

***** NOTICE OF GRANT AWARD *****
RESEARCH PROJECT COOPERATIVE AGREEMENT Issue Date:09/22/2005

Department of Health and Human Services
National Institutes of Health
NATIONAL CENTER FOR COMPLEMENTARY & ALTERNATIVE MEDICINE

Grant Number: 5 U01 AT001156-04
Principal Investigator: LAMAS, GERVASIO A MD
Project Title: Trial to Assess Chelation Therapy (TACT)

DIRECTOR OF RESEARCH
MT SINAI MED CTR OF FLORIDA, INC
4300 ALTON ROAD
MIAMI BEACH, FL 33140
MIAMI BEACH, FL
UNITED STATES

Budget Period: 03/01/2005 - 02/28/2006
Project Period: 08/15/2002 - 02/28/2007

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of \$0(see "Award Calculation" in Section I) to MOUNT SINAI MEDICAL CENTER (MIAMI BEACH) in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 31 USC 6305 & 6306 and is subject to terms and conditions referenced below. Acceptance of this award including the Terms and Conditions is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

Award recipients are responsible for reporting inventions derived or reduced to practice in the performance of work under this grant. Rights to inventions vest with the grantee organization provided certain requirements are met and there is acknowledgement of NIH support. In addition, recipients must ensure that patent and license activities are consistent with their responsibility to make unique research resources developed under this award available to the scientific community, in accordance with NIH policy. For additional information, please visit <http://www.iedison.gov>.

If you have any questions about this award, please contact the individual(s) referenced in the information below.

Sincerely yours,

George Tucker
Grants Management Officer
NATIONAL CENTER FOR COMPLEMENTARY & ALTERNATIVE MEDICINE

See additional information below

SECTION I - AWARD DATA - 5 U01 AT001156-04

AWARD CALCULATION (U.S. Dollars):

Salaries and Wages	\$307,525
Personnel Costs	\$307,525
Consultant Services	\$15,000
Equipment	\$500
Supplies	\$10,000
Travel Costs	\$20,604
Other Costs	\$28,560
Consortium/Contractual Cost	\$9,264,769
Federal Direct Costs	\$9,646,958
Federal F&A Costs	\$240,464
Less Unobligated Balance	\$9,887,422
TOTAL FEDERAL AWARD AMOUNT	\$0

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project, is as follows.

05 \$5,482,267

FISCAL INFORMATION:

CFDA 93.213

Number:

EN

Document Number: U1AT01156A

IC/ CAN /	FY2005	/	FY2006
AT/8424951/		0/	1,482,267
HL/8424300/		0/	4,000,000

NIH ADMINISTRATIVE DATA:

PCC: 10 / OC: 41.4P /Processed: TUCKERG 050919 0707

SECTION II - PAYMENT/HOTLINE INFORMATION - 5 U01 AT001156-04

For Payment and HHS Office of Inspector General Hotline Information, see the NIH Home Page at <http://grants.nih.gov/grants/policy/awardconditions.htm>

SECTION III - TERMS AND CONDITIONS - 5 U01 AT001156-04

This award is based on the application submitted to, and as approved by, the NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

- a. The grant program legislation and program regulation cited in this Notice of Grant Award.
- b. The restrictions on the expenditure of federal funds in appropriations acts, to the extent those restrictions are pertinent to the award.
- c. 45 CFR Part 74 or 45 CFR Part 92 as applicable.
- d. The NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
- e. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(see NIH Home Page at <http://grants.nih.gov/grants/policy/awardconditions.htm> for certain references cited above.)

Carry over of an unobligated balance into the next budget period requires Grants Management Officer prior approval.

This award provides support for one or more NIH defined Phase III clinical trials. The NIH Policy for research supported as an NIH Phase III Clinical Trial has been amended in Section II.B. of the NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research - Amended October 2001
http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm.

A description of plans to conduct analyses, as appropriate, by sex/gender and racial/ethnic groups must be included in clinical trial protocols. Cumulative subject accrual and progress in conducting subset analyses must be reported to NIH in the annual Progress Reports. Final analyses of sex/gender and racial/ethnic differences must be reported in the required Final Progress Report or Competitive Renewal Applications (or Contract Renewals/Extensions) as stated in Section II.B. of the Guidelines.

Treatment of Program Income:
Additional Costs

SECTION IV - ADDITIONAL TERMS AND CONDITIONS
5 U01 AT-01156-03
DR. GERVASIO LAMAS

NIH FUNDING ACKNOWLEDGEMENT REQUIREMENT: Grantees are required to place an acknowledgement of NIH grant support and a disclaimer, as appropriate, on any publication written or published with such support and, if feasible, on any publication reporting the results of, or describing, a grant-supported activity. An acknowledgment shall be to the effect that:

"This publication or project was made possible by Grant Number _____ from the National Center for Complementary and Alternative Medicine (NCCAM). Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the NCCAM, or the National Institutes of Health."

Grant recipients presenting NCCAM-sponsored research at scientific,

professional, and consumer meetings are asked to acknowledge the publicly funded support they receive. A copy of the NCCAM Grantee Acknowledgement slide in PowerPoint is available at:
<http://nccam.nih.gov/research/acknowledgement.htm>

CARRYOVER INFORMATION: This award authorizes a carryover of \$9,887,422 (\$9,646,958 direct costs and \$240,464 associated facilities and administrative costs) in unexpended funds from the -03 year to be used in the 04 year for carrying out the scope and goals of the proposed research. The carryover is subject to the availability of the funds. If the actual balance as reported on the -03 year Financial Status Report is less than \$9,887,422 the carryover authorization is reduced accordingly.

These funds are restricted and may not be used for any other purpose without the written prior approval of the National Center for Complementary and Alternative Medicine (NCCAM). These funds are not available for carryover under expanded Authorities or the Federal Demonstration Partnership without the written prior approval of the NCCAM.

CO-FUNDING INFORMATION: This award includes total costs funds of \$3,000,000 provided by the National Heart Lung and Blood Institute (NHLBI).

HUMAN SUBJECTS RESEARCH INFORMATION: See the NIH Grants Policy Statement

(rev. 12/03), Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General, Human Subjects, for specific requirements related to the protection of human subjects, which are applicable to and a term and condition of this award. This information is available online at the following NIH website:
http://grants2.nih.gov/grants/policy/nihgps_2003/NINGPS_Part5.htm#_Toc54600083

Notice: Under governing regulations, Federal funds administered by the department of Health and Human Services may not be expended for research involving human subjects and individuals may not be enrolled in research at any site, domestic or foreign, that does not have an Office for Human Research Protections (OHRP)-approved Assurance to comply with the requirements of 45 CFR Part 46 to protect human subjects and an Institutional Review Board (IRB) approval of the research that satisfies the requirements of 45 CFR Part 46.

It is the grantee institution's responsibility (1) to ensure that all sites engaged in research involving human subjects have an appropriate OHRP-approved Assurance and an IRB approval of the research consistent with 45 CFR Part 46 and (2) to retain documentation of compliance with the requirements of 45 CFR Part 46. The list of institutions with approved Assurances and information on and instructions for submitting and negotiating a Federal wide Assurance of Protection for Human Subjects are available at the OHRP website: <http://www.hhs.gov/ohrp/>

No funds may be drawn down from the payment system and no obligations may be made against Federal funds for research involving human subjects at any site engaged in such research for any period not covered by an OHRP-approved Assurance and an IRB approval consistent with 45 CFR Part 46. Failure to comply with the above requirements may result in suspension and/or termination of this award, withholding of support, audit disallowances, and/or other appropriate action.

PARTICIPANT RECRUITMENT REQUIREMENT: Future NCCAM support for this study is contingent upon adequate participant recruitment (based on: target patient accrual as stated in the application or projected milestones. An executive committee will establish these milestones prior to the initiation of data collection.) In the event that actual recruitment fall significantly below projected recruitment numbers (milestones), NCCAM may consider withholding future support and/or negotiating an orderly phase out of this study.

CONSORTIUM/CONTRACTUAL COST INFORMATION: This award includes funds for consortium activities that will be provided with this award. Consortia are to be established and administrated in accordance with the NIH Grants Policy Statement.

STAFF CONTACTS:

Richard Nahin, Program Official
 Phone: (301)-496-7801 Email: nahinr@od.nih.gov Fax: (301) 435-6549

Debera Campbell, Grants Specialist
 Phone: 301-594-3788 Email: campbelde@mail.nih.gov Fax: 301-480-1552

SPREADSHEET

GRANT NUMBER: 5 U01 AT001156-04

P.I.: LAMAS, GERVASIO A

INSTITUTION: MOUNT SINAI MEDICAL CENTER (MIAMI BEACH)

	YEAR 04	YEAR 05
	=====	=====
<input type="checkbox"/>		
Salaries and Wages	307,525	
Personnel Costs	307,525	
Consultant Services	15,000	
Equipment	500	
Supplies	10,000	
Travel Costs	20,604	
<input type="checkbox"/>		

	YEAR 04	YEAR 05
	=====	=====
Other Costs	28,560	
Consortium/Contractual Cost	9,264,769	

TOTAL FEDERAL DC	9,646,958	5,245,544
TOTAL FEDERAL F&A	240,464	236,723
TOTAL COST	9,887,422	5,482,267

	YEAR 04	YEAR 05
	=====	=====
F&A Cost Rate 1	63.00%	63.00%

F&A Cost Base 1 381,689 375,751

F&A Costs 1 240,464 236,723

.....END OF NGA.....

Department of Health and Human Services
Public Health Services

Review Group	Type	Activity	Grant Number
	5	001	U01 AT01156-04
Total Project Period			
From: 08/15/2002		Through: 02/28/2007	
Requested Budget Period			
From: 03/01/2005		Through: 02/28/2006	

Grant Progress Report

1. TITLE OF PROJECT
Trial to Assess Chelation Therapy (TACT)

2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR
(Name and address, street, city, state, zip code)
Gervasio A. Lamas, MD
Mount Sinai Medical Center
4300 Alton Road; Butler Building
Miami Beach, FL 33140

3. APPLICANT ORGANIZATION
(Name and address, street, city, state, zip code)
Mount Sinai Medical Center of Florida, Inc.
4300 Alton Road
Miami Beach, FL 33140

2b. E-MAIL ADDRESS
TACTNIH@aol.com

4. FACILITY IDENTIFICATION NUMBER
EIN

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Medicine

5. TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
William Abraham, Ph.D
Director of Research
4300 Alton Road
Miami Beach, FL 33140

2d. MAJOR SUBDIVISION
Cardiology

E-MAIL: Abraham@msmc.com

6. HUMAN SUBJECTS

No Yes

6a. Research Exempt No Yes

6b. Human Subjects Assurance No. FWAA00000176

6c. NIH-Defined Phase III Clinical Trial No Yes

If Exempt ("Yes" in 6a):
Exemption No.

If Not Exempt ("No" in 6a):
IRB approval date 3/22/2001

Full IRB or Expedited Review

7. VERTEBRATE ANIMALS

No Yes

7a. If "Yes," IACUC approval Date

7b. Animal Welfare Assurance No.

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD

8a. DIRECT \$8,710,556

8b. TOTAL \$8,957,820

9. INVENTIONS AND PATENTS

No Yes

If "Yes," Previously Reported Not Previously Reported

10. PERFORMANCE SITE(S) (Organizations and addresses)

Mount Sinai Medical Center
4300 Alton Road
Miami Beach, FL 33140

Duke Clinical Research Institute
Box 3300
Durham, NC 27715

11a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Item 2a)

TEL 305-674-2162
FAX 305-674-3970

11b. ADMINISTRATIVE OFFICIAL NAME (Item 5)

William Abraham, PhD
TEL 305-674-2790
FAX 305-674-2198

11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION (Item 14)

NAME Paul Katz, MD
TITLE Vice President
TEL 305-674-2633 FAX 305-674-2007
E-MAIL pkatz@msmc.com

12. Corrections to Page 1 Face Page

13. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR ASSURANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application.

SIGNATURE OF PI/PPD NAMED IN 2a.
(In ink. "Per" signature not acceptable.)

[Signature]

DATE
12/28/04

14. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11c. (In ink. "Per" signature not acceptable.)

[Signature]

DATE
12-28-04

Principal Investigator/Program Director (Last, First, Middle): Lamas, Gervasio A., MD

DETAILED BUDGET FOR NEXT BUDGET PERIOD -- DIRECT COSTS ONLY			FROM 03/01/05	THROUGH 02/28/06	GRANT NUMBER 1 U01 AT01156-03		
PERSONNEL (Applicant organization only)			TYPE APPT. (months)	% EFFORT ON PROJ.	DOLLAR AMOUNT REQUESTED (omit cents)		
NAME	ROLE ON PROJECT	SALARY REQUESTED			FRINGE BENEFITS	TOTALS	
Gervasio A. Lamas, MD	Principal Investigator	12		64,480	0	64,480	
Jacqueline Arciniega, MPH	Project Director	12		73,388	0	73,388	
Kayvan Amini, DO	Clinical Manager	12		41,162	0	41,162	
Virginia Martini	Admin. Coordinator	12		28,323	0	28,323	
Renea L. Moss	Office Coordinator	12		40,299	0	40,299	
Parminder Singh, MD	Research Assistant	12		31,360	0	31,360	
Jewmaull Reed	Research Assjstant	12		28,513	0	28,513	
SUBTOTALS →				307,525	0	307,525	
CONSULTANT COSTS Chelation Consultants: Martin Dayton (3,744) Ted Rozema (3,744) Misc. Consultants: (7,512)						15,000	
EQUIPMENT (Itemize) Scanner/Color Printer						500	
SUPPLIES (Itemize by category) General Office: 7,000 FAX and copier: 1,000 Paper: 2,000						10,000	
TRAVEL CCC Travel						20,604	
PATIENT CARE COSTS		INPATIENT	0			0	
		OUTPATIENT	0			0	
ALTERATIONS AND RENOVATIONS (Itemize by category) 0						0	
OTHER EXPENSES (Itemize by category) Telephone: 12,000 Pagers/Cellulars: 2,000 Postage: 4,160 Advertisement: 10,400						28,560	
SUBTOTAL DIRECT COSTS FOR NEXT BUDGET PERIOD						\$ 382,189	
CONSORTIUM/CONTRACTUAL COSTS			DIRECT COSTS			8,328,367	
			FACILITIES AND ADMINISTRATIVE COSTS			240,464	
TOTAL DIRECT COSTS FOR NEXT PROJECT PERIOD (Item 8a, Face Page)						\$ 8,951,020	

BUDGET JUSTIFICATION

GRANT NUMBER
1 U01 AT01156-03

Provide a detailed budget justification for those line items and amounts that represent a significant change from that previously recommended. Use continuation pages if necessary.

More study patients will be enrolled during year 4 than during year 3. Nonetheless we are requesting the same estimated number of personnel and costs for consortia. In addition, there has been sub-category rebudgeting among the following subcontractor:

Omnicom: Omnicomm is receiving additional funding for covering costs related to the reprogramming the TrialMaster system for patient safety measures detailed in the progress report. These funds were taken from CCC Travel since all three required study meetings were completed by year 3.

CURRENT BUDGET PERIOD

FROM
03/01/2004

THROUGH
02/28/2005

Explain any estimated unobligated balance (including prior year carryover) that is greater than 25% of the current year's total budget. Consortium: Because of the modified patient enrollment curve, there have been less expenditures for central lab and clinical units as of December 2004. These expenses will be incurred during year 4 as the number of enrolled patients increases. A carryover request will be forthcoming.

Principal Investigator/Program Director (Last, First, Middle): Lamas, Gervasio, A., MD

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.

Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Arciniega, Jacqueline	POSITION TITLE Project Director
eRA COMMONS USER NAME	

EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as

INSTITUTION AND LOCATION	DEGREE (if applicable)	YEAR(s)	FIELD OF STUDY
Macalester College, St. Paul, MN	BA	1992-1996	Biology
Mailman School of Public Health Columbia University, New York, NY	MPH	1998-2000	Epidemiology

A. Positions and Honors.

Positions and Employment

Research Assistant, Sergievsky Center of Columbia University, New York, NY	1999-2000
Health Services Analyst, HIP Health Plan of New York, New York, NY	2000-2001
Manager, Health Services Analysis Unit, HIP Health Plan of New York, New York, NY	2001-2002
Assistant Director, HIP Health Plan of New York, New York, NY	2002-2003
Senior Consultant, Outcomes Research, NDCHealth, Yardley, PA	2003-2004
Research Associate/TACT Project Director, Mt. Sinai Medical Center, Miami Beach, FL	2004-Present

Other Experience

Research Assistant, Biology Department, Macalester College, St. Paul, MN	1993-1995
Intern Research Assistant, Institute of Human Genetics, University of MN, Minneapolis, MN	1995-1998

Honors

- Midwest Chapter INROADS Scholar, 1994
- Midwest Ronald E. McNair Scholar, 1995
- Macalester College, Presidential Leadership Award, 1996
- HIP Health Plan Team Player of the Year, 2002

Selected peer-reviewed publications (in chronological order).

