

AN ORDINANCE 2008-04-03-0264

AUTHORIZING THE EXECUTION OF TWO CONTRACTS WITH GLAXOSMITHKLINE CORPORATION ONE FOR AN AMOUNT UP TO \$126,480.00 FOR THE MEASLES, MUMPS, RUBELLA AND VARICELLA STUDY WHICH WILL RUN UNTIL JANUARY 30, 2011, AND ONE FOR UP TO \$48,169.00 FOR THE HUMAN PAPILOMAVIRUS STUDY WHICH WILL RUN UNTIL DECEMBER 31, 2010 TO BE CONDUCTED BY THE SAN ANTONIO METROPOLITAN HEALTH DISTRICT; AND AUTHORIZING PAYMENTS.

* * * * *

WHEREAS, the San Antonio Metropolitan Health District (SAMHD) has been collaborating with the GlaxoSmithKline Corporation (GSK) for several years in conducting a variety of vaccine clinical trials; and

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

WHEREAS, the objective of the Measles, Mumps, Rubella and Varicella (MMRV) study is to evaluate the safety and effectiveness of the MMRV vaccine versus ProQuad® vaccine when co-administered with hepatitis A vaccine and pneumococcal conjugate vaccine at 12-14 months of age; and

WHEREAS, although licensed in the European Union, Australia and Canada, the effectiveness of GSK Biologicals' MMRV vaccine has not been evaluated previously in the U.S. population; and

WHEREAS, this clinical study agreement will allow the SAMHD to enroll up to 50 children who are 12-14 months of age; and

WHEREAS, the Human Papillomavirus (HPV) study is a follow-up to a previous vaccine trial in which the HPV vaccine was administered to prevent cervical infection in adolescent and young adult women; and

WHEREAS, the objective of the proposed study is to evaluate the safety and effectiveness of an additional dose(s) of the HPV vaccine; and

WHEREAS, participants in the study will include those same clients who were vaccinated in a previous clinical trial conducted at the SAMHD, up to a maximum of thirteen clients; and

WHEREAS, all study participants will receive a stipend to offset transportation costs, leave from work, and other expenses; and

WHEREAS, the GSK will pay SAMHD the contracted budget amounts for participation in these studies depending on patient enrollment and their cooperation with follow-up visits and telephone conferences; **NOW THEREFORE:**

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 two contracts with GlaxoSmithKline Corporation one for an amount up to \$126,480.00 for the Measles, Mumps, Rubella and Varicella (MMRV) study which will run until January 30, 2011, and one for up to \$48,169.00 for the Human Papillomavirus (HPV) study which will run until December 31, 2010 to be conducted by the San Antonio Metropolitan Health District. A copy of the two contracts in substantially final form are attached hereto and incorporated herein for all purposes as Attachment I and III.

SECTION 2. Fund 2601236011 entitled "GSK HPV Study 109628" and Internal Order 136000000377, and Fund 2601236015 entitled GSK MMRV 110058/054 and Internal Order 136000000389 are hereby designated for use in the accounting for the fiscal transaction of these two contracts.

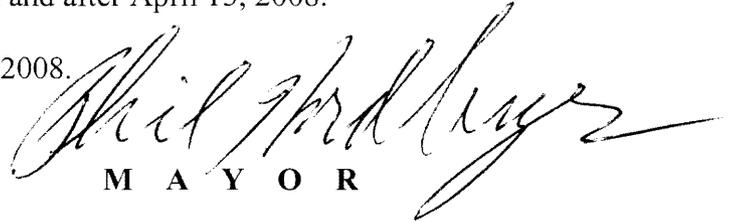
SECTION 3. The budgets which are attached hereto and incorporated herein for all purposes as Attachment II and IV are approved and adopted for entry in the City books.

SECTION 4. Payments of stipends to the participants or parents/guardians of participants enrolled in the study are hereby authorized.

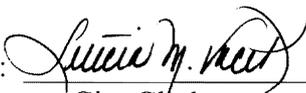
SECTION 5 The financial allocations in this Ordinance are subject to approval by the Director of Finance, City of San Antonio. The Director of Finance may, subject to concurrence by the City Manager or the City Manager's designee, correct allocations to specific SAP Fund Numbers, SAP Project Definitions, 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.

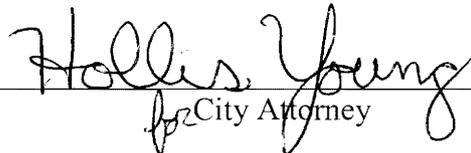
SECTION 6. This ordinance shall be effective on and after April 13, 2008.

PASSED AND APPROVED this 3rd day of April, 2008.


M A Y O R

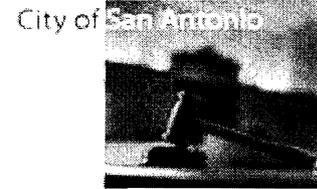
PHIL HARDBERGER

ATTEST: 
City Clerk

APPROVED AS TO FORM: 
for City Attorney



Request for
COUNCIL



Agenda Voting Results - 28

Name:	6, 10, 13, 14, 17, 18, 20, 22, 23, 24, 26, 27, 28, 29, 30, 31, 32, 33, 35, 36, 37, 38A, 38B, 38C
Date:	04/03/2008
Time:	10:06:43 AM
Vote Type:	Motion to Approve
Description:	An Ordinance approving two contracts with GlaxoSmithKline Corporation, one for an amount up to \$126,480.00 for the Measles, Mumps, Rubella and Varicella study which will run until January 30, 2011, and one for up to \$48,169.00 for the Human Papillomavirus study which will run until December 31, 2010 to be conducted by the San Antonio Metropolitan Health District; and authorizing payments. [Frances A. Gonzalez, Assistant City Manager; Dr. Fernando A. Guerra, Director, Health]
Result:	Passed

Voter	Group	Not Present	Yea	Nay	Abstain	Motion	Second
Phil Hardberger	Mayor		x				
Mary Alice P. Cisneros	District 1		x				
Sheila D. McNeil	District 2		x				
Jennifer V. Ramos	District 3		x				x
Philip A. Cortez	District 4		x				
Lourdes Galvan	District 5	x					
Delicia Herrera	District 6		x				
Justin Rodriguez	District 7		x				
Diane G. Cibrian	District 8		x				
Louis E. Rowe	District 9		x			x	
John G. Clamp	District 10		x				



CMS or Ordinance Number: CN0040002640

TSLGRS File Code:1025-08-A

Document Title:

CONT - GlaxoSmithKline MMRV Study 10058/054, 1/17/08 - 1/30/11

Commencement Date:

1/17/2008

Expiration Date:

1/30/2011

CLINICAL STUDY AGREEMENT

This CLINICAL STUDY AGREEMENT (this "Agreement") is effective 04/07/2008 (the "Effective Date") between the City of San Antonio on behalf of the San Antonio Metropolitan Health District Immunization Department ("Institution") and SmithKline Beecham Corporation, doing business as GlaxoSmithKline ("GSK").

BACKGROUND

GSK and its Affiliates develop, manufacture, distribute, and sell pharmaceutical and healthcare products. Institution conducts clinical studies. GSK and Institution intend for this Agreement to establish terms and conditions for the performance of the clinical study identified below.

DEFINITIONS

"Affiliate" means any entity that controls, is controlled by, or is under common control with, GSK. In this context, "control" shall mean (1) ownership by one entity, directly or indirectly, of at least forty percent (40%) of the voting stock of another entity; (2) power of one entity to direct the management or policies of another entity, by contract or otherwise; or (3) any other relationship between GSK and an entity which GSK and Institution have agreed in writing may be considered an "Affiliate" of GSK.

"GSK Confidential Information" means all information (including, without limitation, study protocols, case report forms, clinical data, other data, reports, specifications, computer programs or models and related documentation, know-how, trade secrets, or business or research plans) of GSK or GSK's Affiliates that are: (1) provided to Institution in connection with this Agreement or the Study; (2) Study data, results, or reports created by Institution, Investigators, or Study Staff in connection with the Study (except for a Study subject's medical records); and (3) cumulative Study data, results, and reports from all sites conducting the Study.

"Invention" means any discovery, development, invention (whether patentable or not), improvement, work of authorship, formula, process, composition of matter, formulation, method of use or delivery, specification, computer program or model and related documentation, know-how or trade secret, that is made by Institution, Investigators, or Study Staff: (1) in connection with the Study; or (2) which incorporate GSK Confidential Information.

"Investigator" means the individual(s) responsible for the conduct of the Study at Institution and for direct supervision of Study Staff.

"Materials" means Study drug(s) and related devices, equipment, or other materials provided by GSK for the conduct of the Study.

"Protocol" means the written document that describes the Study and sets forth specific activities to be performed as part of Study conduct.

“Study” means the clinical study sponsored by GSK and conducted by Institution as specifically identified in this Agreement.

“Study Staff” means the individuals providing services on behalf of Institution with respect to the Study at Institution, including without limitation subinvestigators, study coordinators, and other Institution employees, agents, or subcontractors.

1. THE STUDY

STUDY TITLE AND PROTOCOL NUMBER: "A Phase II randomized, observer blind, multicenter study of GlaxoSmithKline Biologicals' combined measles-mumps-rubella-varicella vaccine (MMRV) versus ProQuad®, according to a one dose schedule, both administered subcutaneously at 12-14 months of age, concomitantly with hepatitis A vaccine (HAV) and pneumococcal conjugate vaccine (PCV) but at separate sites."110058/054

INVESTIGATOR'S NAME: Jorge Flores, MD, MPH

INSTITUTION'S TARGET ENROLLMENT: 25 subjects.

INSTITUTION'S ENROLLMENT MAXIMUM: 50 subjects

TOTAL ENROLLMENT TARGET AT ALL STUDY SITES: 4400 subjects

INSTITUTION'S TAX ID NUMBER: 1746002070

2. STUDY CONDUCT

- (a) Institution agrees to conduct the Study in strict compliance with:
- (i) the Study Protocol, as approved by GSK, Investigator, and the responsible Institutional Review Board (along with any subsequently approved amendments to the Study Protocol);
 - (ii) all applicable local, state and federal laws, rules and regulations, including, but not limited to, the Federal Food, Drug and Cosmetic Act and the regulations of the FDA, FDA and ICH Good Clinical Practices, and the Form FDA 1572 Statement of Investigator;
 - (iii) all applicable medical privacy laws or regulations, including without limitation, by obtaining any required subject consent or authorization to allow GSK access to Study subject's medical information as may be necessary to monitor the Study and to receive and use Study data; and
 - (iv) the terms of this Agreement.
- (b) The following Enrollment plan will apply to the Study:
- (i) Subject enrollment up to Institution's Enrollment Maximum shall be completed on or before **30 June, 2008**.
 - (ii) Institution or Investigator will not enroll more Study subjects than Institution's Enrollment Maximum, and GSK will not be obligated to make any payment with respect to any subject enrolled in excess of Institution's Enrollment Maximum. Without any obligation to do so, the parties may agree in writing to modify Institution's Enrollment Maximum.

(iii) All subject visits will be completed no later than **27 December, 2008**.

(iv) Case Report Forms ("CRFs") information associated with a subject's visit must be satisfactorily completed within seven (7) days after the subject's visit or, if applicable, receipt of the subject's test results.

(v) All final CRF data will be completed no later than **24 January, 2009**.

(vi) All data Queries from GSK must be completed and returned to GSK within seven (7) days or, if during final clean up, one (1) day, or such other time set by GSK.

(vii) In exceptional circumstances GSK may intervene in the routine process of CRF corrections to make data clarifications on behalf of the Investigator/Institution. With prior notification to Institution and with specific managerial oversight, GSK data managers may make data clarifications on behalf of the Investigator/Institution based upon an embedded query response or comment (e.g., the answer has been provided in response to the query but the corresponding data has not been edited). All clarifications made by GSK will be evidenced in the audit trail of the data.

(c) Institution and Investigator shall use Materials only to conduct the Study in accordance with the Protocol; shall not chemically, physically or otherwise modify Materials, unless specifically required to do so by the Protocol; and shall handle, store, and ship or dispose of Materials in compliance with all applicable local, state and federal laws, rules and regulations including, but not limited to, those governing hazardous substances. Institution and Investigator shall not charge any Study subject or third-party payor for any Materials, or for Study procedures for which payment by GSK has or will be made under this Agreement.

(d) Institution agrees that no individual or entity shall provide services on behalf of Institution in connection with the Study if that individual or entity has been debarred under the provisions of the Generic Drug Enforcement Act of 1992, 21 U.S.C. § 335a(a) and (b); disqualified as a testing facility under the provisions of 21 C.F.R. Part 58, Subpart K; or disqualified as a clinical investigator under the provisions of 21 C.F.R. § 312.70. Institution shall notify GSK of any action with respect to debarment or disqualification against Institution or any individual or entity providing services on behalf of Institution in connection with the Study.

(e) Institution shall make this Agreement available to Investigator and Study Staff and require Investigator and Study Staff to comply with the provisions of this Agreement. Should GSK request changes to the terms and conditions in this section titled "Study Conduct," changes may be executed by the Institution acting by and through the Investigator.

(f) In the event GSK provides computer hardware and software systems for Investigator and Study Staff to use to collect, enter and report Study data to GSK electronically, Institution agrees that:

(i) Investigator and Study Staff will make themselves available for training in using the systems;

- (ii) the systems will be used only for the Study and only as described in written directions provided by GSK;
- (iii) the systems will be kept in a safe and secure location, and will be used only by Study Staff designated by Investigator as responsible for entering Study data;
- (iv) Institution will be responsible for any theft, damage or loss to the systems other than normal wear and tear;
- (v) Institution will be responsible for arranging and paying for any required internet connection as necessary to use the systems; and
- (vi) at the completion of the Study or at GSK's request, Institution will return to GSK the systems and all system related training materials and documentation.

3. COMPENSATION

(a) In consideration for conducting the Study, GSK shall pay Institution as described in this Section 3. The parties agree that these payment terms are consistent with the principles of fair market value payments for the performance of Study-related activities. All of GSK's payment obligations are conditioned upon Institution's compliance with standards identified in this Agreement. GSK will not make payments, or, if payment has been made by GSK, Institution will repay to GSK any payments, for study visits, procedures, or other work associated with a Study subject if GSK determines that the subject's data is not evaluable because of a violation of the Protocol by Investigator or Study Staff.

(b) Following execution of this Agreement and receipt of a completed form W-9, GSK will pay a non-refundable Study start-up payment of **\$2500.00 (two thousand five hundred dollars)** for the completion of all required regulatory and financial disclosure documents by Institution, Investigator, and Study Staff, to be due only upon the receipt by GSK of all required documents completed to GSK's satisfaction or the execution of this Agreement, whichever is later.

(c) GSK will pay for Study visits, procedures, or other work associated with a Study subject in accordance with the Per Subject Budget (Exhibit 1) attached and incorporated herein for all purposes by reference as part of this Agreement. All such payments are earned upon the completion of the relevant Study visits or procedures, subject to GSK's determination regarding Protocol compliance. The timing of payments by GSK will be as follows:

(i) Ongoing payments: Based on enrollment and subject progress updates received by GSK throughout the Study, Institution will earn payment as Study visits or procedures in the Per Subject Budget are completed. GSK will pay **80%** of amounts earned (that is, payment will be subject to a **20%** withholding by GSK for final payment as described below) on an ongoing basis as the amount of accrued payment, after withholding, totals at least **\$2,000.00 (two thousand dollars)**.

(iii) Final Payment: GSK will pay the withheld **20%** of the total amount earned by Institution for completing Study visits or procedures upon completion of all subjects and receipt and acceptance by GSK of all required documents (including but not limited to completed CRFs, laboratory data, resolved data queries and completed

financial disclosure forms parts A & B) and the delivery or destruction of Materials provided by GSK as described in Section 5(c).

(d) GSK will also pay, in addition to a start-up payment and payment for Study visits, procedures or other work associated with a Study subject in accordance with the Per Subject Budget, the following additional Study related costs on an actual cost basis without additional overhead charges.

(i) GSK will retain a vendor directly for retention efforts. All expenses will be paid directly through GSK. Any proposed materials or additional efforts must be approved by GSK prior to implementation. Costs will be reimbursed upon receipt of an invoice for actual charges incurred along with supporting documentation. Invoices must be originals or copies of original invoices. Faxed copies of invoices are not acceptable.

(ii) A one-time IRB Review Processing fee will be reimbursed upon receipt of an original invoice at the beginning of the study. IRB renewal fees, IRB amendment review fees and/or translation fees will be reimbursed upon receipt of an original IRB invoice for the duration of the study. All Central IRB fees will be billed directly to GSK and paid.

(e) For those sites who do not have a freezer that meets the GSK Study requirements, GSK will provide one to those sites through a third party vendor at no cost to the site. The freezer will be utilized solely for the purpose of storing frozen vaccine and/or serum samples for this study as well as any future GSK studies.

(f) All checks shall be made payable to the entity identified on the Federal Tax Form W-9 provided by Institution. Institution represents and warrants that such entity identified in is the appropriate entity to receive payments under this Agreement.

Mailing address for checks (if different from mailing address on Federal Tax form W-9):

Fernando A. Guerra, MD, MPH, Director of Health
Attention: Clinical Trials Team
San Antonio Metropolitan Health District
345 West Commerce Street
San Antonio, Texas 78205

4. TERM; TERMINATION

(a) This Agreement shall take effect on the Effective Date and shall continue until terminated as provided below.

(b) Either party may terminate this Agreement immediately upon written notice if the other party becomes insolvent, or if proceedings are instituted against the other party for reorganization or other relief under any bankruptcy law, or if any substantial part of the other

party's assets come under the jurisdiction of a receiver or trustee in an insolvency proceeding authorized by law.

(c) GSK may terminate this Agreement, in whole or in part, with or without cause, immediately upon written notice to Institution. Notice by GSK that the Study is terminated shall also constitute effective notice of termination of this Agreement.

5. EFFECT OF TERMINATION

(a) Upon notice of termination of this Agreement by either Institution or GSK, Institution shall cease enrolling subjects into the Study, and shall discontinue conduct of the Study as soon as is medically practicable.

(b) Upon notice of termination of this Agreement by either Institution or GSK, Institution shall use reasonable efforts to revoke any financial obligations incurred and shall avoid incurring any additional costs in connection with the Study. Institution shall be compensated only for Study-related work actually performed or reimbursed only for expenses actually and reasonably incurred through the effective date of termination which GSK has agreed to pay as part of the Study under this Agreement. If, upon the effective date of termination, GSK has advanced funds which are unearned by Institution, Institution shall repay such funds within sixty (60) days of the effective date of termination. In the event Institution fails to repay such funds in a timely manner, GSK may deduct an equivalent amount from any payment then or later due from GSK to Institution under this or any other arrangement between the parties.

(c) Upon termination of this Agreement, all unused Materials and all GSK Confidential Information (except for such records that Institution is required by law or regulation to retain) in Institution's possession shall be promptly delivered to GSK at GSK's expense, or, at GSK's option, destroyed with the destruction certified in writing.

6. RECORDKEEPING; ACCESS

(a) Institution shall make and retain records regarding the Study as required by the Protocol and applicable law or guidelines.

(b) Authorized representatives of GSK, upon reasonable advance notice and during regular business hours, shall have the right to inspect Institution's facilities used in the conduct of the Study and to inspect and copy all records relating to the Study (including, without limitation, access to records as necessary for study monitoring or to audit the conduct of the Study in accordance with GSK standards). GSK will maintain the confidentiality of any subject-identifiable medical records in accordance with all applicable laws.

(c) If any governmental or regulatory authority notifies Institution that it will inspect Institution's records, facilities, equipment, or procedures, or otherwise take action related to the Study, Institution shall promptly notify GSK, allow GSK to be present at the inspection/action or participate in any response to the inspection/action, and provide GSK with copies of any reports issued by the authority and Institution's proposed response.

(d) The obligations of this Section shall survive termination of this Agreement.

7. CONFIDENTIALITY

(a) GSK Confidential Information and all tangible expressions, in any media, of GSK Confidential Information are the sole property of GSK.

(b) Institution agrees not to use GSK Confidential Information for any purposes other than to conduct the Study. To the extent allowed by law, Institution agrees not to disclose GSK Confidential Information to third parties except as necessary to conduct the Study and under an agreement by the third party to be bound by the obligations of this Section. Institution shall safeguard GSK Confidential Information with the same standard of care that is used with Institution's Confidential Information, but in no event less than reasonable care.

(c) The obligations of confidentiality and limited use under this Section shall not extend to any information:

(i) which is or becomes publicly available, except through breach of this Agreement;

(ii) which Institution can demonstrate that it possessed prior to, or developed independently from, disclosure or development under this Agreement;

(iii) which Institution receives from a third party which is not legally prohibited from disclosing such information;

(iv) which Institution is required by law to disclose, provided that GSK is notified of any such requirement with sufficient time to seek a protective order or other modifications to the requirement;

(v) which is appropriate to include in a Multicenter Publication of which Investigator or other representatives of Institution participate as a named author and which is otherwise made in accordance with this Agreement;

(vi) which is appropriate to include in an Institution Publication made in accordance with this Agreement or

(vii) a Study subject's specific medical information, as necessary for the appropriate medical care of the subject.

(d) The obligations of this Section shall survive termination of this Agreement.

8. PUBLICATION

(a) Institution and Investigator agree that GSK may make public Study results from all Study sites, including, without limitation, by posting a summary of study results in GSK's on-line Clinical Trials Register before or after publication by any other method. In the event GSK coordinates a publication or presentation of Study results from all Study sites (a "Multicenter Publication"), the participation of Investigator or other representatives of Institution as a named author shall be determined in accordance with GSK policy and generally accepted standards for authorship. If the Investigator or other representative of Institution is a named author of the Multicenter Publication, such person shall have access to the Study data from all Study sites as necessary to fully participate in the development of the Multicenter Publication.

(b) Institution and Investigator, consistent with scientific standards and in a scientific forum, may publish or present the Study results from Institution's Study data (an "Institution Publication"), provided that the Institution Publication does not also disclose any GSK Confidential Information other than the Study results from Institution's Study data. Institution and Investigator shall submit to GSK for review and comment any proposed Institution Publication at least thirty (30) days prior to submitting the Institution Publication to any third party. If GSK requests a delay in order to file patent applications relating to an Invention, Institution and Investigator agree to delay submitting the Institution Publication to any third party for up to one hundred twenty (120) days after GSK's request. Institution and Investigator also agree that any Institutional Publication shall only be made after the Multicenter Publication, provided that the Multicenter Publication is submitted within twelve (12) months after conclusion of the Study at all sites.

(c) The obligations of this Section shall survive termination of this Agreement.

9. INTELLECTUAL PROPERTY

(a) Institution will notify GSK, promptly and in writing, of any Invention.

(b) Institution hereby assigns, and will cause Investigators and Study Staff to assign, to GSK any and all rights, title, and interest in any Invention, each without additional consideration from GSK.

(c) If GSK requests, Institution will execute and will cause Investigators and Study Staff to execute any instruments or testify as GSK deems necessary for GSK to obtain patents or otherwise to protect GSK's interest in an Invention. GSK will reasonably compensate Institution for the time devoted to such activities and will reimburse Institution for reasonable and necessary expenses incurred.

(d) The obligations of this Section shall survive termination of this Agreement.

10. INDEMNIFICATION

(a) GSK covenants and agrees to FULLY INDEMNIFY and HOLD HARMLESS, the Institution and the elected officials, employees, officers, directors, volunteers and representatives of the Institution, individually or collectively, from and against any and all costs, claims, liens, damages, losses, expenses, fees, fines, penalties, proceedings, actions, demands, causes of action, liability and suits of any kind and nature, including but not limited to, personal or bodily injury, death and property damage, made upon the Institution directly or indirectly arising out of, resulting from or related to GSK's activities under this Agreement, including any acts or omissions of GSK, any agent, officer, director, representative, employee, consultant or subcontractor of GSK, and their respective officers, agents, employees, directors and representatives while in the exercise of performance of the rights or duties under this Agreement. The indemnity provided for in this paragraph shall not apply to any liability resulting from the

failure of Institution to conduct the Study in accordance with the Protocol, GCPs, GSK's written instructions, applicable laws or regulations, or the willful misconduct or negligence of Institution, its officers, or employees, in instances where such willful misconduct or negligence causes personal injury, death, or property damage. IN THE EVENT GSK AND Institution ARE FOUND JOINTLY LIABLE BY A COURT OF COMPETENT JURISDICTION, LIABILITY SHALL BE APPORTIONED COMPARATIVELY IN ACCORDANCE WITH THE LAWS OF THE STATE OF TEXAS, WITHOUT, HOWEVER, WAIVING ANY GOVERNMENTAL IMMUNITY AVAILABLE TO THE Institution UNDER TEXAS LAW AND WITHOUT WAIVING ANY DEFENSES OF THE PARTIES UNDER TEXAS LAW.

