ALBERT EINSTEIN COLLEGE OF MEDICINE
OF YESHIVA UNIVERSITY
JACK & PEARL RESNICK CAMPUS
Belfer Educational Center for Health Sciences, Room 1002
1300 Morris Park Avenue, Bronx, NY 10461

Chairman, Committee on Clinical Investigations

November 22, 2002

Ms. Irene Stith-Coleman
Policy Director
Office of Human Research Protections
The Tower Building, Suite 200
1101 Wootton Pkwy
Rockville, MD 20852

Re: Dr. Gabriel G. Haddad
Study Titled: Sleep Mechanisms in Children: Role of Metabolism

Dear Ms. Stith-Coleman:

The Committee on Clinical Investigations, the Institutional Review Board for Yeshiva University, Albert Einstein College of Medicine, reviewed a research protocol entitled *Sleep Mechanisms in Children: Role of Metabolism* at its regular meeting on November 13, 2002. As you will see from the enclosed research the participants to be included in this project are healthy children, aged 13 through 17.

On the basis of the procedures involved, including a night of sleep deprivation, extended periods nuclear magnetic resonance spectroscopy, and infusion of ^{13}C acetate and ^{13}C glucose, it was determined research involved greater than minimal risk, as defined under 45 C.F.R. § 46.102(i). Therefore, it could approved under 45 C.F.R. § 46.404. Although the Committee concluded that the research represented a increase over minimal risk, it could not be approved under 45 C.F.R. § 46.405 or 45 C.F.R. § 46.406, s would be no benefit to individual subjects and, as healthy children, the knowledge to be gained would n "understanding or amelioration of the subjects' disorder or condition".

The Committee determined that "the research presents a reasonable opportunity to further the un prevention, or alleviation of a serious problem affecting the health or welfare of children and that the pr other requirements of 45 C.F.R. § 46.407 and 45 C.F.R. § 46.408. Therefore, I am requesting that the reviewed by the Secretary for a final determination.

Please let me know if you require additional information.

Sincerely,

Chairman
Committee on Clinical Investigations

cc: Dr. Gabriel G. Haddad

jf/cme