

UNIVERSITY OF ILLINOIS
AT CHICAGO

Office for the Protection of Research Subjects (OPRS)
Office of the Vice Chancellor for Research (MC 672)
203 Administrative Office Building
1737 West Polk Street
Chicago, Illinois 60612-7227

March 22, 2013

Kristina C. Borrer, PhD
Director, Division of Compliance Oversight
Office for Human Research Protections
Department of Health and Human Services
The Tower Building
1101 Wootton Parkway, Suite 200
Rockville, MD 20852

RE: Serious Non-Compliance concerning the UIC IRB #1 review of UIC IRB protocol #2008-0624

Research Protocol # 2008-0624

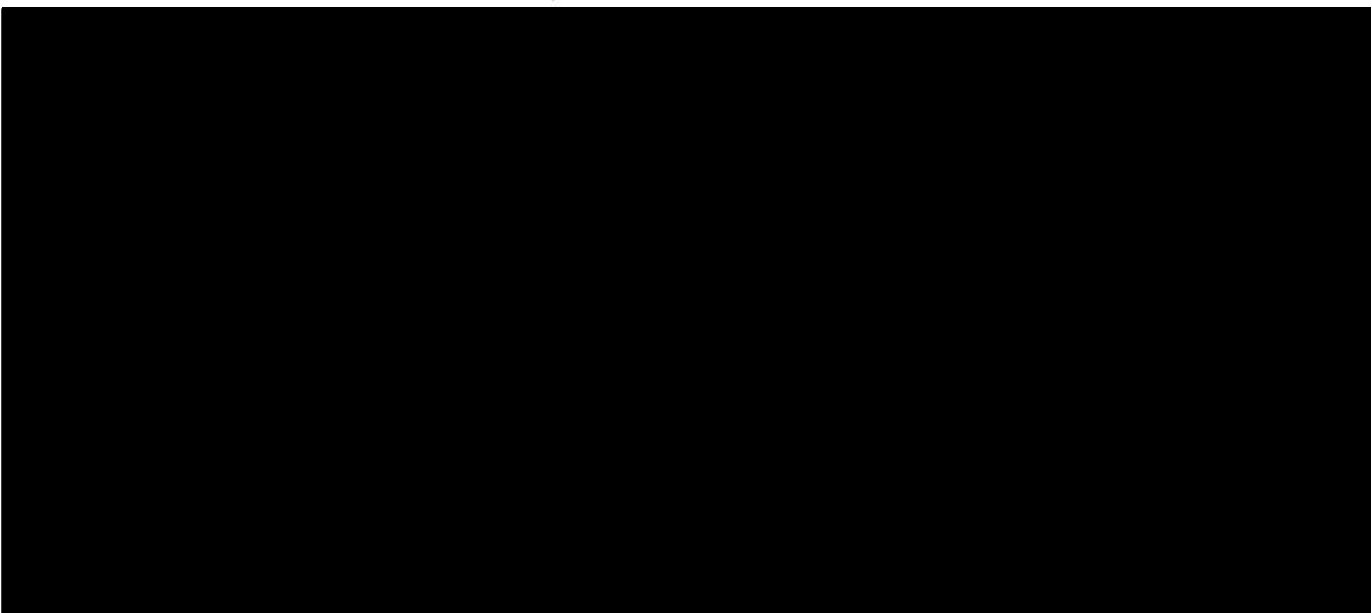
“Affective Neuroscience of Pediatric Bipolar Disorder”

