

INSTITUTIONAL REVIEW BOARD

MINUTES

October 9, 2002

COMMITTEE: 02 NPC

COMMENCED - 3:35 PM

ADJOURNED - 5:10 PM

Members Present

Angela Brown, MD; Virginia Buckles, PhD; Denise Canfield, RN; Donald Clayton, MA; Diane Clemens, DC(non-voting); Ellen Deibert, MD; Rebecca Dresser, JD; Sarah Frankel, PhD(Alternate); Richard Hudgens, MD; Margaret Latta, MSW; Stephanie Porto, RPH; Robert Schwendinger, JD; Lloyd Vasquez, JD; Timothy Walton, BS(non-voting)

Members Absent

R. Fallert, MSW; Randall Gibb, MD; Kara Kniska, PharmD; Mark Manary, MD; Bryan Meyers, MD; Scott Minor, PhD, PT; Laurel Wiersema-Bryant, BSN, RN

Quorum

11

Staff

Linda Van Zandt

Guests

Dan Haupt, MD

Other

The recommendations of the Sub-Committee and the Expedited/Exempt Sub-Committee for approval, disapproval, or required revisions for all Amendments, Advertisements, Adverse Events, and Expedited/Exempt protocols were reported to the Committee.

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

Research Risk/Review Freq.

NEW SUBMISSIONS

Spence, Kimberly

Newborn Medicine

02-0898

M / Annual

Precursor Preference in Surfactant Synthesis of Human Preterm Infants

Reviewers: Buckles / Wiersema-Bryant

General Comments

The Committee designated administrative review of your revisions.

Because this study is being sponsored by Forest Pharmaceuticals, please change the Source of Funding to "Industry Sponsor."

Submit a letter from the Director of the NICU documenting approval by the Joint Practice Committee of Children's Hospital.

Form 1

Recruitment:

Because your proposed recruitment process does not comply with the upcoming HIPAA regulation, the Committee asks that you revise the procedure to protect patient privacy. The HSC recommended procedure is to ask treating physicians to approach their patients who may be eligible for the study and refer the patient to talk with the PI if interested. If you choose to adopt this policy, please submit your physician recruitment materials to the HSC for review.

Consent Process:

Assure the Committee that the Urgent Consent Process will be followed.

Form E:

The research proposal involves children and was reviewed in accordance with the conditions set forth in 45 CFR Section 46.406 - Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition - based on the information provided on Form E. The HSC finds: (a) the risk represents a minor increase over minimal risk; (b) the intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations; c) the intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and (d) adequate provisions are made for soliciting permission of the parents or guardians, as set forth in 46.408.

Provide a scientific or medical rationale for the inclusion of minors.

Financial Conflict:

Please complete this section.

Consent Form

Purpose:

Expand the discussion of the purpose of the study.

Your Consent Form with reviewers` comments and recommended changes is enclosed to assist you in making revisions.

Minutes Comments: Although Laurel Wiersema-Bryant was not present at the meeting, the comments and concerns noted on her reviewer sheet were presented to the Committee by the Chairperson.

Approval contingent upon review and approval of requested clarifications and/or revisions.

Voting Record

Approve: 0	Conditional Approval: 12	Back to Comm: 0
Disapprove: 0	Abstain: 0	Total: 12

Comments: