CONSENT AGENDA
ITEM NO. 42

CITY OF SAN ANTONIO
INTERDEPARTMENTAL MEMORANDUM
SAN ANTONIO METROPOLITAN HEALTH DISTRICT

TO: Mayor and City Council

FROM: Fernando A. Guerra, M.D., M.P.H., Director of Health

THROUGH: Terry M. Brechtel, City Manager

COPIES: Frances A. Gonzalez, Assistant City Manager; City Attorney's Office; Office of Management and Budget; Finance Department; Project; File

SUBJECT: ORDINANCE AUTHORIZING A CLINICAL TRIAL AGREEMENT WITH NOVARTIS PHARMACEUTICALS CORPORATION

DATE: December 4, 2003

SUMMARY AND RECOMMENDATIONS

This ordinance authorizes the City Manager to accept and execute a clinical trial agreement with Novartis Pharmaceuticals Corporation providing up to $139,600.00 for the period October 1, 2003 through September 30, 2005 for the San Antonio Metropolitan Health District to participate in a clinical trial to evaluate the effectiveness of Famvir®, a medication for the treatment of recurrent genital herpes in adults. This ordinance will also establish a fund, adopt the project budget and authorize payments for stipends to clinical trial participants.

Staff recommends approval.

BACKGROUND INFORMATION

The San Antonio Metropolitan Health District (SAMHD) has a Sexually Transmitted Disease (STD) Program and Clinic that are supported through grants from the Texas Department of Health and the STD Control activity of the City General Fund. Services provided by the STD Clinic include testing, diagnosis and treatment for sexually transmitted diseases for approximately 11,000 patients each year who visit the SAMHD for sexually transmitted diseases. Clinic staff also conducts counseling to control and prevent the spread of sexually transmitted diseases, including HIV/AIDS and viral hepatitis, and make field investigations for partner notifications.

Novartis Pharmaceuticals Corporation (Novartis) has offered an Investigator Agreement to the SAMHD for the Sexually Transmitted Disease Clinic to participate in the Novartis Famvir® Vaccine Study Project for the treatment of recurrent genital herpes in adults. The Project will include use of an FDA approved (1995) medication for the treatment of recurrent genital herpes, *Famvir®*. The study will determine the effectiveness of taking a stronger oral medication for one (1) day instead of the currently approved lesser dosage for five (5) days.

The Project will look at an alternative way to treat recurrent genital herpes in adults that will have the following benefits if successful:

1. Allow patients to be more compliant with treatment due to the shorter medication period
2. Cost effective use of medications

3. Less risk of unwanted side effects
4. Control of an outbreak sooner to reduce the opportunity for spread of the disease.
5. Heal the lesions faster to lessen the risk of spread to the newborn at delivery

Novartis will pay SAMHD up to $139,600.00 for participation in this clinical trial depending on participant enrollment, cooperation with the follow-up visits and telephone conferences. SAMHD will recruit up to twenty-four (24) participants for the Novartis Famvir® Vaccine Study Project. These participants will be asked to visit the STD clinic on average six (6) times over the two (2) year period of the clinical trial (October, 2003 - September, 2005). Each participant will receive a stipend of approximately $25.00 per visit as compensation for time and travel. This clinical trial will be conducted with current existing personnel and positions, supplemented as needed with on-call contract licensed physicians and registered nurses for weekend coverage at the Clinic.

POLICY ANALYSIS

Acceptance of this agreement from Novartis will continue the long-standing practice of utilizing Federal, State, local and other aid that is available to support the public health programs of the City.

FISCAL IMPACT

The Novartis Famvir® Vaccine Study Project will provide up to $139,600.00 for the STD Program in the SAMHD for the period October 1, 2003 through September 30, 2005. Acceptance of this agreement will place no demands on the City General Fund.

COORDINATION

The City Attorney's Office and the Office of Management and Budget, Risk Management Division, have reviewed the Clinical Trial Agreement with Novartis. The Finance Department has approved the project budget.

SUPPLEMENTARY COMMENTS

Provisions of the Ethics Ordinance do not apply.

Attachments: Attachment I: Project Budget
Attachment II: Clinical Trial Agreement

Fernando A. Guerra, MD, MPH
Director of Health

Frances A. Gonzalez
Assistant City Manager

APPROVED:

Terry M. Brechtel
City Manager

ATTACHMENT I

Novartis Famvir Protocol CFAM810A 2402 Vaccine Study Project

Fund and Project No. 26-012252

Budget for Period: October 1, 2003 through September 30, 2005

INDEX	ESTIMATED REVENUES	OBJECT CODE	CURRENT BUDGET
062422	Novartis Pharmaceuticals Agreement	00-008	$ 139,600
	Total Estimated Revenues		139,600
	APPROPRIATIONS		
783092	Overtime Salaries and Wages	01-011	63,000
783233	Social Security	01-030	4,820
783373	TMRS	01-040	7,195
783514	Life Insurance	01-051	110
783654	Communications: Telephones	02-110	500
783795	Mail and Parcel Post Service	02-113	4,000
783936	Car Expense Allowance	02-130	700
784074	Fees to Professional Contractors	02-160	8,275
784215	Temporary Services	02-161	20,000
784355	Automatic Data Processing Services	02-172	5,000
784496	Advertising and Publication	02-175	2,000
784637	Other Contractual Services	02-193	3,000
784777	Office Supplies	03-210	4,000
784918	Chemicals, Medical and Drugs	03-228	8,000
785055	Computer Equipment	05-360	4,000
785196	Machinery & Equipment - Other	05-373	2,000
785337	Furniture and Fixtures	05-375	3,000
	Total Appropriations		$ 139,600

