

2009-06-25-0584

AN ORDINANCE

AUTHORIZING A CONTRACT IN AN AMOUNT UP TO \$58,620.00 WITH COVANCE PERIAPPROVAL SERVICES, INC. FOR THE SAN ANTONIO METROPOLITAN HEALTH DISTRICT TO CONDUCT A CLINICAL VACCINE STUDY; AND AUTHORIZING PAYMENTS TO PARTICIPANTS.

* * * * *

WHEREAS, the San Antonio Metropolitan Health District (SAMHD) has collaborated with Covance Periapproval Services., Inc. since 1999 in conducting a number of vaccine clinical trials; and

WHEREAS, Covance has assisted the SAMHD in providing new and upcoming vaccines to the community; and

WHEREAS, the objective of this national study is to evaluate a new varicella vaccine when administered with routine vaccines to healthy children at 12 months of age through 23 months of age; and

WHEREAS, all study participants will receive the measles, mumps, rubella and hepatitis A vaccines along with any necessary routine vaccines; and

WHEREAS, the varicella vaccine is administered to prevent chickenpox, which is an infectious disease caused by a virus and can result in a blister-like rash, itching, tiredness and fever; and

WHEREAS, most cases of chickenpox occur in children less than 15 years of age; and

WHEREAS, chickenpox is highly contagious and spreads from person to person by direct contact or through the air from an infected person's coughing or sneezing; and

WHEREAS, this clinical study agreement will allow the SAMHD to enroll a total of 24 children and provide up to \$58,620.00 to the SAMHD; and

WHEREAS, Covance Periapproval Services Inc. will pay the SAMHD the contracted budget amounts for participation in this study depending on patient enrollment and cooperation with the follow-up visits and telephone conferences; and

BE IT ORDAINED BY THE CITY COUNCIL OF THE CITY OF SAN ANTONIO:

SECTION 1. The City Manager or her designee or the Director of the San Antonio Metropolitan Health District or his designee, is authorized to execute a contract in an amount up to \$58,620.00 with Covance Periapproval Services, Inc. for the San Antonio Metropolitan Health

District to conduct a clinical vaccine study. A copy of the contract is attached hereto and incorporated herein for all purposes as **Attachment I**.

SECTION 2. Fund 26012000 entitled "Misc Grant" is hereby designated for use in the accounting for the fiscal transaction of this contract.

SECTION 3. The sum of up to \$58,620.00 is hereby appropriated in the above designated fund. The proposed budget, which is attached hereto and incorporated herein for all purposes as **Attachment II** is hereby approved. A formal final budget which will include a department specific fund, an Internal Order number, and General Ledger numbers will be submitted by the department upon award.

SECTION 4. The proposed personnel complement, which is attached hereto and incorporated wherein for all purposes as **Attachment II** is approved.

SECTION 5. Payments of stipends to the participants or parents/guardians of the participants enrolled in the study are hereby authorized.

SECTION 6. The financial allocations in this Ordinance are subject to approval by the Director of Finance, City of San Antonio. The Director of Finance may, subject to concurrence by the City Manager or the City Manager's designee, correct allocations to specific SAP Fund Numbers, SAP Project Definitions, SAP WBS Elements, SAP Internal Orders, SAP Fund Centers, SAP Cost Centers, SAP Functional Areas, SAP Funds Reservation Document Numbers, and SAP GL Accounts as necessary to carry out the purpose of this Ordinance.

SECTION 7. This ordinance shall be effective on and after July 5, 2009.

PASSED AND APPROVED this 25th day of June 2009.



M A Y O R
JULIÁN CASTRO

ATTEST: 
City Clerk

APPROVED AS TO FORM: 
for City Attorney

Agenda Item:	34 (in consent vote: 5, 6, 7, 8, 9, 11, 12, 14, 15, 16, 17, 18, 20A, 20B, 21, 22, 23, 24, 25, 28, 29, 30, 32, 33, 34, 36A, 36B, 36C, 36D, 36E, 36F, 36G, 36H, 36I, 36J, 37, 39, 40, 41, 42A, 42B, 43, 44, 46, 47, 48, 49)						
Date:	06/25/2009						
Time:	10:15:24 AM						
Vote Type:	Motion to Approve						
Description:	An Ordinance authorizing a contract in an amount up to \$58,620.00 with Covance Periapproval Services, Inc. for the San Antonio Metropolitan Health District to conduct a clinical vaccine study; and authorizing payments to participants. [Frances A. Gonzalez, Assistant City Manager; Dr. Fernando A. Guerra, Director, Health]						
Result:	Passed						
Voter	Group	Not Present	Yea	Nay	Abstain	Motion	Second
Julian Castro	Mayor		x				
Mary Alice P. Cisneros	District 1		x			x	
Ivy R. Taylor	District 2		x				
Jennifer V. Ramos	District 3		x				
Philip A. Cortez	District 4		x				x
David Medina Jr.	District 5		x				
Ray Lopez	District 6		x				
Justin Rodriguez	District 7		x				
W. Reed Williams	District 8		x				
Elisa Chan	District 9		x				
John G. Clamp	District 10	x					

CLINICAL STUDY AGREEMENT

This Agreement is entered into as of this ___ day of ___, ___ between the City of San Antonio on behalf of the San Antonio Metropolitan Health District, a Municipal Corporation, with its principal location at 332 W. Commerce, San Antonio, Texas 78205, (hereinafter referred to as "INSTITUTION") and Covance Periapproval Services Inc. (hereafter known as "Covance") a company located at 555 North Lane, Conshohocken, PA 19428, USA.

Merck & Co., Inc., a New Jersey corporation with its principal place of business in Whitehouse Station, New Jersey (hereinafter referred to as "MERCK") has contracted with Covance to conduct the below described clinical study .

ARTICLE 1.

SCOPE OF PROJECT, TERM OF STUDY AND RELATED MATTERS.

1.1. INSTITUTION agrees to conduct a clinical research study entitled "**Safety, Tolerability, and Immunogenicity of VARIVAX (2007 Commercial VZV Bulk Process) Administered Concomitantly with M-M-R II in Healthy Children 12-to-23 Months of Age**" Protocol No. V210-057 (the "Protocol") in accordance with the protocol.

1.2. The Study shall commence on or about **January 2009** and be completed within approximately **eighteen (18) months** from its initiation, unless extended for an additional period by written notice by Covance. The Study may be terminated in accordance with Article 6.

1.3. INSTITUTION agrees to devote its best efforts to perform efficiently the work required hereunder and agrees to perform the Study in conformance with the Protocol; generally accepted standards of good clinical practice; and all applicable laws, rules and regulations relating to the conduct of the Study, particularly such laws, rules and regulations concerning or promulgated by the United States Food and Drug Administration.

1.4. INSTITUTION shall provide Covance with written evidence of review and approval of the Protocol and the patient consent form by the applicable Institutional Review Board prior to the initiation of the Study and of the Institutional Review Board's continuing review and approval of the Study whenever it is reviewed, but at least once per year.

1.5. INSTITUTION shall (i) prepare and maintain complete and accurate Study documentation in compliance with good clinical practice standards and applicable Federal, state and local laws, rules and regulations; and (ii) for each patient participating in the Study, promptly prepare and submit to Covance all original case report forms and such other reports as required by the Protocol following completion or termination of the Study, or as otherwise required pursuant to the Protocol. The completed case report forms and the information contained therein shall be the property of Covance and may be used by Covance in any manner whatsoever.

1.6. Study documentation (including all case report forms, source documents and all clinical and other information generated as a result of the Study) will be promptly and fully disclosed to Covance by INSTITUTION upon request or as set forth in the Protocol, and also shall be made available at INSTITUTION's site upon request for inspection, copying, review and audit at reasonable times by representatives of Covance, the US Food and Drug Administration or any other regulatory agencies. INSTITUTION agrees to promptly advise Covance of any regulatory inspection relating to the Study (of either the INSTITUTION'S site or of the Institutional Review Board) and to promptly provide Covance with a copy of any inspection report. INSTITUTION agrees to promptly take any reasonable steps that are requested by Covance as a result of an audit to cure deficiencies in the study documentation and case report forms. Study documentation, as defined above and as further delineated in the Protocol and Exhibit B, shall be retained in conformance with applicable federal and local regulations and as specified by Covance.

1.7. INSTITUTION represents and warrants that INSTITUTION is not and does not use in any capacity the services of any person debarred under subsections 306(A) or 306(B) of the Generic Drug Enforcement Act of 1992, disqualified as a testing facility under 21 CFR Part 58, Subpart K, or disqualified as a clinical investigator under 21 CFR 312.70, in connection with any of the services performed by INSTITUTION hereunder. INSTITUTION covenants it will not use in any capacity the services of any person debarred or disqualified and will immediately disclose in writing to Covance if any person who is performing services hereunder is debarred or disqualified or if any action, suit, claim, investigation or legal or administrative proceeding is pending or threatened, relating to the debarment or disqualification of INSTITUTION or any person performing services hereunder. INSTITUTION agrees to assure that all investigators treating patients are appropriately licensed by the state medical boards in which the Study will be conducted and that their licenses are current throughout the Study

1.8. INSTITUTION represents and warrants that it is, and throughout the course of the Study will be, in compliance in all material respects with all applicable Federal and local laws and regulations regarding the privacy of individually identifiable information, including, but not limited to, the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the regulations promulgated thereunder, as may be amended from time to time.

ARTICLE 2.

PAYMENT TERMS.

2.1. For and in consideration of the performance by INSTITUTION of its obligations hereunder, Covance shall pay to INSTITUTION **two thousand and thirty dollars (\$2,030.00)** per satisfactorily completed patient, up to a **maximum of forty-eight thousand seven hundred and twenty dollars (\$48,720.00)** for completion of all patients, based on **24** patients completing the study. In addition, INSTITUTION will be paid up to **nine thousand nine hundred dollars (\$9,900.00)** of additional "not to exceed" pass through costs, as identified in the budget, upon receipt of invoices from INSTITUTION. Accordingly, the grant will not exceed the total sum of **fifty-eight thousand six hundred and twenty dollars (\$58,620.00)** (the "Grant"),

2.2. The Grant shall be due and payable in accordance with the schedule set forth in Exhibit C.

2.3. Amounts due and owing hereunder shall be adjusted as follows:

- (i) Payments will not be made for costs resulting from the enrollment of patients who upon entering the study violate protocol inclusionary or exclusionary criteria, unless agreed to in writing by the Covance clinical monitor;
- (ii) If patients are enrolled for less than the specified length of time for completion of the Study, payments will be made for such patients based on the prorated costs per patient as set forth in the budget attached hereto as Exhibit D; and
- (iii) Payments shall be made for the number of patients who successfully complete the Study in accordance with this Agreement and the Protocol, and for which case report forms are submitted in accordance with Section 1.5.

2.4. INSTITUTION acknowledges that it has included all its direct and indirect costs for the Study in the approved budget attached hereto as Exhibit D and in no event shall the Grant exceed the total sum of **fifty-eight thousand six hundred and twenty dollars (\$58,620.00)** without written authorization from Covance.

2.5. Payments shall be made on receipt by Covance of a correct and valid invoice addressed to Covance Periapproval Services, Inc, 555 North Lane, Suite 6000, Conshohocken, PA, USA and delivered to Jill Drummond. Payments will be made payable to the following account and address:

Attention:
City of San Antonio
Attn: Fernando A. Guerra, MD. MPH
P.O. Box 839966
San Antonio, Texas 78283
74-6002070

2.6 The INSTITUTION acknowledges that all payments due hereunder are pass through payments from MERCK to Covance and Covance shall make prompt payment in accordance with the terms of this Agreement to Institution.

ARTICLE 3.

PRINCIPAL INVESTIGATOR.

The Principal Investigator for this Study shall be Dr. Fernando A. Guerra. INSTITUTION agrees to promptly inform Covance of any event or condition adversely affecting the satisfactory completion of the Study by the Principal Investigator. In the event the Principal Investigator shall be unable to complete this Study and INSTITUTION and Covance shall be unable to mutually agree to a substitute investigator within a period of fifteen (15) days, this Agreement shall be automatically terminated at the discretion of Covance.

ARTICLE 4.

PUBLICATION.

It is understood that this Study is part of a multicenter trial and INSTITUTION will be free to publish the results of its part of the Study in collaboration with the other investigators in this Study, but in complete compliance with Article 5 of this document. Subsequent to the multicenter publication or twenty-four (24) months after completion of the Study, whichever occurs first, INSTITUTION may itself publish the results of its data from the Study, with due regard to Covance's and MERCK's confidential information. In either case, INSTITUTION agrees to submit a copy of any manuscript and/or abstract to Covance for review and comment sixty (60) days prior to its submission for publication. Covance shall have said sixty (60) day period to respond to INSTITUTION with any specified revisions. INSTITUTION agrees to delete information identified by Covance as confidential prior to submitting such manuscript and/or abstract for publication. If reasonably requested by INSTITUTION, Covance will take reasonable steps to expedite the review time to less than said sixty (60) day period to meet INSTITUTION's publication deadlines. Upon notification by Covance that such review has been completed, INSTITUTION may submit the manuscript and/or abstract for publication after deleting information identified by Covance as confidential. Covance and MERCK also have the right to publish the results of this Study.

ARTICLE 5.

CONFIDENTIALITY.

