CONTINUING REVIEW COMMITTEE MEETING

MINUTES

November 18, 2004

COMMITTEE: 03 CRC **COMMENCED -** 3:30 PM **ADJOURNED -** 4:35 PM

Members Present	Randall Bateman, MD; Diane Bohner, RN, BSN; Linda Breuklander, AND; Ed Casabar, PharmD; Patricia Flynn, BSN; Jennifer Gartland; Lee Hoffer, PhD, MA, BA; Cathy Jackson; L.Edward Klein, MS; Matthew Matava, MD; Stephanie Porto, RPH; Patricia Scannell, BA; Robert Strunk, MD; Linda Van Zandt; Alphonso Voorhees
Members Absent	Kim Cella, BS; Yazid Fadl, MD; Ruth Marion, MSW; Phyllis Stein, PhD; Cynthia Wichelman, MD
Quorum	11
Staff	Sarah Uffman
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.

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

The Committee wishes to review your revisions and/or response(s) to the following concerns at the next meeting of the 03 CRC Reviewing Committee on 12/16/2004. Please have your written response and/or revisions to the HSC office by 12/03/2004 for distribution to the Committee members. If you find that you are not in agreement with a requested revision, it will facilitate the review process if your reasoning is discussed in your cover letter.

Form E

The Committee feels the new healthy control group you propose to study presents no direct benefit to the participants. Therefore, the Committee believes this study would not meet the regulatory requirements for research involving minors under category 46.406 as stated on your Form E. Rather it seems this new control group would meet 46.407 which states the following: The research uses healthy minors and is greater than minimal risk. It presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health welfare on minors but presents no direct benefits to the participants.

Please provide the Committee with justification as to why you believe there is direct benefit to this new study population.

Consent Form

Item 9:

> Because studies sponsored by governmental agencies typically do not have programs in place for payments associated with research-related injuries, all decisions about payment for medical treatment for injuries relating to participation in a research study will be made by Washington University. Therefore, please remove the National Institutes of Health from this item of the consent form.

Please submit a consent form for infants with normal lungs for Committee review. This consent should include a description of what is considered normal lungs.

Pages from your consent form with reviewers' comments and suggested changes are attached to assist you in making revisions.

Form 7

How likely is it that you will accrue enough participants with normal lungs in order to complete the comparison between the two groups?

Protocol

Please revise your protocol to include the information on the new study population. When submitting your revised protocol, be sure the inclusion/exclusion criteria is updated.

HIPAA Status: Compliant with Authorization

HIPAA Comments:

Voting Record

Motion: Review the PI's revisions and response to the stated contingencies at the next 03 Continuing Review Committee meeting.

For: 15 Against: 0 Abstain: 0 Total: **15**

Comments: