

**MINUTES OF
THE COMMITTEE ON THE PROTECTION OF THE RIGHTS OF HUMAN SUBJECTS
COMMITTEE A (1st MONDAY)**

MEETING: 1:00 P.M., Monday, February 4, 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 January 7, 2002 meeting. [redacted]

EXPEDITED REVIEWS: Descriptions of 47 submissions given expedited review [45 CFR 46.110] since the last convened meeting were received by the Committee. Of these, 10 were new studies, 17 were amendments and 20 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 30 studies: 1 reconsideration, 9 new, 3 amendments and 17 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: 10 for, 0 opposed, 0 abstained

The memo to the investigator states:

To approve research in children, conditions outlined in 45 CFR 46, Subpart D must be satisfied.

46.404: Bronchoscopy is a procedure which represents greater than minimal risk, so this research cannot be approved under this category.

46.405: Approval in this category requires that research involving greater than minimal risk presents the prospect of direct benefit to the individual subjects. The committee was not convinced of the prospect of direct benefit, especially since the research requires 3 bronchoscopies. Bronchoscopy in an asymptomatic infant is not indicated. Moreover, exclusion of children with any signs of acute infection or respiratory symptoms would appear to tip the scales away from those who might benefit from detection of hidden infections. The committee was also concerned about resistance to antibiotics with early treatment in asymptomatic infants. Is it proven or accepted that antibiotic treatment for bacterial infections in asymptomatic cystic fibrosis patients is beneficial?

46.406: Approval in this category is not possible since bronchoscopy represents more than a minor increase over minimal risk.

46.407: The IRB feels that the research presents a reasonable opportunity to further the understanding of pulmonary disease in cystic fibrosis, but cannot be approved under the three sections outlined above. The research should therefore be reviewed by OHRP, acting on behalf of the Secretary of DHHS. Our office would be happy to help you in your submission to OHRP.

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