Progress Report Scanning Cover Sheet

5U01HL092607-07

PI Name: LAMAS, GERVASIO
Org: MOUNT SINAI MEDICAL CENTER (MIAMI BEACH)
Start Date: 03/01/2008
Snap: N/A (NEEDS TO BE BOOKMARKED)
Appl ID: 7483180
Rec'd Date: 02/01/2008
Grant Number: 5U01HL092607-07 REVISED

Principal Investigator(s):
GERVASIO A LAMAS, MD

Project Title: Trial to Assess Chelation Therapy (TACT)

WILLIAM ABRAHAM, PH.D.
DIRECTOR OF RESEARCH
MT SINAI MED CTR OF FLORIDA, INC
4300 ALTON ROAD
MIAMI BEACH, FL 33140
MIAMI BEACH, FL 33140

Award e-mailed to: ryoldszer@msmc.com

Budget Period: 03/01/2008 - 05/31/2008
Project Period: 08/15/2002 - 05/31/2008

Dear Business Official:

The National Institutes of Health hereby revises this award to reflect an increase in t
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 required to comply with the NIH Public Access Policy. This includ
Award recipients must promote objectivity in research by establishing standards to ensu
If you have any questions about this award, please contact the individual(s) referenced
Sincerely yours,

Raymond L Zimmerman
Grants Management Officer
NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Additional information follows
SECTION I - AWARD DATA - 5U01HL092607-07 REVISED

Award Calculation (U.S. Dollars)

Federal Direct Costs
$889,936
Federal F&A Costs
$39,793
Approved Budget
$929,729
Federal Share
$929,729
TOTAL FEDERAL AWARD AMOUNT
$929,729

AMOUNT OF THIS ACTION (FEDERAL SHARE)
$420,753

SUMMARY TOTALS FOR ALL YEARS
YR
THIS AWARD
CUMULATIVE TOTALS
7
$929,729
$929,729

Fiscal Information:
CFDA Number:
93.837
FIN. [Redacted]
Document Number:
U1AT01156A
Fiscal Year:
2008

IC
CAN
2008
AT
8472676
$234,591
HL
8475146
$695,138

NIH Administrative Data:
FCC: HHAATN / OC: 414P / Processed: ZIMMERMNR 06/03/2009

SECTION II - PAYMENT/HOTLINE INFORMATION - 5U01HL092607-07 REVISED

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

SECTION III - TERMS AND CONDITIONS - 5U01HL092607-07 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. Conditions on activities and expenditure of funds in other statutory requirements, su
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

(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
In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now m
This award provides support for one or more NIH defined Phase III Clinical Trials. The description of plans to conduct analyses, as appropriate, by sex/gender and racial/ethnic This award represents the final year of the competitive segment for this grant. Therefore, a final Financial Status Report (FSR) (SF 269) must be submitted through the eRA Commons for additional information on this electronic submission requirement.

Furthermore, unless an application for competitive renewal is submitted, additional grants will need to be maintained. NIH also strongly encourages electronic submission of the final progress report and the Submissions of the final progress report and HHS 568 may be e-mailed as PDF attachments. Paper submissions of the final progress report and the HHS 568 may be faxed to the NIH.

NIH/OD/OER/DEAS
Central Closeout Center
6705 Rockledge Drive, Room 2207
Bethesda, MD 20892-7987 (for regular or U.S. Postal Service Express mail)
Bethesda, MD 20817 (for other courier/express mail delivery only)

The final progress report should include, at a minimum, a summary of progress toward the objectives of the project, where appropriate, indicate whether children were involved in the study or how the study would impact children.

Describe any data, research materials (such as cell lines, DNA probes, animal models), that will be submitted by the end of the project.

Note, if this is the final year of a competitive segment due to the transfer of the grant.

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

National Heart, Lung, And Blood Institute (NHLBI)

National Center For Complementary & Alternative Medicine (NCCAM)

Treatment of Program Income:

Additional Costs

SECTION IV - HL Special Terms and Conditions - 5U01HL092607-07 REVISED

REVISION
The purpose of this revised award is to adjust the amount awarded per revised relinquishment of funds.

