CONTINUING REVIEW COMMITTEE MEETING MINUTES

December 16, 2004

COMMITTEE: 03 C	RC 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; Stephar Cynthia Wichelman, MD	ie Porto, RPH; Alphonso Voorhees;
Quorum	11	
Staff	Michelle Abernathy	
Other	The recommendations of the MRCR 08 Sub-Comm required revisions for all minimal risk renewals wer Committee.	

M=Minimal, >M=Greater than Minimal, N=N/A

Research Risk/Review Freq.

Research Risk: Greater than Minimal

Spence, Kimberly

Newborn Medicine

02-0898 >M/Annual

Precursor Preference in Surfactant Synthesis of Newborns Reviewers: Strunk / Klein

General Comments

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).