

**Complete Final Version of the Continuing Review Minutes
From December 16, 2004**

(02-0898)

Dr. Kimberly Spence

**Title: Precursor Preference in Surfactant Synthesis of
Newborns**



Human Studies Committee (HSC)

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**CONTINUING REVIEW COMMITTEE MEETING
 MINUTES
 December 16, 2004**

COMMITTEE: 03 CRC **COMMENCED - 3:35 PM ADJOURNED - 5:17 PM**

Members Present Randall Bateman, MD; Diane Bohner, RN, BSN; Linda Breuklander, AND; Kim Cella, BS; Yazid Fadl, MD; Jennifer Gartland; Lee Hoffer, PhD, MA, BA; Cathy Jackson; L. Edward Klein, MS; Ruth R. Marion, MSW; Matthew Matava, MD; Patricia Scannell, BA; Phyllis Stein, PhD; Robert Strunk, MD; Linda Van Zandt

Members Absent Ed Casabar, PharmD; Patricia Flynn, BSN; Stephanie Porto, RPH; Alphonso Voorhees; Cynthia Wichelman, MD

Quorum 11

Staff Michelle Abernathy

Other The recommendations of the MRCR 08 Sub-Committee for approval, disapproval, or required revisions for all minimal risk renewals were reported to the Continuing Review Committee.

M=Minimal, >M=Greater than Minimal, N=N/A
 Research Risk/Review Freq.

Spence, Kimberly	Newborn Medicine	02-0898	>M/Annual
Precursor Preference in Surfactant Synthesis of Newborns			
Reviewers: Strunk / Klein			
<u>General Comments</u>			
Because the new healthy control group you propose to study falls under the regulatory requirements for research involving minors category 46.407 final approval of this study is pending the review by the Office for Human Research Protections (OHRP) DHHS secretary.			

The HSC would like to remind you that the addition of infants with normal lungs cannot be initiated at this time until approval is received from the OHRP.

HIPAA Status: Compliant with Authorization

HIPAA Comments:

Voting Record

Motion: Approval of the protocol pending the Principal Investigator's concurrence with the suggested revisions.

For: 12 Against: 0 Abstain: 0 Total: 12

Comments: Dr. Randall Bateman arrived late but was present for the discussion and vote on this protocol and for the remainder of the meeting (unless otherwise noted).