

Canada
Memorandum of Agreement
Trial to Assess Chelation Therapy (TACT)
Grant Number: 1 U01 AT001156
CFDA Number: 93.213 Research and Training in Complementary and
Alternative Medicine
Study Sponsors: National Institutes of Health (NCCAM and NHLBI)
Initial Award Date: 8/15/2002

This agreement is entered into to specify the terms and conditions under which the Mount Sinai Medical Center of Florida, Inc. located at 4300 Alton Road, Miami Beach, FL 33140 (hereinafter "Mount Sinai") and _____ the "Enrolling Center", located at

_____ and _____ M.D. or D.O. (hereinafter the "Participating Investigator"), will participate in the conduct of a clinical trial, "Trial to Assess Chelation Therapy" (hereinafter "TACT" or "the Trial") awarded to Mount Sinai by the National Institutes of Health (hereinafter "NIH") with Gervasio A. Lamas, M.D., Trial Chairman and Principal Investigator at Mount Sinai Medical Center of Florida, Inc. (hereinafter "Principal Investigator").

The Trial tests the central hypothesis, as more fully described in the protocol, that EDTA chelation therapy and/or high-dose vitamin therapy is an effective treatment of coronary heart disease (CHD). The Clinical Coordinating Center (CCC) is at Mount Sinai Medical Center in Miami Beach, FL.

1. Period of Performance

This agreement shall begin on _____ and shall not extend beyond July 2008 unless the period is extended by a written modification of this Agreement, signed by both parties.

2. Scope and Protocol

Enrolling Center agrees to provide all the necessary qualified personnel and facilities, inclusive of all necessary equipment and supplies, to conduct the Trial according to the Protocol titled "Trial to Assess Chelation Therapy," which is included in the site initiation materials. All amendments to the protocol, except those that require immediate implementation to protect the health or safety of subjects, shall require the prior written consent of the parties hereto. Enrolling Center, acting through its Participating Investigator, will assume responsibility for the proper enrollment of each patient, proper implementation of the final Protocol design for each patient entered, timely submission of Clinical Trial data, and for collaboration with Mount Sinai in the interpretation and reporting of the Clinical Trial results. Enrolling Center will be responsible for following patients according to the Protocol and any subsequent amended protocols. No new protocols (not previously committed to as of the date of the completed execution of this

agreement) will be undertaken by Participating Investigator during the TACT enrollment period. Enrolling Center represents and warrants that (1) the Institutional Review Board has reviewed and approved the Protocol and informed consent form and that (2) it shall obtain a valid, signed informed consent form from each patient entered into the trial.

3. Protection of Human Subjects

Enrolling Center shall comply with all United States Department of Health and Human Services ("DHHS") and other applicable United States policies and regulations on the protection of human subjects (collectively, "federal law"), as they now exist or as they may later be amended, as well as all policies, laws, and regulations related to the protection of human subjects that are applicable in the state or nation in which Enrolling Center is located, so long as such policies, laws, and regulations do not conflict with federal law. Specifically, without limitation on the generality of the foregoing, the Enrolling Center shall have on file with DHHS, Office of Protection from Research Risks, an Assurance of Compliance, approved in accord with the applicable regulations, setting forth Enrolling Center's policies and procedures established for the protection of human research subjects. The Enrolling Center shall assure continued monitoring and compliance with these requirements during the course of all work under this agreement carried out at the Enrolling Center.

4. Payments

Mount Sinai agrees to reimburse the Enrolling Center, based on completed reports, follow-up visit reports, all edits, and other submissions received by the DCC as described in the Appendix of this agreement, for each patient appropriately recruited and studied according to the Protocol. Reimbursement will be contingent upon review and approval by the Principal Investigator, which approval shall not be unreasonably withheld. The reimbursement rates in the Appendix of this agreement are subject, on prior written notice to the Enrolling Center and the Participating Investigator, to change based on any reduction or reallocation in funding of the Trial. Sites will be paid \$2,300 upon successfully enrolling a patient in the study through the electronic data capture system as described in schedule 1b of the Appendix. If trial management reports indicate that a patient has discontinued infusions and fewer than 26 infusions were administered, the site will be paid \$70 for each administered infusion as recorded in trial management reports. Remaining infusions are considered incomplete and will be deducted from future payments. When a patient reaches the 40th infusion as recorded in trial management reports, an additional payment of \$1,000 will be paid to the site. Follow-up payments will be paid as described in the Appendix and will be based upon successful completion of all necessary data as recorded in trial management reports. Any patients transferring between sites will be paid according to Schedule 2 as described in the Appendix. Payments will be based upon successful transfer of patients and completion of all necessary data as recorded in trial management reports.