5.1. INSTITUTION agrees not to disclose to any third party any information disclosed to it under this Agreement for a period of five (5) years from the date of disclosure or from the termination date of this Study, whichever is later, except INSTITUTION may disclose information to staff members, employees or medical students necessary for the conduct of the Study and who are bound by similar written obligations of confidentiality. This non-disclosure obligation shall not apply to:

- (i) information that is in the public domain or subsequently enters the public domain through no fault of INSTITUTION;
- (ii) information that is presently known or becomes known to INSTITUTION from its own independent sources from a person having the legal right to disclose information;
- (iii) information that INSTITUTION receives from any third party not under a confidential obligation to keep such information confidential; or
- (iv) information that is required to be disclosed by law.

INSTITUTION acknowledges that all information relating to this Study, including, but not limited to, the Protocol, the Confidential Investigator Brochure and this Agreement is confidential. If INSTITUTION is required to disclose confidential information pursuant to Sections 5.1.(iv), the INSTITUTION shall notify Covance, and the INSTITUTION and Covance shall agree to a mutually satisfactory way to disclose such information as necessary and in accordance with applicable law.

Data generated by this Study will be considered confidential, except to the extent that it is included in a publication, pursuant to Article 4.

INSTITUTION agrees to return to Covance, upon request, the materials, samples, graphics, writings, and information in other tangible forms, containing any confidential information provided by Covance, and any copies of such confidential information, except for one archival copy to be retained by INSTITUTION for purposes of observing compliance with this Agreement.

No license, express or implied, to use the confidential information is granted to INSTITUTION other than to use the confidential information in the manner and to the extent authorized by this Agreement.

5.2. Notwithstanding anything to the contrary in Section 5.1., INSTITUTION, shall hold in confidence any data collected or produced in the Study which identifies or could be used to identify a Study subject ("Study Data"), except as required or permitted under the Protocol or this Agreement, or to the extent necessary to be disclosed to regulatory agencies as part of the review process. In addition, notwithstanding anything to the contrary in Section 5.1, INSTITUTION shall comply with all applicable laws and regulations, as amended from time to time, with respect to the collection, use, storage, and disclosure of any Study Data, including, without limitation, the Health Insurance Portability and Accountability Act (HIPAA) and the regulations promulgated thereunder.

5.3. INSTITUTION agrees to ensure that all appropriate technical and organization measures are taken to protect Study Data against loss, misuse, and any unauthorized, accidental, or unlawful access, disclosure, alteration or destruction, including without limitation, implementation and enforcement of administrative, technical and physical security policies and procedures applicable to Study Data.

5.4. INSTITUTION agrees to use study drug(s)/vaccine(s) and any patient diagnostic tests, bodily fluids, tissue biopsies, data, and/or other materials collected, solely for the purposes of the Study and in accordance with the Protocol unless agreed to otherwise in writing by Covance.

5.5. Covance agrees to collect, use and disclose Study Data with respect to any Study subject only in accordance with the informed consent(s) and authorization obtained from such Study subject as part of the study, unless otherwise required by law or as set forth in Section 5.6 below.

5.6. Covance may use the Study Data to create data sets that contain dates, ages, towns, cities, states and zip codes related to Study subjects (hereinafter referred to as "Research Data Sets"). Covance may use and disclose the Research Data Sets, alone or in combination with data that cannot be used to identify an individual (hereinafter referred to as "non-identifiable Study Data"), for medical research, including but not limited to research unrelated to the Study, and any filings of medical research Study results with government regulatory agencies worldwide. Covance will not use or disclose Research Data Sets for any purpose other than as permitted by this Agreement, or as otherwise required by law, will use appropriate safeguards to prevent the creation, use or disclosure of Research Data Sets other than as provided for by this Agreement, and will not use the Research Data Sets to identify any Study subject or contact any Study subject. Nothing in this paragraph shall limit Covance's use or disclosure of non-identifiable Study Data.

ARTICLE 6.

TERMINATION.

6.1. Covance may terminate this Study or the enrollment of patients into this Study for any reason upon thirty (30) days written notice to the INSTITUTION. INSTITUTION may terminate this Agreement or the enrollment of patients into the Study for any reason upon thirty (30) days written notice to Covance. Upon receipt of the termination notice, the INSTITUTION shall immediately cease enrollment of patients into the study, and within thirty (30) days from receipt of such notice, shall terminate the Study with respect to the enrolled patients.

6.2. Upon termination of the Study, INSTITUTION shall deliver to Covance within sixty (60) days from the receipt of the termination notice all completed case report forms and shall return to Covance all unused drug supplies.

Title to any and all equipment purchased at the expense of Covance under this Agreement shall be given to Covance upon termination of this Agreement. INSTITUTION shall deliver to Covance within sixty (60) days from the receipt of the termination notice all such equipment, unless otherwise directed by Covance. Covance will withhold the value of the equipment in the final payment until return of the equipment.