CHANGE OF GRANTEE
Total costs awarded have been revised downward (and future year deleted) due to change in the grantee.

NOTE: The following statement should be included on the final Financial Status Report.
STAFF CONTACTS

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

Grants Management Specialist: Carol Lander
Email: landerc@nhlbi.nih.gov Phone: 301-435-0185 Fax: 301-452-5462

Program Official: Robin Boineau
Email: boineaur@nhlbi.nih.gov Phone: (301) 435-0455 Fax: (301) 480-3667

SPREADSHEET SUMMARY
GRANT NUMBER: 5U01HL092607-07 REVISED

INSTITUTION: MOUNT SINAI MEDICAL CENTER (MIAMI BEACH)

Budget
Year 7
TOTAL FEDERAL DC
$889,936
TOTAL FEDERAL F&A
$39,793
TOTAL COST
$929,729

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

Grant Number: 5U01HL092607-07 REVISED

Principal Investigator(s):
GERVASIO A LAMAS, MD

Project Title: Trial to Assess Chelation Therapy (TACT)

WILLIAM ABRAHAM, PH.D.
DIRECTOR OF RESEARCH
MT SINAI MED CTR OF FLORIDA, INC
4300 ALTON ROAD
MIAMI BEACH, FL 33140
MIAMI BEACH, FL 33140

Award e-mailed to: pkatz@msmc.com

Budget Period: 03/01/2008 - 05/31/2008
Project Period: 08/15/2002 - 05/31/2008

Dear Business Official:
The National Institutes of Health hereby revises this award to reflect a decrease in the
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-supponed
Award recipients are required to comply with the NIH Public Access Policy. This includ
Award recipients must promote objectivity in research by establishing standards to ensu
If you have any questions about this award, please contact the individual(s) referenced
Sincerely yours,

David L Reiter
Grants Management Officer
NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Additional information follows
SECTION I - AWARD DATA - 5U01HL092607-07 REVISED

Award Calculation (U.S. Dollars)

Federal Direct Costs
$469,183
Federal F&A Costs
$39,793
Approved Budget
$508,976
Federal Share
$508,976
TOTAL FEDERAL AWARD AMOUNT
$508,976

AMOUNT OF THIS ACTION (FEDERAL SHARE)
($) -2,915,000

SUMMARY TOTALS FOR ALL YEARS

YR

THIS AWARD
CUMULATIVE TOTALS

7
$508,976
$508,976

Fiscal Information:
CFDA Number:
93.837

Document Number:
ULAT01156A
Fiscal Year:
2008
NIH Administrative Data:
PCC: HHAA8T / OC: 414P / Processed: REITERD 09/08/2008

SECTION II - PAYMENT/HOTLINE INFORMATION - 5U01HL092607-07 REVISED

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

SECTION III - TERMS AND CONDITIONS - 5U01HL092607-07 REVISED

This award is based on the application submitted to, and as approved by, NIH on the above date.

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as 45 CFR Part 74 or 45 CFR Part 92 as applicable.
c. 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 Management Assistance at P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory.

This award provides support for one or more NIH defined Phase III Clinical Trials. The award provides support for the following activities, as appropriate, by sex/gender and racial/ethnic subgroup.

This award represents the final year of the competitive segment for this grant. Thereafter, a final Financial Status Report (FSR) (SF 269) must be submitted through the eRA Commons for additional information on this electronic submission requirement.

Furthermore, unless an application for competitive renewal is submitted, additional grants require the submission of the final progress report and the paper copy of the final progress report and the HHS 568 may be faxed to NIH.