All invoices, to be eligible for reimbursement, must be submitted by Enrolling Center within 90 days of the termination, for whatever reason, of this agreement or the

Enrolling Center's work hereunder. Final payment shall be predicated upon receipt and acceptance by Mount Sinai of all services and reports called for hereunder.

Payment should be payable to:

PAYEE: _____

Tax I.D.#: _____

MAILING

ADDRESS: _____

5. Change of Investigator

If _____ ceases to serve as Participating Investigator under this Agreement a mutually agreed substitute shall be designated within thirty (30) days.

6. Publication and Conflict of Interest

Enrolling Centers must abide by all TACT and NIH conflict of interest policies. Decisions about authorship on all multi-center publications resulting from research under this agreement will be made by the TACT Publications Committee prior to publication. No publications or other public disclosure shall be made until the TACT results are unblinded and results from all sites have been received and analyzed or TACT has been abandoned at all sites.

7. Reports

The Enrolling Center shall make all reports to Mount Sinai as required by the protocol, as well as prompt reports of all unexpected complications, injuries or other unexpected events.

8. Notices

All notices required or permitted shall be sufficient if delivered in person or mailed by prepaid certified or registered mail, return receipt requested, to each party at the address set forth below or at such address as a party may give to the other in the manner set forth in this Paragraph.

For Enrolling Center/Participating Investigator:

For Mount Sinai:
Paul Katz, MD
Vice President of Academic and Research Affairs
Mount Sinai Medical Center
4300 Alton Road
Miami Beach, FL 33140

With copy to:
Mount Sinai Medical Center
4300 Alton Road, Butler Building
Miami Beach, FL 33140
Attn: Gervasio Lamas, MD

9. Audit and Inspection

Enrolling Center will allow Mount Sinai, its agent, or designee, to inspect, on reasonable prior notice, all non-privileged medical records and reports related to this Trial for accuracy of data. This may include a visit to Enrolling Center's premises. If an audit of Enrolling Center records results in a disallowance of costs claimed, Enrolling Center shall refund promptly such costs.

10. Financial Management

Enrolling Center shall abide by the financial management guidelines and audit requirements in accordance with OMB Circular A-133, reporting record retention, and other requirements, as presently written or as later amended.

11. Insurance

Throughout the term of this agreement, the Enrolling Center shall maintain at its sole cost, a policy or policies of insurance covering its faculty, staff, employees, agents, and students, on an occurrence basis, for general liability and professional liability (malpractice) in amounts not less than \$1,000,000 per occurrence and \$5,000,000 in the aggregate for claims related to the performance of this agreement. Promptly upon Mount Sinai's request, Enrolling Center will provide a valid certificate of insurance evidencing the foregoing coverage. Such certificate shall provide for at least 14 days prior written notice to Investigator and Mount Sinai of any cancellation, non-renewal, or diminution in the foregoing coverage. The insurance described herein shall be deemed primary to any insurance carried by Principal Investigator or Mount Sinai.

12. Non-Publicity

No party hereto shall use the name of or, insignia or symbols of any other, their physicians or departments, or any variation thereof, for any advertising or promotional purpose whatsoever, without the prior written consent of the such party, which consent shall not be unreasonably withheld.

13. Independent Contractors

Enrolling Center, Participating Investigator, and Mount Sinai are independent contractors. No party shall represent itself to be the agent of another. No party shall enter into any obligation on behalf of any other.

14. Entire Agreement

This agreement constitutes the entire agreement between the parties and all prior discussions, agreements, and understandings entered into orally, or otherwise, between the parties are hereby merged in this agreement, and this agreement may be modified only by writing duly executed by both parties.

15. Termination

As long as the Enrolling Center has TACT patients, this contract cannot be terminated.

16. Indemnity

Mount Sinai does not indemnify the Enrolling Center, and the Enrolling Center does not indemnify Mount Sinai.

