



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
National Institute of Health

National Center for Complementary
and Alternative Medicine
6707 Democracy Blvd., Suite 401
Bethesda, Maryland 20892-5475
nccam.nih.gov

March 23, 2004

Our Reference: 5 U01 AT 001156-02

Paul Katz, M.D.
Vice President for Academic Affairs
Mount Sinai Medical Center
4300 Alton Road
Miami Beach, Florida 33140

Dear Dr. Katz:

Thank you for letter dated February 6, 2004 in which you provided a detailed response to our previous inquiries (January 15, 2004) concerning Mount Sinai Medical Center (MSMC) financial conflict of interest policies.

We have carefully reviewed your response in consultation with Dr. Stephen Straus, Director, National Center for Complementary and Alternative Medicine (NCCAM) and Dr. Barbara Alving, Acting Director, National Heart, Lung and Blood Institute. The information you provided has adequately addressed our existing concerns. In particular, we are pleased by changes you have implemented in the review of Conflict of Interest forms, including a process to ensure yearly review, and by your efforts to guarantee staff education regarding of the increasingly scrutinized federal conflict of interest policies.

If you have questions, please feel free to contact one of us at the telephone numbers listed below.

Sincerely,

Richard Nahin, Ph.D., MPH
Senior Advisor for
Scientific Coordination and Outreach
Office of the Director
(301) 496-7801
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David L. Mineo
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(301) 594-8854
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cc:

Stephen E. Straus, M.D., Director, NCCAM
Margaret Chesney, M.D., Deputy Director, NCCAM
Barbara Alving, M.D. Acting Director, NHLBI
Steven D. Sonenreich, M.D., President, MSMC
Gervasio A. Lamas, Principal Investigator, MSMC



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January 15, 2004

Our Reference: 5 U01 AT 001156-02

ORIGINAL

Paul Katz, M.D.
Vice President for Academic Affairs
Mount Sinai Medical Center
4300 Alton Road
Miami Beach, Florida 33140

Dear Dr. Katz:

This letter follows-up the discussion between Dr. Stephen Straus, Director, National Center for Complimentary and Alternative Medicine (NCCAM) and you on January 14 regarding issues related to the potential conflict of interest by Dr. Gervasio A. Lamas, M.D. Dr. Lamas serves as the Principal Investigator of the above referenced clinical cooperative Trial to Assess Chelation Therapy (TACT). This trial is extremely important and controversial; therefore, potential conflicts of interest or the appearance of such conflicts would have deleterious and potentially ruinous impacts on this study.

We have carefully reviewed the information you provided by facsimile to Dr. Richard Nahin on December 17, 2003. Our review of the information provided raises a number of additional issues that we feel must be addressed prior to determining an appropriate future course. These questions are as follows:

1. Does Mount Sinai Medical Center (MSMC) have a written, enforced policy on financial conflict of interest? If so, please provide us with a copy of this policy.
2. How does MSMC inform its investigators of the MSMC and Federal financial conflict of interest policies? How does MSMC educate faculty about their reporting responsibilities under federal regulations? Does this training include the necessity of reporting the existence of conflicts and how they are managed to the awarding office? Did Dr. Lamas receive this training?
3. In the MSMC ad hoc review committee communication to Dr. Katz, they identified a number of lapses in reporting requirements. What steps have been taken to correct these lapses? What does MSMC plan to do to ensure that additional lapses do not occur?

In addition to the previously mentioned concerns, the email identified another potential issue related to administrative requirements on assistance awards. This issue relates to institutional requirements to apply competitive procedures to procurement of services and materials under assistance awards. Please provide us with MSMC policies and procedures for procuring services and materials. Were the MSMC procedures used in securing services related to this clinical trial?

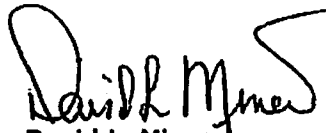
As previously stated, TACT is an extremely large and important study; therefore, it is imperative that the highest ethical standards be applied to ensure the integrity of the study results. Any questions about conflicts of interest and the management of these conflicts cannot be allowed to linger. Please respond to these questions by February 10, so that we can review the information during our annual non-competing progress review of the grant. Upon completion of our review of the supplemental information being requested, we will determine if future steps must be taken to ensure that any identified conflict is managed, eliminated or otherwise removed.

If you have questions, please feel free to contact one of us at the telephone numbers listed below.

Sincerely,



Richard Nahin, Ph.D., MPH
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President Steven D. Sonenreich, MSMC
Gervasio A. Lamas, Principal Investigator, MSMC