Contract No.: PR-0272

STANFORD UNIVERSITY

CONTRACT FOR RESEARCH SERVICES

SAN MATEO COUNTY

AMENDMENT NO. 4

The original agreement bearing Stanford University Contract No. PR-0272, is hereby modified as follows:

Description of change(s) made effective January 1, 2001:

1. Article 2, PERIOD OF PERFORMANCE

The Period of Performance is extended for two years, through December 31, 2002.

2. Article 3.a.(2). ALLOWABLE COSTS AND PAYMENT, is amended to include the following:

"The budget, included herein at Attachment A to this Amendment No. 4. For the period of performance from January 1, 2001 through December 31, 2002, Stanford shall pay Contractor an amount not to exceed ONE HUNDRED FORTY-TWO THOUSAND TWO HUNDRED SIXTY-SIX AND NO/100 DOLLARS (\$142,266.00)."

3. Article 4, BILLING, is deleted in its entirety and replaced with the following:

"Invoices shall be submitted quarterly (April 15, July 15, October 15, January 15) in duplicate for approval to the following Stanford representative, who will forward the approved invoices to the Controller's Office for payment:

Kristen Wong Division of Infectious Diseases Grant Bldg., Room S-156 Stanford University Stanford, CA 94305-5107 Phone: (650) 725-3933

Fax: (650) 725-2395

Email: kristen.wong@stanford.edu"

4. Article 5, HUMAN SUBJECTS, is deleted in its entirety and replaced with the following:

"Article 5, HUMAN SUBJECTS IN RESEARCH PROJECTS

Contractor assures that adequate safeguards shall be taken whenever using human subjects in research and that an institutional review committee composed of sufficient members with varying background to assure complete and adequate review of projects involving the use of human subjects has reviewed and approved the projects. Contractor shall comply with all applicable elements of Title 45 Code of Federal Regulations, Part 46.

By execution of this Contract, Contractor assures to Stanford University that it complies with the education requirement for all its key personnel as enumerated in the NIH Guide dated June 5, 2000 (revised August 25, 2000), Notice No. OD-00-039."

5. Article 6, LABORATORY ANIMALS, is deleted in its entirety and replaced with the following:

"Article 6, CARE AND TREATMENT OF LABORATORY ANIMALS

Contractor assures that whenever vertebrate animals are used in research, Contractor shall comply with the applicable portions of the Animal Welfare Act (P.L. 89-544, as amended) and its implementing regulations and shall follow the guidelines prescribed in DHHS Publication No. 86-23 (NIH), "Guide for the Care and Use of Laboratory Animals."

6. Article 8, INCORPORATION OF PHS GRANTS POLICY STATEMENT, is deleted in its entirety and replaced with the following:

"Article 8, INCORPORATION OF NIH GRANTS POLICY STATEMENT

Incorporated into this Contract by reference with the same force and effect as if set forth in full text are all the provisions of the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period, modified appropriately to reflect the circumstances that the contractual relationship created by this Contract is between Stanford and the Contractor."

7. <u>Article 9, REBUDGETING OF CONTRACT FUNDS</u>, is deleted in its entirety and replaced with the following:

"This contract is excluded from Expanded Authorities."

8. <u>Article 19, MISCONDUCT IN SCIENCE CERTIFICATION</u>, is deleted in its entirety and replaced with the following:

"Article 19, MISCONDUCT IN SCIENCE

Contractor assures that it maintains an administrative review process for dealing with and reporting possible misconduct in science and that it has an assurance on file with the Office of Research Integrity, National Institutes of Health, or, if not, it agrees to be subject to the policies of Stanford

University for dealing with and reporting possible misconduct in science with respect to research supported through this Contract."

9. Article 25, NIH GRANT AWARD TERMS AND CONDITIONS, is inserted following Article 24.

"Article 25, NIH GRANT AWARD TERMS AND CONDITIONS

The following provisions are flowed-down from Stanford's prime NIH grant and apply to this Contract:

a. "45 CFR PART 74, "UNIFORM ADMINISTRATIVE REQUIREMENTS FOR AWARDS AND SUBAWARDS TO INSTITUTIONS OF HIGHER EDUCATION, HOSPITALS, OTHER NONPROFIT ORGANIZATIONS, AND COMMERCIAL ORGANIZATIONS; AND CERTAIN GRANTS AND AGREEMENTS WITH STATES, LOCAL GOVERNMENTS AND INDIAN TRIBAL GOVERNMENTS"