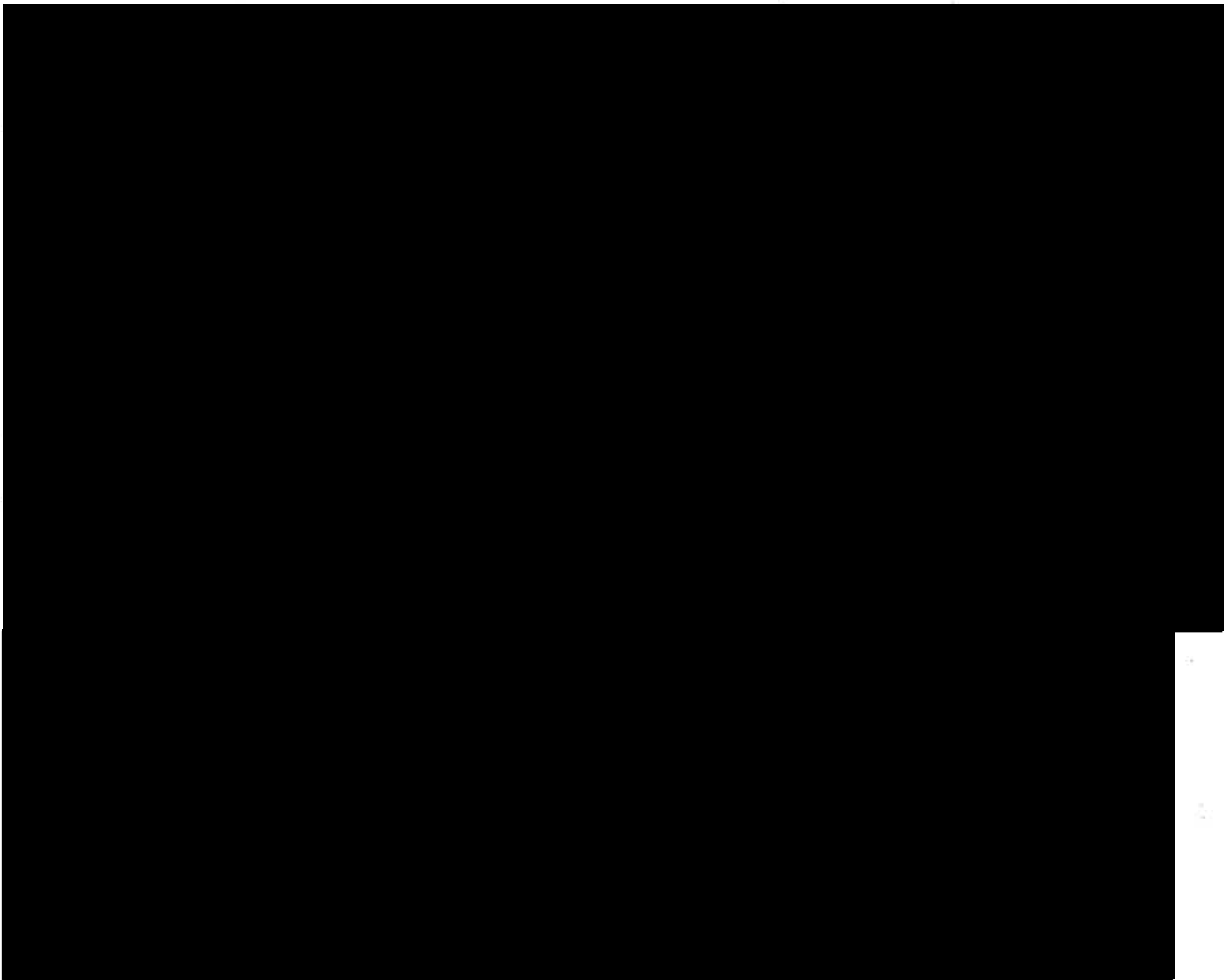
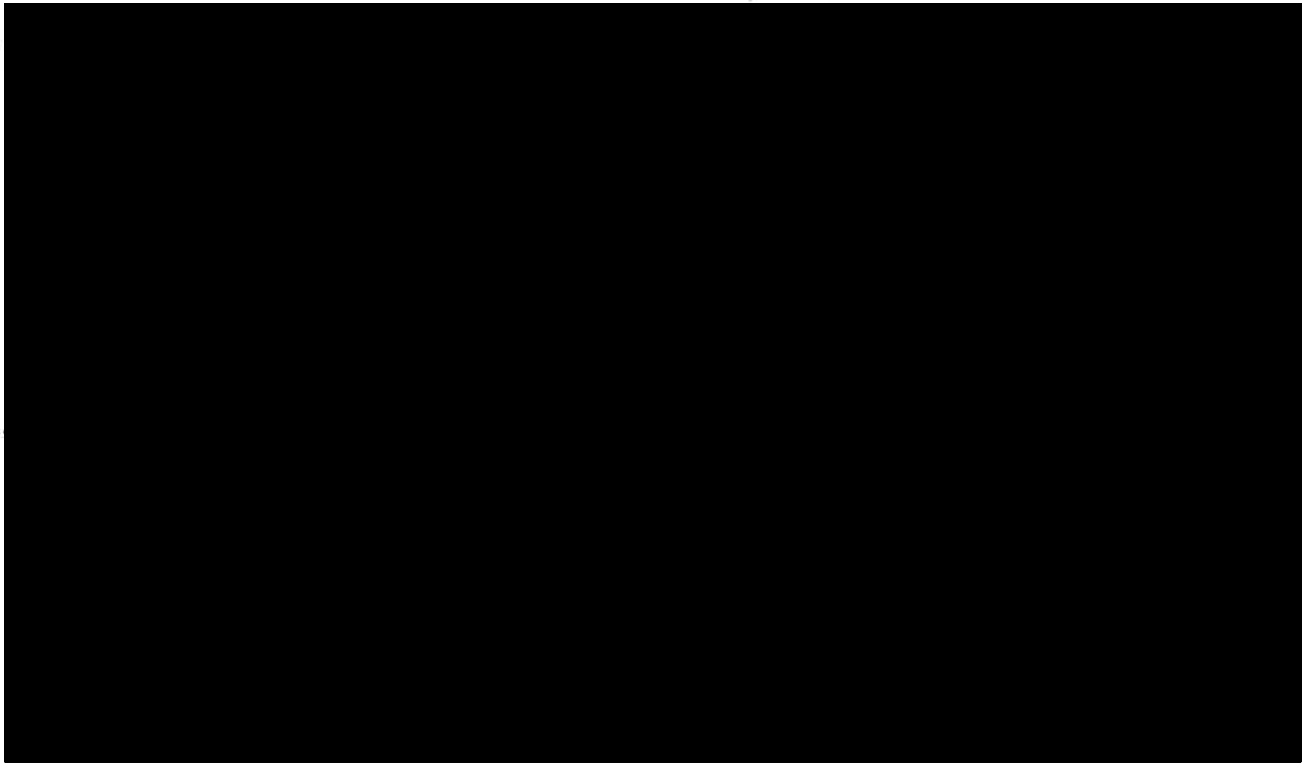
Sponsor: National Institutes of Health; Grant #5R01MH081019

Principal Investigator: Mani Pavuluri, MD

Dear Dr. Borrer:

In fulfillment of the reporting requirements at 45 CFR 46.103(b)(5), I am writing on behalf of the University of Illinois at Chicago (UIC) Institutional Review Board #1 (IRB00000115) to self-report a determination of serious non-compliance by the IRB. The IRB's determination is in regard to the review of UIC IRB protocol #2008-0624, “Affective Neuroscience of Pediatric Bipolar Disorder,” for which Dr. Mani Pavuluri, Director of the Pediatric Mood Disorders Clinic at UIC, is the Principal Investigator.







Sincerely,



James H. Fischer, PharmD

Director, Office for the Protection of Research Subjects

Human Protections Administrator, Office of the Vice Chancellor for Research

FWA #00000083

cc: Mitra Dutta, PhD, Vice Chancellor for Research
Clyde Wheeler, PhD, Associate Director, Investigator Outreach and Quality
Improvement
Barbara Corpus, CIP, Associate Director, External Relations and Quality Assurance
Patricia West-Thielke, PharmD, Chair, IRB #1