Tilden AR, Becker MA, Amma LL, Arciniega J, McGaw AK. Melatonin Production in an Aerobic Photosynthetic Bacterium: An Evolutionary Early Association with Darkness. *Journal of Pineal Gland Research*, 1997; 22: 102-106.

Reich L, Jaramillo B, Kaplan L, Arciniega J and Kolbasovsky A. Improving Continuity of Care: Success of a Behavioral Health Program. *Journal for Health Care Quality*, 2003; 25: 4-9.

Research Support

1 U01 AT01156-03 (Project Director) 7/26/2004-Present
TACT is a randomized clinical trial with a 2 X 2 factorial design to independently test the effects of the standard chelation solution recommended by the American College for Advancement in Medicine (ACAM) versus placebo solution, and the effects of a high-dose oral vitamin supplementation, versus a low dose regimen to simply replace chelation-related losses.

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Kayvan Amini, DO	POSITION TITLE Clinical Trial Manager
eRA COMMONS USER NAME	

EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)

INSTITUTION AND LOCATION	DEGREE (if applicable)	YEAR(s)	FIELD OF STUDY
University of Miami, FL	BS	1992-1996	Chemistry/Biology/Math
University of Miami, FL	Masters	1997	Masters of Chemistry Level
Nova Southeastern College of Osteopathic Medicine FL	DO	1997-2001	Doctor of Osteopathic Medicine
Mount Sinai School of Medicine, NY	Residency	2002	Internal Medicine Residency (PGYI)
University of Southern California and Los Angeles County Medical Center, CA	Residency	2002-2004	Internal Medicine Residency (PGYII – III)
Mount Sinai Medical Center, FL	Fellowship	2004	Cardiology Fellowship (PGYIV)

Positions and Honors**EXPERIENCE**

University of Miami Department of Chemistry, Teaching Assistant 1996-1997
 University of Miami School of Medicine, Lab Assistant 1994-1995
 University of Miami School of Medicine, Research Assistant Immunochemistry Lab 1994-1995
 Keck School of Medicine, University of Southern California, Volunteer Faculty 2002-2204
 Licensed by California Board of Osteopathic Medicine, 2003-Present
 Board Certified in Internal Medicine, 2004-Present

PROFESSIONAL AND HONORARY ORGANIZATIONS

Recipient of University of Miami Grant A and B (1992-1996)
 President of Chemistry Honor Society, and Chemistry Society at University of Miami (1994-96)
 Award for Excellence in Student Involvement, University of Miami (1996)
 American Chemical Society Award for Superior Achievements in Chemistry (1996)
 2nd Place University of Miami Research Symposium (1996)
 Florida Osteopathic Association Member since 2001
 American College of Internists Member since 2001
 American College of Cardiology Member since 2004
 American Medical Association Member since 2001
 American College of Physicians Member since 2001
 American Osteopathic Association Member since 2001

Research Support

1 U01 AT01156-03 (Project Director)

7/26/2004-Present

TACT is a randomized clinical trial with a 2 X 2 factorial design to independently test the effects of the standard chelation solution recommended by the American College for Advancement in Medicine (ACAM) versus placebo solution, and the effects of a high-dose supplementation, versus a low dose regimen to simply replace chelation-related losses.

Principal Investigator/Program Director (Last, First, Middle): Lamas, Gervasio, A, MD

PROGRESS REPORT SUMMARY	GRANT NUMBER 1 U01 AT01156-03	
	PERIOD COVERED BY THIS REPORT	
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR Gervasio A. Lamas, MD	FROM 03/01/2005	THROUGH 02/28/2006
APPLICANT ORGANIZATION Mount Sinai Medical Center		
TITLE OF PROJECT (Repeat title shown in Item 1 on first page) Trial to Assess Chelation Therapy (TACT)		
A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	<input checked="" type="checkbox"/> No Change Since Previous Submission	<input type="checkbox"/> Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	<input checked="" type="checkbox"/> No Change Since Previous Submission	<input type="checkbox"/> Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

Has there been a change in the other support of key personnel since the last reporting period?
The following are organizational changes in the TACT CCC since the last reporting period (December 2003). All changes were made without a significant increase in total cost.
Danielle Hollar, PhD (Project Director): Dr. Hollar resigned from TACT.

Jaime Zimmerman, MPH (Research Assistant/Interim Project Director): Ms. Zimmerman took on the Project Director's responsibilities upon Danielle Hollar's resignation until a permanent Project Director was found. Ms. Zimmerman resigned from TACT.

Matt Shields (Research Assistant): Mr. Shields resigned from TACT.

Jacqueline Arciniega, MPH (Project Director): Ms. Arciniega has been added to the CCC as a full-time Project Director. She will spend [REDACTED] committed to TACT, with a base salary of [REDACTED] Institutional Base Salary increasing by 3% each year. Her TACT related duties are the following:

1. Maintaining the organization integrity of the Clinical Coordinating Center. The Project Director will assist the Principal Investigator in selecting personnel with scientific experience and clinical expertise to fill the funded positions in the CCC. All NIH hiring policies will be adhered to and any gaps in CCC personnel will be promptly filled.
2. Maintaining communication and cohesion among the organizational units of TACT. The Project Director will assist the Principal Investigator in maintaining open lines of communication with the organizational units of TACT. Scheduled conference calls will occur weekly to discuss the progress of the trial. The staffs at each of the organizational units will maintain close telephone and email contact.
3. Maintaining close contact and collaboration with the chelation medicine community. The Project Director will assist the Principal Investigator in developing a liaison committee with the chelation community, educating the traditional medicine clinical investigators, presenting at annual meeting of ACAM when invited, and publishing methodological and other aspects of the study in the alternative medicine literature as well as in the traditional scientific literature.
4. Identify and recruit clinical units. The Project Director will assist the Principal Investigator in recruiting

competent clinical units for study performance.

5. Setting standards of productivity and scientific performance for TACT clinical units. The Project Director will assist the Principal Investigator in developing and enforcing expectations of quality, safety, and productivity.
 6. Developing contractual relationships with over 120 Clinical Units and with the organizational and performance units. The Project Director will assist the Principal Investigator in developing the clinical units' Memoranda of Agreement to formalize the scientific and economic relationships that will cement participation in the study.
 7. Assisting clinical units to obtain OHRP clearance. The Project Director will lead the CCC staff in identifying those clinical units that do not carry MPA or FWA numbers. Those clinical units will be assisted in obtaining FWA numbers so the study can proceed rapidly.
 8. Planning and directing training and yearly meetings. The Project Director will assist the Principal Investigator in deciding the timing, location, and content of the training meeting and of the subsequent yearly study meetings.
 9. Maintain close interaction with the NCCAM and NHLBI Project Offices. The Project Director will assist the Principal Investigator in maintaining close contact with the Project Office, keeping it apprised of the progress of the trial. This includes participation in conference calls, active participation in meetings, and, when necessary, assisting in management of recruitment or quality control issues with the clinical units.
 10. Coordinating the collection of regulatory documents from clinical units.
 11. Coordinating yearly NCCAM Progress Report and non-competitive renewal applications.
 12. Coordinating the Ancillary Studies applications.
 13. Identifying, recruiting, and activating international sites. Submitting regulatory documentation to appropriate country agencies for International sites. The Project Director will assist the Principal Investigator in writing and submitting documents following each country's regulatory requirements when establishing International clinical sites.
 14. Coordinate efforts for establishing International sites. The Project Director will assist the Principal Investigator in identifying and resolving any barriers and issues when establishing International clinical sites.
 15. Develop and establish standard operating procedures for site activation process, annual IND submission process, informed consent process, site payment process.
 16. Coordinate efforts with consortia: DCRI, Omnicomm, and Central Pharmacy.
- The Project Director reports to the Principal Investigator.

Kayvan Amini, DO (Clinical Manager): Dr. Amini has been added to the CCC as a full-time Clinical Manager for one-year as part of his clinical research fellowship program. Dr. Amini will spend [redacted] time committed to TACT. His TACT related duties follow:

1. Training and assisting clinical units with the clinical management of TACT patients.
2. Training and assisting clinical units with patient recruitment strategies.
3. Training and assisting clinical units with patient retention strategies.
4. Responding to clinical inquires from clinical units.
5. Working with the DCC site monitors to assure a smooth operation of TACT.
6. Participating in weekly Operations Committee calls.
7. Participation in the Steering Committee as an ex-officio member.
8. Developing educational materials for TACT patients.
9. Developing educational materials for TACT clinical units.
10. Assist clinical sites in patient monitoring to ensure the safety of all TACT patients.

Principal Investigator/Program Director (Last, First, Middle): Lamas, Gervasio, A., MD

11. The Clinical Trial Manager will assist the Principal Investigator in reviewing and modifying (if necessary) the TACT protocol.
 12. Assists Project Director in coordinating and managing study related tasks.
 13. Manages, coordinates, and develops changes for Electronic Data Capture (EDC-TrialMaster) system with Omnicomm.
 14. Involved in all management aspects of the Central Pharmacy.
 15. Responsible for assisting clinical units with the clinical management of study patients.
 16. Responsible for monitoring clinical units to assure the integrity and compliance to TACT protocol.
- The Clinical Trial Manager reports to the Principal Investigator and Project Director.

Parminder Singh, MD (Research Assistant): Dr. Singh was added to the CCC as a full-time Research Assistant for one-year in Spring 2004. Dr. Singh will be with the TACT study until mid-Spring 2005. He will spend [REDACTED] time committed to TACT, with a base salary of [Institutional Base Salary] with an annual increase of 3%. His principal duties are:

1. Assist clinical units in submitting required regulatory documents required for study.
 2. Assist in identifying new clinical sites.
 3. Maintain and update contact information for clinical sites.
 4. Assist in the development of study reports as directed by Project Director.
 5. Serve as a liaison between study sites and the Clinical Coordinating Center.
 6. Follow-up on site monitoring reports generated after each DCC site monitor visits.
 7. Participate in weekly Operations call.
 8. Assist in the yearly IRB re-review and re-approval process so sites are notified at least three (3) months prior to their IRB expiration date, and assist in yearly submissions.
 9. Assist sites in obtaining FWA number.
 10. Assist with IRB and OHRP submissions of individual clinical sites.
- The Research Assistant reports to the Project Director and Clinical Trial Manager.

Jewmaull Reed, BA (Research Assistant): Mr. Reed was added to the CCC as a full-time Research Assistant for one-year in Spring 2004. Mr. Reed will be with the TACT study until mid-Spring 2005. He will spend [REDACTED] time committed to TACT, with a base salary of [Institutional Base Salary] with an annual increase of 3%. His duties are as follows:

1. Assist clinical units in submitting required regulatory documents required for study.
 2. Assist in identifying new clinical sites.
 3. Maintain and update contact information for clinical sites.
 4. Assist in the development of study reports as directed by Project Director.
 5. Serve as a liaison between study sites and the Clinical Coordinating Center.
 6. Submit and coordinate IRB submissions.
 7. Participate in weekly Operations call.
 8. Maintain site regulatory documents through regular auditing of clinical site files for expiration of IRB approval dates, change of staffing in clinical sites.
 9. Assist in coordinating the distribution of study related materials to sites.
- The Research Assistant reports to the Project Director and Clinical Trial Manager.

Principal Investigator/Program Director (Last, First, Middle): Lamas, Gervasio, A., MD

Renee Moss (Office Coordinator): Ms. Moss was promoted to an Office Coordinator position. She will spend [redacted] time committed to TACT, receiving a base salary of [redacted] with an annual increase of 3%. The Office Coordinator's duties are as follows:

1. Monitoring and maintaining the integrity of the TACT budget.
 2. Process weekly clinical site payments. The Office coordinator is responsible for paying clinical units upon each patient randomization with a completed EQOL questionnaire.
 3. Process consortium payments upon receipt. The Office coordinator is responsible for timely payment of all subcontractors in accordance with MOA: Accucare Pharmacy, Duke Clinical Research Institute, Omnicomm Systems, Brigham and Women's Hospital, Quest, and Pharmed.
 3. Creates and maintains database for clinical sites to track site related expenses including patient lab procedures and other miscellaneous expenses.
 4. Analyzes and updates current and projected expenditures of assigned projects.
 5. Develops and maintains budgetary database for clinical units and consortia.
 6. Reviews and verifies Notice of Grant Award reports from National Institute of Health.
 7. Develops and submits Financial Status Reports to National Institute of Health.
 8. Assists with budget aspects of TACT Progress Report to National Institute of Health.
- The Office Coordinator reports to the Project Director.

Virginia Martini (Administrative Coordinator/International Coordinator): Ms. Martini has reduced her time commitment to TACT to [redacted] with a base salary of [redacted] Institutional Base Salary increasing by 3% each year. The Administrative Coordinator's duties are as follows:

1. Translating TACT protocol into Spanish.
 2. Maintain and audit Memoranda of Agreement (MOA) for clinical sites and study subcontractors. The Administrative Coordinator is responsible for reviewing MOAs with the following subcontractors: Accucare Pharmacy, Omnicomm, Duke Clinical Research Institute, Pharmed, Quest, and Brigham and Women's Hospital.
 3. Coordinates with Mount Sinai Medical Center Grants and Research Administration implementing MOAs for clinical sites and subcontractors.
 4. Assists in identifying new clinical sites for the study.
 5. Assists Project Director in coordinating submission of regulatory documents for international sites.
 6. Translating TACT patient recruitment materials into Spanish.
 7. Supports in the development of letters and reports.
 8. Acts as a secondary liaison with international sites. The Administrative Coordinator will assist in the coordination of establishing international sites.
 9. Assists Project Director in organizing conference calls.
 10. Supports in the development of reports, charts, letters.
- The Administrative Coordinator/International Coordinator reports to the Project Director.

Ingrid Bazin, BS (Administrative Assistant): Ms. Bazin has resigned from the study. The responsibilities for this position were divided between the coordinator positions.

Will there be, in the next budget period, a significant change in the level of effort for the PI or other personnel designated on the Notice of Grant Award from what was approved for this project?

Is it anticipated that an estimated unobligated balance (including prior year carryover) will be greater than 25 percent of the current year's total budget?

Administrative delays in receiving year 3's carryover may cause the prior year's carryover to be greater than 25% of the current year's total budget. The modified curve predicted fewer patients in year three, than anticipated leading to lower expenditures for central lab and clinical units. More expenses will be incurred during year 4 when the number of enrolled patients is predicted to be the highest. A carryover request will be forthcoming.

Progress Report Summary

a. Specific Aims

The specific aims of the Trial to Assess Chelation Therapy (TACT) remain the same as listed in the original award.

b. Studies and Results

No results have been obtained. This is a double-blind trial therefore results are not expected until completion of the study.

c. Significance

As mentioned above, no results have been obtained thus far. The trial, however, remains as significant as when it was conceived.

d. Plans

Milestones accomplished:

Site Activation Process

As of December 21, 2004, 105 clinical sites have completed the regulatory document process. Of these seventy-two clinical sites have randomized at least one patient in TACT. The overall average number of patients enrolled per site is 0.92. Enrollment at the site level has a wide range of variation (0 to 5.3 patients per month). Conference calls with sites that have not recruited patients has helped the Clinical Coordinating Center identify specific barriers faced by the sites. The CCC has been working with NCCAM to coordinate activities that will address barriers identified by sites. The number of enrolling sites will remain at approximately 120 sites at study completion by implementing two measures: all new sites (as of November 2004) are required to consent two patients prior to activation and all currently activated sites that have not randomized any patients for 3 months will be given 30-days to enroll a patient in order to retain their active status. These two efforts will help the CCC maintain the number of clinical sites at approximately 120 and only retain productive sites in the trial.

Site Recruitment Efforts

The aforementioned measures to maintain the number of sites to 120 require concentrated efforts in identifying more interested sites. We intend to have a continuous source of potential sites by the following efforts:

1. Duke University Cooperative Cardiovascular Studies (DUCCS) group fax: Letter from Drs. Lamas and Lee describing TACT to 2,400 cardiologists in DUCCS database. Number of DUCCS sites sent additional information on TACT: 3% (74/2500)
2. Distribution of TACT site recruitment brochure at recent American Heart Association (AHA) meeting at NHLBI booth.
3. Distribution of TACT study description at AHA meeting at DCRI booth.

4. Key cities targeted site recruitment: Site recruitment letters were sent to 98 cardiologist offices in Atlanta, GA.
5. General Clinical Research Center (GCRC) Site Recruitment: 50 letters were sent inviting GCRCs to become TACT sites.

The Clinical Coordinating Center is in process of contacting the following groups to invite to apply to become TACT sites:

1. ALLHAT sites
2. American Osteopathic Association 200/600 letters of invitations were sent to DO physicians identified as cardiologists. The other 400 letters will go out early January 2005.
3. Family practice and cardiology programs in osteopathic medical schools
4. Society of Cardiac Rehabilitation
5. Cardiologists in selected urban areas as listed in the American College of Cardiology directory to target minority enrollment.
6. The CCC is in the process of establishing sites in Canada and Argentina. Contact was established with cardiologists in each country who are willing to become country leaders to facilitate the coordination of TACT sites in their countries. The country leaders will help the CCC identify new clinical units in their country, facilitate regulatory document submission, clinical unit monitoring, and developing sensible logistical plans for clinical unit training and receipt of study materials. International sites will be directly managed by the CCC therefore will not incur any additional study costs, since the CCC would manage these sites in the same fashion as domestic (USA) sites. The addition of international sites only presents additional administrative time.