(b) The provisions of this INDEMNIFICATION are solely for the benefit of the parties hereto and not intended to create or grant any rights, contractual or otherwise, to any other person or entity.

(c) GSK shall promptly advise the Institution in writing of any claim or demand against the Institution or GSK known to GSK related to or arising out of GSK's activities under this Agreement.

(d) GSK will offer Study subjects compensation for Study-related injuries, through the Study's informed consent process. If Institution provides a Study subject medical care for which compensation is available from GSK under the terms of the informed consent for the Study, GSK agrees, subject to the Study subject's authorization, to pay Institution directly on the Study subject's behalf, for the care provided.

(e) The obligations of this Section shall survive termination of this Agreement.

11. INSURANCE

(a) Institution shall maintain medical professional liability insurance with limits in accordance with local standards for each medical professional involved in the Study, or require that each medical professional maintain such insurance. Upon GSK's request, Institution shall have its insurance carrier (or shall cause the medical professional to have his or her insurance carrier) furnish to GSK certificates that all insurance required under this Agreement is in force.

(b) GSK shall, through its self-insurance program, maintain comprehensive general liability insurance in amounts not less than \$2,000,000.00 per incident and \$5,000,000.00 annual aggregate. Such insurance shall provide (1) product liability coverage and (2) broad form contractual liability coverage. GSK shall provide Institution with written evidence of its self-insurance program.

(c) Nothing herein contained shall be construed as limiting in any way the extent to which GSK may be held responsible for payments of damages to persons or property resulting from the performance of the work covered under this Agreement

(d) It is agreed that GSK's self-insurance program shall be deemed primary and non-contributory with respect to any insurance or self insurance carried by the Institution for liability arising out of the operations of this Agreement

e) It is understood and agreed that the insurance required is in addition to and separate from any other obligation in this agreement.

12. INDEPENDENT CONTRACTOR

The relationship of the parties is that of independent contractors. Neither party is the partner, joint venturer, or agent of the other and neither party has authority to make any statement, representation, commitment, or action of any kind which purports to bind the other without the other's prior written authorization.

13. USE OF PARTIES' NAMES

Neither party shall make (or have made on its behalf) any oral or written release of any statement, information, advertisement or publicity in connection with this Agreement, or the Study, which uses the other party's name, symbols, or trademarks without the other party's prior written approval.

14. NOTICES

All notices under this Agreement shall be sent by registered or certified mail, postage prepaid, or by overnight courier service. Notices pertaining to this Agreement shall be sent to:

If to GSK:

June McGinn
2301 Renaissance Blvd / Mailstop RN0220
King of Prussia, PA 19406

If to Institution:

Jorge Flores
San Antonio Metropolitan Health District
332 West Commerce Street
San Antonio, Texas 78205

15. ASSIGNMENT

GSK may assign its rights and duties under this Agreement without Institution's consent. Any assignment by Institution is valid only upon the prior written consent of GSK. To the extent permitted above, this Agreement shall be binding upon and inure to the benefit of the parties and their permitted successors and assigns.

16. SEVERABILITY

If any provision(s) of this Agreement should be illegal or unenforceable in any respect, the legality and enforceability of the remaining provisions of this Agreement shall not be affected.

17. WAIVER; MODIFICATION OF AGREEMENT

No waiver, amendment, or modification of any of the terms of this Agreement shall be valid unless in writing and signed by authorized representatives of both parties. Failure by either party to enforce any rights under this Agreement shall not be construed as a waiver of such rights nor shall a waiver by either party in one or more instances be construed as constituting a continuing waiver or as a waiver in other instances.

18. GOVERNING LAW

This Agreement shall be governed by and interpreted in accordance with the laws of the state in which Institution is located.

19. ENTIRE AGREEMENT

This Agreement represents the entire and integrated agreement between the parties and supersedes all prior negotiations, representations or agreements, either written or oral, regarding its subject matter. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original and all of which shall constitute the same instrument.

SMITHKLINE BEECHAM CORPORATION
d/b/a GLAXOSMITHKLINE

By: Anne Marie Inglis
«GSK_Signatory»
«GSK_Signatory_Title»

Anne Marie Inglis
Director
Study Management
Vaccines - N.A.

Date: 23 Apr 08

APPROVED AS TO FORM:

Michael D. Bernard
Michael D. Bernard, City Attorney

CITY OF SAN ANTONIO ON BEHALF
OF THE SAN ANTONIO
METROPOLITAN HEALTH DISTRICT
IMMUNIZATION DEPARTMENT

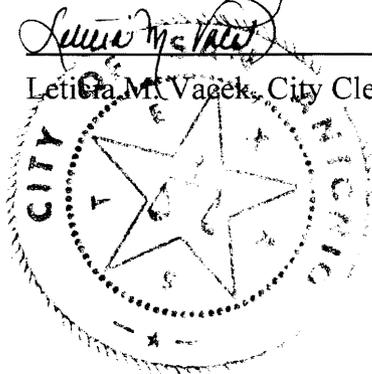
By: [Signature]
Name: Fernando A. Guerra, MD, MPH
Title: Director of Health
Date: 4/16/08

By my signature I indicate my agreement to fulfill the role and obligations of Investigator under this Agreement.

By: Jorge Flores MD
Jorge Flores, MD, MPH
Date: 4-14-08

ATTEST:

[Signature] 4-18-08
Leticia M. Vacek, City Clerk Date



**Exhibit 1
Per Subject Budget**

MMRV-US-054/110058 - Version 1
(28-Sep-07)

Assessments	Visit 1	Visit 2	Visit 3	Totals*₁	Unscheduled Visit for Evaluation of Rash or Parotid or Salivary Gland Swelling _{2, 4}
Informed Consent	\$70.00			\$70.00	
Inclusion/Exclusion Criteria	\$65.00			\$65.00	
Telephone Call to Subject (Guardian) ₃	\$67.00			\$67.00	
Initial examination: Medical History, Physical Exam, Pre-vaccination body temperature	\$225.00			\$225.00	
Blood Sampling	\$43.00	\$43.00		\$86.00	
Vaccination	\$201.00		\$67.00	\$268.00	
History directed Physical Examination, Pre-vaccination body temperature as appropriate		\$119.00	\$119.00	\$238.00	\$119.00
Clinical Coordinator Fee ₅	\$110.00	\$110.00	\$110.00	\$330.00	\$110.00
Un-Blinded Clinical Coordinator Fee	\$110.00			\$110.00	
Investigator Fee ₆	\$143.00	\$143.00	\$125.00	\$411.00	\$143.00
Pharmacy Fee	\$44.00		\$44.00	\$88.00	
Patient Travel Stipend	\$50.00	\$50.00	\$50.00	\$150.00	\$50.00
SUBTOTAL	\$1,128.00	\$465.00	\$515.00	\$2,108.00	\$422.00
Overhead (20%)	\$225.60	\$93.00	\$103.00	\$421.60	\$84.40
GRAND TOTAL	\$1,353.60	\$558.00	\$618.00	\$2,529.60	\$506.40

1 Total per patient amounts do not include reimbursement for Unscheduled Visits.

2 Unscheduled Visits may not be performed on all subjects and will be reimbursed as they occur.

3 Telephone call includes compensation for time and effort spent recruiting subjects for study at your site.

4 At the Unscheduled Visit, this will be a limited examination for skin rash and swollen glands.

5 Clinical coordinator fee includes compensation for time and effort to ensure 100% diary card completion by subjects.

6 Investigator fee includes compensation for time and effort to ensure that 100% of blood draws and unscheduled visits are completed per protocol.

Principal Investigator Name: Jorge Flores ,MD

Institution Name: San Antonio Metropolitan Health District Immunization Department



CMS or Ordinance Number: CN0040002639

TSLGRS File Code:1025-08-A

Document Title:

CONT - GlaxoSmithKline Study 109628 (HPV-024 BST 001), 12/1/07-12/31/10

~~US Male Health Services~~

Commencement Date:

12/1/2007

Expiration Date:

12/31/2010

CLINICAL STUDY AGREEMENT

This CLINICAL STUDY AGREEMENT (this "Agreement") is effective 12 September, 2007 (the "Effective Date") between the City of San Antonio on behalf of the San Antonio Metropolitan Health District ("Institution") and SmithKline Beecham Corporation, doing business as GlaxoSmithKline ("GSK").

BACKGROUND

GSK and its Affiliates develop, manufacture, distribute, and sell pharmaceutical and healthcare products. Institution conducts clinical studies. GSK and Institution intend for this Agreement to establish terms and conditions for the performance of the clinical study identified below.

DEFINITIONS

"Affiliate" means any entity that controls, is controlled by, or is under common control with, GSK. In this context, "control" shall mean (1) ownership by one entity, directly or indirectly, of at least forty percent (40%) of the voting stock of another entity; (2) power of one entity to direct the management or policies of another entity, by contract or otherwise; or (3) any other relationship between GSK and an entity which GSK and Institution have agreed in writing may be considered an "Affiliate" of GSK.

"GSK Confidential Information" means all information (including, without limitation, study protocols, case report forms, clinical data, other data, reports, specifications, computer programs or models and related documentation, know-how, trade secrets, or business or research plans) of GSK or GSK's Affiliates that are: (1) provided to Institution in connection with this Agreement or the Study; (2) Study data, results, or reports created by Institution, Investigators, or Study Staff in connection with the Study (except for a Study subject's medical records); and (3) cumulative Study data, results, and reports from all sites conducting the Study.

"Invention" means any discovery, development, invention (whether patentable or not), improvement, work of authorship, formula, process, composition of matter, formulation, method of use or delivery, specification, computer program or model and related documentation, know-how or trade secret, that is made by Institution, Investigators, or Study Staff: (1) in connection with the Study; or (2) which incorporate GSK Confidential Information.

"Investigator" means the individual(s) responsible for the conduct of the Study at Institution and for direct supervision of Study Staff.

"Materials" means Study drug(s) and related devices, equipment, or other materials provided by GSK for the conduct of the Study.

“Protocol” means the written document that describes the Study and sets forth specific activities to be performed as part of Study conduct.

“Study” means the clinical study sponsored by GSK and conducted by Institution as specifically identified in this Agreement.

“Study Staff” means the individuals providing services on behalf of Institution with respect to the Study at Institution, including without limitation subinvestigators, study coordinators, and other Institution employees, agents, or subcontractors.

1. THE STUDY

STUDY TITLE AND PROTOCOL NUMBER: An open, phase II, multicenter study to assess the safety and immune response to a HPV-16/18 L1 VLP AS04 vaccine fourth dose in healthy, young, adult women in North America previously vaccinated with 3 doses of GlaxoSmithKline Biologicals’ HPV-16/18 L1 VLP AS04 vaccine. 109628 (HPV-024 BST 001)

INVESTIGATOR’S NAME: Fernando A. Guerra, MD, MPH

INSTITUTION’S ENROLLMENT MAXIMUM: 13 subjects

TOTAL ENROLLMENT TARGET AT ALL STUDY SITES: 150 subjects

INSTITUTION’S TAX ID NUMBER: 1746002070

2. STUDY CONDUCT

- (a) Institution agrees to conduct the Study in strict compliance with:
 - (i) the Study Protocol, as approved by GSK, Investigator, and the responsible Institutional Review Board (along with any subsequently approved amendments to the Study Protocol);
 - (ii) all applicable local, state and federal laws, rules and regulations, including, but not limited to, the Federal Food, Drug and Cosmetic Act and the regulations of the FDA, FDA and ICH Good Clinical Practices, and the Form FDA 1572 Statement of Investigator;
 - (iii) all applicable medical privacy laws or regulations, including without limitation, by obtaining any required subject consent or authorization to allow GSK access to Study subject’s medical information as may be necessary to monitor the Study and to receive and use Study data; and
 - (iv) the terms of this Agreement.

- (b) The following Enrollment plan will apply to the Study:
 - (i) Subject enrollment up to Institution's Enrollment Maximum shall be completed on or before **29 February, 2008**.

 - (ii) Institution or Investigator will not enroll more Study subjects than Institution's Enrollment Maximum, and GSK will not be obligated to make any

payment with respect to any subject enrolled in excess of Institution's Enrollment Maximum. Without any obligation to do so, the parties may agree in writing to modify Institution's Enrollment Maximum.

(iii) All subject visits will be completed no later than **29 August, 2009**.

(iv) Case Report Forms ("CRFs") information associated with a subject's visit must be satisfactorily completed within seven (7) days after the subject's visit or, if applicable, receipt of the subject's test results.

(v) All final CRF data will be completed no later than **29 October, 2009**.

(vi) All data Queries from GSK must be completed and returned to GSK within seven (7) days or, if during final clean up, one (1) day, or such other time set by GSK.

(vii) In exceptional circumstances GSK may intervene in the routine process of eCRF corrections to make data clarifications on behalf of the Investigator/Institution. With prior notification to Institution and with specific managerial oversight, GSK data managers may make data clarifications on behalf of the Investigator/Institution based upon an embedded query response or comment (e.g., the answer has been provided in response to the query but the corresponding data has not been edited). All clarifications made by GSK will be evidenced in the audit trail of the data.

(c) Institution and Investigator shall use Materials only to conduct the Study in accordance with the Protocol; shall not chemically, physically or otherwise modify Materials, unless specifically required to do so by the Protocol; and shall handle, store, and ship or dispose of Materials in compliance with all applicable local, state and federal laws, rules and regulations including, but not limited to, those governing hazardous substances. Institution and Investigator shall not charge any Study subject or third-party payor for any Materials, or for Study procedures for which payment by GSK has or will be made under this Agreement.

(d) Institution agrees that no individual or entity shall provide services on behalf of Institution in connection with the Study if that individual or entity has been debarred under the provisions of the Generic Drug Enforcement Act of 1992, 21 U.S.C. § 335a(a) and (b); disqualified as a testing facility under the provisions of 21 C.F.R. Part 58, Subpart K; or disqualified as a clinical investigator under the provisions of 21 C.F.R. § 312.70. Institution shall notify GSK of any action with respect to debarment or disqualification against Institution or any individual or entity providing services on behalf of Institution in connection with the Study.

(e) Institution shall make this Agreement available to Investigator and Study Staff and require Investigator and Study Staff to comply with the provisions of this Agreement.

(f) In the event GSK provides computer hardware and software systems for Investigator and Study Staff to use to collect, enter and report Study data to GSK electronically, Institution agrees that:

(i) Investigator and Study Staff will make themselves available for training in using the systems;

(ii) the systems will be used only for the Study and only as described in written directions provided by GSK;

(iii) the systems will be kept in a safe and secure location, and will be used only by Study Staff designated by Investigator as responsible for entering Study data;

(iv) Institution will be responsible for any theft, damage or loss to the systems other than normal wear and tear;

(v) Institution will be responsible for arranging and paying for any required internet connection as necessary to use the systems; and

(vi) at the completion of the Study or at GSK's request, Institution will return to GSK the systems and all system related training materials and documentation.

3. COMPENSATION

(a) In consideration for conducting the Study, GSK shall pay Institution as described in this Section 3. The parties agree that these payment terms are consistent with the principles of fair market value payments for the performance of Study-related activities. All of GSK's payment obligations are conditioned upon Institution's compliance with standards identified in this Agreement. GSK will not make payments, or, if payment has been made by GSK, Institution will repay to GSK any payments, for study visits, procedures, or other work associated with a Study subject if GSK determines that the subject's data is not evaluable because of a violation of the Protocol by Investigator or Study Staff.

(b) Following execution of this Agreement and receipt of a completed form W-9, GSK will pay a non-refundable Study start-up payment of **\$1,000.00 (one thousand dollars)** for the completion of all required regulatory and financial disclosure documents by Institution, Investigator, and Study Staff, to be due only upon the receipt by GSK of all required documents completed to GSK's satisfaction or the execution of this Agreement, whichever is later.

(c) GSK will pay for Study visits, procedures, or other work associated with a Study subject in accordance with the Per Subject Budget (Exhibit 1) attached and incorporated herein for all purposes by reference as part of this Agreement. All such payments are earned upon the completion of the relevant Study visits or procedures,

subject to GSK's determination regarding Protocol compliance. The timing of payments by GSK will be as follows:

(i) Ongoing payments: Based on enrollment and subject progress updates received by GSK throughout the Study, Institution will earn payment as Study visits or procedures in the Per Subject Budget are completed. GSK will pay **80%** of amounts earned (that is, payment will be subject to a **20%** withholding by GSK for final payment as described below) once the initial payment described above is earned by Institution, on an ongoing basis as the amount of accrued payment, after withholding, totals at least **\$2,000.00 (two thousand dollars)**.