Fund Only Index: 001468

Organization Code: 36-07-92

NOVARTIS PHARMACEUTICALS CORPORATION
East Hanover, NJ 07936

ATTACHMENT II

CLINICAL TRIAL AGREEMENT
for Institutions

Effective Date: October 1, 2003 through September 30, 2005

Project: CFAM810A

Study #: 2402

Center #: 516 (Guerra)

CLINICAL TRIAL AGREEMENT
for Institutions

INDEX

CLINICAL TRIAL AGREEMENT

This Agreement is entered into by and between the **City of San Antonio,** a Texas Municipal Corporation, acting by and through the Assistant City Manager for the **San Antonio Metropolitan Health District**, with its principal office and place of business at **332 W. Commerce, Suite 307, San Antonio, TX 78205-2489** hereinafter called "Institution", and Novartis Pharmaceuticals Corporation, a corporation with its principal office and place of business at 59 Rt. 10, East Hanover, NJ 07936, hereinafter called "Novartis".

1. **SCOPE OF WORK**
The Institution shall exercise its best efforts to carry out the research ("Research") set forth in Protocol No.CFAM810A **2402**, entitled **" RANDOMIZED, DOUBLE-BLIND, PLACEBO CONTROLLED, MULTICENTER STUDY TO ASSESS THE EFFICACY AND SAFETY OF A PATIENT INITIATED 1-DAY TREATMENT WITH FAMCICLOVIR 1000 MG B.I.D. FOR RECURRENT GENITAL HERPES INFECTION IN IMMUNOCOMPETENT PATIENTS "** ("Protocol"), in accordance with this Agreement.

2. **PRINCIPAL INVESTIGATOR**
Institution's principal investigator is **Fernando A. Guerra, MD, MPH** ("Principal Investigator"), who will be responsible for the direction of the Research in accordance with applicable Institution policies which Institution warrants and represents are not inconsistent with the terms of this Agreement and the Protocol. If for any reason, he/she is unwilling or unable to continue to serve as Principal Investigator and a successor, acceptable to both the Institution and Novartis, is not available, this Agreement shall be terminated as provided in Article 13.

3. **PERFORMANCE PERIOD**
The effective period of this Agreement will be from **October 1, 2003** through **September 30, 2005**. In the event that the Research is not completed within the effective period, Novartis may extend the effective period by written notification to the Institution.

4. **RECORDKEEPING, REPORTING AND ACCESS**
A. It is agreed that Novartis authorized representative(s), and regulatory authorities to the extent required by law, may, during regular business hours, arrange in advance with the Principal Investigator and Institution to:

(1) examine and inspect the Institution's facilities required for performance of the Research; and

(2) inspect and copy all data and work products relating to the Research.

B. The Institution and the Principal Investigator shall perform the following recordkeeping and reporting obligations in a timely fashion:

(1) Preparation and maintenance of complete, accurately written records, accounts, notes, reports and data of the Research. Federal regulations require that copies of case report forms and all source documentation be retained by the Principal Investigator for a period of no less than two years following either the approval of the New Drug Application or the withdrawal of the Investigational New Drug Application. Foreign laws and regulations may require longer retention periods. For example, current International Conference on Harmonization ("ICH") guidelines currently provide:

"Essential documents should be retained until at least 2 years after the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applications in an ICH region or at least 2 years have elapsed since the formal discontinuation of clinical development of the investigational product. These documents should be retained for a longer period however if required by the applicable regulatory requirements or by an agreement with the sponsor. It is the responsibility of the sponsor to inform the investigator/institution as to when these documents no longer need to be retained."

Institution shall retain the above records unless and until Novartis provides written permission to dispose of the same, consistent with applicable laws, regulations and guidelines. Novartis will respond promptly to Institution's requests direct to the Novartis contact for "Research Related Matters", to dispose of records.

Attention of the Principal Investigator is drawn to the fact that he/she may be subject to a field audit by inspectors of the U.S. Food and Drug Administration ("FDA") or comparable foreign regulatory agencies and by representatives from Novartis to verify that the study is conducted in accordance with the requirements of the Protocol, as well as in compliance with the federal regulations concerning the distribution and administration of Investigational New Drugs; and

(2) Preparation and submission to Novartis of all original case report forms ("Case Reports") and electronic files (if applicable) for each patient or subject participating in the Research ("Research Subject") as provided in the Protocol.

C. All written records, reports and data of the Research (other than individual patient records) shall be the sole and exclusive property of Novartis. However, nothing shall prevent the Institution and the Principal Investigator from:

(1) maintaining copies of such materials;

(2) using such materials for their own internal educational, research and patient care purposes;

(3) using such materials to comply with any federal, state or local government laws or regulations; or

(4) publishing articles based on these materials under the provisions of this Agreement.

D. Novartis and its affiliates, assigns, licensees and its licensors and its licensors' affiliates, assigns and other licensees shall be free to incorporate the results of the Research in any regulatory filing concerning the study drug(s). The Institution and the Principal Investigator understand and agree that they shall have no ownership, license or access rights in, or to, such regulatory filings solely based upon the inclusion of the results of the Research therein.

5. **COST AND PAYMENT**

Payment shall be made to the Institution according to Schedule A appended hereto and incorporated herein by reference. All costs outlined on Schedule A shall remain firm for the duration of the Research, unless otherwise agreed to in writing by the Institution and Novartis.

Neither Institution nor Investigator shall directly or indirectly seek or receive compensation from patients or third-party payers for any treatment or services that are required by the Protocol and are paid for by Novartis. These services shall include, but are not limited to, study drug provided by Novartis, patient screening, treatment visits, infusion, physician or nurse fee, diagnostic tests or study drug administration.