Patient Safety

The current calcium low normal range (9.0 mg/dL) in the protocol will be changed to 8.5 mg/dL. The decrease in calcium does not affect the specific aims of the study. This change was implemented to reflect the central laboratory (Quest) normal calcium lab values. A closer review of patient safety measures were conducted and led to the development of two additional patient safety measures focusing on improving the infusion times at each clinical site, correcting abnormal calcium levels based on albumin concentration, and notifying patients and primary care physicians of critical laboratory values. The following detail these processes:

1. Fast Infusions:

Current protocol allows for active infusion to occur over 3 hours, while below-normal calcium levels require the infusion to occur over a minimum of 4 hours. In order to ensure a safe infusion, the time and volume of the infusion given will be recorded via the TrialMaster®, allowing for proper rate calculations. The TrialMaster® will then automatically notify the CCC, DCRI, and the Site investigator of a fast infusion. Fast infusions will be addressed by the CCC following a specific process (diagram 1). A second mechanism of ensuring proper infusion rates is the incorporation of flowmeters.

2. Calcium Correction:

The standard measurement of serum calcium does not take into account patients with hypoalbuminemia. Since calcium is bound to albumin, patients with low albumin will have a different true value of serum calcium. In order to account for this, the serum calcium level must be corrected using the serum albumin. We will automate the process of calculating corrected calcium through TrialMaster®:

1) All serum calcium will require a calcium correction for albumin level.

corrected calcium = serum calcium + (0.8 x [normal serum albumin - patient's albumin]).

(Note: normal serum albumin is defined as the midpoint of the central lab normal albumin range 4.2 mg/dL)

2) If corrected calcium is 8 mg/dl to 8.4 mg/dl, it will be considered a lab alert, hence will require a long infusion (4-5 hrs).

3) Any corrected calcium below 8.0 mg/dl will place the patient in Lab Delay. Therefore, patient will not receive an infusion and will be required to repeat lab draw in two weeks.

3. Laboratory Critical Values

Modifications have been made to ensure more clinically relevant ranges for the lab alert system. In addition, an automated alert and check system monitored by the CCC via TrialMaster® will be set up to notify the site to contact the patients' primary care physician (PCP) in case a critical lab value is reached (diagram 2). EDTA can affect renal function: Lab alerts will be triggered when a decline in estimated creatinine clearance of 25% or greater occurs. This will be addressed by the CCC.

Patient Enrollment Update

Patient enrollment is closely monitored on a weekly basis to assess recruitment. Weekly site calls with the CCC help sites discuss barriers. These calls also serve to identify interventions that can address these site barriers. These calls also help foster interactions with sites and the CCC. The following list represents the CCC and NCCAM efforts to help site recruit patients:

1. Development of Patient Recruitment Toolkit that provides tips to help sites develop and implement their own patient recruitment action plan.
2. IRB approved fliers and brochures.
3. NCCAM website: <http://nccam.nih.gov/chelation/>
NCCAM clearinghouse number collects and disseminates patient contact information to sites.
Media training at last investigators' and coordinators' meeting addressed how to successfully approach local media to discuss TACT.
4. Weekly conference calls with Clinical Trial Manager and Research Assistants to sites with no patients to identify barriers in recruiting patients and propose solutions to help in their efforts. NCCAM Communications Specialist joins many calls to discuss patient recruitment toolkit.
5. Point-of-service displays are provided to sites upon request. These displays can be placed in physicians' waiting rooms.
6. Weekly site calls from TACT Principal Investigator to sites that have not enrolled any patients. These phone calls give sites an opportunity to talk directly with PI about barriers faced when recruiting patients.
7. Weekly site calls from TACT Principal Investigator to dormant sites (enrolled at least one patient but had no enrollment activity in the past three months).
8. Referring Cardiologist Program: Letter is sent from TACT PI to site-identified cardiologists requesting patient referrals to TACT site:
Mailed 484 letters to cardiologists for 9 sites.
9. General patient recruitment program: Letters were sent to 56 Cardiac Rehabilitation Centers across the United States referring them to call the Clinical Coordinating Center or the NCCAM clearinghouse number.

The Clinical Coordinating Center is in the process of implementing the following:

1. Patient Waiting Room Toolkit: This toolkit will provide sites with a poster board and patient information that they can place in their waiting room.
2. Patient Ambassador Program: This program recruits enthusiastic patients interested in passing on information of TACT to other patients.
3. Site Advertising Program: One of the barriers identified during site calls was funding for paid media. Many sites determined the best method of advertising in their local area were radio, newspaper, and other circulars. The vast majority of these media forms are not free. Through this program sites are asked to submit a proposal requesting extra funding for a paid advertisement. As part of the program the site is required to commit to tracking the number of patient responses to the advertisement.
4. Referring Cardiologist Program Phase 2: Revised referral letter, PI bio-sketch, and STEMI guidelines are sent to site-identified cardiologists requesting patient referrals (attachment 9).
5. TACT Teleconference Lunch: sites will host a lunch for interested cardiologists to hear a 20-30 minute teleconference by Dr. Lamas on the TACT study. This forum will allow sites to initiate and recruit local cardiologists to refer patients to their TACT site.
6. Targeted media outreach using NCCAM's IRB approved B-roll in cities with TACT sites: short video describing TACT profiling a TACT patient, TACT site investigator, and Dr. Lamas. Available in English and Spanish.

6. Targeted media outreach using NCCAM's IRB approved B-roll in cities with TACT sites: short video describing TACT profiling a TACT patient, TACT site investigator, and Dr. Lamas. Available in English and Spanish.
7. IRB approved article on TACT will be distributed through the North American Precis Syndicate (NAPS).

Planned Activities to Improve Enrollment of Minorities and Women

The CCC is in the process of implementing the following action plan to improve enrollment of minorities and women in the study:

1. Activation of clinical units in urban areas with denser populations of minorities.
2. The Mount Sinai Medical Center (MSMC) TACT clinical unit was activated, the medical center has a large pool of post-MI Hispanic patients which will be assessed for eligibility into the trial.
3. Pursuit of clinical sites in Puerto Rico. The CCC is in the process of identifying clinical units in Puerto Rico who had success in previous clinical trials like ALLHAT.
4. The CCC will begin, in February 2005, a campaign focused on increasing enrollment of women. This will be initiated via our study newsletter where sites with high proportions of women will be highlighted.

Review and Approval of Site Informed Consent Forms

A guideline was created to accurately audit and approval each site's informed consent forms. These guidelines include review of elements of each sites consent form prior to submission for IRB approval by site. A checklist detailing all the essential elements required on every consent form was developed and is used when reviewing all site consent forms.

Principal Investigator/Program Director (Last, first, middle): Lamas, Gervasio A., MD

GRANT NUMBER
1, U01AT01156-03

CHECKLIST

1. PROGRAM INCOME (See Instructions.)

All applications must indicate whether program income is anticipated during the period(s) for which grant support is requested. If program income is anticipated, use the format below to reflect the amount and source(s).

Budget Period	Anticipated Amount	Source(s)

2. ASSURANCES/CERTIFICATIONS (See Instructions.)

In signing the application Face Page, the authorized organizational representative agrees to comply with the following policies, assurances and/or certifications when applicable. Descriptions of individual assurances/certifications are provided in Part III of the PHS 398. If unable to certify compliance, where applicable, provide an explanation and place it after this page.

• Human Subjects • Research Using Human Embryonic Stem Cells
• Research on Transplantation of Human Fetal Tissue • Women and Minority Inclusion Policy • Inclusion of Children Policy • Vertebrate Animals

• Debarment and Suspension • Drug-Free Workplace (applicable to new [Type 1] or revised [Type 1] applications only); • Lobbying • Non-Delinquency on Federal Debt • Research Misconduct • Civil Rights (Form HHS 441 or HHS 690); • Handicapped Individuals (Form HHS 641 or HHS 690) • Sex Discrimination (Form HHS 639-A or HHS 690) • Age Discrimination (Form HHS 680 or HHS 690); • Recombinant DNA Research, Including Human Gene Transfer Research • Financial Conflict of Interest (except Phase I SBIR/STTR) • Prohibited Research • Select Agents
• STTR ONLY: Certification of Research Institution Participation.

3. FACILITIES AND ADMINISTRATIVE (F&A) COSTS

Indicate the applicant organization's most recent F&A cost rate established with the appropriate DHHS Regional Office, or, in the case of for-profit organizations, the rate established with the appropriate PHS Agency Cost Advisory Office.

F&A costs will *not* be paid on construction grants, grants to Federal organizations, grants to individuals, and conference grants. Follow any additional instructions provided for Research Career Awards, Institutional National Research Service Awards, Small Business Innovation Research/Small Business Technology Transfer Grants, foreign grants, and specialized grant applications.

DHHS Agreement dated: 12/21/2000

No Facilities and Administrative Costs Requested.

No DHHS Agreement, but rate established with _____ Date _____

CALCULATION*

Entire proposed budget period: Amount of base \$ 381,689 x Rate applied 63.00 % = F&A costs \$ 240,464

Add to total direct costs from Form Page 2 and enter new total on Face Page, item 8b.

*Check appropriate box(es):

Salary and wages base

Modified total direct cost base

Other base (Explain)

Off-site, other special rate, or more than one rate involved (Explain)

Explanation (Attach separate sheet, if necessary.):

Principal Investigator/Program Director (Last, First, Middle): Lamas, Gervasio A., MD

KEY PERSONNEL REPORT

GRANT NUMBER
1 U01 AT01156-03

Place this form at the end of the signed original copy of the application. Do not duplicate.

All Key Personnel for the Current Budget Period (do not include Other Significant Contributors)

Name	Degree(s)	SSN (last 4 digits)	Role on Project (e.g. PI, Res. Assoc.)	Date of Birth (MM/DD/YY)	Annual % Effort
Gervasio A. Lamas	MD		PI		
Jacqueline Arciniega	MPH		Project Director		
Kayvan Amini	DO		Clinical Manager		
Kerry Lee	PhD		Co-PI		
Daniel Mark	MD		Co-PI		

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: Trial to Assess Chelation Therapy (TACT)

Total Planned Enrollment: 2,372

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	Sex/Gender		
	Females	Males	Total
Hispanic or Latino	57	133	190
Not Hispanic or Latino	655	1,528	2,182
Ethnic Category: Total of All Subjects *	712	1,660	2,372
Racial Categories			
American Indian/Alaska Native	7	17	24
Asian	14	33	47
Native Hawaiian or Other Pacific Islander	14	33	47
Black or African American	85	199	285
White	591	1,378	1,969
Racial Categories: Total of All Subjects *	712	1,660	2,372

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: Trial to Assess Chelation Therapy (TACT)Total Enrollment: 2,372Protocol Number: 00-21-H-03Grant Number: 1 U01 AT01156-03**PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative)
by Ethnicity and Race**

Ethnic Category	Sex/Gender			Total
	Females	Males	Unknown or Not Reported	
Hispanic or Latino	2	10	0	12 **
Not Hispanic or Latino	72	366	0	438
Unknown (Individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	74	376	0	450 *
Racial Categories				
American Indian/Alaska Native	0	3	0	3
Asian	0	3	0	3
Native Hawaiian or Other Pacific Islander	0	2	0	2
Black or African American	8	11	0	19
White	66	359	0	425
More Than One Race	0	2	0	2
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	74	376	0	450 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	2	10	0	12
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	2	10	0	12 **

* These totals must agree.

** These totals must agree.

PHS 2590 OTHER SUPPORT

Lamas, Gervasio A. MD

ACTIVE

 (Lamas) 1/10/99 - present
\$500,000

Advanced Elements of Pacing Trial (ADEPT)

The major goal is to determine how effective the dual sensor rate modulation and automatic mode switching features in the Kappa 400 are in improving patients' quality of life.

Overlap: None

105292 09/15/01 - 09/01/05
NIH/NHLBI \$259,250.00
Heart Failure Home Care (HFHC)

The major goal is to compare enhanced heart failure follow-up with conventional care.

Overlap: None

RO1 HL 62509-01A1 (Hochman) 12/1/99 - 11/30/06
NIH/NHLBI \$15,000,000
Occluded Artery Trial (OAT)
Co-Chairman

The major goal is to evaluate if the late reestablishment of blood flow to the artery that caused the heart attack will decrease clinical events and improve the quality of life.

Overlap: None

R01 HL 72906 (Rashba) 9/1/02 - 8/31/06
NIH/NHLBI \$900,000
Electrophysiologic effects of late PCI (OAT-EP)
Co-Chairman

The major goal is to characterize the effects of late PCI of occluded IRAs on the most prognostically important and clinically relevant noninvasive markers of vulnerability to malignant ventricular arrhythmias: heart rate variability, T wave variability and signal averaged electrocardiography.

Overlap: None

U01HL49804 12/1/98 - 9/30/01
NIH/NHLBI \$11,000,000
Mode Selection Trial (MOST)

Clinical benefits of dual versus single chamber pacing.

Overlap: None

1 U01 AT01156-01 (Lamas; PI) 08/15/2002-02/28/2007
NIH/NHLBI \$30,000,000
Trial to Assess Chelation Therapy (TACT)

The major goal of the Trial to Assess Chelation Therapy is to determine whether an intensive course of EDTA chelation, will reduce major adverse coronary events in patients with coronary artery disease who have recovered from a prior myocardial infarction.

Lee, Kerry L.

ACTIVE

HL55297(Lee)
NIH/NHLBI

5/1/97-4/30/04
\$5,085,587 (total costs)

% Effort

Data Coordinating Center for the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT)
The objective of this project is to provide the Statistical and Data Coordinating Center for the multicenter randomized clinical trial of prophylactic amiodarone or implantable defibrillator therapy versus conventional heart failure therapy in patients with Class II or Class III heart failure and a reduced ejection fraction.

(Lee)

5/1/97-4/30/04
\$13,000,000

0%

Data Coordinating Center for the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT)
This grant provides additional support for the SCD-HeFT trial to cover study materials, expenses for investigator/coordinator meetings, and the payments to sites for enrolling and following the study patients.

1U01HL69015-01 (Lee)
NIH/NHLBI

1/1/02-12/31/08
\$2,965,075 (Total Direct Costs)

STICH (Surgical Treatment for Ischemic Heart Failure Trial)
This grant supports the Statistical and Data Coordinating Center for the STICH trial. The study is a multicenter, international, randomized trial in patients with clinical heart failure and left ventricular dysfunction who have coronary artery disease amenable to surgical revascularization.

1U01HL63747 (O'Connor, Christopher)
NIH/NHLBI

9/30/2002-9/29/2007
\$30,179,911 Total Direct Cost

HF-ACTION (A CHF Trial Investigating Outcomes of Exercise Training)
This grant supports the Coordinating Center for the multi-center HF-ACTION trial. The objective of this trial is to assess whether exercise training improves clinical outcomes for heart failure patients.

1 U01-AT01156 (Lamas, G.A.)
NIH/NCCAM/NHLBI/Mt Sinai

8/15/02 - 2/28/07
\$1,879,530 (Year 1 Total Costs)

Trial to Assess Chelation Therapy (TACT)
Duke Clinical Research Institute (under leadership of Dr. Lee) is a subcontractor to Mt. Sinai Medical Center to provide the Statistical and Data Coordinating Center for this trial. The study is a multicenter, randomized clinical trial of chelation therapy in patients with a prior myocardial infarction.

1 U01-HL67972 (Bardy, Gust) 9/30/02 – 8/31/07
NIH/NHLBI/Seattle Institute for Cardiac Research \$430,245 (Year 1 Total Costs)
Home Automatic External Defibrillator Trial – H.A.T.

Duke Clinical Research Institute (under leadership of Dr. Lee) is a subcontractor to the Seattle Institute for Cardiac Research to provide statistical services and perform economic and quality of life analyses for this trial. The study is a multicenter, randomized clinical trial to assess the effects of home use of automatic external defibrillators in reducing mortality in patients with a prior anterior myocardial infarction.

OVERLAP

No overlap exists at this time.

MARK, DANIEL B.

ACTIVE

U01 HL62251 (Mark, Daniel B.; PI) 09/01/1999-08/31/2005
NIH/NHLBI \$222,225
Economics and Quality of Life in the Occluded Artery Trial (OAT)

Role: Principal Investigator

The objective of this study is to establish an Economics and Quality of Life Coordinating Center for the Occluded Artery Trial, a multi-center, randomized trial of late (3-42 days) percutaneous revascularization versus standard medical therapy in 3200 asymptomatic high-risk acute myocardial infarction (MI) survivors and who are found at diagnostic catheterization to have an occluded infarct related artery. Cost, cost effectiveness, and health-related quality of life are secondary endpoints.

