

## MEMORANDUM

TO: Terry L. Noah, M.D.  
Dept. of Pediatrics  
CB # 7220  
Carolina Campus

FROM: Committee on the Protection of the Rights of Human Subjects

DATE: December 18, 2001

SUBJECT: 01-PED-632 Characterization of Mucus and Mucins in Bronchoalveolar Lavage Fluids  
From Infants with Cystic Fibrosis

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The Committee on the Protection of the Rights of Human Subjects, at its December 17, 2001 meeting, voted to **DEFER** consideration of the above-referenced proposal, in order to allow you to provide further information, or to make substantive changes, as detailed below. Your response will receive reconsideration at a convened meeting of the IRB, and must include all materials and copies required with the original submission.

- 1) The primary concern of the Committee is that the protocol does not appear to offer any benefit to subjects yet represents more than a minor increase above minimal risk. In order to meet criteria for research in children under Code of Federal Regulations 45 CFR 46, Subpart D, the protocol must either hold out the prospect of "direct benefit to the individual subjects" 46.405 or, if not providing benefit, then it must not represent more than a minor increase over minimum risk and provide information of "vital importance for the understanding or amelioration of the subject's disorder or condition", 46.406. Research not meeting either of these criteria can only be approved after submission to the Secretary of the Department of Health and Human Services, see 46.407 in Subpart D
  
- 2) Please see the enclosed marked consent for further recommended changes to be made prior to resubmission.