6.3. In the event of termination, the sum for professional services and expenses payable under this Agreement shall be limited to the pro-rated fees based on actual work performed and actual non-cancelable expenses committed pursuant to the protocol, except in the event of termination by INSTITUTION for any reason not relating to patient safety, the sum for professional services

and expenses payable under this Agreement shall be limited to the pro-rated fees based on actual work performed. If, at the date of termination of the Study, the total amount that Covance has paid to INSTITUTION exceeds the amount to which INSTITUTION is entitled, INSTITUTION shall return the difference to Covance within sixty (60) days from the termination date. If, at the date of termination of the Study, the total amount that Covance has paid INSTITUTION is less than the amount to which INSTITUTION is entitled, INSTITUTION shall submit a statement to Covance for the difference within sixty (60) days from the termination date. Covance shall pay the approved amount of INSTITUTION's request within sixty (60) days after receiving INSTITUTION's statement and all documentation required to be submitted by INSTITUTION pursuant to Section 1.6. In no event shall the amount owed under this Agreement exceed the amount of the Grant set forth in Section 2.1.

6.4. 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 1, 4, 5, 7 and 8 survive the termination or expiration of this Agreement.

ARTICLE 7.

PATENTS AND INVENTIONS

It is recognized and understood that the existing inventions and technologies of MERCK or INSTITUTION are their separate property, respectively, and are not affected by this Agreement (including, but not limited to, the MERCK study drug, and information and technology relating to the protocol) and neither party shall have any claims to or rights in such existing inventions and technologies of the other party. Title to any inventions or discoveries arising from this Study and conceived and reduced to practice solely by INSTITUTION employees and not from MERCK confidential information or from data collected in breach of Article 5.4, shall be owned by the INSTITUTION and shall be promptly disclosed in writing to Covance. The INSTITUTION, consistent with the INSTITUTION's patent policy, will offer MERCK the first opportunity to enter into a royalty-bearing license for INSTITUTION's rights in such invention or discovery. Such license shall be exclusive and worldwide to the maximum extent permitted by the established policy of INSTITUTION with a reasonable royalty and will provide MERCK with an exclusive right to make, have made, use, sell and offer for sale such invention or discovery and the right to sublicense such rights. INSTITUTION shall promptly disclose in writing to Covance any invention or discovery conceived by employees arising from the Study. Except as otherwise stated herein, any and all inventions and discoveries arising from this Study are the sole and exclusive property of MERCK.

ARTICLE 8.

INDEMNIFICATION.

8.1 Any indemnification of the INSTITUTION by MERCK shall be through an Agreement between INSTITUTION and MERCK directly.

ARTICLE 9.

INSURANCE.

Since this agreement is between Covance and the INSTITUTION, Merck's insurance provision is included in the letter of indemnification, which will be provided to the INSTITUTION under a separate cover.

ARTICLE 10.

ASSIGNMENT AND SUBCONTRACTING.

Neither this Agreement nor the rights or obligations hereunder shall be assignable or otherwise transferred or subcontracted by INSTITUTION without Covance's prior written consent.

ARTICLE 11.

INDEPENDENT CONTRACTOR.

In undertaking to perform this research study for Covance, it is understood that INSTITUTION is doing so as an independent contractor and not as an employee of Covance.

The INSTITUTION acknowledges that Covance's ability to make the payments to the INSTITUTION depends not only on the Investigator's and/or INSTITUTION's complete performance of obligations under this Agreement and other terms and conditions specified here, but shall also be conditioned on Covance receiving from MERCK the funds necessary to make the payments contemplated herein.

ARTICLE 12.

GOVERNING LAW.

This Agreement shall be governed by and construed in accordance with the laws of the state of the principal location of the INSTITUTION set forth in the first page to this Agreement.

ARTICLE 13.

NOTICES.

All notices or other communications which are required or permitted hereunder shall be in writing and sufficient if delivered personally, sent by prepaid air courier, sent by mail or sent by telefax transmission, addressed as follows:

if to INSTITUTION, to:

San Antonio Metropolitan Health District
332 W. Commerce, # 307
San Antonio, Texas 78205-2489
Attention: Fernando A. Guerra, MD. MPH

if to PRINCIPAL INVESTIGATOR, to:

San Antonio Metropolitan Health District

Attn: Fernando A. Guerra, MD. MPH
332 W. Commerce, # 307
San Antonio, Texas 78205-2489

if to Covance, to:

Covance Periapproval Services, Inc.