The costs of the Research set forth on the Schedule A attached hereto represent all costs of performing the Research, including overhead. The Institution and the Principal Investigator agree that no additional funding that may jeopardize or adversely impact on the rights granted to Novartis in Article 8 or any other article of this Agreement, such as a "funding agreement" (as defined in 35 USC 201) with the United States Government or a department or agency thereof, shall be used for any part of the Research.

6. **CONFIDENTIAL INFORMATION**

A. The Institution agrees not to disclose or to use for any purpose other than performance of the Research any and all trade secrets, privileged records or other confidential or proprietary information (collectively "Information") disclosed to or developed by the Institution pursuant to this Agreement or any previous confidentiality agreement(s) relating to the Research. The obligation of non-disclosure and non-use shall not apply to the following:

(1) Information at or after such time that it is or becomes publicly available through no fault of the Institution;

(2) Information that is already independently known to the Institution as shown by its prior written records, provided that the Institution so advises Novartis promptly upon the Institution's discovery that the Information is already independently known to the Institution;

(3) Information at or after such time that is disclosed to the Institution on a non-confidential basis by a third party with the legal right to do so; or

(4) Information required to be released by any governmental entity with jurisdiction, provided that the Institution notifies Novartis prior to making such release of Information.

B. The obligations of the Institution under this Article shall survive and continue for five (5) years after termination of this Agreement.

C. In the event Novartis shall come into contact with Research Subject's medical records, Novartis shall hold in confidence the identity of the patient and shall comply with all applicable law(s) regarding the confidentiality of such records.

D. In the event the Institution finds it necessary to disclose Information to a proper authority to permit the Institution to defend its research against an allegation of fraud, the Institution shall first notify Novartis and the Institution and Novartis shall agree to a mutually satisfactory way to disclose such Information as necessary for this limited purpose.

E. Institution agrees to hold the results of the study in confidence, subject to its rights under Article 7.

F. Institution hereby represents, warrants and agrees that, as of the date of enrollment of each individual participating as a Research subject, it will obtain from each such individual an authorization that meets the requirements of the privacy rule issued under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA Privacy Rule") set forth at 45 C.F.R. § 164.508(b) & (c). Such authorization shall permit (i) all necessary uses of the individual's "protected health information" ("PHI"), as that term is defined in the HIPAA Privacy Rule, 45 C.F.R. § 164.501, by Institution and the Principal Investigator as part of the Research and (ii) all disclosures of such PHI by Institution and the Principal Investigator, to Novartis and its authorized agents and the Research team and other professionals involved in the Research for purposes relating to the Research or other purposes permitted by law.

7. **PUBLICATION/PRESENTATIONS**

Publication of a summary of the results of the Research is permissible in the view of Novartis and is not inconsistent with the preceding affirmation regarding confidentiality. Any formal presentation or publication of data collected as a direct or indirect result of the Research will be considered as a joint publication by the Institution and the appropriate personnel of Novartis. Authorship will be determined by mutual agreement.

For any publication or presentation, a manuscript of the paper, abstract or other materials must be reviewed by Novartis prior to any outside submission. A period of fifteen (15) working days for presentational materials and abstracts and forty-five (45) working days for manuscripts will be required for Novartis review. These requirements acknowledge Novartis' responsibility to evaluate such publications for their accuracy, to ascertain whether proprietary information (including trade secrets and patent protected materials) is being utilized and inappropriately released, to provide the Principal Investigator with information which may not yet have been available to him/her, and to provide input from co-authors regarding content and conclusions of the publication or presentation.

If an invention is described in a proposed publication which in the opinion of Novartis should be made the subject of a patent application, Novartis shall have four (4) months after full disclosure to Novartis to file such patent application. Institution shall withhold publication respecting that invention until such application is so filed by Novartis.

For multicenter studies it is mandatory that the data will be pooled and analyzed as stipulated in the Protocol. Authorship will include representatives from each active trial site and from Novartis. It is agreed that no presentations or publications will be authorized individually or by subgroups participating in the trial without the consent of all the relevant parties prior to publication of the pooled data, but in no event shall any institution or principal investigator involved in this study be restricted from publishing independently after the expiration of twenty-four (24) months from the completion of Research.

8. **INVENTIONS AND PATENTS**

A. All inventions and patents resulting from the performance of the Research shall be owned by Novartis and may be used and/or transferred by Novartis for any lawful purpose with no further payment to the Institution and/or Principal Investigator. The Institution and Principal Investigator shall be free to use such inventions and patents for their own internal educational, research and patient care purposes, as well as to comply with any federal, state or local government laws or regulations.

B. In the event that Novartis decides to file one or more United States and/or foreign patent applications covering one or more inventions resulting from the performance of the Research, the Institution and each Principal Investigator shall, at the request and expense of Novartis, assist Novartis in the preparation and prosecution of such patent application(s) and shall execute all documents deemed necessary by Novartis for the filing thereof and/or for the vesting in Novartis of title thereto.

9. **PUBLICITY**
Neither party shall use the other party's name, nor issue any public statement about this Agreement, including its existence, without the prior written permission of the other party, except as required by law (and, in such case, only with prior notice to the other party). Such prior permission shall not be unreasonably withheld. The parties agree that in order for Institution to satisfy its reporting obligations, it may identify Novartis as the Research sponsor and the amount of funding received from Novartis for the Research, but will not include in such report any information which identifies the name of the Research compound or the therapeutic areas of the Research.

10. **APPLICABLE LAW**
This Agreement shall be governed by the laws of the State of New Jersey.