NIH/OD/OER/DEAS
Central Closeout Center
6705 Rockledge Drive, Room 2207
Bethesda, MD 20892-7987 (for regular or U.S. Postal Service Express mail)
Bethesda, MD 20817 (for other courier/express mail delivery only)

The final progress report should include, at a minimum, a summary of progress toward the achievement of the specific aims. Where appropriate, indicate whether children were involved in the study or how the study affect children. Describe any data, research materials (such as cell lines, DNA probes, animal models),
Note, if this is the final year of a competitive segment due to the transfer of the gra

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

National Center For Complementary & Alternative Medicine (NCCAM)

National Heart, Lung, And Blood Institute (NHLBI)

Treatment of Program Income:
Additional Costs

SECTION IV - HL Special Terms and Conditions - 5U01HL092607-07 REVISED

CHANGE OF GRANTEE
Total costs awarded have been revised downward (and future year deleted) due to change
NOTE: The following statement should be included on the final Financial Status Report.

STAFF CONTACTS

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

Grants Management Specialist: Carol Lander
Email: landerc@nhlbi.nih.gov Phone: 301-435-0185

Program Official: Robin Boineau
Email: boineaur@nhlbi.nih.gov Phone: (301) 435-0455 Fax: (301) 480-3667

SPREADSHEET SUMMARY
GRANT NUMBER: 5U01HL092607-07 REVISED

INSTITUTION: MOUNT SINAI MEDICAL CENTER (MIAMI BEACH)

Budget
Year 7
TOTAL FEDERAL DC
$469,183
TOTAL FEDERAL F&A
$39,793
TOTAL COST
$508,976

..................END OF NGA..................
Grant Number: 5U01HL092607-07 REVISED

Principal Investigator(s):
GERVASIO A. LAMAS, MD

Project Title: Trial to Assess Chelation Therapy (TACT)

WILLIAM ABRAHAM, PH.D.
DIRECTOR OF RESEARCH
MT SINAI MED CTR OF FLORIDA, INC
4300 ALTON ROAD
MIAMI BEACH, FL 33140
MIAMI BEACH, FL 33140

Award e-mailed to: pkatz@msmc.com

Budget Period: 03/01/2008 - 02/28/2009
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 grantee. Each publication, press release or other document that cites results from NIH grant-supp Award recipients are required to comply with the NIH Public Access Policy. This includ

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

Sincerely yours,

Raymond L. Zimmerman
Grants Management Officer
NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Additional information follows

SECTION I - AWARD DATA - 5U01HL092607-07 REVISED

Award Calculation (U.S. Dollars)

Salaries and Wages $182,977
Personnel Costs (Subtotal) $182,977
Consultant Services $6,609
Supplies $8,575
Travel Costs $24,500
Other Costs $6,860
Consortium/Contractual Cost $3,079,662

Federal Direct Costs $3,309,183
Federal F&A Costs $114,793
Approved Budget
$3,423,976
Federal Share
$3,423,976
TOTAL FEDERAL AWARD AMOUNT
$3,423,976

AMOUNT OF THIS ACTION (FEDERAL SHARE)
$0

SUMMARY TOTALS FOR ALL YEARS
YR
THIS AWARD
CUMULATIVE TOTALS
7
$3,423,976
$3,423,976
8
$4,085,517
$4,085,517

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

Fiscal Information:
CPDA Number:
93.837
RIN:

Document Number:
UIAT01156A
Fiscal Year:
2008

IC
CAN
2008
2009
AT
8472676
$1,680,776
$2,042,759
HL
8475146
$1,743,200
$2,042,758

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

NIH Administrative Data:
PCC: H1AATW / GC: 414P / Processed: ZIMMERMAN 03/26/2008

SECTION II - PAYMENT/HOTLINE INFORMATION - 5U01HL092607-07 REVISED

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

SECTION III - TERMS AND CONDITIONS - 5U01HL092607-07 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

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now ma

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:
Additio nal Costs

SECTION IV - HL Special Terms and Conditions - 5001HL092607-07 REVISED

REVISION #1

This Notice of Grant Award has been revised to make an adjustment of the Fiscal Informa

RFA NOTICE
The Terms and Conditions of this award incorporate the operating guidelines in the RFA