555 North Lane, Suite 6000
Conshohocken, PA 19428
Attention: Jill Drummond

Any such communication shall be deemed to have been given when delivered if personally delivered, on the business day after dispatch if sent by air courier, on the third business day following the date of mailing if sent by mail and on the date of telefax if sent by telefax transmission.

ARTICLE 14.

CONFLICT OF INTEREST STATEMENT.

INSTITUTION agrees to fully disclose to Covance any proposed or existing contractual relationship for services under this Agreement in which a conflict of interest may, either by implication or in fact, exist.

ARTICLE 15.

USE OF NAME, LOGO, OR OTHER SYMBOLS.

INSTITUTION shall not use the name, logo, or other symbols of Covance or MERCK for any marketing or promotional purposes without prior written consent of Covance.

ARTICLE 16.

ENTIRE AGREEMENT.

This Agreement constitutes the entire agreement between the parties relating to the Study and supersedes all prior negotiations, representations, agreements, and understandings among the parties with respect thereto.

In the event of a conflict between the terms of this Agreement and the Study protocol, the terms of the Study Protocol shall have precedence with respect to patient care matters and the terms of this Agreement shall have precedence with respect to administrative matters.

ARTICLE 17.

AMENDMENT, MODIFICATION AND WAIVER.

This Agreement shall not be altered or otherwise amended except pursuant to an instrument in writing signed by each of the parties hereto, except that any party to this Agreement may waive any obligation owed to it by another party under this Agreement. The waiver by any party hereto of a breach of any provision of this Agreement shall not operate or be construed as a waiver of any subsequent breach.

IN WITNESS WHEREOF, the parties have caused this Agreement to be duly executed by an appropriate officer as of the day and year first above written.

EXHIBITS

Exhibit B -	Study Documentation
Exhibit C -	Schedule of Payments
Exhibit D -	Budget
Exhibit E -	Indemnification Terms

EXHIBIT B

Study Documentation includes copies of all case report forms, data correction forms, workbooks, source documents, monitoring logs and appointment schedules, sponsor-investigator correspondence and regulatory documents (e.g., signed protocol and amendments, ethics or Institutional Review Committee correspondence and approval, signed and approved patient consent forms, authorization forms, statement of investigator, clinical supplies receipts and distribution records).

Source documents include all original observations or notations of clinical activities and all reports and records necessary for the evaluation and reconstruction of the Study. Accordingly, source documents include all laboratory reports, ECG tracings, X-rays, radiologist reports, biopsy reports, ultrasound photographs, patient progress notes, hospital charts or pharmacy records and any other similar reports or records of any procedure performed in accordance with the Protocol. Source documentation may also include workbooks when information is recorded directly onto such forms. In the event that the workbook is used as a source document by a physician not identified as a primary or secondary investigator in the Protocol (e.g., ophthalmologist) or not under the direct supervision of the primary investigator, the workbook must be signed and dated by the individual making the entry.

EXHIBIT C

See Payment Schedule in the attached Budget Exhibit D.

EXHIBIT D
BUDGET

IIN:



Investigator Budget & Payment Schedule V210-057-00

Safety, Tolerability, and Immunogenicity of VARIVAX (2007 Commercial VZV Bulk Process) Administered Concomitantly with M-M-R II in Healthy Children 12-to-23 Months of Age

PI Name: Dr. Guerra

Site Name: San Antonio Metropolitan Health District

BUDGET INFORMATION:

Grant

- **US\$ 2,030** will be paid to the site for each patient who completes the study.
- The Grant will be adjusted if the study design is modified.
- Merck reserves the right to decrease or increase the number of patients at any time during the enrollment period without renegotiating based on the per patient costs listed in this budget. Such notification by Merck shall be in writing.

VISIT COSTS:

Per Patient Costs	V1	V2	V3	Total / Patient
Includes OH	US\$ 908	US\$ 627	US\$ 495	US\$ 2,030
Total number of Patients				24
Total Per Patient Costs				US\$ 48,720

- This budget includes all study-related costs as referenced in the protocol, including procedure costs, primary investigator fees, study coordinator fees (including electronic data capture), administrative fees, lab draws, patient stipends (if elected), other miscellaneous fees and overhead. All of the study related costs are included in the Visit costs outlined above.
- A Central Laboratory will be used for this study. No processing fees will be incurred by the site other than lab collection fees.
- For randomized patients who do not complete the study, the site will be paid according to the per visit schedule noted above for those visits documented by electronic data capture or other approved data input.
- Unless otherwise agreed upon, payments will only be made for patients who have met patient selection criteria as stated in the protocol and who are studied in compliance with the protocol.