17. Debarment

You: (a) represent that you have never been, and your employees have never been debarred or convicted of a crime for which a person can be debarred under 21 USC Sec. 335a ("335a"); nor threatened to be debarred or indicted for a crime or otherwise engaged in conduct for which a person can be debarred under 335a; (b) agree that you will promptly notify MSMC and Dr. Lamas in the event of any such debarment, conviction, threat or indictment occurring during the term of this Agreement or within one (1) year following its expiration or earlier termination; and (c) agree not to employ any person in connection with any of the work to be performed under this Agreement who has been debarred or convicted of a crime for which a person can be debarred.

18. Binding Effect.

This Agreement shall be binding upon, and insure the benefit of, the parties hereto and their successors and assigns.

Additionally, Mount Sinai reserves the right to refuse study participation based on information received from the Site Investigator and Sub-Investigator Professional History Form.

IN WITNESS WHEREOF the parties have authorized their officers or representatives to execute this Agreement as of the date and the year indicated below the signatures.

For Institution

By: _____

Title: _____

Date: _____

For Mount Sinai Medical Center of Florida, Inc.

By: _____
Paul Katz, MD

Title: Senior VP of Academic and Research Affairs

Date: _____

Gervasio A. Lamas, M.D.
Study Chairman

Date: _____

Appendix

Reimbursement for TACT clinical activities will be provided according to the following schedules:

Schedule 1a: TACT Payment Schedule:

Payment Type

Randomization	\$500
Infusion Visits \$70/visit	\$2,800
Follow-up (\$30 for 3 telephone FU & \$110 for one annual clinical visit)	\$200
2009 Follow-up	\$50
Close-out	\$50

Schedule 1b: Breakdown by year of patient randomization:

Year Patient Randomized	Randomization	40 Infusion Visits (\$70/visit)	Total Payment for Follow-up	Close-out	Total Payment
9/2003-2/2004	\$ 500	\$ 2,800	\$ 850	\$ 50	\$ 4,200
3/2004-2/2005	\$ 500	\$ 2,800	\$ 650	\$ 50	\$ 4,000
3/2005-2/2006	\$ 500	\$ 2,800	\$ 450	\$ 50	\$ 3,800
3/2006-2/2007	\$ 500	\$ 2,800	\$ 250	\$ 50	\$ 3,600
3/2007-3/2008	\$ 500	\$ 2,800	\$ 50	\$ 50	\$ 3,400

\$2,300 paid for randomization (\$500) and ~26 infusion visits. If fewer than 26 infusions are administered, cost for administered infusions will be assessed. The difference between the actual number of administered infusions (at \$70 per infusion) and \$1,800 will be deducted from future payments.

When patient reaches infusion 40 \$1,000 are disbursed for total of \$3,300 (\$500 for randomization plus \$2,800 for 40 infusion visits at \$70 per visit).

Follow-up visits are paid at the end of TACT budget year (February 28th).

If a patient expires during the course of the trial, the site will receive full payment according to the year the patient was randomized.

Schedule 2: Patient Transfers

Payment Type	
Transfer acceptance (In)	\$50
Transfer completion (Out)	\$50

Administrative costs associated with transferring patients are covered by the study and are not included as part of site patient payments.

Patient Related Patients	
Infusion visit	\$70
Follow-up (\$30 for 3 telephone FU & \$110 for one annual clinical visit)	\$200
2009 Follow-up	\$50
Close-out	\$50

Permanent Transfers: Accepting site will receive \$50 upon accepting the patient, after the patient reaches infusion 40 the accepting will receive payment for the total number of infusions and any follow-up payments according to schedule 1. The randomizing site will receive \$500 for randomizing the patient, \$50 for completing transfer paperwork, plus \$70 for each infusion administered prior to patient transferring. Adjusted payments are deducted from the randomizing site's next site payment if patient randomization and infusion costs are less than \$2,300.

Temporary Transfers: Accepting site will receive \$50 upon accepting the patient; after the patient is transferred back to the randomizing site the accepting site will receive \$70/infusion for the total number of infusions administered, The randomizing site will continue to receive payment for the remaining number of infusions and follow-up.

All payments are disbursed upon accurate data entry by site.