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# NOTICE OF GRANT AWARDS REPORT

\*\*\*\*\* NOTICE OF GRANT AWARD \*\*\*\*\*

PROJECT COOPERATIVE AGREEMENT Issue Date:03/10/2003  
Department of Health and Human Services  
National Institutes of Health

NATIONAL CENTER FOR COMPLEMENTARY & ALTERNATIVE MEDICINE  
\*\*\*\*\*

Number: 1 U01 AT001156-01 (Revised)  
Principal Investigator: LAMAS, GERVASIO A MD  
Project Title: Trial to Assess Chelation Therapy (TACT)

DEPARTMENT OF RESEARCH  
SINAI MED CTR OF FLORIDA, INC  
15000 BIRCHWOOD ROAD  
MIAMI BEACH, FL 33140  
UNITED STATES

Contract Period: 08/15/2002 - 02/28/2003  
Funding Period: 08/15/2002 - 02/28/2007

**Business Official:**

The National Institutes of Health hereby revises this award (see "Award Explanation" in Section I and "Terms and Conditions" in Section III) to the MOUNT SINAI MEDICAL CENTER (MIAMI BEACH) in support of the above referenced project. This award is pursuant to the authority of 42 USC 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.

Grantee recipients are responsible for reporting inventions derived or discovered in the performance of work under this grant. Rights in 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.

**NOTICE OF GRANT AWARDS REPORT**

ION INFORMATION: Revised Notice of Grant Award (NGA) issued to: case provisional status and provide authority to expend funds in the amount of \$3,676,787 (\$ 3,494,449 Direct Cost, \$182,338 Facilities and Administration F&A) for the 08/15 /2002-02 /28/03 Year 1 budget segment. Find restrictions based on the receipt of documentation regarding required certifications.

NG DETERMINATION INFORMATION: Specific budget categories have been added based on the receipt, review and acceptance of the revised budget (dated: 11/8/02) reflecting a target patient accrual of 2,372. Direct costs are limited and will not exceed the \$6,207,279 provided in the award. Year 2 has been revised, providing a categorical cost based on the revised 11/8/02 budget.

SPENDING RESTRICTION: Although total costs of: \$6,207,279 have been identified, funds representing (60 %) of the total funds awarded \$3,676,787 (3,494,449 Direct; 182,338 F/A) are authorized at this time to provide start up support for 7 months. Remaining funds of \$2,530,492 (2,400,250 Direct; 130,242 F/A) are restricted and may not be expended or rebudgeted without the prior written approval from the awarding unit.

Equipment and all travel expenses have not been prorated by 7 months and funding has been provided.

Patient Care RESTRICTION: All funds associated with patient care activities are restricted and are not available for expenditure pending clinical protocol review and approval by DSMB.

Unobligated funds resulting from these restrictions must be reported and identified on the Financial Status Report and may not be carried forward for any purpose without the prior approval of the NCCAM Staff. Should the status of these restricted funds change, notification will be provided via the issuance of a revised Notice of Grant Award.

PERCENT AND FUTURE YEAR LEVELS INFORMATION & REVISED BUDGET SUBMISSION REQUIREMENT: The attached summary of budget calculations for the future years is shown in total costs. In accordance with the October 27, 1995 NIH Guide announcement and NIH implementation, future year recommended budget levels are shown as total costs (the sum of direct plus facilities and administrative costs). Adjustments to facilities and administrative costs (increases or decreases in rate or base changes) will not routinely be made for future year awards. Itemized budget categories will be provided, upon receipt and review of a revised budget reflecting target patient accrual of 2,372. The revised budget for years 3 through 5 is due to Victoria C. Carper by 6/30/2003.

**FUNDING ACKNOWLEDGEMENT REQUIREMENT:**

Grantees are required to place an acknowledgement of NIH grant support in 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

**NOTICE OF GRANT AWARDS REPORT**

pledgment shall be to the effect that:

publication was made possible by Grant Number \_\_\_from the

nal Center for Complementary and Alternative Medicine (NCCAM) or project described was supported by Grant Number \_\_\_from the nal Center for Complementary and Alternative Medicine" and "Its nts are solely the responsibility of the authors and do not sarily represent the official views of the NCCAM , or the nal Institutes of Health."

recipients presenting NCCAM-sponsored research at scientific, ssional, and consumer meetings are asked to acknowledge the cly funded support they receive. A copy of the NCCAM Grantee wldgement slide in PowerPoint is available at: .nih.gov/research/information for grantees.

ED TERMS INFORMATION: Supersedes NGA issued 08/08/2002. All ous terms and conditions still applicable are incorporated by tle listed below \*\*\*. Refer to original NGA for a complete iption of terms and conditions.

LING BUDGET PERIOD INFORMATION:

NDING INFORMATION: This award includes total costs funds of 0,000 provided by the National Heart Lung and Blood Institute 3I).

