DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Office of Public Health and Science

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January 13, 2003

Mary A. Carskadon, Ph.D.
E.P. Bradley Hospital
Sleep Research Laboratory
1011 Veterans Memorial Parkway
East Providence, RI 02915

Subject: Protocol 1 R01 AA13252-01 - Alcohol, Sleep and Circadian Rhythms in Young Humans
Re: Study 3 - Effects of Circadian Phase and Sleep/Wake Homeostasis on Alcohol's Effects on Sleep, Performance, Sleepiness, and Mood

Dear Dr. Carskadon:

This letter is written in response to our November 2002 telephone conversation, during which we discussed the above-referenced research study. As you know, the Lifespan Office of Research Administration, on behalf of the E.P. Bradley Hospital, forwarded the above-cited protocol to the Office for Human Research Protections (OHRP) for consideration pursuant to requirements of the Department of Health and Human Services (HHS) regulations for the protection of human subjects at 45 CFR 46.407 (Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children). OHRP convened a panel of experts in September 2001 to consider this protocol and HHS/OHRP currently is developing a Federal Register notice to solicit public comment on the proposed research in Study 2 of the protocol, *Effects of Evening Ingestion of Alcohol on Sleep, Circadian Phase, and Performance as a Function of Parental History of Alcohol Abuse/dependence*.

As we discussed with you in November, the panel of experts did not include Study 3 of the protocol, *Effects of Circadian Phase and Sleep/Wake Homeostasis on Alcohol's Effects on Sleep, Performance, Sleepiness, and Mood,* in their considerations (nor will HHS/OHRP solicit public comment on Study 3) because Study 3 proposes to include participants who are male and female young adults, ages 18 to 22.

Subpart D of 45 CFR part 46, which includes sections 46.401 through 46.407, provides additional regulatory protections for children involved as subjects in research. Pursuant to 45 CFR 46.402(a), "children" are defined as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." During our telephone conversation in November, you indicated that in Rhode Island, the jurisdiction in which the research will be conducted, persons who are 18 years of age are legally authorized to consent to participate in research. You also informed OHRP that the Rhode Island State Attorney General's office had provided you with a written opinion to the effect that the participation of the young adults aged 18 to 22 in Study 3 would not be considered to contravene Rhode Island law regarding the consumption of alcohol by minors. Given this information, Study 3 of the proposed protocol would not involve "children" as defined by the HHS regulations and thus would not be eligible for review under the provisions of 45 CFR 46.407.

Please feel free to contact me if you have any further questions about this matter.

Sincerely,

Irene Stith-Coleman, PhD
Director,
Division of Policy, Planning and Special Projects