U01 HL69011 (Mark, Daniel B.; PI) 01/01/2002-12/31/2008
NIH/NHLBI \$208,533

Economics and Quality of Life Core Laboratory in Surgical Treatment of Ischemic Heart Failure (STICH)

Role: Principal Investigator

The major goal of this substudy of the Surgical Treatment of Heart Failure Trial is to determine cost effectiveness and health-related quality of life of CABG +/- ventricular reconstruction versus medical therapy.

1R01 HL69081-01 (Newman, Mark; PI) 12/01/2001-11/30/2005
NIH \$393,123

Peri-Operative Interventional Neuroprotection Trial: POINT

Role: Co-Investigator

The major goal of this project is to determine the impact of magnesium administration to therapeutic serum levels on short- and long-term neurocognitive function after cardiac surgery evaluated by preoperative and postoperative neurocognitive and neurologic testing.

R01 HS013345-01 (Eisenstein, Eric L.; PI) 09/12/2002-08/31/2005
AHRQ \$227,777

Dialysis Facility Management

Role: Co-Investigator

The goal of this study is to define the impact of dialysis facility characteristics on dialysis patient mortality, morbidity, and total medical costs.

1U01 HL66530 (Mark, Daniel B.; PI) 08/15/2002-08/14/2007
NIH/NHLBI \$86,478

Economics and Quality of Life in the Trial to Assess Chelation Therapy (TACT)
Role: Principal Investigator

The major goal of the Trial to Assess Chelation Therapy is to determine whether an intensive course of EDTA chelation, administered over 18 months, will reduce major adverse coronary events in patients with coronary artery disease who have recovered from a prior myocardial infarction. The objective of this project is to assess the secondary endpoints of cost effectiveness and health-related quality of life of the treatment strategies being tested in TACT.

U01 HL67972-01 (Bardy Gust; PI) 10/01/2002-08/30/2007
NIH/NHLBI \$1,965,243

Home Automatic External Defibrillator Trial (HAT)
Role: Co-Investigator

The major objective of this study is to conduct a randomized clinical trial of automatic external defibrillator therapy, provided by spouses or other family members, superimposed on the local emergency medical system vs. the local emergency medical system in 3400 survivors of anterior myocardial infarction. Duke University will act as subcontractor to Seattle Institute for Cardiac Research for this trial. Duke will provide data management and statistical services for the trial, as well as performing economic and quality of life analyses.

(Mark, Daniel B.; PI) 02/10/1998-12/31/2005
\$335,460

Treating to New Targets (TNT) Economics Substudy
Role: Principal Investigator

The objective of this substudy of the TNT clinical trial is to determine cost effectiveness of lowering LDL-C beyond the currently accepted minimum targets for patients at high risk for developing coronary heart disease.

(Mark, Daniel B.; PI) 01/01/2002 - 12/31/2004
Private Source /Alexion \$95,625

Economic Outcomes in Phase III of Pexelizumab in CABG (PRIMO CABG)
Role: Principal Investigator

The major goals of this substudy are to perform a detailed comparison of medical resource consumption and medical costs in the PRIMO-CABG trial; and to perform a series of cost-effectiveness analyses of the Pexelizumab arm versus placebo in CABG patients.

1U01-AR-052186-01 (Schulman, KA, PI) 09/01/04 - 08/31/09
NIH (NIH Roadmap PRO) \$567,720

Dynamic Outcome Assessment in Multi Center Trials
Role: Co-Investigator

The goal of the Patient-Reported Outcomes Measurement Information System (PROMIS) Network is to develop a unified approach for assessing PROs using computerized adaptive testing (CAT).

(Mark, Daniel, PI) 03/01/2004 - 04/30/2006
Private Source \$126,054

APEX-MI EQOL
Role: Principal Investigator

Principal Investigator/Program Director (*Last, first, middle*): Lamas Gervasio A. MD

The specific objectives of this study are to compare medical resource use patterns and associated medical costs for the Pexelizumab arm versus the control arm by intention-to-treat in patients randomized into APEX-MI; and to perform a cost-effectiveness analysis of Pexelizumab versus control using the empirical outcomes observed in overall APEX-MI and the Economic study to provide base case parameters for the model.

FACT CLINICAL COORDINATING CENTER BUDGET											
Y2005-2006											
Year 4											
								Requested	Awarded	Needed from Carryover	
				Salary	Fringe	Fringe	Salary				
Name	Position	Appointment	Effort	Salary	Requested	Rate	Total	Total			
Gervasio Lamas MD	Study Chairman	12	%	Institution	\$64,480	0	\$0.00	\$64,480			
Jacqueline Arciniega, MPH	Project Director	12	Effort	al Base	\$73,368	0	\$0.00	\$73,368			
Kayvan Arslani, DO	Clinical Trial Manager	12		Salary	\$41,162	0	\$0.00	\$41,162			
Virginia Martini, BA	Admin Coordinator	12			\$28,323	0	\$0.00	\$28,323			
Renee Moes	Office Coordinator	12			\$40,299	0	\$0.00	\$40,299			
Parminder Singh	Research Assistant	12			\$31,360	0	\$0.00	\$31,360			
Jeanette Reed	Research Assistant	12			\$28,513	0	\$0.00	\$28,513			
								Total Salaries	\$327,525		
Consultants				Salary							
Martin Dayton DO				\$3,744							
Theodore Rozema				\$3,744							
Misc. Consultants				\$7,512							
Equipment											
Scanner/ Color Printer		\$500									
								Total equipment	\$500		
Supplies											
copier supplies											
fax supplies											
paper											
								Total supplies	\$10,000		
Travel											
Yearly meetings		\$0									
CCC travel		\$20,504									
								Total Travel	\$20,504		
Patient care costs											
		\$0									
								Total Patient Costs	\$0		
Other expenses											
Telephone		\$12,000									
Pagers		\$2,000									
Postage		\$4,160									
Advertisement		\$10,400									
								Total other (A)	\$28,560		
								Subtotal	\$382,189	\$230,740	\$25,659
Consortium/ contractual costs											
Direct costs											
DCRI		\$1,044,492									
OmniComm		\$120,200									
Brigham and Women's		\$42,203									
Clinical units		\$2,935,409									
Central Pharmacy		\$3,357,529									
Central Lab		\$161,569									
Pharmed		\$125,000									
Total direct costs		\$7,786,393									
Indirect costs											
DCRI		\$831,423									
Brigham and Women's		\$10,551									
Total indirect costs		\$841,974									
								Total Consortium	\$8,328,367	\$4,605,794	\$3,722,573
TOTAL DIRECT COSTS YEAR 4 =>								\$8,710,556	\$4,972,548	\$3,738,508	
COST BASE FOR CALCULATING INDIRECT								\$381,689	\$368,254		
INDIRECT COST								0.63	\$240,464	\$238,740	
TOTAL COST								\$8,961,020	\$5,202,788	\$3,748,232	

Progress Report Scanning Cover Sheet

5U01AT001156-05

PI Name: **LAMAS, GERVASIO**
Org: **MOUNT SINAI MEDICAL CENTER (MIAMI BEACH)**
Start Date: **03/01/2006**
Snap: **N/A (NEEDS TO BE BOOKMARKED)**
Appl ID: **7125411**
Rec'd Date: **12/30/2005**

Grant Number: 5U01AT001156-05 REVISED

Principal Investigator(s):
GERVASIO A LAMAS, MD

Project Title: Trial to Assess Chelation Therapy (TACT)

DIRECTOR OF RESEARCH
MT SINAI MED CTR OF FLORIDA, INC
4300 ALTON ROAD
MIAMI BEACH, FL 33140
MIAMI BEACH, FL

Award e-mailed to: pkatz@mmsmc.com

Budget Period: 03/01/2006 - 06/30/2007
Project Period: 08/15/2002 - 02/28/2010

Dear Business Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Acceptance of this award including the "Terms and Conditions" is acknowledged by the gr Each publication, press release or other document that cites results from NIH grant-sup. Award recipients are strongly encouraged to submit to PubMed Central (PMC), upon accept If you have any questions about this award, please contact the individual(s) referenced Sincerely yours,

George Tucker
Grants Management Officer
NATIONAL CENTER FOR COMPLEMENTARY & ALTERNATIVE MEDICINE

Additional information follows
SECTION I - AWARD DATA - 5U01AT001156-05 REVISED

Award Calculation (U.S. Dollars)			
Salaries and Wages		\$194,018	
Personnel Costs (Subtotal)			\$194,018
Consultant Services		\$15,111	
Supplies	\$6,720		
Travel Costs	\$120,955		
Other Costs	\$33,656		
Consortium/Contractual Cost			\$4,787,081

Federal Direct Costs
\$5,157,541
Federal F&A Costs
\$233,390

Approved Budget
\$5,390,931
Federal Share
\$5,390,931
Less Unobligated Balance
\$5,390,931
TOTAL FEDERAL AWARD AMOUNT
\$0

AMOUNT OF THIS ACTION (FEDERAL SHARE)
\$0

SUMMARY TOTALS FOR ALL YEARS
YR
THIS AWARD
CUMULATIVE TOTALS

5
\$0
\$0

Fiscal Information:

CFDA Number:
93.837

EIN:

Document Number:

U1AT01156A

Fiscal Year:
2006

IC
CAN
2006
HL
8424300
\$0
AT
8424951
\$0

NIH Administrative Data:

PCC: 10 / OC: 414P / Processed: TUCKERG 09/19/2007

SECTION II - PAYMENT/HOTLINE INFORMATION - 5U01AT001156-05 REVISED

For payment and HHS Office of Inspector General Hotline information, see the NIH Home P

SECTION III - TERMS AND CONDITIONS - 5U01AT001156-05 REVISED

This award is based on the application submitted to, and as approved by, NIH on the abo

- a. The grant program legislation and program regulation cited in this Notice of Award.
- b. The restrictions on the expenditure of federal funds in appropriations acts to the ex
- c. 45 CFR Part 74 or 45 CFR Part 92 as applicable.
- d. The NIH Grants Policy Statement, including addenda in effect as of the beginning date
- e. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at '<http://grants.nih.gov/grants/policy/awardconditions.htm>' for cer
Carry over of an unobligated balance into the next budget period requires Grants Manage
This award provides support for one or more NIH defined Phase III Clinical Trials. The
A description of plans to conduct analyses, as appropriate, by sex/gender and racial/et

This award is funded by the following list of institutes. Any papers published under t

National Heart, Lung, And Blood Institute (NHLBI)

National Center For Complementary & Alternative Medicine (NCCAM)

Treatment of Program Income:
Additional Costs

SECTION IV - AT Special Terms and Conditions - 5U01AT001156-05 REVISED

Principal Investigator(s):
Gervasio A. Lamas, MD
Revision #5

REVISION INFORMATION:
Revised Notice of Award (NOA) issued to change project period end date, per request of

REVISION #4
REVISION INFORMATION:
Revised Notice of Award (NOA) issued to change project and budget period end dates. Sup

REVISION #3
REVISION INFORMATION:
Revised Notice of Grant Award (NGA) issued to terminate grant early in order to transfe

REVISION #2
REVISION INFORMATION:
Revised Notice of Grant Award (NGA) issued to add additional years to the grant in orde

REVISION #1
REVISION INFORMATION:
Revised Notice of Grant Award (NGA) issued to rescind foreign clearance restriction. Su

FOREIGN RESTRICTION RESCINDED:
Revised Notice of Grant Award (NGA) issued to rescind restriction and provide approval

PREVIOUS TERMS AND CONDITIONS:
Refer to original NGA for a complete description of terms and conditions.

NIH FUNDING ACKNOWLEDGEMENT REQUIREMENT:

INTERIM PROGRESS REPORT RESTRICTION:

PUBLIC ACCESS:

FY06 BUDGET ADJUSTMENT INFORMATION:

CO-FUNDING INFORMATION:

HUMAN SUBJECTS RESEARCH INFORMATION:

PARTICIPANT RECRUITMENT REQUIREMENT:

CONSORTIUM/CONTRACTUAL COST INFORMATION:

FINAL YEAR CLOSEOUT REQUIREMENTS:

STAFF CONTACTS

The Grants Management Specialist is responsible for the negotiation, award and administ

Grants Management Specialist: Alice Robinson
Email: robinsona@mail.nih.gov Phone: (301) 594-8738 Fax: (301) 480-1552

Program Official: Richard Nahin
Email: nahinr@od.nih.gov Phone: (301)-496-7801 Fax: (301) 435-6549

SPREADSHEET SUMMARY

GRANT NUMBER: 5U01AT001156-05 REVISED

INSTITUTION: MOUNT SINAI MEDICAL CENTER (MIAMI BEACH)

Budget
Year 5
Salaries and Wages
\$194,018
Personnel Costs (Subtotal)
\$194,018
Consultant Services
\$15,111
Supplies
\$6,720
Travel Costs
\$120,955
Other Costs
\$33,656
Consortium/Contractual Cost
\$4,787,081
TOTAL FEDERAL DC
\$5,157,541
TOTAL FEDERAL F&A
\$233,390
TOTAL COST
\$0

Facilities and Administrative Costs

Year 5
F&A Cost Rate 1
63%
F&A Cost Base 1
\$370,460
F&A Costs 1
\$233,390

.....END OF NGA.....

Grant Number: 5U01AT001156-05 REVISED

Principal Investigator(s):
GERVASIO A LAMAS, MD

Project Title: Trial to Assess Chelation Therapy (TACT)

DIRECTOR OF RESEARCH
MT SINAI MED CTR OF FLORIDA, INC
4300 ALTON ROAD
MIAMI BEACH, FL 33140
MIAMI BEACH, FL

Award e-mailed to: pkatz@msmc.com

Budget Period: 03/01/2006 - 06/30/2007
Project Period: 08/15/2002 - 06/30/2007

Dear Business Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Acceptance of this award including the "Terms and Conditions" is acknowledged by the gr Each publication, press release or other document that cites results from NIH grant-sup. Award recipients are strongly encouraged to submit to PubMed Central (PMC), upon accept If you have any questions about this award, please contact the individual(s) referenced Sincerely yours,

George Tucker
Grants Management Officer
NATIONAL CENTER FOR COMPLEMENTARY & ALTERNATIVE MEDICINE

Additional information follows
SECTION I - AWARD DATA - 5U01AT001156-05 REVISED

Award Calculation (U.S. Dollars)			
Salaries and Wages		\$194,018	
Personnel Costs (Subtotal)		\$194,018	
Consultant Services		\$15,111	
Supplies	\$6,720		
Travel Costs	\$120,955		
Other Costs	\$33,656		
Consortium/Contractual Cost			\$4,787,081

Federal Direct Costs
\$5,157,541
Federal F&A Costs
\$233,390
Approved Budget
\$5,390,931
Federal Share
\$5,390,931
Less Unobligated Balance
\$5,390,931
TOTAL FEDERAL AWARD AMOUNT
\$0

AMOUNT OF THIS ACTION (FEDERAL SHARE)
\$0

SUMMARY TOTALS FOR ALL YEARS
YR
THIS AWARD
CUMULATIVE TOTALS

5
\$0
\$0

Fiscal Information:

CFDA Number:

93.837

EIN:

EN

Document Number:

U1AT01156A

Fiscal Year:

2006

IC

CAN

2006

HL

8424300

\$0

AT

8424951

\$0

NIH Administrative Data:

FCC: 10 / OC: 414P / Processed: TUCKERG 08/29/2007

SECTION II - PAYMENT/HOTLINE INFORMATION - 5U01AT001156-05 REVISED

For payment and HHS Office of Inspector General Hotline information, see the NIH Home P

SECTION III - TERMS AND CONDITIONS - 5U01AT001156-05 REVISED

This award is based on the application submitted to, and as approved by, NIH on the abo

a. The grant program legislation and program regulation cited in this Notice of Award.

b. The restrictions on the expenditure of federal funds in appropriations acts to the ex

c. 45 CFR Part 74 or 45 CFR Part 92 as applicable.

d. The NIH Grants Policy Statement, including addenda in effect as of the beginning date

e. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at '<http://grants.nih.gov/grants/policy/awardconditions.htm>' for cer

Carry over of an unobligated balance into the next budget period requires Grants Manage

This award provides support for one or more NIH defined Phase III Clinical Trials. The

A description of plans to conduct analyses, as appropriate, by sex/gender and racial/et

This award is funded by the following list of institutes. Any papers published under t

National Heart, Lung, And Blood Institute (NHLBI)

National Center For Complementary & Alternative Medicine (NCCAM)

Treatment of Program Income:

Additional Costs

SECTION IV - AT Special Terms and Conditions - 5U01AT001156-05 REVISED

Principal Investigator(s):

Gervasio A. Lamas, MD

Revision #4

REVISION INFORMATION:

Revised Notice of Award (NoA) issued to change project and budget period end dates. Sup

REVISION #3

REVISION INFORMATION:

Revised Notice of Grant Award (NGA) issued to terminate grant early in order to transfe

REVISION #2

REVISION INFORMATION:

Revised Notice of Grant Award (NGA) issued to add additional years to the grant in orde

REVISION #1

REVISION INFORMATION:

Revised Notice of Grant Award (NGA) issued to rescind foreign clearance restriction. Su

FOREIGN RESTRICTION RESCINDED:

Revised Notice of Grant Award (NGA) issued to rescind restriction and provide approval

PREVIOUS TERMS AND CONDITIONS:

Refer to original NGA for a complete description of terms and conditions.

