

ICCR INSTITUTIONAL REVIEW BOARD PROTOCOL

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A. STUDY PURPOSE AND RATIONALE

The professional life of a young physician during his/her postgraduate training years is one traditionally known to be wrought with both physical and emotional stressors that are manifested through lifestyle changes that negatively impact health.

And not only has residency been known to promote unhealthy lifestyle practices, but it is believed that certain medical fields are associated with a higher level of physical stress evidenced solely by longer work hours. Historically, general surgery and its subspecialty residents accumulate more work hours per week on average when compared with internal medicine residents. Additionally, general surgery residency programs' call schedules are designed to have more frequent overnight calls than their medicine counterparts, with the inference that this is also a contributor to a more physically stressful professional life.

As related to both an increase in the frequency of overnight calls and work hours, general surgery and its subspecialty residents tend to have less regimented sleep schedules and average fewer hours of sleep on average per night compared with medicine residents. Medical literature has demonstrated that there exists an association between sleep deprivation and increased body mass index (BMI).

Sleep deprivation is comprised of both a qualitative and quantitative component. Quantity of sleep, though difficult to determine concretely, is often looked at as determining how long one would sleep if left to awaken on his own, as well as how alert one feels after different quantities of sleep. Traditionally, it is thought as somewhere between 7-8 hours of sleep a night. Quality of sleep refers to the percentage, duration, and type of sleep stages, as well as the number of arousals and awakenings from sleep throughout the night. Therefore, the more frequent the arousals in a given night of sleep, the poorer the sleep quality. Both of these entities encompass sleep deprivation, a phenomenon routinely experienced by young adult physicians during their postgraduate training years.

In terms of assessing unhealthy lifestyle practices, it is important to note that it has been established that there exists a relationship between body mass index (BMI) and increased morbidity and mortality. As defined by the NIH and WHO, a BMI between 25 but less than 30 qualifies a person as overweight, and a BMI greater than or equal to 30 as obese. It has also been established that the long-term risk of becoming overweight or obese during adulthood is far from trivial.

Knowing these above realities, one can conclude that there is a relationship between unhealthy lifestyle practices as related to specialty. More specifically, it can be hypothesized that because general surgery and surgery subspecialty residents work

more hours than their internal medicine counterparts, they will experience a more substantial change in their BMI during their first three years of postgraduate training as a result of a higher propensity towards sleep deprivation.

B. STUDY DESIGN AND STATISTICAL ANALYSIS

1. Study arms:

a) General Surgery and surgical subspecialty residents at Columbia University Medical Center – New York Presbyterian Hospital from postgraduate year 1 to postgraduate year 3.

b) Categorical Medicine residents at Columbia University Medical Center – New York Presbyterian Hospital from postgraduate year 1 to postgraduate year 3.

2. Assignment of subjects: Both general and subspecialty surgery residents as well as medicine residents were chosen through the National Residency Match Program (NRMP), which places applicants for postgraduate medical training positions into residency programs at teaching hospitals throughout the United States.

3. Crossed over subjects would include those who change specialties from preliminary or medicine-psychiatry residents who decide to enter the categorical track are to be included in the internal medicine study arm. Similarly, those categorical medicine residents who change residency choice to general surgery, urology, or orthopedics at CUMC are to be crossed over to the surgery group, and vice versa.

4. BMI classifications according to the National Institutes of Health and World Health Organization: a) underweight – BMI < 18.5kg/m², normal weight – BMI ≥ 18.5 to 24.9 kg/m², overweight – BMI ≥ 25.0 to 29.9 kg/m², class I obesity – BMI = 30 to 34.9 kg/m², class II obesity – BMI = 35.0 to 39.9 kg/m², class III obesity – BMI ≥ 40 kg/m². BMI is calculated as follows: body weight (kg)/height (m) squared.

5. Duty hours are defined by the Accreditation Council for Graduate Medical Education (ACGME) as “all clinical and academic activities related to the residency program; i.e., patient care (both inpatient and outpatient), administrative duties relative to patient care, the provision for transfer of patient care, time spent in-house during call activities, and scheduled activities such as conferences. Duty hours do *not* include reading and preparation time spent away from the duty site.”