(ii) Final Payment: GSK will pay the withheld **20%** of the total amount earned by Institution for completing Study visits or procedures upon completion of all subjects and receipt and acceptance by GSK of all required documents (including but not limited to completed CRFs, laboratory data, resolved data queries and completed financial disclosure forms parts A & B) and the delivery or destruction of Materials provided by GSK as described in Section 5(c).

(d) GSK will also pay, in addition to a start-up payment and payment for Study visits, procedures or other work associated with a Study subject in accordance with the Per Subject Budget, the following additional Study related costs on an actual cost basis without additional overhead charges.

(i) Any proposed recruitment and/or retention materials must be approved by GSK prior to implementation and approved by the IRB if necessary. Costs will be reimbursed upon receipt of an invoice for actual charges incurred along with supporting documentation of materials if applicable. Invoices must be originals or copies of original invoices. Faxed copies of invoices are not acceptable.

(ii) A one-time IRB Review Processing fee will be reimbursed upon receipt of an original invoice. If necessary, IRB renewal fees will be reimbursed upon receipt of an IRB invoice. Central IRB Fees will be paid directly through invoicing to GSK from IRB.

(iii) LEEP procedures necessary according to the protocol management algorithm must be approved by the GSK Study Manager prior to payment. Costs will be reimbursed upon receipt of an invoice for actual charges incurred. Invoices must be originals or copies of original invoices. Faxed copies of invoices are not acceptable.

(iv) It is anticipated that it may be possible to transfer subjects to other participating centers due to relocation. All transfers must be approved by the GSK Study Manager prior to the next needed visit. A transfer

agreement between both sites will be generated for these subjects independent of this agreement strictly for the transfer of all subject data in necessary systems and allow for any additional charges incurred by either site.

(v) If it becomes necessary for a subject to need to travel an extensive distance to remain in the program, the HPV Travel Policy (Exhibit 2) will be implemented. Any and all subject travel must be approved by the GSK Study Manager prior to the event.

(e) All checks shall be made payable to the entity identified on the Federal Tax Form W-9 provided by Institution. Institution represents and warrants that such entity identified in is the appropriate entity to receive payments under this Agreement.

Mailing address for checks (if different from mailing address on Federal Tax form W-9):

Fernando A. Guerra, MD, MPH
Director of Health
San Antonio Metropolitan Health District
332 West Commerce Street
San Antonio, Texas 78205

4. TERM; TERMINATION

(a) This Agreement shall take effect on the Effective Date and shall continue until terminated as provided below.

(b) Either party may terminate this Agreement immediately upon written notice if the other party becomes insolvent, or if proceedings are instituted against the other party for reorganization or other relief under any bankruptcy law, or if any substantial part of the other party's assets come under the jurisdiction of a receiver or trustee in an insolvency proceeding authorized by law.

(c) GSK may terminate this Agreement, in whole or in part, with or without cause, immediately upon written notice to Institution. Notice by GSK that the Study is terminated shall also constitute effective notice of termination of this Agreement.

5. EFFECT OF TERMINATION

(a) Upon notice of termination of this Agreement by either Institution or GSK, Institution shall cease enrolling subjects into the Study, and shall discontinue conduct of the Study as soon as is medically practicable.

(b) Upon notice of termination of this Agreement by either Institution or GSK, Institution shall use reasonable efforts to revoke any financial obligations incurred and shall avoid incurring any additional costs in connection with the Study. Institution shall be compensated only for Study-related work actually performed or reimbursed only for expenses actually and reasonably incurred through the effective date of termination which GSK has agreed to pay as part of the Study under this Agreement. If, upon the effective date of termination, GSK has advanced funds which are unearned by Institution, Institution shall repay such funds within sixty (60) days of the effective date of termination. In the event Institution fails to repay such funds in a timely manner, GSK may deduct an equivalent amount from any payment then or later due from GSK to Institution under this or any other arrangement between the parties.

(c) Upon termination of this Agreement, all unused Materials and all GSK Confidential Information (except for such records that Institution is required by law or regulation to retain) in Institution's possession shall be promptly delivered to GSK at GSK's expense, or, at GSK's option, destroyed with the destruction certified in writing.

6. RECORDKEEPING; ACCESS

(a) Institution shall make and retain records regarding the Study as required by the Protocol and applicable law or guidelines.

(b) Authorized representatives of GSK, upon reasonable advance notice and during regular business hours, shall have the right to inspect Institution's facilities used in the conduct of the Study and to inspect and copy all records relating to the Study (including, without limitation, access to records as necessary for study monitoring or to audit the conduct of the Study in accordance with GSK standards). GSK will maintain the confidentiality of any subject-identifiable medical records in accordance with all applicable laws.

(c) If any governmental or regulatory authority notifies Institution that it will inspect Institution's records, facilities, equipment, or procedures, or otherwise take action related to the Study, Institution shall promptly notify GSK, allow GSK to be present at the inspection/action or participate in any response to the inspection/action, and provide GSK with copies of any reports issued by the authority and Institution's proposed response.

(d) The obligations of this Section shall survive termination of this Agreement.

7. CONFIDENTIALITY

(a) GSK Confidential Information and all tangible expressions, in any media, of GSK Confidential Information are the sole property of GSK.

(b) Institution agrees not to use GSK Confidential Information for any purposes other than to conduct the Study. To the extent allowed by law, Institution agrees not to disclose GSK Confidential Information to third parties except as necessary to conduct the Study and under an agreement by the third party to be bound by the obligations of this Section. Institution shall safeguard GSK Confidential Information with the same standard of care that is used with Institution's Confidential Information, but in no event less than reasonable care.

(c) The obligations of confidentiality and limited use under this Section shall not extend to any information:

(i) which is or becomes publicly available, except through breach of this Agreement;

(ii) which Institution can demonstrate that it possessed prior to, or developed independently from, disclosure or development under this Agreement;

(iii) which Institution receives from a third party which is not legally prohibited from disclosing such information;

(iv) which Institution is required by law to disclose, provided that GSK is notified of any such requirement with sufficient time to seek a protective order or other modifications to the requirement;

(v) which is appropriate to include in a Multicenter Publication of which Investigator or other representatives of Institution participate as a named author and which is otherwise made in accordance with this Agreement;

(vi) which is appropriate to include in an Institution Publication made in accordance with this Agreement or

(vii) a Study subject's specific medical information, as necessary for the appropriate medical care of the subject.

(d) The obligations of this Section shall survive termination of this Agreement.

8. PUBLICATION

(a) Institution and Investigator agree that GSK may make public Study results from all Study sites, including, without limitation, by posting a summary of study results in GSK's on-line Clinical Trials Register before or after publication by any other method. In the event GSK coordinates a publication or presentation of Study results from all Study sites (a "Multicenter Publication"), the participation of Investigator or other representatives of Institution as a named author shall be determined in accordance with GSK policy and generally accepted standards for authorship. If the Investigator or other representative of Institution is a named author of the Multicenter Publication, such person shall have access to the Study data from all Study sites as necessary to fully participate in the development of the Multicenter Publication.

(b) Institution and Investigator, consistent with scientific standards and in a scientific forum, may publish or present the Study results from Institution's Study data (an "Institution Publication"), provided that the Institution Publication does not also disclose any GSK Confidential Information other than the Study results from Institution's Study data. Institution and Investigator shall submit to GSK for review and comment any proposed Institution Publication at least thirty (30) days prior to submitting the Institution Publication to any third party. If GSK requests a delay in order to file patent applications relating to an Invention, Institution and Investigator agree to delay submitting the Institution Publication to any third party for up to one hundred twenty (120) days after GSK's request. Institution and Investigator also agree that any Institutional Publication shall only be made after the Multicenter Publication, provided that the Multicenter Publication is submitted within twelve (12) months after conclusion of the Study at all sites.

(c) The obligations of this Section shall survive termination of this Agreement.

9. INTELLECTUAL PROPERTY

(a) Institution will notify GSK, promptly and in writing, of any Invention.