11. **NOTICE**
Any notice required or permitted hereinunder shall be in writing and shall be deemed given as of the date if it is (A) delivered by hand or (B) sent by registered or certified mail, postage prepaid, return receipt request, and addressed to the party to receive such notice at the address set forth below, or such other address as is subsequently specified in writing:

IF TO NOVARTIS:

For all payment queries, the following information must be provided (please refer to Schedule A):

1. Project (compound)
2. Study #
3. Center #
4. PI name
5. PO # (if available)

and Contact:
Marie Ronca
Novartis Pharmaceuticals Corporation
One Health Plaza, Bldg. 419, Rm. 2180
East Hanover, NJ 07936
Phone: 862-778-8526

The above information must also be included on all invoices.

For Contract Matters:
Eileen Sieffert
Novartis Pharmaceuticals Corporation
One Health Plaza, Bldg 419, Rm.
East Hanover, NJ 07936-1080
Phone: 862- 778-4082
Fax: 973-781-3035
E-mail: howard.ngai@pharma.novartis.com

For Research Related Matters:
Erhan Berber, MD
Novartis Pharmaceuticals Corporation
One Health Plaza, Bldg. 701, Rm. 531
East Hanover, NJ 07936-1080
Phone: 862- 778-4208
Fax: 973-781-7749
E-mail: erhan.berber@pharma.novartis.com

IF TO INSTITUTION:

For Technical Matters:
Fernando A. Guerra, MD, MPH
San Antonio Metropolitan Health District
332 W. Commerce, Suite 307
San Antonio, TX 78205-2489
Phone: 210-207-8731
Fax: 210-207-8999
E-mail: fguerra@sanantonio.gov

For Administrative Matters:
Fernando A. Guerra, MD, MPH
San Antonio Metropolitan Health District
332 W. Commerce, Suite 307
San Antonio, TX 78205-2489
Phone: 210-207-8731
Fax: 210-207-8999
E-mail: fguerra@sanantonio.gov

12. **INDEMNIFICATION**

A. Novartis shall defend, indemnify and hold harmless the Institution, the Principal Investigator and any agents and employees of Institution (collectively the "Indemnitees") from any and all liabilities, claims, actions or suits for personal injury or death directly arising out of or in connection with the administration or use of the drugs being studied through the Research ("Research Study Drugs") during the course of the Research; provided however:

(1) that the Research is conducted in accordance with the Protocol, all written instructions delivered by Novartis concerning administration of the Research Study Drugs or devices and Good Clinical Practice regulations;

(2) that such loss does not arise out of the negligence or willful malfeasance of any Indemnitee, or any other person on the Institution's property, exclusive of Novartis employees;

(3) that Novartis is promptly notified in writing no later than ten (10) days of any complaint, claim or injury relating to any loss subject to this indemnification; and

(4) that Novartis shall have the right to select defense counsel and to direct the defense or settlement of any such claim or suit.

B. Deviations from the terms of the Protocol that may arise out of necessity do not constitute negligence or willful malfeasance provided that Institution promptly shall notify Novartis in writing of any such deviations.

C. Novartis warrants that it maintains a policy or program of insurance or self-insurance at levels sufficient to support the indemnification obligations assumed herein. Upon request Novartis will provide evidence of its insurance.

D. The Institution agrees that it will maintain during the performance of this Agreement the following insurance or self-insurance in amounts no less than that specified for each type:

(1) general liability insurance with combined limits of not less than $1,000,000 per occurrence and $1,000,000 per accident for bodily injury, including death, and property damage;

(2) Worker's Compensation Insurance in the amount required by the law of the state in which the Institution's workers are located and employer's liability insurance with limits of not less than $1,000,000 per occurrence; and

(3) In the event that the use of a motor vehicle is required in the performance of this Agreement, Auto Liability Insurance with combined limits of not less than $1,000,000 per occurrence and $1,000,000 per accident for bodily injury, including death, and property damage is required.

E. Upon request, the Institution will provide evidence of its insurance or self-insurance and, unless the Institution is self-insured, will name Novartis as an additional insured party under Institution's insurance policy, and will provide to Novartis, thirty (30) days prior written notice of any change or cancellation in its coverage.

13. **TERMINATION**

A. This Agreement may be terminated by either party for any safety and/or efficacy concerns, upon ten (10) days prior written notice.

B. This Agreement may be terminated by Novartis for any other reason, other than those mentioned in 13A above, upon thirty (30) days written notice.

C. In the event that Novartis exercises its termination right, Novartis will reimburse Institution for costs and non-cancelable commitments incurred prior to the giving of such notice, and shall not be responsible, after such termination, for any other amounts set forth in this Agreement.

D. The Institution will return within sixty (60) days to Novartis any funds not expended or irrevocably obligated by the Institution prior to the effective termination date.

E. Immediately upon receipt of a notice of termination, the Principal Investigator shall stop entering Research Subjects into the Protocol and shall cease conducting procedures on Research Subjects already entered in the Protocol as directed by Novartis, and to the extent medically permissible.

F. Termination of this Agreement by either party shall not affect the rights and obligations of the parties accrued prior to the effective date of the termination. The rights and duties under Articles 4, 6, 7, 8, 9, 10, 12, 18, 19, and 20 survive the termination or expiration of this Agreement.

14. **ENTIRE AGREEMENT**
This Agreement represents the entire understanding of the parties with respect to the subject matter hereof. In the event of any inconsistency between this Agreement and the Protocol, the terms of this Agreement shall govern. The invalidity or unenforceability of any term or provision of this Agreement shall not affect the validity or enforceability of any other term or provision hereof.

15. **ASSIGNMENTS BY INSTITUTION**
This Agreement, and all rights and obligations hereunder may not be assigned by Institution without the express written consent of Novartis.

16. **NO TRANSFER OF PROPRIETARY RIGHTS NOT SPECIFIED**
It is agreed that neither Novartis nor the Institution transfers to the other by operation of this Agreement any patent right, copyright right, or other proprietary right of either party, except as specifically set forth herein.

17. **CHANGES TO THE PROTOCOL**
Novartis may at any time modify the Protocol by written notice to Institution, after approval by the Principal Investigator and, if required, by the Institutional Review Board. No financial adjustments shall be made because of such modification unless the parties hereto amend this Agreement accordingly.

18. **DELIVERY TO NOVARTIS OF UNUSED MATERIALS**
Within thirty (30) days following termination or completion of the Research, all unused compounds, drugs, devices, case reports, whether or not completed, and other related materials that were furnished to the Institution by or on behalf of Novartis shall be returned to Novartis at Novartis' expense.

19. **CONFORMANCE WITH LAW AND ACCEPTED PRACTICE**
The Institution shall perform the Research in conformance with generally accepted standards of good clinical practice, with the Protocol, and with all applicable local, state, federal and foreign laws and regulations governing the performance of clinical investigations including but not limited to the Federal Food, Drug and Cosmetic Act, regulations of the FDA including 21 C.F.R. Part 54 relating to Financial Disclosure by Clinical Investigators [if applicable], and those of comparable foreign agencies, and the privacy rule issued under the Health Insurance Portability and Accountability Act of 1996, 45 C.F.R. Parts 160 & 164.

20. **DEBARMENT CERTIFICATION**
Neither the Institution nor any person employed thereby directly in the performance of the Research has been debarred under section 306(a) or (b) of the Federal Food, Drug and Cosmetic Act and no debarred person will in the future be employed by the Institution in connection with any work to be performed for or on behalf of Novartis. In addition, the Institution has verified that no person employed by the Institution in connection with any work performed for or on behalf of Novartis is on any of the following FDA Restricted Lists: Disqualified/Totally Restricted List for Clinical Investigators, Restricted List for Clinical Investigators, Adequate Assurances List for Clinical Investigators. If at any time after execution of this contract, the Institution becomes aware that the Institution or any person employed thereby is, or is in the process of being debarred or is on any of the 3 FDA Restricted Lists noted above, the Institution hereby certifies that the Institution will so notify Novartis at once.

(THIS SPACE INTENTIONALLY LEFT BLANK)

IN WITNESS WHEREOF, the parties hereto have executed this Agreement in duplicate by proper persons thereunto duly authorized.

NOVARTIS PHARMACEUTICALS CORPORATION

By: _____
(signature)

Sheila Straub
(print or type name)

Title: Vice President
US International Clinical Research Operations

Date: _____

CITY OF SAN ANTONIO:
SAN ANTONIO METROPOLITAN HEALTH DISTRICT

By: _____
Frances A. Gonzalez
Assistant City Manager

ATTEST:

By: _____
Yolanda L. Ledesma
Acting City Clerk

APPROVED AS TO FORM:

By: _____
Andrew Martin
City Attorney

PRINCIPAL INVESTIGATOR

I have read this Agreement and understand and accept my obligations hereunder.

By: _____
Fernando A. Guerra, MD, MPH
Director of Health

Date: _____

INTERNAL REVENUE SERVICE REQUIREMENT

FOR INFORMATIONAL PURPOSES ONLY

Regulatory changes of the US Internal Revenue Service (IRS) and Small Business Administration (SBA) make it necessary to provide the Standard Industrial Code (SIC), Vendor Classification, Federal Taxpayer Identification Number (tin) or Social Security Number (for an individual) for all vendors. Your department of taxation or financial officer will be able to provide this information, however, the following definitions may be helpful in determining this information.

The two most commonly used SIC Codes for Clinical Trial Sites are 80 and 87 as defined below:

Major Group 80: Hospital or University

Hospital or University providing a service that is health related i.e., research, studies etc.

Major Group 87: Engineering, Accounting, Research, Management, And Related Services

- Agricultural research
- Biological research commercial
- Chemical laboratories, commercial research except testing
- Engineering laboratories, commercial research: except testing
- Food research commercial
- Industrial laboratories commercial research: except testing
- Physical research commercial
- Research and development physical and biological: commercial

The next page will provide definitions of frequently used Business Classification Numbers.

This information must be included on the attached Schedule A.
Please note: This information must be provided before payment can be issued.

FOR INFORMATIONAL PURPOSES ONLY

SUPPLIER/CONTRACTOR CLASSIFICATION FORM

Business Classification:

Contact your nearest Small Business Administration (SBA) office with any classification questions (www.sba.gov/services/.)

(1) Small Business
A small business is a concern that, including affiliates, is independently owned and operated, is not dominant in its field of operation, and meets the appropriate size standards established by the SBA. Size thresholds for different industries, measured either according to the number of employees of a concern or its annual receipts are set forth in various Standard Industrial Classification (SIC) codes. A breakdown of the SIC codes and applicable thresholds may be found on the Internet at **www.sba.gov/gc/siccodes.html**

(1a) Small Disadvantaged Business
A small disadvantaged business (SDB) is a small business owned and controlled by one or more socially and economically disadvantaged individuals. In terms of ownership, to qualify as an SDB a concern must be at least 51% unconditionally owned by one or more socially and economically disadvantaged individuals (in the case of a publicly owned business, at least 51% of its stock must be unconditionally owned by one or more such individuals). In addition, the concern's management and daily business operations must be controlled by one or more socially and economically disadvantaged individuals. Socially and economically disadvantaged individuals include Black Americans, Hispanic Americans, Native Americans, Asian-Pacific Americans, Subcontinent Asian Americans, other minorities, and individuals that are not members of designated groups but can establish their individual disadvantage according to the test set forth in SBA regulations. Firms that have received 8(a) certification automatically qualify as SDBs. Organizations that fall within this description should obtain SBA certification in order to maintain their SDB status.

