

**MINUTES OF  
THE COMMITTEE ON THE PROTECTION OF THE RIGHTS OF HUMAN SUBJECTS  
COMMITTEE C (3<sup>rd</sup> MONDAY)**

MEETING: 1:00 P.M., Monday, April 15, 2002 Executive Board Room, Atrium, Lineberger Cancer Center

PRESENT: [redacted]

ABSENT WITHOUT ALTERNATE: [redacted]

CHAIR OF TODAY'S MEETING: [redacted]

STAFF: [redacted]

PREVIOUS MINUTES: The Committee voted to approve the Minutes of the March 18, 2002 meeting. [redacted]

EXPEDITED REVIEWS: Descriptions of 37 submissions given expedited review [45 CFR 46.110] since the last convened meeting were received by the Committee. Of these, 5 were new studies, 21 were amendments and 11 were renewals.

EXEMPTIONS: Descriptions of 3 submissions that met the federal criteria for exemption [45 CFR 46.101] since the last convened meeting were received by the Committee.

FULL BOARD REVIEWS: The Committee reviewed 19 studies: 4 reconsiderations, 5 new, 2 amendments and 8 renewals.

The following were **DISAPPROVED** for reasons detailed below and in a memo to the principal investigator. The investigator will be given the option of appealing the decision. Any appeals or resubmissions will be returned for consideration by the convened Committee.

**(RECONSIDERATION) 01-PED-632 Characterization of Mucus and Mucins in Bronchoalveolar Lavage Fluids From Infants with Cystic Fibrosis (Terry L. Noah, M.D.)**

**motion for disapproval: 9 for, 0 opposed, 0 abstained**

**The memo to the investigator states:**

1. 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 46.405, or 46.406.
2. 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 inclosing 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 other sites in the Cystic Fibrosis Network. Our office would be happy to help you in your submission to OHRP.

**[...INFORMATION NOT RELEVANT TO PROTOCOL # 01-PED-632 HAS BEEN REDACTED...]**