NIH FUNDING ACKNOWLEDGEMENT REQUIREMENT:

INTERIM PROGRESS REPORT RESTRICTION:

PUBLIC ACCESS:

FY06 BUDGET ADJUSTMENT INFORMATION:

CO-FUNDING INFORMATION:

HUMAN SUBJECTS RESEARCH INFORMATION:

PARTICIPANT RECRUITMENT REQUIREMENT:

CONSORTIUM/CONTRACTUAL COST INFORMATION:

FINAL YEAR CLOSEOUT REQUIREMENTS:

STAFF CONTACTS

The Grants Management Specialist is responsible for the negotiation, award and administ

Grants Management Specialist: Alice Robinson
Email: robinsona@mail.nih.gov Phone: (301) 594-8738 Fax: (301) 480-1552

Program Official: Richard Nahin
Email: nahinr@od.nih.gov Phone: (301)-496-7801 Fax: (301) 435-6549

SPREADSHEET SUMMARY

GRANT NUMBER: 5U01AT001156-05 REVISED

INSTITUTION: MOUNT SINAI MEDICAL CENTER (MIAMI BEACH)

Budget

Year 5

Salaries and Wages

\$194,018

Personnel Costs (Subtotal)

\$194,018

Consultant Services

\$15,111

Supplies

\$6,720

Travel Costs

\$120,955

Other Costs

\$33,656

Consortium/Contractual Cost

\$4,787,081

TOTAL FEDERAL DC

\$5,157,541

TOTAL FEDERAL F&A

\$233,390

TOTAL COST

\$0

Facilities and Administrative Costs

Year 5

F&A Cost Rate 1

63%

F&A Cost Base 1

\$370,460

F&A Costs 1

\$233,390

.....END OF NGA.....

Grant Number: 5U01AT001156-05 REVISED

Principal Investigator(s):
GERVASIO A LAMAS, MD

Project Title: Trial to Assess Chelation Therapy (TACT)

DIRECTOR OF RESEARCH
MT SINAI MED CTR OF FLORIDA, INC
4300 ALTON ROAD
MIAMI BEACH, FL 33140
MIAMI BEACH, FL
Award e-mailed to: pkatz@msmc.com

Budget Period: 03/01/2006 - 07/31/2007
Project Period: 08/15/2002 - 07/31/2007

Dear Business Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in
Acceptance of this award including the "Terms and Conditions" is acknowledged by the gr
Each publication, press release or other document that cites results from NIH grant-sup
Award recipients are strongly encouraged to submit to PubMed Central (PMC), upon accept
If you have any questions about this award, please contact the individual(s) referenced
Sincerely yours,

George Tucker
Grants Management Officer
NATIONAL CENTER FOR COMPLEMENTARY & ALTERNATIVE MEDICINE

Additional information follows
SECTION I - AWARD DATA - 5U01AT001156-05 REVISED

Award Calculation (U.S. Dollars)			
Salaries and Wages		\$194,018	
Personnel Costs (Subtotal)			\$194,018
Consultant Services		\$15,111	
Supplies	\$6,720		
Travel Costs	\$120,955		
Other Costs	\$33,656		
Consortium/Contractual Cost			\$4,787,081

Federal Direct Costs

\$5,157,541
Federal F&A Costs
\$233,390
Approved Budget
\$5,390,931
Federal Share
\$5,390,931
Less Unobligated Balance
\$5,390,931
TOTAL FEDERAL AWARD AMOUNT
\$0

AMOUNT OF THIS ACTION (FEDERAL SHARE)
\$0

SUMMARY TOTALS FOR ALL YEARS
YR
THIS AWARD
CUMULATIVE TOTALS

5
\$0
\$0

Recommended future year total cost support, subject to the availability of funds and sa

Fiscal Information:

CFDA Number:

93.837

EIN:

EIN

Document Number:

U1AT01156A

Fiscal Year:

2006

IC
CAN
2006
HL
8424300
\$0
AT
8424951
\$0

Recommended future year total cost support , subject to the availability of funds and s

NIH Administrative Data:

PCC: 10 / OC: 414P / Processed: TUCKERG 07/24/2007

SECTION II - PAYMENT/HOTLINE INFORMATION - 5U01AT001156-05 REVISED

For payment and HHS Office of Inspector General Hotline information, see the NIH Home P

SECTION III - TERMS AND CONDITIONS - 5U01AT001156-05 REVISED

This award is based on the application submitted to, and as approved by, NIH on the abo

a.The grant program legislation and program regulation cited in this Notice of Award.

- b. The restrictions on the expenditure of federal funds in appropriations acts to the extent of 45 CFR Part 74 or 45 CFR Part 92 as applicable.
- d. The NIH Grants Policy Statement, including addenda in effect as of the beginning date of this award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at '<http://grants.nih.gov/grants/policy/awardconditions.htm>' for details.)

Carry over of an unobligated balance into the next budget period requires Grants Management System approval.

This award provides support for one or more NIH defined Phase III Clinical Trials. The award includes a description of plans to conduct analyses, as appropriate, by sex/gender and racial/ethnic group.

This award is funded by the following list of institutes. Any papers published under this award should be submitted to the following:

National Heart, Lung, And Blood Institute (NHLBI)

National Center For Complementary & Alternative Medicine (NCCAM)

Treatment of Program Income:
Additional Costs

SECTION IV - AT Special Terms and Conditions - 5U01AT001156-05 REVISED

Principal Investigator(s):
Gervasio A. Lamas, MD
Revision #3

REVISION INFORMATION:
Revised Notice of Grant Award (NGA) issued to terminate grant early in order to transfer funds to another grant.

REVISION #2
REVISION INFORMATION:
Revised Notice of Grant Award (NGA) issued to add additional years to the grant in order to complete the study.

REVISION #1
REVISION INFORMATION:
Revised Notice of Grant Award (NGA) issued to rescind foreign clearance restriction. See attached for details.

FOREIGN RESTRICTION RESCINDED:
Revised Notice of Grant Award (NGA) issued to rescind restriction and provide approval for foreign travel.

PREVIOUS TERMS AND CONDITIONS:
Refer to original NGA for a complete description of terms and conditions.

NIH FUNDING ACKNOWLEDGEMENT REQUIREMENT:

INTERIM PROGRESS REPORT RESTRICTION:

PUBLIC ACCESS:

FY06 BUDGET ADJUSTMENT INFORMATION:

CO-FUNDING INFORMATION:

HUMAN SUBJECTS RESEARCH INFORMATION:

PARTICIPANT RECRUITMENT REQUIREMENT:

CONSORTIUM/CONTRACTUAL COST INFORMATION:

FINAL YEAR CLOSEOUT REQUIREMENTS:

STAFF CONTACT INFORMATION:

The Grants Management Specialist is responsible for the negotiation, award and administ

STAFF CONTACTS

Grants Management Specialist: Alice Robinson

Email: robinsona@mail.nih.gov Phone: (301) 594-8738 Fax: (301) 480-1552

Program Official: Richard Nahin

Email: nahinr@od.nih.gov Phone: (301)-496-7801 Fax: (301) 435-6549

SPREADSHEET SUMMARY

GRANT NUMBER: 5U01AT001156-05 REVISED

INSTITUTION: MOUNT SINAI MEDICAL CENTER (MIAMI BEACH)

Budget

Year 5

Salaries and Wages

\$194,018

Personnel Costs (Subtotal)

\$194,018

Consultant Services

\$15,111

Supplies

\$6,720

Travel Costs

\$120,955

Other Costs

\$33,656

Consortium/Contractual Cost

\$4,787,081

TOTAL FEDERAL DC

\$5,157,541

TOTAL FEDERAL F&A

\$233,390

TOTAL COST

\$0

Facilities and Administrative Costs

Year 5

F&A Cost Rate 1

63%

F&A Cost Base 1

\$370,460

F&A Costs 1

\$233,390

.....END OF NGA.....

Grant Number: 5U01AT001156-05 REVISED

Principal Investigator(s):
GERVASIO A LAMAS, MD

Project Title: Trial to Assess Chelation Therapy (TACT)

DIRECTOR OF RESEARCH
MT SINAI MED CTR OF FLORIDA, INC
4300 ALTON ROAD
MIAMI BEACH, FL 33140
MIAMI BEACH, FL

Budget Period: 03/01/2006 - 02/28/2008
Project Period: 08/15/2002 - 02/28/2009

Dear Business Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Acceptance of this award including the "Terms and Conditions" is acknowledged by the grantee. Each publication, press release or other document that cites results from NIH grant-supported award recipients are strongly encouraged to submit to PubMed Central (PMC), upon acceptance. If you have any questions about this award, please contact the individual(s) referenced below.

Sincerely yours,

George Tucker
Grants Management Officer
NATIONAL CENTER FOR COMPLEMENTARY & ALTERNATIVE MEDICINE

Additional information follows
SECTION I - AWARD DATA - 5U01AT001156-05 REVISED

Award Calculation (U.S. Dollars)			
Salaries and Wages		\$194,018	
Personnel Costs (Subtotal)			\$194,018
Consultant Services		\$15,111	
Supplies	\$6,720		
Travel Costs	\$120,955		
Other Costs	\$33,656		
Consortium/Contractual Cost			\$4,787,081

Federal Direct Costs
\$5,157,541
Federal F&A Costs
\$233,390
Approved Budget
\$5,390,931

Federal Share
\$5,390,931
Less Unobligated Balance
\$5,390,931
TOTAL FEDERAL AWARD AMOUNT
\$0

AMOUNT OF THIS ACTION (FEDERAL SHARE)
\$0

SUMMARY TOTALS FOR ALL YEARS
YR
THIS AWARD
CUMULATIVE TOTALS

5
\$0
\$0

6
\$1
\$1

Recommended future year total cost support, subject to the availability of funds and sa

Fiscal Information:

CFDA Number:

93.837

FIN:

Document Number:

U1AT01156A

Fiscal Year:

2006

IC

CAN

2006

2008

HL

8424300

\$0

\$1

AT

8424951

\$0

Recommended future year total cost support , subject to the availability of funds and s

NIH Administrative Data:

PCC: 10 / OC: 414P / Processed: TUCKERG 07/12/2007

SECTION II - PAYMENT/HOTLINE INFORMATION - 5U01AT001156-05 REVISED

For payment and HHS Office of Inspector General Hotline information, see the NIH Home P

SECTION III - TERMS AND CONDITIONS - 5U01AT001156-05 REVISED

This award is based on the application submitted to, and as approved by, NIH on the abo

- a. The grant program legislation and program regulation cited in this Notice of Award.
- b. The restrictions on the expenditure of federal funds in appropriations acts to the extent of 45 CFR Part 74 or 45 CFR Part 92 as applicable.
- d. The NIH Grants Policy Statement, including addenda in effect as of the beginning date of the award.
- e. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at '<http://grants.nih.gov/grants/policy/awardconditions.htm>' for details.)

Carry over of an unobligated balance into the next budget period requires Grants Management System (GMS) approval.

This award provides support for one or more NIH defined Phase III Clinical Trials. The award includes support for the following activities:

- A description of plans to conduct analyses, as appropriate, by sex/gender and racial/ethnic group.

This award is funded by the following list of institutes. Any papers published under this award should be submitted to the following journals:

National Center For Complementary & Alternative Medicine (NCCAM)

National Heart, Lung, And Blood Institute (NHLBI)

Treatment of Program Income:
Additional Costs

SECTION IV - AT Special Terms and Conditions - SU01AT001156-05 REVISED

Principal Investigator(s):
Gervasio A. Lamas, MD
Revision #2

REVISION INFORMATION:
Revised Notice of Grant Award (NGA) issued to add additional years to the grant in order to complete the study.

REVISION #1
REVISION INFORMATION:
Revised Notice of Grant Award (NGA) issued to rescind foreign clearance restriction. See the attached NGA for details.

FOREIGN RESTRICTION RESCINDED:
Revised Notice of Grant Award (NGA) issued to rescind restriction and provide approval for the award.

PREVIOUS TERMS AND CONDITIONS:
Refer to original NGA for a complete description of terms and conditions.

NIH FUNDING ACKNOWLEDGEMENT REQUIREMENT:

INTERIM PROGRESS REPORT RESTRICTION:

PUBLIC ACCESS:

FY06 BUDGET ADJUSTMENT INFORMATION:

CO-FUNDING INFORMATION:

HUMAN SUBJECTS RESEARCH INFORMATION:

PARTICIPANT RECRUITMENT REQUIREMENT:

CONSORTIUM/CONTRACTUAL COST INFORMATION:

FINAL YEAR CLOSEOUT REQUIREMENTS:

STAFF CONTACT INFORMATION:

The Grants Management Specialist is responsible for the negotiation, award and administ

STAFF CONTACTS

Grants Management Specialist: Alice Robinson

Email: robinsona@mail.nih.gov Phone: (301) 594-8738 Fax: (301) 480-1552

Program Official: Richard Nahin

Email: nahinr@od.nih.gov Phone: (301)-496-7801 Fax: (301) 435-6549

SPREADSHEET SUMMARY

GRANT NUMBER: 5U01AT001156-05 REVISED

INSTITUTION: MOUNT SINAI MEDICAL CENTER (MIAMI BEACH)

Budget

Year 5

Year 6

Salaries and Wages

\$194,018

Personnel Costs (Subtotal)

\$194,018

Consultant Services

\$15,111

Supplies

\$6,720

Travel Costs

\$120,955

Other Costs

\$33,656

\$1

Consortium/Contractual Cost

\$4,787,081

TOTAL FEDERAL DC

\$5,157,541

\$1

TOTAL FEDERAL F&A

\$233,390

TOTAL COST

\$0

\$1

Facilities and Administrative Costs

Year 5

Year 6

F&A Cost Rate 1

638

F&A Cost Base 1
\$370,460

F&A Costs 1
\$233,390

.....END OF NGA.....

***** NOTICE OF GRANT AWARD *****
RESEARCH PROJECT COOPERATIVE AGREEMENT Issue Date:09/29/2006

Department of Health and Human Services
National Institutes of Health
NATIONAL CENTER FOR COMPLEMENTARY & ALTERNATIVE MEDICINE

Grant Number: 5 U01 AT001156-05 (Revised)
Principal Investigator: LAMAS, GERVASIO A MD
Project Title: Trial to Assess Chelation Therapy (TACT)

DIRECTOR OF RESEARCH
MT SINAI MED CTR OF FLORIDA, INC
4300 ALTON ROAD
MIAMI BEACH, FL 33140
MIAMI BEACH, FL
UNITED STATES
Award e-mailed to: pkatz@msmc.com

Budget Period: 03/01/2006 - 02/28/2007
Project Period: 08/15/2002 - 02/28/2007

Dear Business Official:

The National Institutes of Health hereby revises this award (see 'Award Calculation' in Section I and 'Terms and Conditions' in Section III) to MOUNT SINAI MEDICAL CENTER (MIAMI BEACH) in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 31 USC 6305 & 6306 and is subject to terms and conditions referenced below.

Acceptance of this award including the Terms and Conditions is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

Award recipients are responsible for reporting inventions derived or reduced to practice in the performance of work under this grant. Rights to inventions vest with the grantee organization provided certain requirements are met and there is acknowledgement of NIH support. In addition, recipients must ensure that patent and license activities are consistent with their responsibility to make unique research resources developed under this award available to the scientific community, in

accordance with NIH policy. For additional information, please visit
<http://www.iedison.gov>.

If you have any questions about this award, please contact the
individual(s) referenced in the information below.

Sincerely yours,

George Tucker
Grants Management Officer
NATIONAL CENTER FOR COMPLEMENTARY & ALTERNATIVE MEDICINE

See additional information below

SECTION I - AWARD DATA - 5 U01 AT001156-05 (Revised)

AWARD CALCULATION (U.S. Dollars):

Salaries and Wages	\$194,018
Personnel Costs (Subtotal)	\$194,018
Consultant Services	\$15,111
Supplies	\$6,720
Travel Costs	\$120,955
Other Costs	\$33,656
Consortium/Contractual Cost	\$4,787,081
Federal Direct Costs	\$5,157,541
Federal F&A Costs	\$233,390
Less Unobligated Balance	\$5,390,931
TOTAL FEDERAL AWARD AMOUNT	\$0
AMOUNT OF THIS ACTION (FEDERAL SHARE)	+\$0

FISCAL INFORMATION:

CFDA 93.837

Number:

EIN

Document Number: U1AT01156A

IC/ CAN / FY2006

AT/8424951/ 0

HL/8424300/ 0

NIH ADMINISTRATIVE DATA:

PCC: 10 / OC: 41.4P /Processed: TUCKERG 060928 0134

SECTION II - PAYMENT/HOTLINE INFORMATION - 5 U01 AT001156-05 (Revised)

For Payment and HHS Office of Inspector General Hotline Information,

see the NIH Home Page at
<http://grants.nih.gov/grants/policy/awardconditions.htm>

SECTION III - TERMS AND CONDITIONS - 5 U01 AT001156-05 (Revised)

This award is based on the application submitted to, and as approved by, the NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

- a. The grant program legislation and program regulation cited in this Notice of Grant Award.
- b. The restrictions on the expenditure of federal funds in appropriations acts, to the extent those restrictions are pertinent to the award.
- c. 45 CFR Part 74 or 45 CFR Part 92 as applicable.
- d. The NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
- e. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(see NIH Home Page at
<http://grants.nih.gov/grants/policy/awardconditions.htm> for certain references cited above.)