(3) Minority Owned
A business that is at least 50% owned by one or more minority US citizens; it's management and daily operation controlled by one or more such individuals. In the case of a publicly owned business, at least 51% of the stock must be owned by one or more such individuals. A minority individual must be a member of one of the following groups: Black American, Hispanic American, Native American (i.e. American Indian, Eskimo, Aleut, and Native Hawaiian), Asian-Pacific American (i.e. US citizen whose origin is from Japan, China, the Philippines, Vietnam, Korea, Samoa, Guam, and US Trust Territories of the Pacific Northern Marianas, Laos, Cambodia or Taiwan).

(2) Women-Owned Small Business
A women-owned small business is a small business that is at least 51% owned by one or more women, (or, in the case of any publicly owned business, at least 51% of the stock of which is owned by one or more women) and whose management and daily business operations are controlled by one or more women.

(37) HUBZone Small Business
A HUBZone small business concern is a business that is considered a small business (according to the test described above), is exclusively owned and controlled by United States citizens, has its principal office located in a HUBZone, and can show that 35% of its employees reside in a specified HUBZone. (www.sba.gov/hubzone)

(39) Disabled Veteran
Veteran of the military with service connected disability.

(4) Large Business
(6) University
(35) Non-Profit Organization
(8) Hospital

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NOVARTIS PHARMACEUTICALS CORPORATION

SCHEDULE A

TA # TA Name:

PART I: INSTITUTION INFORMATION

Project (compound): **CFAM810A**
Effective Period: **July 1, 2003 to December 31, 2004**
Principal Investigator: Fernando A. Guerra, MD
Institution Name: San Antonio Metropolitan Health District
Payee: San Antonio Metropolitan Health District
Payee Remit To Address:
Attn: Fernando A. Guerra, MD
San Antonio Metropolitan Health District
332 W. Commerce
San Antonio, TX 78205-2489

Study #: **2402**
Center #: **516**
Phone: 210-207-8731
SIC Number: 87
Business Class: 1
Tax ID #: **74-6002070**
Instit. Admin. Contact Name: Fernando Guerra, MD
Admin. Phone: 210-207-8731

Novartis Contract Manager (Contract & Budget Negotiation): **Eileen Sieffert** **Phone:** **862-778-7549**
Novartis Payments Contact: **Marie Ronca** **Phone:** **862-778-8526**
Novartis TA/Medical Contact: **Erhan Berber, MD** **Phone:** **862-778-4208/FAX 973 781-7749**

PART I: PAYMENT SCHEDULE

#Pts	**24**
CPP $	**2,457.50**

Add/ Delete/ Change (A, D, C)	P.O. Line Item #	% of Total Cost Per Patient	Amount ($)	Expected Date	Condition of Payment	Cost Center	G/L Acct #
	1	5%	$2,949.00	Oct-03	Initial Payment Upon Drug Shipment (automatic payment)	8720	
	2	75%	$44,235.00	Jan-04 Mar-04 Jun-04 Sep-04	Interim Payments based on submission of Novartis-generated internal invoices completed by the Novartis LTL for: **The number of visits completed X Cost per Visit(s) in accordance with Schedule A Less:** initial and final payment amounts in accordance to this Agreement and as verified by Novartis.		6 2 0 3 2 1
	3	20%	$11,796.00	Dec-04	Final Review and Acceptance of ALL Clinical Data for all Enrolled Patients by Novartis and Completion of all Required Administrative Matters by the Investigator. The maximum sum assumes completion of ALL patients. **(including completion and return of Financial Disclosures Form to Novartis if applicable)**		
		100%	**$58,980.00**		**SUBTOTAL - Patient Costs**		
	4	n/a	$9,091.20	***Invoiced by site on Novartis-generated invoice form***	Screen Failures		
	5	n/a	$1,320.00	***Internally Invoiced by Novartis LTL on Novartis-generated invoice form***	Electronic Data Capture Support (paid after the first patient visit)		
	6	n/a	$2,220.00	***Invoiced by site on Novartis-generated invoice form***	Unscheduled Visits		

TOTAL AMOUNT	**$71,611.20**

	7	n/a	$58,980.00	Dates of payment TBD	**24**	Additional Patients if Approved by Novartis			
	8	n/a	$9,091.20	Dates of payment TBD	**12**	Additional Screen Failures if Approved by Novartis			

GRAND TOTAL	**$139,682.40**

R & D PURCHASING			
Purchase Order #:	**Vendor #:**	**Date:**	**WBS Element: D-FAM810A / 2402**

Schedule A (Page 2 of 5)

COST AND PAYMENT TERMS

As consideration for performance under the terms of this Agreement, Novartis agrees to pay the Institution an amount **as outlined in the attached Detailed Cost Page**. Actual charges shall be based upon completed, evaluable Research Subjects. The maximum sum assumes completion of **the agreed upon number of** Research Subjects in accordance with the scope of work set forth in the Protocol. **Additional Research Subjects, if** approved by Novartis, shall be paid **at the same negotiated cost per patient** . Payment includes all applicable overheads. Invoiced Items **as outlined on the attached Detailed Cost Page** will be paid upon receipt of itemized invoices. Any payment(s) for partially completed enrolled patients will be prorated and dependent on Novartis' verification and approval. Checks will be made payable to Payee as listed above and will be sent to the address as listed under Payee.

All non-procedural invoiced items will be paid based on expenses incurred up to the amount on the first page of the Schedule A upon receipt of:

1) an invoice on Institution letterhead or on a Novartis-generated invoice form, if available, and
2) back-up documentation for third party expenses.

Novartis does not pay for work not performed nor expenses not incurred.

