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 21, 2003

William J. Martin II, M.D.
Christian R. Holmes Professor
and Dean, College of Medicine
Acting Senior Vice President
University of Cincinnati Medical Center
P.O. Box 670555
Cincinnati, OH 45267-0555

RE: Human Research Subject Protections Under Multiple Project Assurance (MPA) M-1138 and Federalwide Assurance (FWA) 00003152

Research Project A: Use of 5% Mafenide Acetate (Sulfamylon) Solution in Burn Wound Management
Principal Investigator: Dr. Glenn D. Warden
Project Number: 91-02-20-4

Research Project B: Autologous Cultured Skin Substitutes for Treatment of Full-Thickness Burns
Principal Investigator: Dr. Steven Boyce
Project Number: 90-5-7-1

Dear Dr. Martin:

The Office for Human Research Protections (OHRP) has reviewed the University of Cincinnati's (UC) December 30, 2003 report submitted in response to OHRP's November 21, 2002 letter regarding the above-referenced research.

Based on the review of your report, OHRP notes that UC has required the investigators in the above-referenced research to conduct an audit of research subjects enrolled to ensure that no additional

protocol violation had occurred. In addition, OHRP notes that the investigators have been made aware of the requirement to request changes to a protocol approved by an institutional review board (IRB) prior to the initiation of such changes, except when necessary to eliminate apparent immediate hazards to the subject. OHRP recommends that UC also consider reminding all investigators of the regulatory requirements to obtain IRB approval for changes in approved research during the period for which IRB approval has already been given, as required by HHS regulations at 45 CFR 46.103(b)(4)(iii).

OHRP finds that the corrective actions noted above adequately address the findings of noncompliance noted in OHRP's November 21, 2002 letter and are appropriate under the UC MPA and FWA. As a result of this determination, 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,

Patrick J. McNeilly, Ph.D.
Compliance Oversight Coordinator
Division of Compliance Oversight

cc: Ms. Mary Belkis, Director, Institutional Research and Compliance Services, UC
Dr. Peter Frame, Chair, IRB #1A, UC
Dr. James Mulchahey, Chair, #1B, UC
Dr. Margaret Miller, Chair, IRB #2, UC
Dr. Glenn Warden, Director of Research, Shriners Burn Institute
Dr. Steven Boyce, UC
Mr. Carlos Lott, Director, Cincinnati VA Medical Center
Dr. John Mather, Director, Office of Research Compliance and Assurance, Department of Veterans Affairs
Commissioner, FDA
Dr. David Lepay, FDA
Dr. Melody H. Lin, OHRP
Dr. Michael Carome, OHRP
Dr. Kristina Borror, OHRP
Mr. George Gasparis, OHRP
Ms. Shirley Hicks, OHRP
Dr. Harold Blatt, OHRP
Ms. Melinda Hill, OHRP