PASS-THROUGH COSTS**

TOTAL NOT TO EXCEED: **US\$ 9,900**

Advertising/Recruitment**

NOT TO EXCEED: **US\$ 500**

Reimbursement of advertising/recruitment expenses will be paid upon receipt of invoices. advertising/recruitment may not be increased without pre-approval obtained through the Project Manager at Covance.

IRB Renewal Fee**

NOT TO EXCEED: **US\$ 700**

IRB fees will be paid on receipt of invoices

Site Validation**

NOT TO EXCEED: **US\$ 300**

A site validation fee will be paid for reimbursement of time spent for the site validation visit/phone call.

Contingency Allotment, Site**

NOT TO EXCEED: **US\$ 2,500**

This allotment is representative of unexpected site costs not covered above. Costs may vary and will be reviewed and approved through the Project Manager at Covance.

Study Start-Up Fee/Site Set-Up Fee**

NOT TO EXCEED: **US\$ 2,500**

Payable upon contract agreement execution and IRB (Regulatory) review.

Local Ethics Committee Fee, IRB Fee**

NOT TO EXCEED: **US\$ 2,000**

IRB fees will be paid on receipt of invoices

Unscheduled Visits**

NOT TO EXCEED: **US\$ 1,400**

Refer to Annotations below for reimbursement details.

Annotations: If the site is using a local Ethics committee or IRB, the fee, if applicable, will be paid when the contract is signed. Any applicable site validation or start-up fees will also be paid on execution of the contract. Advertising fees will be paid only on receipt of an invoice with any invoices attached. Unscheduled visits will be reimbursed at the rate of \$350/visit. It is estimated that approximately 3% of patients may require an unscheduled visit for rashes.

**Pass-through costs will be paid upon receipt of an invoice with documentation from the third party, when applicable.

Total Cost of Study per Investigator	US\$ 58,620
Maximum per patient Grant	US\$ 2,443

IIN:



**Investigator Budget & Payment Schedule
V210-057-00**

Safety, Tolerability, and Immunogenicity of VARIVAX (2007 Commercial VZV Bulk Process) Administered Concomitantly with M-M-R II in Healthy Children 12-to-23 Months of Age

PI Name: Dr. Guerra

Site Name: San Antonio Metropolitan Health District

GRANT PAYMENT SCHEDULE:

The Grant shall be due and payable as follows:

Monthly Payments:

US\$ 46,220

 payments will be made in monthly installments based on the number of completed visits per randomized patient. Patient visit data is obtained in-house according to information provided by the Electronic Data Capture System (EDC). The final payment of \$2500 will be withheld from the monthly installments until study completion.

Final Payments:

US\$ 2,500

 Final payment will be sent to site upon receipt by Covance of all completed case report forms and transferred data, and satisfactory resolution of data inquiries for your site.

- A check for the applicable amount is generally issued by Covance within 60 days. Amounts will be adjusted and payments will not be made for unsatisfactory patient visit data in the Data Capture System or for patients with unresolved data deficiencies within the Data Capture System.
- The payment schedule is based on the total Per Patient Grant for 24 completed patients. Payments may be pro-rated at any time based on the number of completed visits per randomized patient.

IIN:



**Investigator Budget & Payment Schedule
V210-057-00**

Safety, Tolerability, and Immunogenicity of VARIVAX (2007 Commercial VZV Bulk Process) Administered Concomitantly with M-M-R II in Healthy Children 12-to-23 Months of Age

PI Name: Dr. Guerra

Site Name: San Antonio Metropolitan Health District

CONTRACT INFORMATION: (Please Print or Type) and return to the Covance Project Team.

Does the site require a signed contract prior to screening patients? Yes

	Budget Administrator:	Contract Administrator:
Name:	Marcela Martinez	Marcela Martinez
Phone #	(210) 207-3968	(210) 207-3968
Fax #:	(210) 224-5710	(210) 224-5710
e-mail:	marcela.martinez@sanantonio.gov	marcela.martinez@sanantonio.gov

Mailing address information (for the Agreement):

	Institution Contact Information:	Investigator Contact Information:
Name:	Marcela Martinez	Fernando A. Guerra, MD, MPH
Address:	345 W. Commerce San Antonio, TX 78205	332 W. Commerce San Antonio, TX 78205
e-mail:	marcela.martinez@sanantonio.gov	fernando.guerra@sanantonio.gov
Phone #	(210) 207-3968	(210) 207-8731
Fax #:	(210) 224-5710	(210) 224-5710
Attention:	Marcela Martinez	Marcela Martinez

Payee name, address, contact, and tax ID (for Payments):

Payee Name (checks should be made payable):	San Antonio Metropolitan Health District
Payee Address (checks should be mailed):	332 W. Commerce San Antonio, TX 78205 United States
Attention (to whom checks should be mailed):	Marcela Martinez-Clinical Trial Program
Payee Federal Tax ID # (required):	74-6002070

Mark Allen Bach, M.D.
Vice President
Clinical Research Operations

Merck & Co., Inc.
P.O. Box 1000
North Wales, PA 19454-1099

May 11, 2009



San Antonio Metropolitan Health District
332 W. Commerce, #307
San Antonio, Texas 78205-2489

Attn: Fernando A. Guerra, M.D.

