

January 13, 2005

Re: Request for Review by 45 CFR 46.407 Panel

The Washington University Medical Center IRB finds that the following protocol cannot be approved under 46.404, 405, or 406 but presents a reasonable opportunity to understand, prevent or alleviate a serious problem affecting the health or welfare of children.

Purpose of Study: To evaluate pulmonary surfactant metabolism and the effect of interventions on surfactant metabolism with stable, non-radioactive isotopes in preterm neonates with respiratory dysfunction and to compare these findings with a control group of 10 intubated full-term infants in the NICU with normal lungs (no evidence of lung disease, normal chest x-ray, and not requiring much extra oxygen to breath comfortably).

Participation of Infants with Normal Lungs:

- 24 hour infusion through existing IV of sterile, non-radioactive, stable isotopes [For research only]
- 5 blood samples (collected from an existing tube) of 1/10 of a teaspoon each for a total of ½ teaspoon in 27 hours. If no indwelling catheter 2-3 samples will be collected at clinically indicated times. If extra sticks are needed for research purposes only we will limit these to 1-2 and only with consent of the parents [additional blood for research only]
- Lung fluid obtained from clinically required suctioning will be saved for 2 weeks. [analysis of fluid for research only]

Note: Study may be repeated if parents give permission and infant is still on a respirator with intravascular access in place.

Deemed Greater than Minimal Risk for the Following Reasons: The Committee determined that this research was greater than minimal risk based on the rare risk of a bloodstream infection from the 24-hour isotope infusion and the extra blood draws.

Institution Name: Washington University School of Medicine
Assurance Number: 0000 2284
IRB: 03 Continuing Review Committee

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Title: Precursor Preference in Surfactant Synthesis of Newborns
Principal Investigator: Kimberly Spence, M.D.
Grant Number/Funding Agency: F32 HL074601/NIH
Grant Application: Attachment 1
IRB Protocol Application: Attachment 2
Permission Document: Attachment 3
Relevant IRB Minutes and Correspondence: Attachment 4

