

Office of the Chancellor (MC 102)
2833 University Hall
601 South Morgan Street
Chicago, Illinois 60607-7128

July 27, 2015

Mark D. Grabiner, Ph.D.
Research Integrity Officer
Office of the Vice Chancellor for Research
AOB 310, MC 672

RE: Research Integrity Case UIC 113/ORI DIO 5227

Dear Dr. Grabiner:

I am writing pursuant to the University of Illinois Policy and Procedures on Integrity in Research and Publication (Policy), Section VII.I to issue my decision on the final disposition of research integrity case UIC 113/ORI DIO 5227 with Nagamani (Mani) Kilaru Pavuluri, Professor and Berger-Colberth Chair in Child Psychiatry, Department of Psychiatry and Director, Pediatric Brain Research and Intervention (BRAIN) Center, College of Medicine, Chicago.

I have reviewed both the Investigation Panel Report, which included Dr. Pavuluri's written response to the draft report, and Vice Chancellor for Research Mitra Dutta's recommendations. Based on the evaluation, my decision is in support of the conclusion provided by the Office of the Vice Chancellor for Research.

Specifically, the history and pattern of behavior that repeatedly put subjects at risk and damaged the credibility of the research data by not adhering to research protocols approved by NIMH and the UIC IRB collectively represent serious deviations that violate accepted ethical guidelines and professional standards in clinical practice. The actions leading to these outcomes included reckless disregard for the approved eligibility criteria, failure to perform required safety assessments and falsification and fabrication of research data in an attempt to obfuscate evidence of noncompliance with the research protocols. These events go to the very heart of the conduct of clinical research and underscore the role and value of IRB and ORI processes and federal regulations in the protection of human subjects and ensuring integrity of the research data. Further, the use of unapproved medication washouts, recruitment of individuals outside of approved inclusion and exclusion criteria, lack of pregnancy and laboratory testing, and recruitment of individuals with co-morbid substance use and medical disorders all form a pattern of placing research priorities above patient welfare. These actions form a core violation of human subjects research ethics. I will direct that a formal review of Respondent's clinical practice will be conducted by the Dean of the College of Medicine.

The following official sanctions of the University are to be imposed:

1. Immediate retraction by the Respondent for the three publications:
 - a. "Where, when and how high, and how long? The hemodynamics of emotional response in psychotropic-naïve patients with adolescent bipolar disorder (Wegbreit et al., Journal of Affective Disorders, 147:304-311, 2013);
 - b. "Deficits in emotion recognition in pediatric bipolar disorder: the mediating effects of irritability (Shankman et al., Journal of Affective Disorders, 144:134-140, 2013); and
 - c. "Altered affective, executive and sensorimotor resting state networks in patient with pediatric mania" (Wu et al., Journal of Psychiatry and Neuroscience, 38:232-240, 2013).
2. Indefinite revocation of all research rights and privileges of the Respondent, including but not limited to the debarment of the Respondent at UIC from any submission of grant applications with any funding entities and the prohibition of the Respondent from serving in any advisory capacity related to research with any organization.

Pursuant to the Policy, please notify all appropriate parties, including federal agencies, of the outcome of this case.

Sincerely,



Michael Amiridis, PhD
Chancellor

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