OPERATING GUIDELINES
This non-competing award reflects an adjustment of the amount recommended on the previo

PERSONNEL COSTS
The FY 2006 Appropriation Act (P.L. 109-149) restricts the amount of direct salary to E

CURRENT AND FUTURE YEAR LEVELS
In accordance with the October 27, 1995 NIH Guide announcement and NIH implementation,

NHLBI ADJUSTMENTS FOR SALARY BASED AWARDS
Salary funds provided on NHLBI research grants will be adjusted if investigators receiv

KEY PERSONNEL: use this term when there is a co-investigator (DELETE IF NO NEEDED

In addition to the PI, any absence, replacement, or substantial reduction in effort of
Dr. Kerry Lee, Dr. Dan Mark, and Ms. Ana Mon.

GRADUATE STUDENT COMPEN SATION
In accordance with the January 9, 2006, NIH Guide for Grants and Contracts Notice on Gr

CONSORTIUM/CONTRACTUAL COSTS
This award includes funds awarded for consortium activities. The grantee, as the di

FOREIGN TRAVEL
U.S. Flag carriers must be used for departure from or entry into the U.S. and for any o

RESTRICTION OF PARTICIPANT RECRUITMENT
Future NHLBI support for this study is contingent upon adequate participant recruitment In the event that actual recruitment falls significantly below projected recruitment nu

PUBLICATIONS
All publications resulting from the research supported by this award must acknowledg s

This project was supported by NIH Research Grant # HL 92607 and AT 01156 funded by National Center for Complementary and Alternative Medicine.

Cooperative Agreement Statement
Terms and Conditions

The cooperative agreement is an award instrument establishing an (assistance) relation

1. The awardee(s) will have lead responsibilities in all aspects of the study, inclu the study, quality control, data analysis and interpretation, preparation of pub investigators, unless otherwise provided for in these terms or by action of the S

2. The NHLBI Project Scientist (Robin Boineau, MD) and the NCCAM Project Scientist (Ri he/she or another NHLBI scientist may serve on other study committees, when app Project Scientist (and the other cited NHLBI scientists) may work with awardees o as appropriate, other committees, e.g.: recruitment, intervention, follow-up, qu problems affecting the study and potential changes in the protocol, interim data interpretation, preparation of publications, and development of solutions to majo

3. Awardee(s) agree to the governance of the study through a Steering Committee. Ste the principal investigators (i.e., cooperative agreement awardees) and the NHLBI Committee will ordinarily be held by telephone conference call or in the metropol

4. A Data and Safety Monitoring Board will be appointed by the Director, NHLBI to provi

5. Awardees will retain custody of and have primary rights to their data developed u access consistent with current HHS, PHS, and NIH policies. The collaborative pro continued submission of data centrally to the coordinating center for a collabora collaborative datasets to each non-NIH principal investigator upon completion of and publication; and procedures to protect and ensure the privacy of medical and

6. Support or other involvement of industry or any other third party in the study --of study resources or citing the name of the study or NHLBI support; or special ac resources -- may be advantageous and appropriate. However, except for licensing o any third party will occur only following notification of and concurrence by NHLBI

7. Study investigators are encouraged to publish and to release publicly and disseminat

8. The NHLBI reserves the right to terminate or curtail the study (or an individual a implement a mutually agreeable collaborative protocol, (b) substantial shortfall data reporting, quality control, or other major breach of the protocol, (c) subst which NHLBI cannot concur, (d) reaching a major study endpoint substantially bef significance, or (e) human subject ethical issues that may dictate a premature ter
9. Any disagreement that may arise in scientific/programmatic matters (within the scope of NHLBI) may be brought to arbitration. An arbitration panel will be composed of three members: the NHLBI Committee (with the NHLBI member not voting) or by the individual awardee selected by NHLBI, and the third member selected by the two prior awardee's right to appeal an adverse action that is otherwise appealable in accordance with 45 CFR part 50, Subpart D and HHS regulation at 45 CFR part 16, or the rights of NHLBI under a