Dear Dr. Guerra:

MERCK agrees to indemnify PRINCIPAL INVESTIGATOR, any person working directly with or under the supervision of PRINCIPAL INVESTIGATOR and INSTITUTION against liabilities imposed by law for adverse vaccine experiences to patients caused directly from administration of the MERCK study vaccine or the control vaccine in the clinical study entitled, **"Safety, Tolerability, and Immunogenicity of VARIVAX (2007 Commercial VZV Bulk Process) Administered Concomitantly with M-M-R II in Healthy Children 12-to-23 Months of Age"** Protocol No. V210-057. This indemnification does not cover liabilities resulting from a negligent or wrongful act or failure to act on the part of any indemnified party.

MERCK'S indemnification policy is subject to the following conditions:

1. compliance by all indemnified parties with applicable federal, state, and local laws and regulations, and strict administration of the vaccine in accordance with the approved protocol of the study and the recommendations, suggestions, and pertinent literature provided by MERCK;
2. proper maintenance and availability to MERCK of records concerning the receipt, storage, handling, and administration of the study vaccine;
3. submission to MERCK of documentation in accordance with the protocol;
4. prompt reporting to MERCK of any significant or alarming developments that may occur during the study;
5. prompt notification to MERCK of any claim and authorization to allow MERCK to assume the defense of any such claim, including, without limitation, the right to select defense counsel and the right to settle any claims or suits at its discretion; and
6. full cooperation by the indemnified parties with MERCK in defense of any claim.

In addition, if a patient suffers an adverse vaccine experience resulting directly from administration of the MERCK study vaccine or the control vaccine, MERCK will provide reimbursement for the reasonable costs of medical treatment to the extent such costs are not covered by the patient's medical or hospital insurance or by third party providing such coverage.

MERCK represents and warrants that it is self-insured to protect against general liability under this provision.

I trust the foregoing is acceptable to you. We look forward to your continued interest and participation in medical research.

Sincerely,

A handwritten signature in black ink, appearing to read 'M. Bach', written over a horizontal line.

Mark Allen Bach, M.D.

cc TMF-UN-101, Jeff Hastings MPFS

Merck-V210-057 Budget

<u>ESTIMATED REVENUES</u>	<u>SAP GL No.</u>		
Revenue	4402100	\$	29,310
Grants Founds - Rest	4501160		
Contr Priv Restrict	4502220		
Studies Project Misc. Revenue	4502230		
TOTAL ESTIMATED REVENUES		<u>---</u> <u>==</u>	29,310
APPROPRIATIONS			
Clinical Trials Program			
Funds Center			
Cost Center			
Internal Order 136000000XXX			
Regular Salaries & Wages	5101010	\$	9,634
Temporary Salaries	5202010		2,120
Language Skill Pay	5101050		24
Social Security	5103005		757
Temp - FICA	5103007		243
Life Insurance	5103010		10
Personal Leave Buy Back Pay	5103035		180
Transportation Allowance	5103056		54
Group Health Insurance	5104030		1,520
TMRS	5105010		1,293
Other Contractual Services	5202025		3,600
Advertising & Publication	5203040		500
Travel Other - Transportation Fees	5203090		100
Mail and Parcel Post Service	5205010		200
Rental of Office Equipment	5205020		1,500
Travel-Official	5207010		200
Office Supplies	5302010		2,223
Ice	5304020		250
Chemicals, Medical & Drugs	5304040		2,100
Indirect Cost	5406530		2,803
APPROPRIATIONS:		\$	29,310

Current Year Expenditures

Budget reflects 10% of Spec Proj Administrative Budget for one year

Budget reflects 50% of Sponsor Proposed Budget of \$58,620=\$29,310

<u>Title</u>	<u>Current Positions</u>
Cost Center 3607**	
Internal Order 136000000XXX	
Activity 36-07-**	
Sr. Management Analyst	1
Community Services Supervisor	1
Temporary - Administrative Associate	1
PERSONNEL 36-07-**	3