ORTIUM/CONTRACTUAL COST INFORMATION: This award includes funds for ortium activities that will be provided with this award. ortiums are to be established and administrated in accordance with IJH Grants Policy Statement.

award includes total costs funding of \$5,409,941 for the following ortium:

ical Sites	\$1,612,500	RESTRICTED	
University:	1,963,376	(Dr. Lee:	\$1,563,848
	,528)		Dr. Mark:
Durham	\$31,250		
	\$60,232		
comm	\$227,200		
ham and Women's Hospital	\$10,503		
tum	\$1,462,000		
t	\$42,880		

N SUBJECTS RESEARCH INFORMATION  
ICIPANT RECRUITMENT REQUIREMENT  
ICATIONS REQUIREMENT  
AL PROGRESS REPORTS REQUIREMENT  
ONNEL COSTS INFORMATION  
LATION INFORMATION

# NOTICE OF GRANT AWARDS REPORT

## CONTACTS INFORMATION

ADDITIONAL RFA TERMS AND CONDITIONS: This award is being issued according to the guidelines and requirements in RFA AT-01-004, entitled "RELATION THERAPY FOR CORONARY ARTERY DISEASE."

Line M Goertz, Program Official  
(301) 402-1030 Email: goertzzc@mail.nih.gov Fax: (301) 480-3621

Lia Carper, Grants Specialist  
301-594-9102 Email: vp8g@nih.gov Fax: 301-480-3621

SHEET NUMBER: 1 U01 AT001156-01 (Revised)

LAMAS, GERVASIO A  
LOCATION: MOUNT SINAI MEDICAL CENTER (MIAMI BEACH)

	YEAR 01	YEAR 02	YEAR 03	YEAR 04	YEAR 05
Salaries and Wages	332,760	330,222			

	YEAR 01	YEAR 02	YEAR 03	YEAR 04	YEAR 05
Personnel Costs	332,760	330,222			
Consultant Services	6,000	12,000			
Travel	13,600				
Supplies	10,000	10,000			
Material Costs	120,500	81,283			
Other Costs	107,022	46,120			
Equipment/Contractual	5,254,339	6,877,884			

FEDERAL DC	5,844,221	7,357,509	7,997,047	3,972,048	3,245,544
FEDERAL F&	363,058	302,164	287,663	230,740	236,723
TOTAL COST	6,207,279	7,659,673	8,284,710	4,202,788	3,482,267
	YEAR 01	YEAR 02	YEAR 03	YEAR 04	YEAR 05

**NOTICE OF GRANT AWARDS REPORT**

&A Cost Rate 1	63.00%	63.00%	63.00%	63.00%	63.00%
&A Cost Base 1	576,282	479,625	456,608	366,254	375,751
&A Costs 1	363,058	302,164	287,663	230,740	236,723

NOTICE OF GRANT AWARDS REPORT

DA 93.213

Number:

510

Grant Number: U1AT01156A

CAN	/	FY2002	/	FY2003	/	FY2004	/	FY2005	/	FY2006
24951/		3,207,279/		4,659,673/		5,284,710/		1,202,788/		482,267
24300/		3,000,000/		3,000,000/		3,000,000/		3,000,000/		3,000,000

ADMINISTRATIVE DATA:

2 / OC: 41.4L /Processed: PUTPRUSHV 030307 0525

SECTION II - PAYMENT/HOTLINE INFORMATION - 1 U01 AT001156-01 (Revised)

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 - 1 U01 AT001156-01 (Revised)

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

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

2. Any restrictions on the expenditure of federal funds in appropriations to the extent those restrictions are pertinent to the award.

3. 45 CFR Part 74 or 45 CFR Part 92 as applicable.

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

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

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

6. Any carryover of an unobligated balance into the next budget period requires Grants Management Officer prior approval.

7. Supplemental Program Income:  
8. Indirect Costs

SECTION IV - ADDITIONAL TERMS AND CONDITIONS

1 AT-01156-01 Revision # 1

GERVASIO LAMAS

NOTICE OF GRANT AWARDS REPORT

ely yours,

ria Carper  
s Management Officer  
NAL CENTER FOR COMPLEMENTARY & ALTERNATIVE MEDICINE

dditional information below

ION I - AWARD DATA - 1 U01 AT001156-01 (Revised)

o CALCULATION (U.S. Dollars):

ries and Wages	\$332,760
onnel Costs	\$332,760
ultant Services	\$6,000
pment	\$13,600
olies	\$10,000
rel Costs	\$120,500
er Costs	\$107,022
ortium/Contractual Cost	\$5,254,339
eral Direct Costs	\$5,844,221
eral F&A Costs	\$363,058
ROVED BUDGET	\$6,207,279
NAL FEDERAL AWARD AMOUNT	\$6,207,279
OUNT OF THIS ACTION (FEDERAL SHARE)	+\$0

commended future year total cost support, subject to the  
ailability of funds and satisfactory progress of the project, is as  
llows.

- \$7,659,673
- \$8,284,710
- \$4,202,788
- \$3,482,267

ISCAL INFORMATION: