

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: April 16, 2002

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

The Committee appreciates your input at the Committee meeting on April 15, 2002. We considered your comments and the material that you brought. We feel that this is an important research question and may alter the paradigm for this group of children; however, we still feel that bronchoscopy in this setting represents a procedure that is more than a minor increase over minimal risk, and there is likely to be no prospect of direct benefit to individual asymptomatic subjects. We are thus not able to approve this study under 45 CFR 46.404, 46.405, or 46.406.

The IRB feels that the research presents a reasonable opportunity to further the understanding of pulmonary disease in cystic fibrosis, and approval should be sought under 45 CFR 46.407. We are enclosing a copy of the page from the Code of Federal Regulations that contains this subsection. Review under this subsection requires review by OHRP, acting on behalf of the Secretary of DHHS. We strongly encourage you to submit this study to them, as a favorable ruling would then allow the study to proceed here as well as at other sites in the Cystic Fibrosis Network. Our office would be happy to help you in your submission to OHRP.

