

## **SEC Investigations and Clinical Trials**

To the Faculty:

Dear Colleagues:

In a June issue of JAMA, Eric Topol and David Blumenthal published an editorial in which they described growing consulting relationships between some clinical investigators and investment firms (matchmakers, hedge funds, investment bankers, venture capital firms, brokerage houses, etc.). In particular, they called attention to some clinical investigators who have been paid to consult and disclose confidential information about the conduct, status, and preliminary results of ongoing clinical trials. Investment companies then use this information to invest or advise clients on how to invest, based on information that is not available to other investors.

The JAMA editorial was followed in August by investigative reports and editorials in The Seattle Times, and The New York Times. , Senator Charles Grassley has asked the Securities and Exchange Commission (SEC) to investigate these reports.

Clinical trial agreements with the University nearly always contain confidentiality agreements about the data and results, though they do appropriately allow faculty to publish their results after a reasonable period of time once the trials are completed. Directly or indirectly disclosing material, confidential information from a trial to individuals or companies that trade stock based on the information is unethical. Further, disclosure of this confidential information may be considered a violation of insider trading laws and a breach of the clinical trial contract. The considerations are even more serious if the faculty physician invests in the investment fund or the company related to the information that has been exchanged.

These articles indicate that amazingly subtle tactics are employed for getting faculty who are investigators on clinical trials or who serve on data safety monitoring boards to inadvertently divulge confidential information. Further, some of our university colleagues describe emails and phone calls to their clinical investigators from these matchmaker companies. Because of these two facts, we are providing the following information as help and guidance to you, in the event you are approached to engage in one of these consulting relationships.

First, it goes without saying that it is implicit in our Emory University and School of Medicine policies that apply to conflict of interest and the ethical conduct of research that providing confidential information on the results of ongoing clinical trials to anyone other than to those allowed by the clinical trial agreement prior to publication is prohibited.

Second, please let us remind you that all consulting relationships and agreements are to be reviewed and approved by the departmental chair and the Dean's Office before faculty members may sign them and begin the relationship. Please see School of Medicine Policies on Commitment, Private Consulting, and Other Extraordinary Contributions. The agreements (written or verbal) are reviewed for compliance with University and School policy, for whether the relationship is beneficial for the academic career of the faculty member and for the medical school, and for commitment of effort. Agreements and explanations, once approved by the

departmental chair, should be sent to Assistant Dean Brenda Seiton <[bseiton@emory.edu](mailto:bseiton@emory.edu)> for review.

Other policies related to conflict of interest and commitment in the School of Medicine are listed and linked below.

Thank you so much for your attention to this important matter.

Sincerely,

Thomas J. Lawley, M.D.  
Dean

Claudia R. Adkison, J.D., Ph.D.  
Executive Associate Dean  
Administration & Faculty Affairs