

Memo

To: Gervasio Lamas, MD TACT Study Chair

From: Robert C. Goldszer, MD

Senior VP & Chief Medical Officer

ca: Trial to Assess Chelation Therapy- TACT

Date: 3/14/2011

Re: Letter from TACT Investigator- Dr. Zbigniew Grudzien

I have reviewed the letter by Dr. Grudzien dated January 27, 2011, regarding recent Medicaid audit findings at his clinical site and his subsequent follow-up information. Based on that information, while there was a single TACT patient involved in the audit, Dr. Grudzien has assured us that no third-party payors, including the Washington State Medicaid program, were billed for any services or supplies associated with the TACT study.

We have therefore concluded that there are no actions required from MSMC at this time.

From:

Ana Mon

To: Cc: Agresti, Anthony (NIH/NHLBI) [E] Bolneau, Robin (NIH/NHLBI) [E]

Subject:

RE: 7U01HL092607-09 PI: Lamas, Gervasio Tuesday, March 15, 2011 3:10:39 PM

Date: Attachments:

MSMC Memo site 402.pdf

Hello Mr. Agresti,

Attached please find a memo from Mt. Sinai's Chief Medical Officer, regarding the audit at Hope Holistic Medical Clinic (TACT site 402)

Please let me know if this is acceptable.

Thank you,

Ana

From: Agresti, Anthony (NIH/NHLBI) [E] [mailto:agrestia@nhlbi.nih.gov]

Sent: Thursday, February 03, 2011 8:34 AM

To: Ana Mon

Subject: RE: 7U01HL092607-09 PI: Lamas, Gervasio

For Mount Sinai, just having an AOR (Authorized Organizational Official) signing off on the letter is fine.

From: Ana Mon [mailto:Ana.Mon@msmc.com] Sent: Wednesday, February 02, 2011 5:02 PM

To: Agresti, Anthony (NIH/NHLBI) [E]

Subject: RE: 7U01HL092607-09 PI: Lamas, Gervasio

From what we know about this site, it is a small private clinic owned by Dr. Grudzien and I don't believe he has a business office. I will double-check with the site Pl.

As far as Mount Sinal's business office, what type of documentation is required from them? Thank you for your help,

Ana

From: Agresti, Anthony (NIH/NHLBI) [E] [mailto:agrestia@nhlbi.nih.gov]

Sent: Tuesday, February 01, 2011 2:11 PM

To: Ana Mon

Cc: Boineau, Robin (NIH/NHLBI) [E]; Robert C. Goldszer; Gervasio Lamas

Subject: RE: 7U01HL092607-09 PI: Lamas, Gervasio

Ana,

Thank you for your quick response. However for this to be considered official it must pass through the site PI's business office as well as Mount Sinai's business office.

Tony

From: Ana Mon [mailto:Ana.Mon@msmc.com] Sent: Monday, January 31, 2011 2:41 PM To: Agresti, Anthony (NIH/NHLBI) [E]

Cc: Boineau, Robin (NIH/NHLBI) [E]; Robert C. Goldszer; Gervasio Lamas

Subject: RE: 7U01HL092607-09 PI: Lamas, Gervasio

Hello Mr. Agresti,
Please see attached a copy of the letter from the site regarding this issue
Thank you
Ana

Ana C. Mon, MPH
TACT Project Manager | Mount Sinai Medical Center
4300 Alton Road Suite 2070-A | Miami Beach, FL 33140
305.674.2162 | 866.285.8228 (f) | amon@msmc.com

From: Gervasio Lamas

Sent: Monday, January 31, 2011 11:11 AM

To: 'agrestia@nhlbi.nih.gov'

Cc: 'boineaur@nhibi.nih.gov'; Ana Mon; Robert C. Goldszer Subject: Re: 7U01HL092607-09 PI: Lamas, Gervasio

Thanks. We will do so. Tony

From: Agresti, Anthony (NIH/NHLBI) [E] <agrestia@nhlbi.nih.gov>

To: Gervasio Lamas

Cc: rgolds2er@msmc.com <rgolds2er@msmc.com>; Boineau, Robin (NIH/NHLBI) [E]

<boineaur@nhlbi.nih.gov>; Agresti, Anthony (NIH/NHLBI) [E]

<agrestia@nhlbi.nih.gov>

Sent: Mon Jan 31 10:35:07 2011

Subject: 7U01HL092607-09 PI: Lamas, Gervasio

Dr. Lamas,

The NHLBI received the attached letter from the State of Washington, Department of Social and Health Services regarding the Hope Holistic Medical Clinic, a TACT site. Please obtain a written statement from the site (signed by their business office) indicating how TACT patients are or are not involved in this audit and the use of chelation in these patients, if any of these patients are enrolled in the TACT trial.

Thank you.

Anthony Agresti
Team Leader
NHLBI/Office of Grants Management
6701 Rockledge Drive
Room 7158
Rockledge II

Bethesda, MD 20892 Phone: 301-435-0186 Fax: 301-451-5462

Help support Mount Sinal's lifesaving mission. Text SHARE to 27722 and donate \$10 to Mount Sinal. *message & data rates may apply

Confidentiality Notice: This e-mail message, including any attachments, is for the sole use of the intended recipient(s) and may contain CONFIDENTIAL or PRIVILEGED information. Any unauthorized review, use, disclosure or distribution is prohibited. If you are not the intended recipient, please contact the sender by reply e-mail and immediately destroy all copies of the original message and all attachments.