(http://www.access.gpo.gov/nara/cfr/waisidx 01/45cfr474 01.html)

or

45 CFR PART 92-"UNIFORM ADMINISTRATIVE REQUIREMENTS FOR GRANTS AND COOPERATIVE AGREEMENTS TO STATE AND LOCAL GOVERNMENTS" (http://www.access.gpo.gov/nara/cfr/waisidx 01/45cfr92 01.html), as applicable.

b. "The Terms and Conditions of Award as set forth in the SPECIAL REQUIREMENTS section of RFA A1-98-013, NIH Guide to Grants and Contracts, 07/31/98. These special terms and conditions are incorporated in this award by reference.

Copies of the RFA may be accessed at the following internet address:

http://grants.nih.gov/grants/guide/rfa-files/RFA-A1-98-013.html."

10. Article 26, FINANCIAL CONFLICT OF INTEREST, is inserted following Article 25:

"Article 26, FINANCIAL CONFLICT OF INTEREST

Contractor shall comply with 42 CFR Part 50 subpart F. Contractor assures to Stanford University and PHS that it has an active and enforced policy and that its investigators are in compliance with such policy in order to protect the research from bias."

11. CERTIFICATION REGARDING DEBARMENT, SUSPENSION OR INELIGIBILITY FOR AWARD

Contractor certifies, to the best of its knowledge and belief, that -

- a. The Contractor and/or any of its principals are not presently debarred, suspended, proposed for debarment, or declared ineligible for the award of contracts by any Federal agency, and
- b. Contractor has not, within a three-year period preceding this Contract, been convicted of or had a civil judgment rendered against it for: commission of fraud or criminal offense in connection with obtaining, attempting to obtain, or performing a Federal, state or local government contract

or subcontract; violation of Federal or state antitrust statutes relating to the submission of offers; or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, tax evasion, or receiving stolen property; and

- c. Contractor is not presently indicted for, or otherwise criminally or civilly charged by a Government entity with commission of any of these offenses.
- d. Contractor shall provide immediate written notice to Stanford University if, at any time, the Contractor learns that its certification was erroneous when submitted or has become erroneous by reason of changed circumstances.

12. CERTIFICATION REGARDING PAYMENTS TO INFLUENCE FEDERAL TRANSACTIONS

- a. Contractor certifies to the best of its knowledge and belief that no Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress or an employee of a Member of Congress on Contractor's behalf in connection with the award of any resultant contract.
- b. If any funds other than Federal appropriated funds (including profit or fee received under a covered Federal transaction) have been paid, or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress on Contractor's behalf in connection with this Contract, the Contractor shall notify Stanford University and complete and submit OMB standard form LLL, Disclosure of Lobbying Activities, and
- c. Contractor will include the language of this certification in all subcontract awards at any tier and require that all recipients of subcontract awards in excess of \$100,000.00 shall certify and disclose accordingly.

13. CLEAN AIR AND WATER CERTIFICATION

Contractor certifies and represents that -

- a. Any facility to be used in the performance of this proposed contract is not listed on the Environmental Protection Agency (EPA) List of Violating Facilities.
- b. Contractor will immediately notify Stanford University of the receipt of any communication from the Administrator, or a designee, of the EPA, indicating that any facility that the Contractor proposes to use for the performance of the contract is under consideration to be listed on the EPA List of Violating Facilities; and
- c. Contractor will include a certification substantially the same as this certification, including this paragraph c. in every nonexempt subcontract (of \$100,000.00 or more).

Except as modified above, all other terms and conditions remain unchanged.

SAN MATEO COUNTY	Summary of Contract Amounts:		
By: Signature	Original Amount:	\$53,544.00	
Jerry Hill Type Name	Previous Amendments:	<u>\$136,883.00</u>	
President, Board of Supervisors San Mateo County Type Title	Total to Date:	\$190,427.00	
Signature Date	This Amendment:	<u>\$142,266.00</u>	
THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY	Revised Amount of this Agreement:	<u>\$332,693.00</u>	
By: Susan Webert Director of Procurement			
3 - 4- 0 2			