10. These special terms of award are in addition to and not in lieu of otherwise applicable Administration Regulations at 45 CFR part 74, and other HHS, PHS, and NIH grant ad

STAFF CONTACTS

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

Grants Management Specialist: Carol Lander
Email: landerc@nlbi.nih.gov Phone: 301-435-0185

Program Official: Robin Boineau
Email: boineaur@nlbi.nih.gov Phone: (301) 435-0455 Fax: (301) 480-3667

SPREADSHEET SUMMARY

INSTITUTION: MOUNT SINAI MEDICAL CENTER (MIAMI BEACH)

Budget
Year 7
Year 8
Salaries and Wages
$182,977
$380,821
Personnel Costs (Subtotal)
$182,977
$380,821
Consultant Services
$6,609
$9,488
Supplies
$8,575
$8,750
Travel Costs
$24,500
$25,000
Other Costs
$6,860
$10,500
Consortium/Contractual Costs
$3,079,662
$3,583,613
TOTAL FEDERAL DC
$3,309,183
$3,918,172
TOTAL FEDERAL F&A
$114,793
$167,345
TOTAL COST
$3,423,976
$4,085,517

Facilities and Administrative Costs
Year 7
Year 8
F&A Cost Rate 1
50%
50%
F&A Cost Base 1
$229,586
$334,690
F&A Costs 1
$114,793
$167,345

END OF NGA

Grant Number: 5U01HL092607-07
Principal Investigator(s):
GERVASIO A LAMAS, MD

Project Title: Trial to Assess Chelation Therapy (TACT)

WILLIAM ABRAHAM, PH.D.
DIRECTOR OF RESEARCH
MT SINAI MED CTR OF FLORIDA, INC
4300 ALTON ROAD
MIAMI BEACH, FL 33140
MIAMI BEACH, FL 33140

Award e-mailed to: pkatz@msmc.com

Budget Period: 03/01/2008 - 02/28/2009
Project Period: 08/15/2002 - 02/28/2010

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of $3,423,976 (see
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 required to comply with the NIH Public Access Policy. This includ
If you have any questions about this award, please contact the individual(s) referenced
Sincerely yours,

Raymond L Zimmerman
Grants Management Officer
NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Additional information follows
SECTION I - AWARD DATA - 5U01HL092607-07

Award Calculation (U.S. Dollars)

Salaries and Wages $182,977
Personnel Costs (Subtotal) $182,977
Consultant Services $6,609
Supplies $8,575
Travel Costs $24,500
Other Costs $5,860
Consortium/Contractual Cost $3,079,662

Federal Direct Costs
$3,309,183
Federal F&A Costs
$114,793
Approved Budget
$3,423,976
Federal Share
$3,423,976
TOTAL FEDERAL AWARD AMOUNT
$3,423,976

AMOUNT OF THIS ACTION (FEDERAL SHARE)
$3,423,976

SUMMARY TOTALS FOR ALL YEARS

YR
THIS AWARD
CUMULATIVE TOTALS

7
$3,423,976
$3,423,976

8
$4,085,517
$4,085,517

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

Fiscal Information:
CFDA Number:
93.837
EIN:
Document Number:
U1AT01156A
Fiscal Year:
2008
Recommended future year total cost support, subject to the availability of funds and sa

NIH Administrative Data:
PCC: HHAATN / OC: 414P / Processed: ZIMMERMAN 03/18/2008

SECTION II - PAYMENT/HOTLINE INFORMATION - 5U01HL092607-07

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

SECTION III - TERMS AND CONDITIONS - 5U01HL092607-07

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

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National Center For Complementary & Alternative Medicine (NCCAM)

National Heart, Lung, And Blood Institute (NHLBI)

Treatment of Program Income:
Additional Costs

SECTION IV - HL Special Terms and Conditions - 5U01HL092607-07
RFA NOTICE
The Terms and Conditions of this award incorporate the operating guidelines in the RFA .
OPERATING GUIDELINES
This non-competing award reflects an adjustment of the amount recommended on the previous spending plan.