6. On-call activities as defined by the ACGME as those that “provide residents with continuity of patient care experiences throughout at least a 24-hour period. *In-house call* is defined as those duty hours beyond the normal work day, when residents are required to be immediately available to the assigned institution.”

7. At-home, or pager call, is defined by the ACGME as “a call taken from outside the assigned institution...When residents are called into the hospital from home, the hours residents spend in-house are counted” towards the logged in duty-hours found in “E-value.”

8. Statistical analysis: Using an unpaired t-test, and a p value equal to 0.05, 20 subjects in each study arm are required to show a change of BMI of 1 (the effect).

The standard deviation of the measured outcome across subjects has been determined as 1.

$$n \text{ (in each group)} = 1 + 16 (\pm 1/1)^2$$

C. STUDY PROCEDURE

1. In this observational study, we will follow residents in each arm during their first three postgraduate years of residency training. During this time, subjects are obliged to log in their work-hours through the established “E-value” duty hours database over the period of three years, which is already required of them as members of the CUMC residency training program.
2. During the three years that the subjects are observed, resident physicians will be required to log in the number of hours they sleep per day, while both on-call and in their homes through “E-value,” similar to how it is done with duty hours.
3. As part of incoming residents’ Occupational Health Services visit prior to their beginning residency, residents’ height and weight will be measured, and their BMIs calculated. Their height and weight will be measured at the end of each postgraduate year at OHS by the end of the three-year mark, and their BMIs calculated.

D. STUDY DRUGS, MEDICAL DEVICES

There will be no use of any study drugs or medical devices.

E. STUDY SUBJECTS

1. Internal Medicine Residents
 - a) Inclusion criteria: Internal Medicine residents following the accepted to Columbia University Medical Center’s Internal Medicine Residency Program beginning in June 2009, followed through June 2012 who will be following the “categorical track.”
 - b) Exclusion criteria: Preliminary medicine residents and medicine-psychiatry patients are also to be excluded from the study. Also excluded are residents who enter the residency program pregnant, or subjects who get pregnant at some point during any of the three postgraduate years during which they are studied.
2. Surgery residents
 - a) Inclusion criteria: General surgery, urology, orthopedics, plastic surgery, and neurosurgery residents are to be included in the study.
 - b) Exclusion criteria: Otolaryngology residents secondary to the fact that their call schedules differ significantly from the general surgery and other surgical subspecialties after they have completed their preliminary year of general surgery residency; specifically, the number of overnight calls are less frequent.

F. RECRUITMENT OF SUBJECTS

1. All categorical internal medicine residents who had accepted a position in the internal medicine residency training program at Columbia University Medical Center starting in June 2008 will be asked to participate in the study. From these resident physicians, the first 25 physicians who sign the consent form will be enrolled.
2. All general, urology, orthopedic, plastic, and neurosurgery residents who accept a position in the Columbia University Medical Center Program starting in June 2008 will be asked to participate in the study. From this pool of resident physicians, the first 25 physicians who sign the consent form will be enrolled.

G. CONFIDENTIALITY OF STUDY DATA

1. Given that duty hour records are required to be documented as part of the guidelines outlined by the Accreditation Council for Graduate Medical Education, this data will not be subject to confidentiality.
2. Sleep hour logs, however, will be confidential, and each subject will be assigned a number code and password used to log in their sleep hours.
3. Similarly, patient's height and weight that are measured at different points in the study will be deemed confidential, as it is part of their medical record. The same code assigned to them that is to be used to log in sleep hours will be used to distinguish each subject's medical record.

H. LOCATION OF THE STUDY

The study is to be conducted at the hospitals in which the resident physicians work, including Columbia University Medical Center and the Allen Pavillion. If resident physicians choose to do an "away elective" at an institution different from either of the above, they are still eligible to remain in the study, as they are still required to log in their work and sleep hours into "E-value" during their "away" rotation time.

I. POTENTIAL BENEFITS/RISKS

As this is an observational study, there are no potential benefits/risks to subjects enrolled in the study.

J. COMPENSATION TO SUBJECTS

Ten taxi vouchers for use from Milstein or the Allen to one destination per year of involvement in the study will be given as compensation to involved subjects.

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