(b) Institution hereby assigns, and will cause Investigators and Study Staff to assign, to GSK any and all rights, title, and interest in any Invention, each without additional consideration from GSK.

(c) If GSK requests, Institution will execute and will cause Investigators and Study Staff to execute any instruments or testify as GSK deems necessary for GSK to obtain patents or otherwise to protect GSK's interest in an Invention. GSK will reasonably compensate Institution for the time devoted to such activities and will reimburse Institution for reasonable and necessary expenses incurred.

(d) The obligations of this Section shall survive termination of this Agreement.

10. INDEMNIFICATION

(a) **GSK covenants and agrees to FULLY INDEMNIFY and HOLD HARMLESS, the Institution and the elected officials, employees, officers, directors, volunteers and representatives of the Institution, individually or collectively, from and against any and all costs, claims, liens, damages, losses, expenses, fees, fines, penalties, proceedings, actions, demands, causes of action, liability and suits of any kind and nature, including but not limited to, personal or bodily injury, death and property damage, made upon the Institution directly or indirectly arising out of, resulting from or related to GSK's activities under this Agreement, including any acts or omissions of GSK, any agent, officer, director, representative, employee,**

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City of San Antonio on behalf of the San Antonio Metropolitan Health District /

Fernando A. Guerra, MD, MPH

Effective date: 12 September, 2007

consultant or subcontractor of GSK, and their respective officers, agents, employees, directors and representatives while in the exercise of performance of the rights or duties under this Agreement. The indemnity provided for in this paragraph shall not apply to any liability resulting from the failure of Institution to conduct the Study in accordance with the Protocol, GCPs, GSK's written instructions, applicable laws or regulations, or the willful misconduct or negligence of Institution, its officers, or employees, in instances where such willful misconduct or negligence causes personal injury, death, or property damage. IN THE EVENT GSK AND Institution ARE FOUND JOINTLY LIABLE BY A COURT OF COMPETENT JURISDICTION, LIABILITY SHALL BE APPORTIONED COMPARATIVELY IN ACCORDANCE WITH THE LAWS OF THE STATE OF TEXAS, WITHOUT, HOWEVER, WAIVING ANY GOVERNMENTAL IMMUNITY AVAILABLE TO THE Institution UNDER TEXAS LAW AND WITHOUT WAIVING ANY DEFENSES OF THE PARTIES UNDER TEXAS LAW.

(b) The provisions of this INDEMNIFICATION are solely for the benefit of the parties hereto and not intended to create or grant any rights, contractual or otherwise, to any other person or entity.

(c) GSK shall promptly advise the Institution in writing of any claim or demand against the Institution or GSK known to GSK related to or arising out of GSK's activities under this Agreement.

(d) GSK will offer Study subjects compensation for Study-related injuries, through the Study's informed consent process. If Institution provides a Study subject medical care for which compensation is available from GSK under the terms of the informed consent for the Study, GSK agrees, subject to the Study subject's authorization, to pay Institution directly on the Study subject's behalf, for the care provided.

(e) The obligations of this Section shall survive termination of this Agreement.

11. INSURANCE

(a) Institution shall maintain medical professional liability insurance with limits in accordance with local standards for each medical professional involved in the Study, or require that each medical professional maintain such insurance. Upon GSK's request, Institution shall have its insurance carrier (or shall cause the medical professional to have his or her insurance carrier) furnish to GSK certificates that all insurance required under this Agreement is in force.

(b) GSK shall, through its self-insurance program, maintain comprehensive general liability insurance in amounts not less than \$2,000,000.00 per incident and

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City of San Antonio on behalf of the San Antonio Metropolitan Health District /

Fernando A. Guerra, MD, MPH

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\$5,000,000.00 annual aggregate. Such insurance shall provide (1) product liability coverage and (2) broad form contractual liability coverage. Upon written request, GSK shall provide Institution with written evidence of its self-insurance program.

12. INDEPENDENT CONTRACTOR

The relationship of the parties is that of independent contractors. Neither party is the partner, joint venturer, or agent of the other and neither party has authority to make any statement, representation, commitment, or action of any kind which purports to bind the other without the other's prior written authorization.

13. USE OF PARTIES' NAMES

Neither party shall make (or have made on its behalf) any oral or written release of any statement, information, advertisement or publicity in connection with this Agreement, or the Study, which uses the other party's name, symbols, or trademarks without the other party's prior written approval.

14. NOTICES

All notices under this Agreement shall be sent by registered or certified mail, postage prepaid, or by overnight courier service. Notices pertaining to this Agreement shall be sent to:

If to GSK:

June McGinn
2301 Renaissance Blvd/RN0220
King of Prussia, PA 19406

If to Institution:

Fernando A. Guerra, MD, MPH
Director of Health
San Antonio Metropolitan Health District
332 West Commerce Street
San Antonio, Texas 78205

15. ASSIGNMENT

GSK may assign its rights and duties under this Agreement without Institution's consent. Any assignment by Institution is valid only upon the prior written consent of GSK. To the extent permitted above, this Agreement shall be binding upon and inure to the benefit of the parties and their permitted successors and assigns.

16. SEVERABILITY

If any provision(s) of this Agreement should be illegal or unenforceable in any respect, the legality and enforceability of the remaining provisions of this Agreement shall not be affected.

17. WAIVER; MODIFICATION OF AGREEMENT

No waiver, amendment, or modification of any of the terms of this Agreement shall be valid unless in writing and signed by authorized representatives of both parties. Failure by either party to enforce any rights under this Agreement shall not be construed as a waiver of such rights nor shall a waiver by either party in one or more instances be construed as constituting a continuing waiver or as a waiver in other instances.

18. GOVERNING LAW

This Agreement shall be governed by and interpreted in accordance with the laws of the state in which Institution is located.

109628 HPV 024
EXHIBIT 1 Per Subject Budget
3 Dose Group (no subset)

Group II	Visit 1: Day 0	Visit 2: Day 7	Visit 3: Month 1	Visit 4: Month 6	Visit 5: Month 7	Visit 6: Month 12	Visit 7: Month 18	
Procedure	V1	V2	V3	V4	V5	V6	V7	TOTAL
Informed consent	\$70.00							\$70.00
Inclusion/Exclusion/Elimination criteria	\$50.00	\$35.00	\$35.00	\$35.00	\$35.00	\$35.00	\$35.00	\$260.00
Concomitant Medications	\$35.00	\$35.00	\$35.00	\$35.00	\$35.00	\$35.00	\$35.00	\$245.00
Pregnancy Test (urine)	\$22.00		\$22.00	\$22.00				\$66.00
Visit 1: Demographics, Medical Hx, History directed physical	\$150.00							\$150.00
Gynecological exam	\$80.00						\$80.00	\$160.00
Collection/handling of cervical specimens (PCR, cytology, CT/NG)	\$30.00				\$50.00	\$50.00	\$30.00	\$160.00
Blood Sampling (HPV, Hem & Chem)	\$25.00	\$25.00	\$25.00		\$25.00		\$25.00	\$125.00
Pre-Vaccination Body temperature	\$15.00		\$15.00	\$15.00				\$45.00
Vaccination	\$50.00		\$50.00	\$50.00				\$150.00
Total Procedure Costs	\$527.00	\$95.00	\$182.00	\$157.00	\$145.00	\$120.00	\$205.00	\$1,431.00
Study Coordinator, Per Visit	\$120.00	\$90.00	\$90.00	\$90.00	\$90.00	\$90.00	\$90.00	\$660.00
Physician, - Per Visit	\$135.00	\$105.00	\$105.00	\$105.00	\$105.00	\$105.00	\$105.00	\$765.00
Patient Travel Allowance	\$50.00	\$50.00	\$50.00	\$50.00	\$50.00	\$50.00	\$50.00	\$350.00
Other Direct Costs	\$305.00	\$245.00	\$245.00	\$245.00	\$245.00	\$245.00	\$245.00	\$1,775.00
Total of Procedures and Other Directs	\$832.00	\$340.00	\$427.00	\$402.00	\$390.00	\$365.00	\$450.00	\$3,206.00
Overhead Costs (25%)	\$208.00	\$85.00	\$106.75	\$100.50	\$97.50	\$91.25	\$112.50	\$801.50
Total Cost Per Patient	\$1,040.00	\$425.00	\$533.75	\$502.50	\$487.50	\$456.25	\$562.50	\$4,007.50