The Total Cost Per Patient will be pro-rated as indicated on Part I: Payment Schedule, unless otherwise noted. Cost Per Patient payments will be made as follows:

1. The initial payment shall be made upon drug shipment.
2. The interim payments are based on:

   The number of visits completed

   Multiplied by: The cost per visit(s) in accordance with the detail page of the Schedule A

   Minus: The initial payment in accordance to this Agreement and as verified by Novartis, until depleted.

3. The final payment will be paid upon final review and acceptance of ALL clinical data for all enrolled patients by Novartis and completion of all required administrative matters by the investigator. The maximum sum assumes completion of ALL patients.

SCREENING FAILURES

Novartis will reimburse Institution for Screen Failure costs **as outlined in the Screen Failure Invoice Page** upon receipt of an itemized invoice. A "Screen Failure" is a subject who fails to meet the screening visit criteria and so is not eligible for enrollment into the study. The total reimbursement amount per Screen Failure is determined by totaling the procedures performed up to the point the subject fails. The procedures to be performed at the screening visit should be performed in the order as seen on the Screen Failure invoice page. Novartis will only pay for procedures performed.

COMPETITIVE ENROLLMENT

Institution acknowledges that this is a multicenter study designed to evaluate a set number of Research Subjects. Each Institution participating in the Research will be expected to enroll the number of Research Subjects provided for under the contract. Additionally, as the study progresses and individual institutions meet the contracted number of Research Subjects, Novartis may invite Institution to enroll more patients. If this is acceptable to Institution, Novartis will notify Institution via written request to allow for the enrollment of the additional patients. Institution further acknowledges that it, therefore, may not have the opportunity to enroll the number of Research Subjects set forth above. When enrollment of the target number of Research Subjects for the entire Study is complete, those sites which have not enrolled the contracted number of Research Subjects will be notified and instructed not to continue enrolling Research Subjects.

STANDARD OF CARE PROCEDURES

Novartis will reimburse Institution for any procedure, or percentage thereof, in accordance with the scope of work set forth in the Protocol and not covered by patient's insurance provider. Institution shall not seek any reimbursement from a Research Subject. Payment will be made semi-annually in July and January upon receipt of documentation and itemized invoice.

Part II: DETAILED COSTS - CORE

Project: CFAM810A **Study:** 2402 **P.I.:** Fernando A. Guerra, MD **Center #:** 516

Procedure	Freq	Cost Per Unit	Recruitment Screen/ Randomization Visit 1	Patient Contact	Treatement and Evaluation Period Day 1 Visit 2	Day 2 Visit 3	Day 3 Visit 4	Day 5 Visit 5	Day 7 Visit 6	End of Study Visit	Total Cost Per Patient
Initial office or other outpatient exam, with comprehensive history, physical	1	$200.00	$200.00								$200.00
Antibody; herpes simplex (HSV Serology)	1	$74.00	$74.00								$74.00
Expanded office or other outpatient exam; expanded problem focused history	6	$125.00			$125.00	$125.00	$125.00	$125.00	$125.00	$125.00	$750.00
Urine pregnancy	1	$31.00	$15.50		$15.50						$31.00
Telephone call to patient for consultation or medical management	5	$16.00		$75.00							$75.00
Procedure Subtotal			$289.50	$75.00	$140.50	$125.00	$125.00	$125.00	$125.00	$125.00	$1,130.00
Nurse---per hour	13.5	$55.00	$165.00		$82.50	$82.50	$82.50	$82.50	$82.50	$165.00	$742.50
Diary Instruction/review	7	$25.00	$25.00		$25.00	$25.00	$25.00	$25.00	$25.00	$25.00	$175.00
Coordinator fee---Preparation for Monitoring Visits	3.5	$40.00	$20.00		$20.00	$20.00	$20.00	$20.00	$20.00	$20.00	$140.00
Pharmacy---per visit	2	$20.00	$20.00		$20.00						$40.00
Patient Reimbursement	7	$25.00	$25.00		$25.00	$25.00	$25.00	$25.00	$25.00	$25.00	$175.00
Patient Supplies---Pregnancy Kit	1	$55.00	$27.50		$27.50						$55.00
Total Other Direct Cost			$282.50	$0.00	$200.00	$152.50	$152.50	$152.50	$152.50	$235.00	$1,327.50
Total Cost Per Visit			$572.00	$75.00	$340.50	$277.50	$277.50	$277.50	$277.50	$360.00	**$2,457.50**
Total Cumulative Cost Per Visit			$572.00	$647.00	$987.50	$1,265.00	$1,542.50	$1,820.00	$2,097.50	$2,457.50	
Number of Patients			24	24	24	24	24	24	24	24	24
Total Cumulative Cost for 24 Pts			$13,728.00	$15,528.00	$23,700.00	$30,360.00	$37,020.00	$43,680.00	$50,340.00	$58,980.00	**$58,980.00**
INVOICED COSTS:											
Screen Failures	Maximum of	12			Failures at	$757.60					$9,091.20
EDC Training	Maximum of	24			Hours						$1,320.00
Unscheduled Visits	Maximum of	8			Unscheduled Visits at		$277.50				$2,220.00
TOTAL Invoice Costs											**$12,631.20**
TOTAL AMOUNT											**$71,611.20**
Additional Patients if Required and Approved by Novartis					24	Patients					**$58,980.00**
Additional Screen Failures to Enroll Additional Patients					12	Screen Failures					**$9,091.20**
GRAND TOTAL											**$139,682.40**

Novartis Pharmaceuticals Corporation
One Health Plaza, East Hanover, NJ 07936

SF INVOICE # _____ (current period only)

Page _____ of _____

Project:	**CFAM810A**
Study #:	**2402**
Center #:	**516**
P.O. #:	
Tax ID #:	**74-6002070**