PERSONNEL COSTS
The FY 2006 Appropriation Act (P.L. 109-149) restricts the amount of direct salary to $X million.

CURRENT AND FUTURE YEAR LEVELS
In accordance with the October 27, 1995 NIH Guide announcement and NIH implementation,

NHLBI ADJUSTMENTS FOR SALARY BASED AWARDS
Salary funds provided on NHLBI research grants will be adjusted if investigators receive

KEY PERSONNEL: use this term when there is a co-investigator (DELETE IF NO NEEDED IN ADDITION TO THE PI, ANY ABSENCE, REPLACEMENT, OR SUBSTANTIAL REDUCTION IN EFFORT OF DR. KERRY LEE, DR. DAN MARK, AND MS. ANA MON.

GRADUATE STUDENT COMPENSATION
In accordance with the January 9, 2006, NIH Guide for Grants and Contracts Notice on Graduate Student Compensation.

CONSORTIUM/CONTRACTUAL COSTS
This award includes funds awarded for consortium activities. The grantee, as the di...

FOREIGN TRAVEL
U.S. Flag carriers must be used for departure from or entry into the U.S. and for any or

RESTRICITION OF PARTICIPANT RECRUITMENT
Future NHLBI support for this study is contingent upon adequate participant recruitment. In the event that actual recruitment falls significantly below projected recruitment by

PUBLICATIONS
All publications resulting from the research supported by this award must acknowledge:

This project was supported by NIH Research Grant # HL 92607 and AT 01156 funded by National Center for Complementary and Alternative Medicine.

Cooperative Agreement Statement
Terms and Conditions

The cooperative agreement is an award instrument establishing an (assistance) relation

1. The awardee(s) will have lead responsibilities in all aspects of the study, including the study, quality control, data analysis and interpretation, preparation of publication, unless otherwise provided for in these terms or by action of the S

2. The NHLBI Project Scientist (Robin Boineau, MD) and the NCCAM Project Scientist (Richard Shekelle, MD) may serve on other study committees, when appropriate, other committees, e.g.: recruitment, intervention, follow-up, and problems affecting the study and potential changes in the protocol. interim data interpretation, preparation of publications, and development of solutions to major

3. Awardee(s) agree to the governance of the study through a Steering Committee. The principal investigators (i.e., cooperative agreement awardees) and the NHLBI Committee will ordinarily be held by telephone conference call or in the metropol
4. A Data and Safety Monitoring Board will be appointed by the Director, NHLBI, to provide
access consistent with current HHS, PHS, and NIH policies. The collaborative pro-
cess of data centrally to the coordinating center for a collabora-
tive datasets to each non-NIH principal investigator upon completion of
and publication; and procedures to protect and ensure the privacy of medical and

5. Awardees will retain custody of and have primary rights to their data developed and
resources -- may be advantageous and appropriate. However, except for licensing
any third party will occur only following notification of and concurrence by NHLBI.

7. Study investigators are encouraged to publish and to release publicly and disseminate

8. The NHLBI reserves the right to terminate or curtail the study or to implement a mutually agreeable collaborative protocol, (b) substantial shortfall in data reporting, quality control, or other major breach of the protocol, (c) substantial changes which NHLBI cannot concur, (d) reaching a major study endpoint substantially before significance, or (e) human subject ethical issues that may dictate premature ter-

9. Any disagreement that may arise in scientific/programmatic matters within the scope
of NHLBI may be brought to arbitration. An arbitration panel will be composed of the
Committee (with the NHLBI member not voting) or by the individual awardee in the e
selected by NHLBI, and the third member selected by the two prior members. This s
awardee's right to appeal an adverse action that is otherwise appealable in accord
50, Subpart D and HHS regulation at 45 CFR part 16, or the rights of NHLBI under a

10. These special terms of award are in addition to and not in lieu of otherwise appl
Administration Regulations at 45 CFR part 74, and other HHS, PHS, and NIH grant ad

STAFF CONTACTS

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

Grants Management Specialist: Carol Lander
Email: landerc@nlbi.nih.gov Phone: 301-435-0185

Program Official: Robin Boineau
Email: boineau@nlbi.nih.gov Phone: (301) 435-0455 Fax: (301) 480-3667

SPREADSHEET SUMMARY

GRANT NUMBER: 5U01HL092607-07

INSTITUTION: MOUNT SINAI MEDICAL CENTER (MIAMI BEACH)

Budget
Year 7
Year 8
Salaries and Wages
$182,977
$280,821
Personnel Costs (Subtotal)
$182,977
$280,821
Consultant Services
$6,609
$9,488
Supplies
$8,575
$8,750
Travel Costs
$24,500
$25,000
Other Costs
$6,860
$10,500
Consortium/Contractual Cost
$3,079,662
$3,583,613
TOTAL FEDERAL DC
$3,309,183
$3,918,172
TOTAL FEDERAL F&A
$124,793
$167,345
TOTAL COST
$3,433,976
$4,085,517

Facilities and Administrative Costs
Year 7
Year 8
F&A Cost Rate 1
50%
50%
F&A Cost Base 1
$229,586
$334,690
F&A Costs 1
$114,793
$167,345

..................................END OF NGA..................................
# Grant Progress Report

**Title of Project:**
Try to Assess Chelation Therapy (TACT)

**Principal Investigator or Program Director:**
Gervasio A. Lamas, MD  
Mount Sinai Medical Center  
4300 Alton Road, Butler Building  
Miami Beach, FL 33140

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

**Entity Identification Number:**
EN

**Department, Service, Laboratory, or Equivalent:**
Cardiology

**Major Subdivision:**
Cardiology

**Human Subjects:**
- Research Exempt: No
- Human Subjects Assurance No.: FWA00000176
- NIH-Defined Phase III: Exemption No.
- Full IRB or Expedited Review: No
- IRB approval date: 03/22/2001

**Costs Requested for Next Budget Period:**
- Direct: $3,954,955
- Total: $4,086,829

**Inventors and Patents:**
- Not Previously Reported

**Institutional Review Board (IRB) Information:**
- Principal Investigator or Program Director: William M. Abraham, PhD
- Administrative Official Name: William M. Abraham, PhD
- NAME and TITLE of Official Signing for Applicant Organization: Alex Mendez  
  - TITLE: Senior Vice President-Chief Financial Officer
  - TEL: 305-674-2089  
  - FAX: 305-674-2007  
  - E-MAIL: amendez@msmc.com

**Corrections to Page 1 Face Page:**

**U-01 Grant Number:** AU01 HL092607-46

**Date:**
- 03/02/18

**Signature of Official Named in 11c. (In ink, "Per" signature not acceptable):**

**Application 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, fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

**Face Page**
## Detailed Budget for Next Budget Period - Direct Costs Only

<table>
<thead>
<tr>
<th>Name</th>
<th>Role on Project</th>
<th>Months Devoted to Project</th>
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<tr>
<td><strong>TOTALS</strong></td>
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<td>Theodore Rozema: ($3,744)</td>
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<td>Outpatient</td>
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</table>
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.

<table>
<thead>
<tr>
<th>CURRENT BUDGET PERIOD</th>
<th>FROM</th>
<th>THROUGH</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>03/01/2006</td>
<td>06/30/2007</td>
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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.
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 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 investigator'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; 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  47 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
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
NIH/NHLBI $2,995,075 (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
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
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.
MARK, DANIEL B.
ACTIVE

5U01 HL69011 (Mark, Daniel B.; PI) 01/01/2002-12/31/2008 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 sub-study 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 calendar months
Mount Sinai Medical Ctr/NH
$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 calendar months
Seattle Institute for Cardiac Research/NH $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 calendar months
NIH (NIH Roadmap PRO) $251,830
Dynamic Outcome Assessment in Multi Center Trials (MCOQ)
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 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 studied 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.
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
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 $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 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
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).

