Committee of Interns and Residents
SEIUHealthcare

BY EMAIL

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Dear Drs. Menikoff and Borror:

The Committee of Interns and Residents/SEIU Healthcare (CIR) represents 14,000 residents and fellows across the country. CIR submits this letter in support of the complaints filed with your office by Public Citizen and the American Medical Student Association regarding the FIRST and iCompare trials.

We are very concerned that these trials violate important principles of informed consent for patients, resident physicians and medical students.

Foremost, we believe that the lack of a formal consent process is a breach of the Department of Health and Human Services regulations for the protection of human subjects (45 CFR Part 46). A truly scientific and well-designed study would at least uphold the ethical standards of informed consent so as to allow subjects to weigh the benefits, risks, and alternatives of participating. Residency and fellowship are the prime time to learn and apply the ethical principles and best practices of informed consent. These studies are antithetical to our learning and promote a culture of medicine that lacks transparency for the human subjects it impacts.

It is difficult to comprehend how the principal investigators could determine there was “minimal risk” to patients and residents in view of the 2009 Institute of Medicine (IOM) report that linked residents’ long work hours to preventable medical errors and an increased risk for residents of needlestick exposures, car accidents, high rates of depression and burnout. In response to the IOM report and the negative effects of excessive hours on residents and patients, the ACGME introduced its new hour limits in 2011. Only three years later, in 2014, the ACGME decided to waive those limits so that the FIRST and iCOMPARE studies could proceed. Now it appears that based on this determination of “minimal risk” the principal investigators did not require that the programs inform the residents of these substantiated and substantial risk factors.

Besides patients and resident physicians, the group of human subjects in the FIRST and iCOMPARE studies also includes the 4th year medical students, who may have matched into a program they believed was adhering to ACGME hours limits and arrived to find a program with "flex" limits. It is unclear whether the programs followed a uniform practice of informing them at the interview stage. Even if they were told at their interview that the program was either a control or experimental group in this study, that does not constitute informed consent. Given the competitive nature of the residency application and match process, candidates are not in a position to question or reject this change in practice.

Students, including medical students, and employees, including resident physicians, are recognized as presenting special concerns for human subject research because they are susceptible to coercion or undue inducement to participate[1]. We understand from direct experience why that is true for medical students and residents. Professional advancement (e.g. entry to and successful completion of a residency, a coveted chief resident appointment, a fellowship, career opportunities after residency) depend on unbiased evaluations and the support of program directors. It is difficult for an individual resident to take a stand that separates him or her from "the team" and thereby jeopardize the recommendations they rely upon after their residency.

We are aware of one Academic Medical Center in Boston that opted out of the FIRST study because the surgery residents determined as a group not to participate. They thought it would be unfair to incoming residents who matched into the program expecting a work schedule compliant with ACGME hours limits. They also thought it would be unfair to residents rotating into the surgical service who would not be consulted. Finally, they would not seriously consider participating in the FIRST study unless it obtained local IRB approval.

We have heard from other residents who are current subjects in the iCOMPARE study who voiced similar concerns about the omission of local IRB approval. In their opinion, a remote IRB was inappropriately empowered to determine the level of risk at their institution where the workload, practice, and expectations of residents had their own characteristics which would need to be weighed in determining risk.

CIR also has concerns about the design of the FIRST and iCOMPARE studies on three fronts: the lack of consistency with respect to the experimental intervention, invalid data for the hours worked by the control groups, and the reliance on resident surveys.

Rather than being obligated to apply policies consistently, the individual sites have been allowed to flex the hours of resident subjects at their individual discretion. We are aware of one experimental site in the iCOMPARE study that chose to change the hours of only one rotation - the Medical Intensive Care

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[1] "As student participation raises questions of the ability to exercise free choice because of the possibility that grades or other important factors will be affected by decisions to participate, employee research programs raise the possibility that the decision will affect performance evaluations or job advancement." Institutional Review Board Guidebook, Special Classes of Subjects, Chapter VI, Section J. Students, Employees and Normal Volunteers, http://www.hhs.gov/ohrp/archive/irb/irb_chapter6ii.htm#g11

Unit (MICU). Particular services within the same program can vary significantly; the MICU is often less labor intensive for residents. The geographic proximity of patients, the nurse-to-patient ratio, and direct supervision by critical care fellows are distinguishing factors for MICU residents compared to their colleagues who are working on other services.

Another consistency problem stems from the variability in supervision of residents. We know that there is a significant variation in the amount of oversight on services at a single institution and certainly, across institutions. The presence of a nocturnist program, a fellowship program and in-house anesthesiologists are a few of the many factors that contribute to the variable level of oversight in residency programs within and among institutions. The supervision variability is compounded by the work load variability, including the not insignificant factor of the non-physician work done by residents.

Therefore, due to this lack of consistency, we are concerned that the study investigators cannot draw reliable comparisons between the control and experimental groups in all sites.

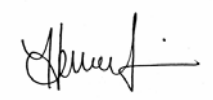
We are also concerned that the study will yield flawed data for the control group because residents will work longer hours than they are reporting officially. There is a recognized and widespread practice of residents underreporting their hours under subtle and not so subtle pressure from their program directors and/or faculty in order for them to appear to be compliant with ACGME hours limits. The actual difference between hours worked in the control group and hours worked in the experimental group will be less than what is being reported. Therefore, the principal investigators will be unable to reasonably conclude from the flawed data whether or not there are significant differences in patient safety and residents' educational and professional development outcomes.

Finally, we are concerned that the reliance on resident surveys for the secondary study questions (resident education and sleep) is a notoriously unreliable measure. A recent study revealed that a physician's self-assessment of alertness does not correlate reliably with established tests measuring cognitive skills.[2] Pairing reliance with the pressure from program directors to inaccurately report work hours introduces bias and distorts the results of a study that is flawed in design and implementation.

CIR eagerly awaits the results of OHRP's investigation of the Public Citizen and American Medical Student Association complaints regarding the FIRST and iCOMPARE studies.

Thank you for your attention to this urgent matter regarding the protection of resident physicians and patients as human research subjects.

Sincerely,



Hemant Sindhu, MD
President, CIR/SEIU Healthcare

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[2] Maltese, François, Mélanie Adda, Amandine Bablon, Sami Hraeich, Christophe Guervilly, Samuel Lehingue, Sandrine Wiramus, Marc Leone, Claude Martin, Renaud Vialet, Xavier Thirion, Antoine Roch, Jean-Marie Forel, and Laurent Papazian. "Night Shift Decreases Cognitive Performance of ICU Physicians." Intensive Care Med (2015). Print.