Incorporates Willow and Edison Clinical Sites

Merigan, Thomas C. Principal Investigator/Program Director (Last, first, middle): FROM THROUGH **DETAILED BUDGET FOR INITIAL BUDGET PERIOD** 1/1/2001 12/31/2001 **DIRECT COSTS ONLY** PERSONNEL (Applicant Organization Only) DOLLAR AMOUNT REQUESTED (omit cents) TYPE **EFFORT** INST. ROLE ON SALARY **FRINGE** APPT. ON BASE NAME PROJECT (months) PROJ SALARY REQUESTED BENEFITS TOTALS Principal Dennis Israelski* Investigator 12 12% 16,956 16,956 141,300 Outreach **TBA** Worker 12 25% 25,000 6,250 6,250 Edison Bill Fanning Pharmacist 10% 12,500 9,375 9,375 Willow David Freehill **Pharmacist** 10% 14,735 11,051 11,051 *Salary Capped **SUBTOTALS** \$43,632 \$43,632 CONSULTANT COSTS EQUIPMENT (Itemize) SUPPLIES (Itemize by category) Clinical and Patient Management Supplies: Alcohol wipes, bandage strips, gloves and vacutainer tubes. Folders, binders and other patient management supplies for both the Edison and Willow Clinic sites \$2,400 TRAVEL \$3,000 PI Domestic Travel PATIENT CARE COSTS INPATIENT \$19,301 OUTPATIENT OTHER EXPENSES (Itemize by category) (for both Edison and Willow Clinic sites) Communication expenses \$1,200 Storage of patient records \$600 Duplicating \$1,000 \$2,800 \$ 71,133 SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD CONSORTIUM/CONTRACTUAL DIRECT COSTS COSTS INDIRECT COSTS TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD \$ 71,133 SUBCONTRACT SAN MATEO CLINICS

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Merigan, Thomas C. Principal Investigator/Program Director (Last first middle): FROM THROUGH DETAILED BUDGET FOR INITIAL BUDGET PERIOD 1/1/2002 **DIRECT COSTS ONLY** 12/31/2002 PERSONNEL (Applicant Organization Only) DOLLAR AMOUNT REQUESTED (omit cents) TYPE **EFFORT** INST. **ROLE ON** APPT. ON BASE SALARY FRINGE NAME **PROJECT** SALARY REQUESTED (months) **PROJ** BENEFITS **TOTALS** Principal Dennis Israelski Investigator 12 10% 161,200 16,120 16,120 Outreach **TBN** Worker 12 10% 3,978 39,780 i 1,193 5,171 SUBTOTALS \$20,098 \$1,193 \$21,291 CONSULTANT COSTS Consulting Clinical Pharmacologists (Willow and Edison Sites) Edison Site: \$13,520; Willow VA Site: \$8,821 \$22,341 EQUIPMENT (Itemize) SUPPLIES (Itemize by category) Clinical Supplies: Alcohol wipes, bandage strips, gloves, vacutainer tubes and other supplies to support this project at both the Edison and Willow Clinic sites \$2,400 TRAVEL PI Domestic Travel - ACTG Meetings \$3,000 PATIENT CARE COSTS INPATIENT OUTPATIENT \$19,301 OTHER EXPENSES (Itemize by category) (for both Edison and Willow Clinic sites) Communication Expenses \$1,200 Storage of patient records, \$600 \$1,000 Duplicating, \$1,000 \$2,800 SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD \$ 71,133 CONSORTIUM/CONTRACTUAL DIRECT COSTS COSTS INDIRECT COSTS TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD 71,133 SUBCONTRACT SAN MATEO CLINIC PHS 2590 (Rev. 5/01) Page ___

COUNTY OF SAN MATEO

HEATH SERVICES Hospital and Clinics Division

MEMORANDUM

Date:	November 28, 2001							
To:	Priscilla Morse, Risk Management/ Pony # EPS 163 Fax # 363-4864							
From:	Tere Larcina, Hospital and Clinics/Pony # HOS316/Fax # 2267							
Subject:	Contract Insurance Approval							
								
CONTRACTO	OR: Stanford	University (for	Research Service	es)				
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NUMBER O	F EMPLOYEES	: More than on	e.					
support research Unit at the Wil	CIFIC): We have the activities for collow and Edison (December 31, 200)	linical trials asso Clinics. This is	ociated with Star an amendment	nford's AIDS Cl to extend the agr	inical Trial reement one			
COVERAGE:		Amount	Approve	Waive	Modify			
Comprehensive	E Liability:	<u>w</u>		1/				
Motor Vehicle	Liability:	<u>w</u>	<u> </u>	L,				
Professional Li	ability:	<u>w</u>		4//				
Worker's Com	pensation:	<u>w</u>		1				
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Drulla Mosse