



National Institutes of Health
National Institute of Mental Health
6001 Executive Boulevard
Room 8235, MSC 9669
Bethesda, Maryland 20892

July 30, 2009

Ms. Kristin H. West, JD
Director, ORC; Emory University
1599 Clifton Road NE, 4th Floor; Mailstop 1599/001/IA Y
Atlanta, GA 30322

Dear Ms. West:

Thank you for the information you provided in your July 10 letter to Kathy Hancock regarding Emory University's plans to identify and eliminate Dr. Zachary Stowe's financial conflicts of interest related to NIH grants. We recognize Emory has adopted a management plan to address Dr. Stowe's perceived conflicts; however, the National Institute of Mental Health (NIMH) has remaining questions about the evaluation and reporting of results on Center grant P50MH077928-03, which is pending NIMH noncompeting continuation.

We specifically are concerned about Dr. Stowe's independence and objectivity with respect to the evaluation and reporting of study results after Emory's two-year bar on conflicts of interest expires. As grant P50MH077928-03 is entering its third year of funding, Dr. Stowe is slated to receive NIH funds for one additional year (grant year 05) beyond the expiration of your institution's two-year bar on payment from industry (Pharma) sources. As such, Dr. Stowe could renew his financial relationships with the makers of antidepressants (including GlaxoSmithKline, Pfizer, and Wyeth) while continuing to analyze data and report the results of a study including the effects of antidepressant use in pregnant women. This research activity would be expected during the final (fifth) year of the P50, and the issue could well extend beyond the five-year funding period of the grant, to the extent that Dr. Stowe continues to analyze and report on this research while potentially maintaining financial relationships with a number of drug companies.

We recognize that Dr. Stowe's research on depressed pregnant women is not a randomized clinical trial, but it will report on a range of clinical outcome measures. Among these will likely be analyses relating clinical outcomes to the types of treatment (e.g., antidepressant medications, psychotherapy, etc.) received naturalistically. Consequently, we believe that any renewed relationships with antidepressant manufacturers might greatly diminish the apparent independence and objectivity of the data evaluation and reporting of the research results supported by this Center grant, and thus we are requesting further clarification on Emory's plans with respect to this matter.

In order to avoid delays in our consideration of this application for continued funding, please respond to this request by August 13, 2009, and contact me if you have any questions. We look forward to your response.

Sincerely yours,

David Shore MD

Associate Director for Clinical Research