Institution Name:	San Antonio Metropolitan Health District
Principal Investigator:	Fernando A. Guerra, MD
Payee:	San Antonio Metropolitan Health District
Payee Mailing Address:	
Fernando A. Guerra, MD	
San Antonio Metropolitan Health District	
332 W. Commerce	
San Antonio, TX 78205-2489	

SITE SHOULD COMPLETE ALL BLANK CELLS IN THE INVOICE FORM BELOW
RECORD $0.00 WHEN A PROCEDURE IS NOT PERFORMED

***SCREEN FAILURES** Procedures/Salaries/Patient Compensation	Frequency	Cost Per Unit	Recruitment Screen/ Randomization Visit 1	Day 1 Visit 2	SITE TO COMPLETE FOR VISIT 1 and VISIT 2			
					Screen Failure # _____ Subject Initials: _____ Date of Screening Visit:	Screen Failure # _____ Subject Initials: _____ Date of Screening Visit:	Screen Failure # _____ Subject Initials: _____ Date of Screening Visit:	Screen Failure # _____ Subject Initials: _____ Date of Screening Visit:
Initial office or other outpatient exam, with comprehensive history, physical	1	$200.00	$200.00					
Urine pregnancy	0.6	$31.00	$18.60	$0.00				
Antibody; herpes simplex (HSV Serology)	1	$55.00	$55.00					
Expanded office or other outpatient exam; expanded problem focused history	1	$100.00		$100.00				
Procedure Subtotal			$273.60	$100.00	$0.00	$0.00	$0.00	$0.00
Nurse—per hour	4	$55.00	$110.00	$110.00				
Coordinator fee—Preparation for Monitoring Visits	1	$40.00	$20.00	$20.00				
Patient Reimbursement	2	$25.00	$25.00	$25.00				
Patient Supplies—Pregnancy kit	1	$50.00	$25.00	$25.00				
Total Other Direct Cost			$180.00	$180.00	$0.00	$0.00	$0.00	$0.00
Maximum Cost Per Visit			$453.60	$280.00	$0.00	$0.00	$0.00	$0.00

A "Screen Failure" is a subject who fails to meet the screening visit criteria and so is not eligible for enrollment into the study. The total reimbursement amount per Screen Failure is determined by totaling the procedures performed up to the point the subject fails. The procedures to be performed at the screening visit should be performed in the order as seen on the Screen Failure invoice page. Novartis will only pay for procedures performed.

Novartis reserves the right to adjust payments for procedures not performed.

Please forward this completed invoice to:
Erhan Berber, MD
Building: *701* ***Room:*** *531*
Novartis Pharmaceuticals Corporation
One Health Plaza
East Hanover, NJ 07936
862-778-4208/FAX 973 781-7749

Submitter's Signature:
Submitter's Title:
Investigator Name:
Date:

By signing this invoice document, I am confirming that the above information is correct and verified, and payment should be made.

NOVARTIS Approval:
CTL Signature:
Date:

If someone other than LTL is approving this invoice, please provide printed name, signature, phone number and location.

Novartis Pharmaceuticals Corporation
One Health Plaza, East Hanover, NJ 07936

UNSCHEDULED VISITS INVOICE

(current period only)

Project:	CFAM810A
Study #:	2402
Center #:	516
P.O. #:	
Tax ID #:	74-6002070

Institution Name:	San Antonio Metropolitan Health District
Principal Investigator:	Fernando A. Guerra, MD
Payee:	San Antonio Metropolitan Health District

Payee Mailing Address:
Fernando A. Guerra, MD
San Antonio Metropolitan Health District
332 W. Commerce
San Antonio, TX 78205-2489

SITE SHOULD COMPLETE ALL BLANK CELLS IN THE INVOICE FORM BELOW
RECORD $0.00 WHEN A PROCEDURE IS NOT PERFORMED

UNSCHEDULED VISITS Procedures/Salaries/Patient Compensation	Frequency	Cost Per Unit	Unscheduled Visit Cost	SITE TO COMPLETE FOR EACH UNSCHEDULED VISIT PER PATIENT Unscheduled Visit # _____ Subject Initials: _____ Date of Unscheduled Visit:	Unscheduled Visit # _____ Subject Initials: _____ Date of Unscheduled Visit:	Unscheduled Visit # _____ Subject Initials: _____ Date of Unscheduled Visit:	Unscheduled Visit # _____ Subject Initials: _____ Date of Unscheduled Visit:
Expanded office or other outpatient exam; expanded problem focused history	1.0	$125.00	$125.00				
Procedure Subtotal			$125.00	$0.00	$0.00	$0.00	$0.00
Nurse—per hour	1.5	$55.00	$82.50				
Diary instruction/review	1.0	$25.00	$25.00				
Coordinator fee—Preparation for Monitoring Visits	0.5	$40.00	$20.00				
Patient Reimbursement	1.0	$25.00	$25.00				
Total Other Direct Cost			$152.50	$0.00	$0.00	$0.00	$0.00
Maximum Cost Per Visit			$277.50	$0.00	$0.00	$0.00	$0.00

Novartis reserves the right to adjust payments for procedures not performed.

Please forward this completed invoice to:
Erhan Berber, MD
Building: 701 *Room: 531*
Novartis Pharmaceuticals Corporation
One Health Plaza
East Hanover, NJ 07936
862-778-4208/FAX 973 781-7749

Submitter's Signature:
Submitter's Title:
Investigator Name:
Date:

By signing this invoice document, I am confirming that the above information is correct and verified, and payment should be made.

NOVARTIS Approval:
CTL Signature:
Date:

If someone other than LTL is approving this invoice, please provide printed name, signature, phone number and location.