Carry over of an unobligated balance into the next budget period requires Grants Management Officer prior approval.

This award provides support for one or more NIH defined Phase III

clinical trials. The NIH Policy for research supported as an NIH Phase III Clinical Trial has been amended in Section II.B. of the NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research - Amended October 2001
http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm.

A description of plans to conduct analyses, as appropriate, by sex/gender and racial/ethnic groups must be included in clinical trial protocols. Cumulative subject accrual and progress in conducting subset analyses must be reported to NIH in the annual Progress Reports. Final analyses of sex/gender and racial/ethnic differences must be reported in the required Final Progress Report or Competitive Renewal Applications (or Contract Renewals/Extensions) as stated in Section II.B. of the Guidelines.

Treatment of Program Income:
Additional Costs

SECTION IV - ADDITIONAL TERMS AND CONDITIONS
5 U01 AT01156-05 (Revision #1)
Gervasio A. Lamas, MD

REVISION INFORMATION:

Revised Notice of Grant Award (NGA) issued to rescind foreign clearance restriction. Supersedes NGA issued on 07/13/2006. All other terms and conditions still applicable are incorporated by subtitle listed below.

FOREIGN RESTRICTION RESCINDED:

Revised Notice of Grant Award (NGA) issued to rescind restriction and provide approval for foreign involvement to Canada. State Department clearance for Canada has been approved.

PREVIOUS TERMS AND CONDITIONS:

Refer to original NGA for a complete description of terms and conditions.

NIH FUNDING ACKNOWLEDGEMENT REQUIREMENT:

INTERIM PROGRESS REPORT RESTRICTION:

PUBLIC ACCESS:

FY06 BUDGET ADJUSTMENT INFORMATION:

CO-FUNDING INFORMATION:

HUMAN SUBJECTS RESEARCH INFORMATION:

PARTICIPANT RECRUITMENT REQUIREMENT:

CONSORTIUM/CONTRACTUAL COST INFORMATION:

FINAL YEAR CLOSEOUT REQUIREMENTS:

STAFF CONTACTS:

Richard Nahin, Program Official

Phone: (301)-496-7801 Email: nahinr@od.nih.gov Fax: (301) 435-6549

□

Alice Robinson, Grants Specialist

Phone: (301) 594-8738 Email: robinsona@mail.nih.gov Fax: (301) 480-1552

SPREADSHEET

GRANT NUMBER: 5 U01 AT001156-05 (Revised)

□

P.I.: LAMAS, GERVASIO A

INSTITUTION: MOUNT SINAI MEDICAL CENTER (MIAMI BEACH)

	YEAR 05
	=====
Salaries and Wages	194,018
Personnel Costs	194,018
(Subtotal)	
Consultant Services	15,111
Supplies	6,720
Travel Costs	120,955
Other Costs	33,656
Consortium/Contractual	4,787,081
Cost	
TOTAL FEDERAL DC	5,157,541

TOTAL FEDERAL F&A 233,390
TOTAL COST 5,390,931

YEAR 05

=====
F&A Cost Rate 1 63.00%
F&A Cost Base 1 370,460

F&A Costs 1 233,390

.....END OF NGA.....

***** NOTICE OF GRANT AWARD *****
RESEARCH PROJECT COOPERATIVE AGREEMENT Issue Date:07/13/2006

Department of Health and Human Services
National Institutes of Health
NATIONAL CENTER FOR COMPLEMENTARY & ALTERNATIVE MEDICINE

Grant Number: 5 U01 AT001156-05
Principal Investigator: LAMAS, GERVASIO A MD
Project Title: Trial to Assess Chelation Therapy (TACT)

DIRECTOR OF RESEARCH
MT SINAI MED CTR OF FLORIDA, INC
4300 ALTON ROAD
MIAMI BEACH, FL 33140
MIAMI BEACH, FL
UNITED STATES

Budget Period: 03/01/2006 - 02/28/2007
Project Period: 08/15/2002 - 02/28/2007

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of \$0(see 'Award Calculation' in Section I) to MOUNT SINAI MEDICAL CENTER (MIAMI BEACH) in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 31 USC 6305 & 6306 and is subject to terms and conditions referenced below.

Acceptance of this award including the Terms and Conditions is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

Award recipients are responsible for reporting inventions derived or reduced to practice in the performance of work under this grant. Rights to inventions vest with the grantee organization provided certain requirements are met and there is acknowledgement of NIH support. In addition, recipients must ensure that patent and license activities are consistent with their responsibility to make unique research resources developed under this award available to the scientific community, in

accordance with NIH policy. For additional information, please visit <http://www.iedison.gov>.

If you have any questions about this award, please contact the individual(s) referenced in the information below.

Sincerely yours,

George Tucker
Grants Management Officer
NATIONAL CENTER FOR COMPLEMENTARY & ALTERNATIVE MEDICINE

See additional information below

SECTION I - AWARD DATA - 5 U01 AT001156-05

AWARD CALCULATION (U.S. Dollars):

Salaries and Wages	\$194,018
Consultant Services	\$15,111
Supplies	\$6,720
Travel Costs	\$120,955
Other Costs	\$33,656
Consortium/Contractual Cost	\$4,787,081
Federal Direct Costs	\$5,157,541
Federal F&A Costs	\$233,390
Less Unobligated Balance	\$5,390,931
TOTAL FEDERAL AWARD AMOUNT	\$0

FISCAL INFORMATION:

CFDA 93.837

Document Number: U1AT01156A

IC/ CAN / FY2006
AT/8424951/ 0
HL/8424300/ 0

NIH ADMINISTRATIVE DATA:

PCC: 10 / OC: 41.4P /Processed: TUCKERG 060712 0243

SECTION II - PAYMENT/HOTLINE INFORMATION - 5 U01 AT001156-05

For Payment and HHS Office of Inspector General Hotline Information,
see the NIH Home Page at
<http://grants.nih.gov/grants/policy/awardconditions.htm>

SECTION III - TERMS AND CONDITIONS - 5 U01 AT001156-05

This award is based on the application submitted to, and as approved by, the NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

- a. The grant program legislation and program regulation cited in this Notice of Grant Award.
- b. The restrictions on the expenditure of federal funds in appropriations acts, to the extent those restrictions are pertinent to the award.
- c. 45 CFR Part 74 or 45 CFR Part 92 as applicable.
- d. The NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
- e. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(see NIH Home Page at <http://grants.nih.gov/grants/policy/awardconditions.htm> for certain references cited above.)

Carry over of an unobligated balance into the next budget period
requires Grants Management Officer prior approval.

This award provides support for one or more NIH defined Phase III clinical trials. The NIH Policy for research supported as an NIH Phase III Clinical Trial has been amended in Section II.B. of the NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research - Amended October 2001

http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm.

A description of plans to conduct analyses, as appropriate, by sex/gender and racial/ethnic groups must be included in clinical trial protocols. Cumulative subject accrual and progress in conducting subset analyses must be reported to NIH in the annual Progress Reports. Final analyses of sex/gender and racial/ethnic differences must be reported in the required Final Progress Report or Competitive Renewal Applications (or Contract Renewals/Extensions) as stated in Section II.B. of the Guidelines.

Treatment of Program Income:
Additional Costs

SECTION IV - ADDITIONAL TERMS AND CONDITIONS
5 U01 AT01156-05
Gervasio A. Lamas, MD

NIH FUNDING ACKNOWLEDGEMENT REQUIREMENT:
Grantees are required to place an acknowledgement of NIH grant support and a disclaimer, as appropriate, on any publication written or published with such support and, if feasible, on any publication reporting the results of, or describing, a grant-supported activity. An acknowledgment shall be to the effect that:

"This publication or project was made possible by Grant Number ___ from

the National Center for Complementary and Alternative Medicine (NCCAM). Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the NCCAM, or the National Institutes of Health."

Grant recipients presenting NCCAM-sponsored research at scientific, professional, and consumer meetings are asked to acknowledge the publicly funded support they receive. A copy of the NCCAM Grantee Acknowledgement slide in PowerPoint is available at:
<http://nccam.nih.gov/research/acknowledgement.htm>

INTERIM PROGRESS REPORT RESTRICTION:

No additional funds are being awarded for the 05 year of this grant, due to the following: 1) concerns regarding patient recruitment being behind schedule; and, 2) substantial carry-over from previous years.

Should the status change, notification will occur via the issuance of a revised Notice of Grant Award.

PUBLIC ACCESS:

Award recipients are strongly encouraged to submit to PubMed Central (PMC), upon acceptance for publication, an electronic version of peer-reviewed, original research publications, resulting from research supported in whole or in part, with direct costs from NIH. The author's final manuscript is defined as the final version accepted for journal publication, and includes all modifications from the publishing peer review process. For additional information, please visit
<http://www.nih.gov/about/publicaccess/>.

FY06 BUDGET ADJUSTMENT INFORMATION:

Non-competing awards for every RPG will be awarded at a level of 97.65 of the amount indicated for the FY2006 budget period in the Notice of Grant Award for the previous budget year. The amounts indicated for future budget periods will be held to this level except for approved changes to program levels in future years (increases or decreases in supported activities).

CO-FUNDING INFORMATION:

This award includes funding from the National Center for Complementary and Alternative Medicine and the National Heart Lung and Blood Institute (NHLBI) that are providing the co-funding. Any papers
□

published under the auspices of this award must cite the funding support of all institutes.

HUMAN SUBJECTS RESEARCH INFORMATION:

See the NIH Grants Policy Statement (rev. 12/03), Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General, Human Subjects, for specific requirements related to the protection of human subjects, which are applicable to and a term and condition of this award. This information is available online at the following NIH website:
http://grants2.nih.gov/grants/policy/nihgps_2003/NIHGPs_Part5.htm#_Toc54600083

Notice: Under governing regulations, Federal funds administered by the department of Health and Human Services may not be expended for research involving human subjects and individuals may not be enrolled in research at any site, domestic or foreign, that does not have an Office for Human Research Protections (OHRP)-approved Assurance to comply with the requirements of 45 CFR Part 46 to protect human subjects and an Institutional Review Board (IRB) approval of the research that satisfies

the requirements of 45 CFR Part 46.

It is the grantee institution's responsibility (1) to ensure that all sites engaged in research involving human subjects have an appropriate OHRP-approved Assurance and an IRB approval of the research consistent with 45 CFR Part 46 and (2) to retain documentation of compliance with the requirements of 45 CFR Part 46. The list of institutions with approved Assurances and information on and instructions for submitting and negotiating a Federal wide Assurance of Protection for Human Subjects are available at the OHRP website: <http://www.hhs.gov/ohrp/>

No funds may be drawn down from the payment system and no obligations may be made against Federal funds for research involving human subjects at any site engaged in such research for any period not covered by an OHRP-approved Assurance and an IRB approval consistent with 45 CFR Part 46. Failure to comply with the above requirements may result in suspension and/or termination of this award, withholding of support, audit disallowances, and/or other appropriate action.

PARTICIPANT RECRUITMENT REQUIREMENT:

Future NCCAM support for this study is contingent upon adequate participant recruitment (based on: target patient accrual as stated in the application or projected milestones. An executive committee will establish these milestones prior to the initiation of data collection.) In the event that actual recruitment fall significantly below projected recruitment numbers (milestones), NCCAM may consider withholding future support and/or negotiating an orderly phase out of this study.

CONSORTIUM/CONTRACTUAL COST INFORMATION:

This award includes funds for consortium activities that will be provided with this award. Consortia are to be established and administered in accordance with the NIH Grants Policy Statement.

This award includes \$00,000 consortium funding for:
Duke Clinical Research Institute

FINAL YEAR CLOSEOUT REQUIREMENTS:

This project is in its final year of support and is scheduled to expire on 02/28/2007. Therefore, as stated in the NIH Grants Policy Statement, December 2003, Part II Subpart A, under Administrative Requirements, Closeout; a Financial Status Report (OMB 269, which can be found at: <http://www.whitehouse.gov/omb/grants/#forms>) must be submitted within 90 days of the expiration date. In addition, grant closeout documents consisting of a Final Invention Statement (HHS 568), (not applicable to training, construction, and conference grants) and a Final Progress Report must also be submitted within 90 days of the expiration date.

The Final Progress Report should be submitted electronically using the NIH commons and include, at a minimum, a summary of progress toward the achievement of the originally stated aims, a list of results (positive or negative) considered significant, and a list of publications resulting from the project as well as plans for further publications. The Final Invention Statement should be mailed directly to:
□

NCCAM Grants Clerk - CLOSEOUT
6707 Democracy Blvd Suite 401
Bethesda, Maryland 20892

The Financial Status Report should be submitted electronically to the Office of Financial Management, NIH. Other Financial Status Reports may be mailed to:

Government Accounting Branch
Office of Financial Management
National Institutes of Health
2115 East Jefferson Street
MSC 8500
Bethesda, MD 20892-8500

Failure to submit these required reports, when due, may result in the imposition of special award provision or the withholding of support for other eligible projects or activities involving the grantee organization or the individual responsible for the delinquency.

STAFF CONTACTS:

Richard Nahin, Program Official
Phone: (301)-496-7801 Email: nahinr@od.nih.gov Fax: (301) 435-6549

Alice Robinson, Grants Specialist
Phone: (301) 594-8738 Email: robinsona@mail.nih.gov Fax: (301) 480-1552

SPREADSHEET
GRANT NUMBER: 5 U01 AT001156-05

P.I.: LAMAS, GERVASIO A
INSTITUTION: MOUNT SINAI MEDICAL CENTER (MIAMI BEACH)

	YEAR 05
	=====
Salaries and Wages	194,018
Consultant Services	15,111
Supplies	6,720
Travel Costs	120,955
Other Costs	33,656
Consortium/Contractual Cost	4,787,081
TOTAL FEDERAL DC	5,157,541
TOTAL FEDERAL F&A	233,390
TOTAL COST	5,390,931

	YEAR 05
	=====
F&A Cost Rate 1	63.00%
F&A Cost Base 1	370,460
F&A Costs 1	233,390

.....END OF NGA.....

Department of Health and Human Services
Public Health Services

Review Group	Type	Activity	Grant Number
	S	U01	1-2004 AT01156-05

Total Project Period	
From: 05/15/2002	Through: 02/28/2007

Requested Budget Period	
From: 03/01/2006	Through: 02/28/2007

Grant Progress Report

1. TITLE OF PROJECT
Trial to Assess Chelation Therapy (TACT)

2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR
(Name and address, street, city, state, zip code)

Gervasio A. Lamas, MD
Mount Sinai Medical Center
4300 Alton Road, Butler Building
Miami Beach, FL 33140

3. APPLICANT ORGANIZATION
(Name and address, street, city, state, zip code)

Mount Sinai Medical Center of Florida, Inc.
4300 Alton Road
Miami Beach, FL 33140

2b. E-MAIL ADDRESS
factnih@aol.com

4. ENTITY IDENTIFICATION NUMBER
EN [REDACTED]

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Medicine

5. TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL

William Abraham, PhD
Director of Research
4300 Alton Road
Miami Beach, FL 33140

E-MAIL: abraham@msmc.com

2d. MAJOR SUBDIVISION
Cardiology

6. HUMAN SUBJECTS

No Yes

6a. Research Exempt No Yes

6b. Human Subjects Assurance No. FWAA00000176

If Exempt ("Yes" in 6a):
Exemption No.

If Not Exempt ("No" in 6a):
IRB approval date 03/22/2001

6c. NIH-Defined Phase III Clinical Trial No Yes

Full IRB or Expedited Review

7. VERTEBRATE ANIMALS

No Yes

7a. If "Yes," IACUC approval date

7b. Animal Welfare Assurance No.

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD

8a. DIRECT \$ 7,675,237

8b. TOTAL \$ 8,022,557

9. INVENTIONS AND PATENTS

No Yes

If "Yes," Previously Reported Not Previously Reported

10. PERFORMANCE SITE(S) (Organizations and addresses)

Mount Sinai Medical Center
4300 Alton Road
Miami Beach, FL 33140

Duke Clinical Research Institute
Box 3300
Durham, NC 27715

11a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Item 2a)

TEL 305-674-2162
FAX 305-674-3970

11b. ADMINISTRATIVE OFFICIAL NAME (Item 5)

William Abraham, PhD
TEL 305-674-2790
FAX 305-674-2198

11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION (Item 14)

NAME Paul Katz, MD
TITLE Vice President
TEL 305-674-2633 FAX 305-674-2007
E-MAIL pkatz@msmc.com

12. Corrections to Page 1 Face Page

13. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR ASSURANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application.

SIGNATURE OF PI/PD NAMED IN 2a. (In Ink. "Per" signature not acceptable.)

Gervasio A. Lamas 12/28/05

14. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11c. (In Ink. "Per" signature not acceptable.)

William Abraham 12/29/05

DEC 29 2005
DEC 30 2005

Principal Investigator/Program Director (Last, First, Middle): Lamas, Gervasio A.

DETAILED BUDGET FOR NEXT BUDGET PERIOD – DIRECT COSTS ONLY			FROM 03/01/2006	THROUGH 02/28/2007	GRANT NUMBER 1 U01 AT01156-05		
PERSONNEL (Applicant organization only)			TYPE APPT. (months)	% EFFORT ON PROJ.	DOLLAR AMOUNT REQUESTED (omit cents)		
NAME	ROLE ON PROJECT	SALARY REQUESTED			FRINGE BENEFITS	TOTALS	
Gervasio A. Lamas, MD	Principal Investigator	12		64,480	0	64,480	
Jacqueline Arciniega, MPH	Project Director	12		71,595	0	71,595	
Pablo Guala, MD	Clinical Manager	12		44,138	0	44,138	
Tristan Edwards	Research Assistant	12		29,369	0	29,369	
Marla Salas	Research Assistant	12		32,300	0	32,300	
Stephanie Escalante	Administrative Assistant	12		26,459	0	26,459	
Mary Beleiro	Secretary	12		5,438	0	5,438	
Virginia Martini	Coordinator	12		14,950	0	14,950	
SUBTOTALS				288,729		288,729	
CONSULTANT COSTS							
Chelation Consultants: Martin Dayton: (\$3,744)			Theodore Rozema: (\$3,744)				
Misc Consultants: (\$15,000)					22,488		
EQUIPMENT (Itemize)							
SUPPLIES (Itemize by category)							
General Office: \$7,000							
FAX & copier: \$1,000							
Paper: \$2,000					10,000		
TRAVEL							
Clinical Coordinating Center					180,000		
PATIENT CARE COSTS		INPATIENT 0				0	
		OUTPATIENT 0				0	
ALTERATIONS AND RENOVATIONS (Itemize by category)							
0							
OTHER EXPENSES (Itemize by category)							
Telephone: 12,000		Pagers/Cellulars: 2,000		Postage: 4,160		Advertisement:	
					50,086		
SUBTOTAL DIRECT COSTS FOR NEXT BUDGET PERIOD					\$ 551,303		
CONSORTIUM/CONTRACTUAL COSTS			DIRECT COSTS		5,994,793		
			FACILITIES AND ADMINISTRATIVE COSTS		1,129,141		
TOTAL DIRECT COSTS FOR NEXT PROJECT PERIOD (Item 8a, Face Page)					\$ 7,675,237		

Principal Investigator/Program Director (Last, First, Middle): Lamas, Gervasio A.

BUDGET JUSTIFICATION

GRANT NUMBER
1 U01 AT01156-05

Provide a detailed budget justification for those line items and amounts that represent a significant change from that previously recommended. Use continuation pages if necessary.

Patient enrollment has been lower than expected during year 4. The study's DSMB committee is presently reviewing decreasing the number of study patients and extending the study time. The decrease in number of patient would still maintain 85% power and maintain costs within the presently granted amount. The decrease in number of patients allows for funds to be reallocated towards activities which have helped increase patient enrollment as detailed in the study's progress report plans.

Part of these activities entails another study meeting which requires reallocation of funds into travel. Part of the group's initiatives to increase enrollment include extending the study to international sites. In order to meet this goal funds will be reallocated into consultants. Increased funding in other expenses to cover costs associated with increased advertising efforts are also reflected.

CURRENT BUDGET PERIOD

FROM
03/01/2005

THROUGH
02/28/2006

Explain any estimated unobligated balance (including prior year carryover) that is greater than 25% of the current year's total budget.

An unobligated balance will be seen in consortium because of low enrollment of patients. These expenses will be used during year 5 and will also cover the period of time the study will be extended.

Principal Investigator/Program Director (Last, First, Middle): Lamas, Gervasio A.

PROGRESS REPORT SUMMARY	GRANT NUMBER 1 U01 AT01156-05	
	PERIOD COVERED BY THIS REPORT	
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR Gervasio A. Lamas, MD	FROM 03/01/2005	THROUGH 02/28/2006
APPLICANT ORGANIZATION Mount Sinai Medical Center		
TITLE OF PROJECT (Repeat title shown in Item 1 on first page) Trial to Assess Chelation Therapy (TACT)		
A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	<input checked="" type="checkbox"/> No Change Since Previous Submission	<input type="checkbox"/> Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	<input checked="" type="checkbox"/> No Change Since Previous Submission	<input type="checkbox"/> Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

Has there been any change in other support of key personnel since the last reporting period?
The following organizational changes in the TACT Clinical Coordinating Center (CCC) occurred since the last reporting period (December 2004). All changes were made without a significant increase in total cost.

Jewmaull Reed (Research Assistant): Mr. Reed completed his one year commitment with TACT.

Parminder Singh, MD (Research Assistant): Dr. Singh completed his one year commitment with TACT.

Renea Moss (Office Coordinator): Ms. Moss resigned from TACT.

Ingrid Bazin (Secretary): Ms. Bazin resigned from TACT.

Kayvan Amini, DO (Clinical Trial Manager): Dr. Amini completed his one-year assignment as research fellow for the cardiology fellowship program.

Pablo Guala, MD (Clinical Trial Manager): Dr. Guala has been added to the CCC as a full-time Clinical Trial Manager as part of his clinical fellowship program. Dr. Guala will spend [redacted] time committed under TACT. His responsibilities remain the same as previously reported for this position in Year 4 Progress Report.

Tristan Edwards, BS (Research Assistant): Mr. Edwards replaced Mr. Reed and has the same responsibilities as reported for his position in Year 4 Progress Report, with same base salary and annual increase. Mr. Edwards will be with TACT until the end of the study.

Maria Salas, MD (Research Assistant): Dr. Salas replaced Dr. Singh and has the same responsibilities as reported for his position in Year 4 Progress Report, with the same base salary and annual increase. Dr. Salas will be with TACT until early summer 2006.

Stephanie Escalante (Administrative Assistant): The previous position for Office Coordinator held by Ms. Moss was removed and an Administrative Assistant position was created. Ms. Escalante will spend [redacted] of

Principal Investigator/Program Director (Last, First, Middle): Lamas, Gervasio, A.

her time committed to TACT, receiving a base salary of [REDACTED] with an annual increase of 3%. The Administrative Assistant's duties are as follows:

1. Process weekly clinical site payments. The Office coordinator is responsible for paying clinical units upon each patient randomization with a completed EQOL questionnaire.
 2. Process consortium payments upon receipt. The Administrative Assistant is responsible for timely payment of all subcontractors in accordance with MOA: Accucare Pharmacy, Duke Clinical Research Institute, Omnicomm Systems, Brigham and Women's Hospital, Quest, and Pharmed.
 3. Maintains database for clinical sites to track site related expenses including patient lab procedures and other miscellaneous expenses.
 4. Maintains budgetary database for clinical units and consortia.
 5. Answers questions related to payments from Clinical units and consortia.
 6. Participate in weekly Operations calls.
 7. Maintain and audit Memoranda of Agreement (MOA) for clinical sites and study subcontractors.
 8. Coordinates with Mount Sinai Medical Center Grants and Research Administration implementing MOAs for clinical sites and subcontractors.
 9. Assists Project Director in organizing conference calls.
- The Administrative Assistant reports to the Project Director.

Virginia Martini (Coordinator): Ms. Martini has reduced her time commitment to TACT to [REDACTED] with a base salary of [REDACTED] increasing by 3% each year. The Coordinator's duties are as follows:

1. Translating TACT materials into Spanish.
 2. Process payments for suppliers, such as Toshiba (copier used by TACT staff) and FEDEX.
 3. Orders capital equipment used by TACT staff.
- The Coordinator reports to the Project Director.

Mary Beleiro (Secretary): Ms. Beleiro was added to the CCC as a secretary with [REDACTED] time commitment to TACT, with a base salary of [REDACTED] increasing by 3% each year. The Secretary's duties are as follows:

1. Assist with TACT Study Meetings.
 2. Assist Principal Investigator with biweekly calls to each clinical site.
 3. Process all correspondence to TACT staff.
 4. Order office supplies for TACT staff.
- The Secretary reports to the Project Director.

Will there be, in the next budget period, a significant change in the level of effort for the PI or other personnel designated on the Notice of Grant Award from what was approved for this project? No.

Is it anticipated that an estimated unobligated balance (including prior year carryover) will be greater than 25 percent of the current year's total budget?

Enrollment for the project has slowed down leading to lower expenditures for central lab and clinical units as expected. A revised Recruitment Plan is presently being reviewed by the study's Data Safety Monitoring Board which evaluates the total number of subject's enrolled and the study length of time. This unobligated balance would be used to cover expenses if the study time is extended.

Principal Investigator/Program Director (Last, First, Middle): Lamas, Gervasio, A.

a. Specific Aims:

The specific aims of the Trial to Assess Chelation Therapy (TACT) remain the same as listed in the original award.

b. Studies and Results:

No results have been obtained. This is a double-blind trial therefore results are not expected until completion of the study.

c. Significance

As mentioned above, no results have been obtained so far. The trial, however, remains as significant as when it was conceived.

d. Plans

The study's Data Safety Monitoring Board (DSMB) reviewed the overall progress of the trial in August 2005, and recognized that at the study's present patient enrollment rates, the trial would not meet its goals by the projected end-date in 2007. The DSMB requested the study team develop a revised recruitment plan that would help the study team meet their objectives for patient enrollment maintaining 85% power and remain within the present budget. Presently the study team intends to decrease the number of patients and increase the length of time for the trial. Decreasing the number of study patients would allow the study to save funding in payment to sites for recruitment and costs associated with study drug (infusions and vitamins). These funds can be used towards increasing funds to achieve the newly proposed patient numbers and study extension period.

The final recruitment plan will be approved in February 2006 by the DSMB.

Milestones accomplished:

Site Activation Process

During this past year the study team focused a great deal of efforts to increase the number of sites who are regulatory approved and enrolled a patient. As of December 22, 2005, 109 clinical sites completed the regulatory document process. Of these 92% clinical sites have enrolled at least one patient in TACT (total of 100 sites). These efforts included requiring sites to submit screening logs as part of the regulatory process to receive study approval. Sites are given three to six months to enroll patients in the trial to remain active. Additionally, the study team has increased telephone contact with individual sites to help address barriers.

Site Recruitment Efforts

We continue to identify clinical sites as follows:

1. Distribution of study site recruitment materials at professional conferences sponsored by the American Heart Association (AHA), American College of Complementary and Alternative Medicine (ACCAM), and International College of Integrative Medicine (ICIM).
2. Site recruitment announcements in *Circulation*, *Journal American College of Cardiology (JACC)*, *Journal of the American Medical Association (JAMA)*, and *New England Journal of Medicine (NEJM)*. Additionally ads were placed in state medical journals where the study had few study sites and the study team felt there may be patient interest based on phone calls to the National Clearinghouse House: Ohio Medicine, California Physician/CMA Alert, and Physician Scribe Oregon. Received inquires from approximately ten interested investigators.

Principal Investigator/Program Director (Last, First, Middle): Lamas, Gervasio, A.

3. Invitation letter to ALLHAT sites in Puerto Rico and across Continental USA. No sites were interested to date.
4. Invitation letter to African American Heart Failure Trial (AHEFT) clinical sites. Approximately five sites were interested in TACT and are presently undergoing the regulatory process.
5. Distributed invitation letters to 200 DO physicians identified as cardiologists by American Osteopathic Association. Approximately three DOs responded.

The Clinical Coordinating Center (CCC) is in the process of the following initiatives to increase site recruitment:

1. Establishing sites in international locations, such as Canada and Argentina. The CCC is still in the process of applying to Canadian Ethics Committee and Health Authority.
2. Five minute video on TACT on Clinical Trials Network best practices website, part of the NIH Roadmap. Approximately 38 hospitals specializing in cardiovascular research participate in this network.

Patient Enrollment Efforts

The following activities were undertaken with NCCAM to help increase patient enrollment at each clinical site:

1. A National Media Campaign was launched that covered thirty states (78 cities) where at least one TACT site was activated. IRB approved patient recruitment ads were placed in 72 daily newspaper and 72 weekly and monthly papers. Additionally a 30-second television commercial on the study was aired on 70 network TV channels. All callers were referred to the NCCAM's National Clearinghouse who transferred callers to a local TACT site.
2. A Derby race was coordinated where each site was paired with a top performing site by CAM or cardiology specialty. Eleven teams were created and provided with weekly updates on each team's enrollment. At the end of the 17-week race 150 patients were enrolled (~9 patients per week).
3. Established IRB approved patient ambassador program.
4. Distribution of IRB approved B-roll in cities with TACT sites.
5. Reallocation of advertising funds directly to clinical sites that demonstrate success in recruiting patients and indicate they need financial help to place more ads in local media.
6. Travel reimbursement to already enrolled patients that express travel expenses as a barrier towards continuing in the study.
7. Continuation of weekly site calls and bimonthly conference calls with sites to discuss barriers when enrolling patients.
8. Increased recognition of sites that enroll patients by highlighting top enrollers in the study's newsletter conference calls, and email communications.

The Clinical Coordinating Center (CCC) is in the process of implementing the following activities to help increase patient enrollment at the site level:

1. Increased reimbursement to sites that exceed enrollment projections over a three-month period. The principal barrier for enrolling patients identified by sites is cost. This activity will be repeated each quarter during 2006, based on budgetary availability.
2. Study meeting during first quarter 2006. The highest weeks of enrollment occurred were seen after a study meeting.
3. Revitalization of patient ambassador program. The program will be expanded by giving participants low-cost gifts.

Principal Investigator/Program Director (Last, First, Middle): Lamas, Gervasio, A.

4. Renewed media campaign. This new media campaign will utilize and expand upon existing tools. This a revision of the study's b-roll which will now include adding state-by-state heart disease statistics, more detail on chelation therapy, and a direct ask for participation. The b-roll will be redistributed to new and existing sites. Additionally, the study's local press releases and newsletters will be revised and redistributed.
5. Create a Patient Recruitment and Retention Subcommittee where high performing site investigators and coordinators meet on a monthly basis with study leadership to discuss the study's patient enrollment progress.
6. Improved screening of potentially eligible clinical pools. Sites will be trained to also screen patients who underwent revascularization procedures for an MI.

Planned Activities to Improve Enrollment of Minorities and Women

1. Continued pursuit of sites at traditionally Black colleges and universities. The study team has obtained IRB approval for a clinical site at Morehouse College (a traditionally African American College) and is in the process of activating a clinical site at Emory University.
2. Presently three clinical sites that participated in AHEFT are interested in TACT.
3. Placement of newsletter article featuring a top female and African American investigator and top Hispanic investigator in minority newsletters, newspapers, and other media.

Patient Safety

During this year the study implemented the previously mentioned patient safety measures for fast infusions, calcium correction, and laboratory critical values. Additionally the following measures were also identified and implemented during year four:

1. Enhanced monitoring of the appearance or worsening of heart failure/angina/rhythm disturbances/and hypertension by requiring patient weight, blood pressure, heart rate, and limited cardiopulmonary exam during each patient's infusion visit.
2. Assessment of angina, heart failure, dyspnea and/or rales, pre and post infusion.
3. Enhanced monitoring of heart failure by closely monitoring patients with persistent weight gain.
4. Increased surveillance of adverse events by defining all safety labs that generate lab alerts or delays as adverse events.
5. Improved review by study Medical Monitor of serious adverse events by including review of all deaths.
6. Enhanced monitoring of use of evidence based medications for heart disease. Sites are given site report cards that compare their performance to the overall study median. Sites with a low percentage of patients taking evidence based cardiac medications are called by the Trial Manager to discuss reasons why patients are not on these medicines. Patients who refuse taking medications are given IRB approved letter informing them of the benefits of taking medicines. Additionally patients are given a letter to take to their Primary Care Provider that informs them patient is not on these medications.

Principal Investigator/Program Director (Last, First, Middle): Lamas, Gervasio, A.

OTHER SUPPORT

Lamas, Gervasio A MD

ACTIVE

(Lamas) 1/10/99 - present
\$500,000

Advanced Elements of Pacing Trial (ADEPT)

The major goal is to determine how effective the dual sensor rate modulation and automatic mode switching features in the Kappa 400 are in improving patients' quality of life.

105292 9/15/01 - 9/01/05
NIH/NHLBI \$259,250.00

Heart Failure Home Care (HFHC)

The major goal is to compare enhanced heart failure follow-up with conventional care.

RO1 HL 62509-01A1 (Hochman) 12/1/99 - 11/30/06
NIH/NHLBI \$15,000,000

Occluded Artery Trial (OAT)

Co-Chairman

The major goal is to evaluate if the late reestablishment of blood flow to the artery that caused the heart attack will decrease clinical events and improve the quality of life.

R01 HL 72906 (Rashba) 9/1/02 - 8/31/06
NIH/NHLBI \$900,000

Electrophysiologic effects of late PCI (OAT-EP)

Co-Chairman

The major goal is to characterize the effects of late PCI of occluded IRAs on the most prognostically important and clinically relevant noninvasive markers of vulnerability to malignant ventricular arrhythmias: heart rate variability, T wave variability and signal averaged electrocardiography.

1 U01 AT01156-01 (Lamas; PI) 8/15/02-2/28/07
NIH/NHLBI \$30,000,000

Trial to Assess Chelation Therapy (TACT)

The major goal of the Trial to Assess Chelation Therapy is to determine whether an intensive course of EDTA chelation, will reduce major adverse coronary events in patients with coronary artery disease who have recovered from a prior myocardial infarction.

Overlap

No overlap exists at this time.

Principal Investigator/Program Director (Last, First, Middle): Lamas, Gervasio, A.

Lee, Kerry L.

ACTIVE

HL55297(Lee)

NIH/NHLBI

5/1/97-4/30/04

\$5,085,587 (total costs)

% Effort

Data Coordinating Center for the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT)

The objective of this project is to provide the Statistical and Data Coordinating Center for the multicenter randomized clinical trial of prophylactic amlodarone or implantable defibrillator therapy versus conventional heart failure therapy in patients with Class II or Class III heart failure and a reduced ejection fraction.

(Lee)

5/1/97-4/30/04

0%

NIH/NHLBI

\$13,000,000

Data Coordinating Center for the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT)

This grant provides additional support for the SCD-HeFT trial to cover study materials, expenses for investigator/coordinator meetings, and the payments to sites for enrolling and following the study patients.

1U01HL69015-01 (Lee)

1/1/02-12/31/08

NIH/NHLBI

\$2,965,075 (Total Direct Costs)

STICH (Surgical Treatment for Ischemic Heart Failure Trial)

This grant supports the Statistical and Data Coordinating Center for the STICH trial. The study is a multicenter, international, randomized trial in patients with clinical heart failure and left ventricular dysfunction who have coronary artery disease amenable to surgical revascularization.

1U01HL63747 (O'Connor, Christopher)

9/30/2002-9/29/2007

NIH/NHLBI

\$30,179,911 Total Direct Cost

HF-ACTION (A CHF Trial Investigating Outcomes of Exercise Training)

This grant supports the Coordinating Center for the multi-center HF-ACTION trial. The objective of this trial is to assess whether exercise training improves clinical outcomes for heart failure patients.

1 U01-AT01156 (Lamas, G.A.)

8/15/02 - 2/28/07

NIH/NCCAM/NHLBI/Mt Sinai

\$1,879,530 (Year 1 Total Costs)

Trial to Assess Chelation Therapy (TACT)

Duke Clinical Research Institute (under leadership of Dr. Lee) is a subcontractor to Mt. Sinai Medical Center to provide the Statistical and Data Coordinating Center for this trial. The study is a multicenter, randomized clinical trial of chelation therapy in patients with a prior myocardial infarction.

1 U01-HL67972 (Bardy, Gust)

9/30/02 - 8/31/07

NIH/NHLBI/Seattle Institute for Cardiac Research

\$430,245 (Year 1 Total Costs)

Home Automatic External Defibrillator Trial - H.A.T.

Duke Clinical Research Institute (under leadership of Dr. Lee) is a subcontractor to the Seattle Institute for Cardiac Research to provide statistical services and perform economic and quality of life analyses for this trial. The study is a multicenter, randomized clinical trial to assess the effects of home use of automatic external defibrillators in reducing mortality in patients with a prior anterior myocardial infarction.

Overlap

No overlap exists at this time.

Principal Investigator/Program Director (Last, First, Middle): Lamas, Gervasio, A.

MARK, DANIEL B.

ACTIVE

U01 HL62251 (Mark, Daniel B.; PI)

9/01/1999-08/31/2005

NIH/NHLBI

\$222,225

Economics and Quality of Life in the Occluded Artery Trial (OAT)

Role: Principal Investigator

The objective of this study is to establish an Economics and Quality of Life Coordinating Center for the Occluded Artery Trial, a multi-center, randomized trial of late (3-42 days) percutaneous revascularization versus standard medical therapy in 3200 asymptomatic high-risk acute myocardial infarction (MI) survivors and who are found at diagnostic catheterization to have an occluded infarct related artery. Cost, cost effectiveness, and health-related quality of life are secondary endpoints.

U01 HL69011 (Mark, Daniel B.; PI)

1/01/02-12/31/08

NIH/NHLBI

\$208,533

Economics and Quality of Life Core Laboratory in Surgical Treatment of Ischemic Heart Failure (STICH)

Role: Principal Investigator

The major goal of this substudy of the Surgical Treatment of Heart Failure Trial is to determine cost effectiveness and health-related quality of life of CABG +/- ventricular reconstruction versus medical therapy.

1R01 HL69081-01 (Newman, Mark; PI)

12/01/01-11/30/05

NIH

\$393,123

Peri-Operative Interventional Neuroprotection Trial: POINT

Role: Co-Investigator

The major goal of this project is to determine the impact of magnesium administration to therapeutic serum levels on short- and long-term neurocognitive function after cardiac surgery evaluated by preoperative and postoperative neurocognitive and neurologic testing.

R01 HS013345-01 (Eisenstein, Eric L.; PI)

9/12/02-8/31/05

AHRQ

\$227,777

Dialysis Facility Management

Role: Co-Investigator

The goal of this study is to define the impact of dialysis facility characteristics on dialysis patient mortality, morbidity, and total medical costs.

1U01 HL66530 (Mark, Daniel B.; PI)

8/15/02-8/14/07

NIH/NHLBI

\$86,478

Economics and Quality of Life in the Trial to Assess Chelation Therapy (TACT)

Role: Principal Investigator

The major goal of the Trial to Assess Chelation Therapy is to determine whether an intensive course of EDTA chelation, administered over 18 months, will reduce major adverse coronary events in patients with coronary artery disease who have recovered from a prior myocardial infarction. The objective of this project is to assess the secondary endpoints of cost effectiveness and health-related quality of life of the treatment strategies being tested in TACT.

Principal Investigator/Program Director (Last, First, Middle): Lamas, Gervasio, A.

U01 HL67972-01 (Bardy Gust; PI)
NIH/NHLBI

10/01/02-8/30/07
\$1,965,243

Home Automatic External Defibrillator Trial (HAT)

Role: Co-Investigator

The major objective of this study is to conduct a randomized clinical trial of automatic external defibrillator therapy, provided by spouses or other family members, superimposed on the local emergency medical system vs. the local emergency medical system in 3400 survivors of anterior myocardial infarction. Duke University will act as subcontractor to Seattle Institute for Cardiac Research for this trial. Duke will provide data management and statistical services for the trial, as well as performing economic and quality of life analyses.

Private Source

(Mark, Daniel B.; PI)

2/10/1998-12/31/05
\$335,460

Treating to New Targets (TNT) Economics Substudy

Role: Principal Investigator

The objective of this substudy of the TNT clinical trial is to determine cost effectiveness of lowering LDL-C beyond the currently accepted minimum targets for patients at high risk for developing coronary heart disease.

(Mark, Daniel B.; PI)

1/01/02 - 12/31/04
\$95,625

Economic Outcomes in Phase III of Pexelizumab in CABG (PRIMO CABG)

Role: Principal Investigator

The major goals of this substudy are to perform a detailed comparison of medical resource consumption and medical costs in the PRIMO-CABG trial; and to perform a series of cost-effectiveness analyses of the Pexelizumab arm versus placebo in CABG patients.

1U01-AR-052186-01 (Schulman,KA, PI)

9/01/04 - 8/31/09
\$567,720

NIH (NIH Roadmap PRO)

Dynamic Outcome Assessment in Multi Center Trials

Role: Co-Investigator

The goal of the Patient-Reported Outcomes Measurement Information System (PROMIS) Network is to develop a unified approach for assessing PROs using computerized adaptive testing (CAT).

(Mark, Daniel, PI)

3/01/04 - 4/30/06
\$126,054

Private Source

APEX-MI EQOL

Role: Principal Investigator

The specific objectives of this study are to compare medical resource use patterns and associated medical costs for the Pexelizumab arm versus the control arm by intention-to-treat in patients randomized into APEX-MI; and to perform a cost-effectiveness analysis of Pexelizumab versus control using the empirical outcomes observed in overall APEX-MI and the Economic study to provide base case parameters for the model.

Principal Investigator/Program Director (Last, first, middle): Lamas, Gervasio A.

GRANT NUMBER
1 U01 AT01156-05

CHECKLIST

1. PROGRAM INCOME (See Instructions.)

All applications must indicate whether program income is anticipated during the period(s) for which grant support is requested. If program income is anticipated, use the format below to reflect the amount and source(s).

Budget Period	Anticipated Amount	Source(s)

2. ASSURANCES/CERTIFICATIONS (See Instructions.)

In signing the application Face Page, the authorized organizational representative agrees to comply with the following policies, assurances and/or certifications when applicable. Descriptions of individual assurances/certifications are provided in Part III of the PHS 398. If unable to certify compliance, where applicable, provide an explanation and place it after this page.

• Human Subjects Research • Research Using Human Embryonic Stem Cells • Research on Transplantation of Human Fetal Tissue • Women and Minority Inclusion Policy • Inclusion of Children Policy • Vertebrate Animals

• Debarment and Suspension • Drug-Free Workplace (applicable to new [Type 1] or revised [Type 1] applications only); • Lobbying • Non-Delinquency on Federal Debt • Research Misconduct • Civil Rights (Form HHS 441 or HHS 690); • Handicapped Individuals (Form HHS 641 or HHS 690) • Sex Discrimination (Form HHS 639-A or HHS 690) • Age Discrimination (Form HHS 660 or HHS 690); • Recombinant DNA Research, Including Human Gene Transfer Research • Financial Conflict of Interest (except Phase I SBIR/STTR) • Prohibited Research • Select Agents and Toxins • STTR ONLY: Certification of Research Institution Participation.

3. FACILITIES AND ADMINISTRATIVE (F&A) COSTS

Indicate the applicant organization's most recent F&A cost rate established with the appropriate DHHS Regional Office, or, in the case of for-profit organizations, the rate established with the appropriate PHS Agency Cost Advisory Office.

F&A costs will not be paid on construction grants, grants to Federal organizations, grants to individuals, and conference grants. Follow any additional instructions provided for Research Career Awards, Institutional National Research Service Awards, Small Business Innovation Research/Small Business Technology Transfer Grants, foreign grants, and specialized grant applications.

DHHS Agreement dated: 12/21/2000 No Facilities and Administrative Costs Requested.

No DHHS Agreement, but rate established with _____ Date _____

CALCULATION*

Entire proposed budget period: Amount of base \$ 551,303 x Rate applied 63.00% = F&A costs \$ 347,321

Add to total direct costs from Form Page 2 and enter new total on Face Page, item 8b.

*Check appropriate box(es):

Salary and wages base Modified total direct cost base Other base (Explain)

Off-site, other special rate, or more than one rate involved (Explain)

Explanation (Attach separate sheet, if necessary):

Principal Investigator/Program Director (Last, First, Middle): Lamas, Gervasio A.

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: Trial to Assess Chelation Therapy (TACT)

Total Planned Enrollment: 2,372

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	Sex/Gender		
	Females	Males	Total
Hispanic or Latino	57	133	190
Not Hispanic or Latino	655	1,527	2,182
Ethnic Category: Total of All Subjects *	712	1,660	2,372
Racial Categories			
American Indian/Alaska Native	7	17	24
Asian	14	33	47
Native Hawaiian or Other Pacific Islander	14	33	47
Black or African American	86	199	285
White	591	1,378	1,969
Racial Categories: Total of All Subjects *	712	1,660	2,372

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

During Summer 2005, the study's Data Safety Monitoring Board (DSMB) determined that present enrollment rates the study would not meet its goals by the expected end date. The DSMB is presently reviewing a revised recruitment plan that would decrease the number of total subjects enrolled but maintain the study's power at 85% and within the currently budgeted amount of funds.

Principal Investigator/Program Director (Last, First, Middle): Lamas, Gervasio A.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: Trial to Assess Chelation Therapy (TACT)
 Total Enrollment: 2,372 Protocol Number: 00-21-H-03
 Grant Number: 1 U01 AT01156-04

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race				
Ethnic Category	Sex/Gender			Total
	Females	Males	Unknown or Not Reported	
Hispanic or Latino	6	20	0	26 **
Not Hispanic or Latino	126	667	0	793
Unknown (individuals not reporting ethnicity)	0	0	0	
Ethnic Category: Total of All Subjects*	132	687		819 *
Racial Categories				
American Indian/Alaska Native	2	1	0	3
Asian	0	7	0	7
Native Hawaiian or Other Pacific Islander	1	2	0	3
Black or African American	8	23	0	31
White	121	652	0	773
More Than One Race	0	2	0	2
Unknown or Not Reported	0	0	0	
Racial Categories: Total of All Subjects*	132	687		819 *
PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)				
Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	1	0	0	1
Asian	0	0	0	
Native Hawaiian or Other Pacific Islander	1	0	0	1
Black or African American	0	0	0	
White	4	20	0	24
More Than One Race	0	0	0	
Unknown or Not Reported	0	0	0	
Racial Categories: Total of Hispanics or Latinos**	6	20		26 **

* These totals must agree.
 ** These totals must agree.

Principal Investigator/Program Director (Last, First, Middle): Lamas, Gervasio A.

KEY PERSONNEL REPORT

GRANT NUMBER

1 U01 AT01156-05

Place this form at the end of the signed original copy of the application. Do not duplicate.

All Key Personnel for the Current Budget Period (do not include Other Significant Contributors)

Name	Degree(s)	SSN (last 4 digits)	Role on Project (e.g. PI, Res. Assoc.)	Date of Birth (MM/DD/YY)	Annual % Effort
Gervasio A. Lamas	MD		PI		
Kerry Lee	PhD		Co-PI		
Daniel Mark	MD		Co-PI		

TACT CLINICAL COORDINATING CENTER BUDGET
Y2006-2007
Year 5

Name	Position	Appointment	Effort	Salary	Salary Requested	Fringe Rate	Fringe Total	Salary Total
Gervasio Lamas MD	Study Chairman	12	% Effort	Institutional	\$84,480	0	\$0.00	\$ 64,480
Jacqueline Arciniega	Project Director	12		Base Salary	\$71,595	0	\$0.00	\$ 71,595
Pablo Guala, MD	Clinical Trial Manager	12			\$44,138	0	\$0.00	\$44,138
Maria Salas	Research Assistant	12			\$32,300	0	\$0.00	\$32,300
Tristan Edwards	Research Assistant	12			\$29,369	0	\$0.00	\$29,369
Stephanie Escalante	Administrative Assistan	12			\$28,459	0	\$0.00	\$28,459
Mary Bebeiro	Secretary	12			\$5,437	0	\$0.00	\$5,437
Virginia Martin, BA	Coordinator	12			\$14,950	0	\$0.00	\$14,950
Total Salaries								\$288,728

Consultants	Salary	
Martin Dayton DO	\$3,744	\$22,488
Theodore Rozema	\$3,744	
Misc. Consultants	\$15,000	
Equipment		

Total equipment \$0

Supplies		
copier supplies		
fax supplies		
paper		
Total supplies		\$10,000

Travel		
Yearly meetings	\$150,000	
CCC travel	\$30,000	
Total Travel		\$180,000

Patient care costs		
	\$0	
Total Patient Costs		\$0

Other expenses		
Telephone	\$12,480	
Pagers	\$2,080	
Postage	\$4,326	
Advertisement	\$31,200	
Total other (A)		\$50,086

Consortium/ contractual costs

Direct costs		
DCRI	\$2,116,709	
OmniComm	\$80,200	
Brigham and Women's	\$89,538	
Clinical units	\$1,599,600	
Central Pharmacy	\$1,887,207	
Central Lab	\$91,539	
Pharmed	\$150,000	
Total direct costs	\$5,994,793	

Indirect costs		
DCRI	\$1,108,756	
Brigham and Women's	\$22,385	
Total Indirect costs	\$1,129,141	

Total Consortium \$7,123,934

TOTAL DIRECT COSTS YEAR 5 ==> \$7,875,237

COST BASE FOR CALCULATING INDIRECT \$551,303
 INDIRECT COST 0.63 \$347,321
 TOTAL COST \$8,022,557