project Number: 8897
Principal Investigator: Dr. Robert S. Brown, Jr.**

Dear Dr. Colten:

The Office for Human Research Protections (OHRP) has reviewed Columbia University Health Sciences' (CUHS's) August 8, 2002 report that was submitted in response to OHRP's May 23, 2002 letter regarding allegations of noncompliance with Department of Health and Human Services (HHS) regulations for the protection of human research subjects (45 CFR part 46) involving the above-referenced research.

Based on its review, OHRP makes the following determination regarding the above-referenced research:

(1) HHS regulations at 45 CFR 46.103(a) and 103(b)(5)(i) require institutions to promptly report to OHRP any unanticipated problems involving risks to subjects or others. OHRP finds that the attempted suicide of a human subject involved in the above research was not an unanticipated problem and CUHS was not required to report the incident to OHRP.

OHRP has the following concerns and questions about the above-referenced research:

(2) [Redacted]

(3) [Redacted]

(4) [Redacted]

Please reply to OHRP's concerns by December 30, 2003. OHRP appreciates CUHS's continued commitment to the protection of human research subjects. Feel free to contact me should you have any questions.

Sincerely,

Carol J. Weil, J.D.
Compliance Oversight Coordinator
Office for Human Research Protections

cc: Mr. George Gasparis, CUHS
Dr. Robert Brown, CUHS
Dr. Andrew Wit, CUHS IRB #1 Chair
Dr. Elaine Larson, CUHS IRB #2 Chair
Dr. Andrew Davidson, IRB #3 Chair
Dr. Bernard Schwetz, OHRP
Dr. Melody Lin, OHRP
Dr. Michael Carome, OHRP
Dr. Kristina Borrer, OHRP
Ms. Yvonne Higgins, OHRP
Ms. Janice Walden, OHRP
Ms. Pat El-Hinnawy, OHRP
Ms. Shirley Hicks, OHRP
Ms. Melinda Hill, OHRP
Commissioner, FDA
Dr. David Lepay, FDA