Unscheduled Visits	\$85.00 per visit	Alone	\$385.00 amount	with Biopsy	\$550.00 amount	Invoice)	\$ 750.00 amount
	\$21.25 overhead		\$96.25 overhead		\$137.50 overhead		\$ 187.50 overhead
	\$106.25 Total		\$481.25 Total		\$687.50 Total		\$ 937.50 Total

Institution: San Antonio Metro Health District
Investigator: Fernando A. Guerra, MD

109628 HPV 024
EXHIBIT 1 Per Subject Budget
4th Dose Group

GROUP I	Visit 1: Day 0	Visit 2: Day 7	Visit 3: Month 1	Visit 4: Month 7	Visit 5: Month 12	Visit 6: Month 18	
Procedure	V1	V2	V3	V4	V5	V6	TOTAL
Informed consent	\$70.00						\$70.00
Inclusion/Exclusion/Elimination criteria	\$50.00	\$35.00	\$35.00	\$35.00	\$35.00	\$35.00	\$225.00
Concomitant Medications	\$35.00	\$35.00	\$35.00	\$35.00	\$35.00	\$35.00	\$210.00
Pregnancy Test (urine)	\$22.00						\$22.00
Visit 1: Demographics, Medical Hx, History directed physical, pre-vaccination body temp	\$165.00						\$165.00
Gynecological exam	\$80.00					\$80.00	\$160.00
Collection/Handling of cervical specimens (PCR, cytology, CT/NG)	\$30.00			\$50.00	\$50.00	\$30.00	\$160.00
Blood Sampling (HPV, Hem & Chem)	\$25.00	\$25.00	\$25.00	\$25.00		\$25.00	\$125.00
Vaccination	\$50.00						\$50.00
Behavioral Questionnaire	\$20.00					\$20.00	\$40.00
Total Procedure Costs	\$547.00	\$95.00	\$95.00	\$145.00	\$120.00	\$225.00	\$1,227.00
Study Coordinator, Per Visit	\$120.00	\$90.00	\$90.00	\$90.00	\$90.00	\$90.00	\$570.00
Physician, Per Visit	\$135.00	\$105.00	\$105.00	\$105.00	\$105.00	\$105.00	\$660.00
Patient Travel Allowance	\$50.00	\$50.00	\$50.00	\$50.00	\$50.00	\$50.00	\$300.00
Other Direct Costs	\$305.00	\$245.00	\$245.00	\$245.00	\$245.00	\$245.00	\$1,530.00
Total of Procedures and Other Directs	\$852.00	\$340.00	\$340.00	\$390.00	\$365.00	\$470.00	\$2,757.00
Overhead Costs (25%)	\$213.00	\$85.00	\$85.00	\$97.50	\$91.25	\$117.50	\$689.25
Total Cost Per Patient	\$1,065.00	\$425.00	\$425.00	\$487.50	\$456.25	\$587.50	\$3,446.25

Unscheduled Visits	\$85.00 per visit	Colposcopy Alone	\$385.00 amount	Colposcopy with Biopsy	\$550.00 amount	LEEP (Paid via Invoice)	\$ 750.00 amount
	\$21.25 overhead		\$96.25 overhead		\$137.50 overhead		\$ 187.50 overhead
	\$106.25 Total		\$481.25 Total		\$687.50 Total		\$ 937.50 Total

Institution: San Antonio Metro Health District
Investigator: Fernando A. Guerra, MD

EXHIBIT 2
109628 HPV 024 Subject Travel Reimbursement Policy
Dated: 31 August 2007

Due to the length of the HPV 024 study, Subjects may relocate during the course of the study. If a Subject relocates, she should first be considered for a permanent transfer to another HPV 024 site which is closest to her new residence. However, if a permanent site-to-site transfer is not possible, Subjects may travel for study procedures/visits to the original study site. GSK has developed a **Subject Travel Reimbursement Policy** to address the associated cost in travelling to the original study site. Prior to applying this policy (i.e., for scheduled visits, for unscheduled study visits that may be required for follow up or as part of the protocol specific management algorithm, or in special or unforeseen circumstances), the **GSK Study Manager must be contacted for approval of travel payments.**

- The site should assist the Subject in making travel arrangements. The site is responsible to invoice GSK for reimbursement, as appropriate (see bulleted points below):
 - GSK will pay for air travel using a central travel account (when booked through BTI*), or if air travel is booked by the site/Subject an invoice should be submitted to GSK.
 - GSK can pay for hotel stays using a central travel account (when booked through BTI*), but only GSK Preferred Provider hotels can be charged to this account. To reimburse stays at non-GSK Preferred Provider hotels, an invoice should be submitted to GSK.
 - To reimburse for airport parking, the appropriate original receipt must accompany an invoice and be submitted to GSK.
 - The subject may choose to drive to the study site. To reimburse mileage, an invoice should be submitted to GSK. Please provide back up documentation, which shows the mileage driven.
- Invoices submitted to GSK by the site must contain the following information:
 - Subject Number and Site Information. Please DO NOT put any personal Subject identifiers on the invoice (and DO NOT include any personal Subject identifiers on any back up documentation).
 - The name of the GSK Study Manager approving the reimbursement and the date of approval.
 - Receipts for reimbursable travel expenses with any reference to Subjects' personal information obscured.
 - Invoices should be submitted to:

GlaxoSmithKline
Attn: June McGinn (RN0220)
2301 Renaissance Blvd
King of Prussia, PA 19406

Reasonable travel expenses are outlined below and should be applied to appropriate study visits, as defined in the HPV 024 protocol:

- **Round trip coach air fare booked a minimum of two weeks prior to the study visit (whenever possible).**
- **Hotel stays including taxes (maximum allowance of \$150.00 per night).**
- **Airport parking for the specific time period for round trip flight (maximum of 3 days/72 hours) with appropriate original receipt.**
- **The GSK approved mileage reimbursement amount (not less than \$0.445 per mile with a maximum allowance of \$300.00 per study visit) for round trip travel (car, bus, train) exceeding 100 miles between home and the study center.**

The following are **not** reimbursed by GSK:

- **Meals, room service or mini-bar**
- **Hotel phone charges**
- **Hotel movie charges or any entertainment costs**
- **Dependent child care**
- **Expenses incurred by persons travelling with the Subject**
- **Wages/salary missed from a Subject's (or person travelling with the Subject) place of employment**

*To book air travel and hotel through BTI, the Subject or Site Staff should call: **#1.800.475.8785**

The caller will need to give BTI the study number (HPV 024), the Subject # of the traveler, the name of the GSK Study Manager and the dates/location of their trip.

19. ENTIRE AGREEMENT

This Agreement represents the entire and integrated agreement between the parties and supersedes all prior negotiations, representations or agreements, either written or oral, regarding its subject matter. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original and all of which shall constitute the same instrument.

SMITHKLINE BEECHAM CORPORATION
d/b/a GLAXOSMITHKLINE

CITY OF SAN ANTONIO ON BEHALF
OF THE SAN ANTONIO
METROPOLITAN HEALTH DISTRICT

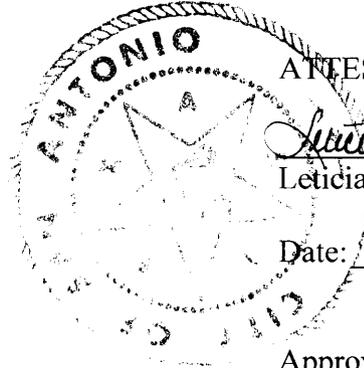
By: Muel Et
GSK Signatory Name
GSK Signatory Title

By: Bryan J. Alsip, MD, MPH
Name: Fernando A. Guerra, MD, MPH
Title: Director of Health
22 APR 2008

By my signature I indicate my agreement to fulfill the role and obligations of Investigator under this Agreement.

By: BRYAN J. ALSIP, MD, MPH
Fernando A. Guerra, MD, MPH
Date: 11 APR 2008
22 APR 2008

Date: 21-Jan-08



ATTEST:
Leticia M. Vacek
Leticia M. Vacek, City Clerk
Date: 4-18-08

Approved as to Form:
Michael D. Bernard
Michael D. Bernard, City Attorney



CMS or Ordinance Number: OR00000200804030264

TSLGRS File Code: 1000-05

Document Title:

ORD - GlaxoSmithKline MMRV Study 10058/054, 1/17/08 - 1/30/11

Ordinance Date:
4/3/2008