



Office for Human Research Protections
Rockville, Maryland 20852

[April 19, 2006]

Philip A. Ludbrook, M.D.
Associate Dean and Chairman, Institutional Review Board
Human Studies Committee Office
Washington University Medical Center
Box 8089
660 South Euclid Avenue
St. Louis, Missouri 63110-1093

Subject: Secretary's Determination under Department of Health and Human Services Regulations at 45 CFR 46.407 on the Research Protocol Entitled "Precursor Preference in Surfactant Syntheses of Newborns" (HSC 02-0898); Principal Investigator: Kimberly L. Spence, M.D.

Dear Dr. Ludbrook:

Thank you for your letter of March 24, 2006. On behalf of the Assistant Secretary for Health, Department of Health and Human Services (HHS), the Office for Human Research Protections (OHRP) finds that all of the stipulations outlined in OHRP's letter of January 12, 2006 have been met.

As a result, OHRP finds that the research conforms with the requirements of HHS regulations at 45 CFR part 46, subpart A, and at 45 CFR 46.407 and 46.408, and now may proceed with the HHS support provided by the National Heart, Lung, and Blood Institute, National Institute of Health under grant number F32 HL0746601.

This concludes the 45 CFR 46.407 review process. It is the responsibility of the Washington University Medical Center's Human Studies Committee to oversee the conduct of this research and to conduct continuing review of this protocol.

Please do not hesitate to contact us with any questions. Thank you for your continuing commitment to the protection of human subjects.

Sincerely,

[/s/ Bernard A. Schwetz]

Bernard A. Schwetz, D.V. M., Ph.D.
Director
Office for Human Research Protections

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cc: Dr. Kimberly Spence, WUMC
Dr. Aaron Hamvas, WUMC
Dr. Lana Skirboll, NIH
Dr. Sandra Colombini-Hatch, NHLBI
Dr. Sara Goldkind, FDA
Dr. Melody Lin, OHRP
Dr. Michael Carome, OHRP
Dr. Irene Stith-Coleman, OHRP
Dr. Kevin Prohaska, OHRP