Form Approved Through 09/30/2007 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
	5	U01	8 U01 HL092607-06 07

Total Project Period
From: 05/15/2002 Through: 02/28/2010

Requested Budget Period
From: 08/01/2007 Through: 02/29/2008

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. ENTITY IDENTIFICATION NUMBER
EIN [redacted]

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

2d. MAJOR SUBDIVISION
Cardiology

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

E-MAIL:

6. HUMAN SUBJECTS
☐ No ☒ Yes
6a. Research Exempt ☒ No ☐ Yes
6b. Human Subjects Assurance No. FWAA00000176
If Exempt ("Yes" in 6a): Exemption No.
6c. NIH-Defined Phase III Clinical Trial ☐ No ☒ Yes
If Not Exempt ("No" in 6a): IRB approval date 03/22/2001
☒ 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 $3,954,955
8b. TOTAL $4,086,829

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 M. Abraham, PhD
TEL 305-674-2790
FAX 305-674-2198

11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 14)*
NAME Alex Mendez
TITLE Senior Vice Precident- Chief Financial Officer
TEL 305-674-2089 FAX 305-674-2007
E-MAIL amendez@msmc.com

12. Corrections to Page 1 Face Page

13. 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.)*

DATE 1/30/08

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

DETAILED BUDGET FOR NEXT BUDGET PERIOD – DIRECT COSTS ONLY	FROM 08/01/2007	THROUGH 02/29/2008	GRANT NUMBER 8 U01 HL092607-06

PERSONNEL (Applicant organization only)		Months Devoted to Project			DOLLAR AMOUNT REQUESTED (omit cents)		
NAME	ROLE ON PROJECT	Cal. Mnths	Acad. Mnths	Summer Mnths	SALARY REQUESTED	FRINGE BENEFITS	TOTALS
Gervasio Lamas, MD	Principal Investigator	EFFORT			64,480	0	64,480
Ana Mon, MPH	Project Director				64,600	0	64,600
Laura Davila	Research Assist.				29,640	0	29,640
Stephanie Feliciano	Admin. Assistant				27,119	0	27,119
Beatriz Acevedo	Secretary				5,647	0	5,647
Arman Tolentino	Research Assist.				4,775	0	4,775
SUBTOTALS →					196,261	0	196,261

CONSULTANT COSTS Chelation Consultants: Martin Dayton: ($3,744) Theodore Rozema: ($3,744) Misc Consultants: ($6,000)	13,488
EQUIPMENT *(Itemize)*	0
SUPPLIES *(Itemize by category)* General Office: $5,000 FAX & copier: $2,000 Paper: $2,000	9,000
TRAVEL Clinical Coordinating Center	35,000
PATIENT CARE COSTS – INPATIENT	
PATIENT CARE COSTS – OUTPATIENT	
ALTERATIONS AND RENOVATIONS *(Itemize by category)*	
OTHER EXPENSES *(Itemize by category)* Telephone: 6,000 Pagers/Cellulars: 2,000 Postage: 2,000	10,000
SUBTOTAL DIRECT COSTS FOR NEXT BUDGET PERIOD	$ 263,749
CONSORTIUM/CONTRACTUAL COSTS – DIRECT COSTS	3,269,483
CONSORTIUM/CONTRACTUAL COSTS – FACILITIES AND ADMINISTRATIVE COSTS	421,723
TOTAL DIRECT COSTS FOR NEXT PROJECT PERIOD *(Item 8a, Face Page)*	$ 3,954,955

BUDGET JUSTIFICATION	GRANT NUMBER 8 U01 HL092607-06

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 was lower than expected in year 5. The study's DSMB reviewed proposed changes to the recruitment plan and approved the recruitment projection of 1900 enrolled patients by the end of 2008. The decrease in number of patient would still maintain 85% power and maintain costs within the presently granted amount. This decrease allows for funds to be reallocated towards activities that can increase patient enrollment as detailed in the study's progress report plans.

Part of these activities entailed another study meeting which requires reallocation of funds into travel. Part of the group's initiatives to increase enrollment includes extending the study to international sites, specifically Canada and Argentina. In order to meet this goal funds will be reallocated into consultants.

CURRENT BUDGET PERIOD	FROM 03/01/2006	THROUGH 06/30/2007

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

There is no unobligated balance in the current year's total budget. The year 5 period was extended by 4 months and there are no carryover funds into year 6.

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

PROGRESS REPORT SUMMARY	GRANT NUMBER 8 U01 HL092607-06	
	PERIOD COVERED BY THIS REPORT	
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR Gervasio A. Lamas, MD	FROM 03/01/2006	THROUGH 06/30/2007

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	☒ No Change Since Previous Submission	☐ Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	☒ No Change Since Previous Submission	☐ Change
C. Select Agent Research	☒ No Change Since Previous Submission	☐ Change
D. Multiple PI Leadership Plan	☒ No Change Since Previous Submission	☐ 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 2005). All changes were made without a significant increase in total cost.

Maria Salas, MD (Research Assistant): Dr. Salas completed her one year commitment with TACT.

Mary Beleiro (Office Coordinator): Ms. Beleiro resigned from TACT.

Tristan Edwards, BS (Research Assistant): Mr. Edwards resigned from TACT.

Jacqueline Arciniega: Ms. Arciniega resigned from TACT.

Pablo Guala, MD (Clinical Trial Manager): Dr. Guala completed his one-year assignment as research fellow for the cardiology fellowship program.

Faisal Shamshad, MD (Clinical Trial Manager): Dr. Shamshad completed his one-year assignment as research fellow for the cardiology fellowship program.

Esteban Escolar, MD (Clinical Trial Manager): Dr. Escolar has been added to the CCC as a full-time Clinical Trial Manager as part of his clinical fellowship program. Dr. Escolar will spend [redacted] % Effort committed under TACT. His responsibilities remain the same as previously reported for this position in Year 5 Progress Report.

Ana Mon, MPH (Project Director): Ms. Mon has been added to the CCC as a full-time Project Director to replace Ms. Arciniega, with the same responsibilities and same base salary and annual increase. Ms. Mon will be with TACT until the end of the study.

Laura Davila, BS (Research Assistant): Ms. Davila replaced Mr. Edwards and has the same responsibilities as reported for his position in Year 5 Progress Report, with same base salary and annual increase. Ms. Davila will be with TACT until summer 2008.

Arman Tolentino, BS (Research Assistant): Mr. Tolentino was added to the CCC to assist with file audits and the annual invstigator's meeting. Mr. Tolentino has completed his time commitment to TACT.

Virginia Martini (Coordinator): Ms. Martini has completed her time commitment to TACT.

Beatriz Acevedo (Secretary): Ms. Acevedo replaced Ms. Beleiro and has the same responsibilities and similar base salary and annual increase. Ms. Acevedo will be with TACT until the end of the study.

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?
No.

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 2006 and February 2007 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 study team developed a revised recruitment plan that could help the study team meet their objectives for patient enrollment maintaining 85% power and remain within the present budget. On February 23, 2007, the DSMB approved the new recruitment projection of 1900 patients by December 2008. This plan decreased the number of patients and increased the length of time for the trial and allowed the study to save funding in payment to sites for recruitment and costs associated with study drug (infusions and vitamins). These funds could also be used towards increasing funds to achieve the newly proposed patient numbers and study extension period.

The NHLBI's ad hoc advisory committee (which convened in September 2006 and recommended that continuation of NHLBI support be made, contingent on the successful establishment of a Canadian network and on the performance of that network) will reconvene in September 2007 to evaluate the sufficiency of the additional recruitment by this network (and any other new sites) to sustain the trial.

Milestones accomplished:

Inclusion of TACT in Canada
The TACT study received approval from Health Canada to carry out the study in participating Canadian Centers, as of December 22, 2006. The TACT Canadian organization is led by Dr. Jean-Claude Tardif from the Montreal Heart Institute.
20 Canadian sites received IRB approval for TACT and the first TACT patient in Canada was enrolled in February 23, 2007. By the end of this reporting period, 42 TACT patients had been enrolled in Canada.

Site Activation Process
During this past year the study team focused their efforts to increase the number of approved sites that can be ready to enroll patients. As of June 30, 2007, 128 clinical sites had completed the regulatory document process. Of these 91% clinical sites have enrolled at least one patient in TACT (total of 117 sites). The study team will continue current efforts to identify high quality sites and drop sites that have been unproductive and have not enrolled any patients for over 1 year after being activated.

Site Recruitment Efforts
We continue to identify clinical sites as follows:

1. Contacted the DCRI network of clinical trial sites (about 3000 sites). Duke University Cooperative Cardiovascular Studies (DUCCS) has been asked to help identify sites to participate in the TACT study and that can potentially enroll 1 patient a month. These sites are mostly community-based practices, seeing over a a large number of patients per year. Invitation letter went out to DUCCS sites in February. No sites were interested to date.

2. Continued the 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).

The Clinical Coordinating Center (CCC) continues to follow initiatives to increase site recruitment, such as establishing sites in other international locations, specifically in Argentina. The CCC is still in the process of applying to the Argentine Ethics Committee and Health Authority.

Patient Enrollment Efforts
All of the standard approaches to increase enrollment continue to be in effect for the trial. Specific efforts included:
•Study Investigator's Meeting— 15 US sites and 20 Canadian sites participated in the TACT meeting in March 2007. The meeting message emphasized patient recruitment and retention tactics. During the meeting each site investigator and coordinator received overall study training on patient safety, effective recruitment strategies, and the electronic data capture system.
•TACT Tips- quarterly newsletter with focus on retention and other practical guidelines for site coordinators. Also the TACT patient newsletter tailored to participating patients with important information on the follow-up phase and the TACT ambassador program.
• Continuous communication with enrolling sites: conference calls with trial manager and regional coordinators to discuss eligibility and assisting with screening for new patients, individual conference calls, global faxes, and emails from DCRI and Mt. Sinai reminding sites to enroll patients.
• 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.
• Travel reimbursement to already enrolled patients that express travel expenses as a barrier towards continuing in the study.
• Increased recognition of sites that enroll patients by highlighting top enrollers in the study's newsletter
conference calls, and email communications.

Public Relations/ Publicity
A CNN news story on TACT/chelation was aired on 12/2/2006 and it was positive for the most part. Call volume and TACT phone inquiries to the NCCAM Clearinghouse for December 2006 and January 2007 was more than double the average monthly volume for the previous months. This increase was due in part to the mention of TACT in a monthly subscription called "Dr. Whitaker's Health and Healing Newsletter;" as over 50% of the callers identified this publication as their initial source of information about the study.
Advertisements and other media efforts that are expensive and difficult to correlate with enrollment have been held back. Instead more focus has been put in the enhanced reimbursement programs and travel assistance to the sites and coordinators.

Continuation of Enhanced Reimbursement Programs
In recognition of the additional work that screening and enrolling TACT patients requires and based on budgetary availability the enhanced reimbursement program were restarted a few times during this reporting period, included enhanced payment for randomization and for the site coordinator.

Planned Activities to Improve Enrollment of Minorities and Women
Recruitment of target numbers of women and minorities continues to be quite difficult. Targeted media outreach efforts did not lead to increased minority enrollment. Efforts at bringing in new sites with the potential for principally minority recruitment have been at least partially frustrated. For example, Dr. Ehrman in Henry Ford has randomized only 3 patients; also after 16 months of discussions and contracting difficulties with Grady Hospital/ Emory University in Atlanta, the site was finally approved for TACT in August 2007, but has not been able to enroll any patients yet.
Other plans include: to invite an NIH expert to speak at a Webex conference and include some of the key site investigators for a panel discussion about importance of recruiting women and minorities.

Patient Safety
During this year the study continued to implement previously mentioned patient safety measures for fast infusions, calcium correction, and laboratory critical values. Additionally the following measures also continued during year five:
1. Assessment of angina, heart failure, dyspnea and/or rales, pre and post infusion.
2. Enhanced monitoring of heart failure by closely monitoring patients with persistent weight gain.
3. Increased surveillance of adverse events by defining all safety labs that generate lab alerts or delays as adverse events.
4. Improved review by study Medical Monitor of serious adverse events by including review of all deaths.
5. Enhanced monitoring of use of evidence based medications for heart disease.

OTHER SUPPORT

Lamas, Gervasio A MD
ACTIVE

RO1 HL 62509-01A1 (Hochman) 4/1/07-5/31/11 [redacted] calendar months
NIH/NHLBI $2,964,913
Occluded Artery Trial (OAT) Long Term Follow-up
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.

1 U01 AT01156-01 (Lamas; PI) 8/15/02-2/28/07 [redacted] calendar months
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.

Lee, Kerry L.

ACTIVE

1U01HL69015-01 (Lee) 1/1/02-12/31/08 EFFORT calendar months
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) 9/30/2002-9/29/07 EFFORT calendar months
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 – 2/28/10 [redacted] calendar months
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 [redacted] calendar months
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

5U01 HL69011 (Mark, Daniel B.; PI) 01/01/2002-12/31/2008 EFFORT calendar months
NIH/NHLBI $211,510
Economics and Quality of Life Core Laboratory in Surgical Treatment of Ischemic Heart Failure (STICH)
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.

1U01 AT01156 (Mark, Daniel B.; PI) 08/15/2002-02/28/2008 [redacted] calendar months
Mount Sinai Medical Ctr/NIH $130,078
Economics and Quality of Life in the 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, 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.

5U01 HL67972 (Bardy Gust; PI) 09/30/2002-08/31/2007 [redacted] calendar months
Seattle Institute for Cardiac Research/NIH $290,359
Home Automatic External Defibrillator Trial (HAT)
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.

5U01-AR052186 (Weinfurt, K; PI) 09/28/04 – 07/31/2009 [redacted] calendar months
NIH (NIH Roadmap PRO) $251,830
Dynamic Outcome Assessment in Multi Center Trials•
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).

5R01 HL54780 (Barefoot, John; PI) 08/01/2005 – 06/30/2009 [redacted] calendar months
NHLBI $195,300
Hostility, depression, social environment & CHD risk
Hostility, depression/depressive personality, and socioeconomic status (SES) have all been shown to influence the risk of coronary heart disease (CHD). While the three factors have been studies separately in previous work, there is evidence that they are interrelated and there is reason to hypothesize that they would interact in a multiplicative fashion to dramatically increase risk when they are present in combination.

(Mark, Daniel B.; PI) 08/28/2006 – 09/30/2008 [redacted] calendar months
Private Source $119,539
MEND CABG
The goal of this project is to evaluate the cardioprotective effects of MC-1 in patients undergoing high-risk coronary artery bypass graft (CABG) surgery.

1R01 HL080416 (Eisenstein, E, PI) 09/29/2006-06/30/2011 [redacted] calendar months
Northwestern University/NIH $119,241
PACE MI Economic and Quality of Life Substudy
The goals of this project are to compare medical resource use patterns and associated medical costs for the pacemaker/beta-blocker arm versus the control arm by intention-to-treat, to compare functional status as measured by the Duke Activity Status Index and Specific Activity Scale for the pacemaker/beta-blocker arm versus the control arm by intention-to-treat, and to perform a cost effective analysis of pacemaker/beta-blocker therapy versus control.

(Eisenstein, E; PI) 01/01/2005 – 12/31/2011 [redacted] calendar months
[redacted] $127,420
Positive Impact of endo Vascular Options for Treating Aneurysm Early (PIVOTAL)
The goal of this project is to compare endovascular repair versus surveillance, with respect to patient survival, AAA rupture, and AAA related death.

1U01 HL84875 (O'Connor, Chris) 09/30/2006 – 06/30/2011 EFFORT calendar months
NIH/NHLBI $347,368
Heart Failure Clinical Research Network
The goal of this project is to accelerate research in the diagnosis, management, and treatment of heart failure, and to improve patient outcomes.

Overlap
No overlap exists at this time

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

GRANT NUMBER
8 U01 HL092607-06

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/resubmission [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 Agent Research • PI Assurance
• STTR ONLY: Certification of Research Institution Participation.

3. FACILITIES AND ADMINSTRATIVE (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: 02/15/2006 ☐ No Facilities and Administrative Costs Requested.

☐ No DHHS Agreement, but rate established with _____ Date _____

CALCULATION*

Entire proposed budget period: Amount of base $ 263,749 x Rate applied 50 % % = F&A costs $ 131,875

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.

KEY PERSONNEL REPORT

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

GRANT NUMBER
8 U01 HL092607-06

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)	Months Devoted to Project		
					Cal	Acad	Summer
Gervasio A. Lamas	MD		PI		EFFORT		
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: 1,900

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	46	106	152
Not Hispanic or Latino	524	1,224	1,748
Ethnic Category: Total of All Subjects *	570	1,330	1,900
Racial Categories			
American Indian/Alaska Native	6	13	19
Asian	11	27	38
Native Hawaiian or Other Pacific Islander	11	27	38
Black or African American	69	159	228
White	473	1,104	1,577
Racial Categories: Total of All Subjects *	570	1,330	1,900

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

In February 2007, the study's Data Safety Monitoring Board (DSMB) reviewed and approved a revised recruitment plan that decreased the number of total subjects enrolled to 1900 but maintained 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: 1,900 **Protocol Number:** 00-21-H-03

Grant Number: 8 U01 HL092607-06

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino	7	34	0	41 **
Not Hispanic or Latino	224	1035	0	1259
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	231	1069	0	1300 *
Racial Categories				
American Indian/Alaska Native	3	2	0	5
Asian	2	9	0	11
Native Hawaiian or Other Pacific Islander	2	3	0	5
Black or African American	14	36	0	50
White	210	1013	0	1223
More Than One Race	0	6	0	6
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	231	1069	0	1300 *

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	0
Native Hawaiian or Other Pacific Islander	1	1	0	2
Black or African American	0	0	0	0
White	5	32	0	37
More Than One Race	0	1	0	1
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	7	34	0	41 **

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