<table>
<thead>
<tr>
<th>Budget Period</th>
<th>Anticipated Amount</th>
<th>Source(s)</th>
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</table>

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/resubmissions [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 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.

☐ DHHS Agreement dated: 02/15/2006
☐ No Facilities and Administrative Costs Requested.

☐ No DHHS Agreement, but rate established with __________________________ Date ________________

CALCULATION*

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<th>Rate applied</th>
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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.

*Check appropriate box(es):
☐ Salary and wages base
☐ Modified total direct cost base
☐ Other base (Explain)

Explanation (Attach separate sheet, if necessary):
**KEY PERSONNEL REPORT**

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

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<th>Name</th>
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<th>SSN (last 4 digits)</th>
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<td>MD</td>
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<td>PI</td>
<td></td>
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<tr>
<td>Kerry Lee</td>
<td>PhD</td>
<td></td>
<td>Co-PI</td>
<td></td>
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<tr>
<td>Daniel Mark</td>
<td>MD</td>
<td></td>
<td>Co-PI</td>
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<td>Summer</td>
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Targeted/Planned Enrollment Table

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

Study Title: Trial to Assess Chefaion Therapy (TACT)
Total Planned Enrollment: 1,900

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<tr>
<td>Ethnic Category: Total of All Subjects *</td>
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</tbody>
</table>

| 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.
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
Grant Number: 8 U01 HL092607-06
Protocol Number: 00-21-H-03

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

<table>
<thead>
<tr>
<th>Ethnic Category</th>
<th>Females</th>
<th>Males</th>
<th>Unknown or Not Reported</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hispanic or Latino</td>
<td>7</td>
<td>34</td>
<td>0</td>
<td>41 **</td>
</tr>
<tr>
<td>Not Hispanic or Latino</td>
<td>224</td>
<td>1035</td>
<td>0</td>
<td>1259</td>
</tr>
<tr>
<td>Unknown (individuals not reporting ethnicity)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>Ethnic Category: Total of All Subjects</strong></td>
<td>231</td>
<td>1069</td>
<td>0</td>
<td>1300</td>
</tr>
</tbody>
</table>

**Racial Categories**

<table>
<thead>
<tr>
<th>Racial Categories</th>
<th>Females</th>
<th>Males</th>
<th>Unknown or Not Reported</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>American Indian/Alaska Native</td>
<td>3</td>
<td>2</td>
<td>0</td>
<td>5</td>
</tr>
<tr>
<td>Asian</td>
<td>2</td>
<td>9</td>
<td>0</td>
<td>11</td>
</tr>
<tr>
<td>Native Hawaiian or Other Pacific Islander</td>
<td>2</td>
<td>3</td>
<td>0</td>
<td>5</td>
</tr>
<tr>
<td>Black or African American</td>
<td>14</td>
<td>36</td>
<td>0</td>
<td>50</td>
</tr>
<tr>
<td>White</td>
<td>210</td>
<td>1013</td>
<td>0</td>
<td>1223</td>
</tr>
<tr>
<td>More Than One Race</td>
<td>0</td>
<td>6</td>
<td>0</td>
<td>6</td>
</tr>
<tr>
<td>Unknown or Not Reported</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>Racial Categories: Total of All Subjects</strong></td>
<td>231</td>
<td>1069</td>
<td>0</td>
<td>1300</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Racial Categories</th>
<th>Females</th>
<th>Males</th>
<th>Unknown or Not Reported</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>American Indian or Alaska Native</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Asian</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Native Hawaiian or Other Pacific Islander</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Black or African American</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>White</td>
<td>5</td>
<td>32</td>
<td>0</td>
<td>37</td>
</tr>
<tr>
<td>More Than One Race</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Unknown or Not Reported</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>Racial Categories: Total of Hispanics or Latinos</strong></td>
<td>7</td>
<td>34</td>
<td>0</td>
<td>41 **</td>
</tr>
</tbody>
</table>