CONSENT AGENDA
ITEM NO. 35

CITY OF SAN ANTONIO
INTERDEPARTMENTAL MEMORANDUM
SAN ANTONIO METROPOLITAN HEALTH DISTRICT

TO: Mayor and City Council

FROM: Fernando A. Guerra, MD, MPH, Director of Health

THROUGH: Terry M. Brechtel, City Manager

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

SUBJECT: ORDINANCE AUTHORIZING A CLINICAL STUDY AGREEMENT WITH GLAXOSMITHKLINE

DATE: December 18, 2003

SUMMARY AND RECOMMENDATIONS

This ordinance authorizes the City Manager to accept and execute a clinical study agreement that will provide up to $50,868.00 from SmithKlineBeecham Corporation, d/b/a/ GlaxoSmithKline (GSK) for the San Antonio Metropolitan Health District (SAMHD) to participate during the period January 1, 2004 through December 31, 2005 in a follow-up vaccine study for the prevention of human papillomavirus (HPV) infection in women. This ordinance will also establish a fund, adopt the project budget, approve the personnel complement, and approve the payment of stipends to participants enrolled in the study.

Staff recommends approval.

BACKGROUND INFORMATION

The SAMHD Human Papillomavirus (HPV) Study Project will be working in collaboration with GSK on a proposed follow-up clinical trial study of a vaccine for the prevention of HPV cervical infection in adolescent and young adult women. Participants in the study will only be those clients who were vaccinated in a previous study conducted at SAMHD. The objective of the proposed study is to evaluate the HPV vaccine previously administered for long-term vaccine effectiveness. The study will consist of seven (7) visits per participant with the payment of stipends per visit as compensation for time and travel. SAMHD will recruit up to 18 clients from the previous study for this project.

The personnel complement will consist of two (2) Health Program Specialists, part-time, to ensure study protocol and coordination, interview and enroll eligible clients, ensure that clients keep timely appointments and perform other duties as needed to make this program successful (See Attachment I). These personnel are current City employees dedicated part-time on other SAMHD vaccine study projects. GSK will pay SAMHD up to $50,868.00 for participation in the study depending on patient enrollment and cooperation with the follow-up visits.

Study project data collected will be provided to GSK for analysis. Participants will receive stipends throughout the study to cover their time and travel to the clinic. Payments as stipends will be made up to $350.00 per participant.

POLICY ANALYSIS

Acceptance of this agreement from GSK will continue the long-standing practice of utilizing Federal, State and other aid that is available to support the local public health programs of the City and will allow for vaccines to be offered free of charge.

FISCAL IMPACT

This study will provide up to $50,868.00 to the SAMHD and will place no demands on the City General Fund.

COORDINATION

The City Attorney's Office and the Office of Management and Budget, Risk Management Division, have reviewed and approved the agreement with GSK. The Finance Department has approved the program budget.

SUPPLEMENTARY COMMENTS

Provisions of the Ethics Ordinance do not apply.

Attachments: Attachment I: Program Budget and Personnel Complement
Attachment II: Study: Clinical Study Agreement

Fernando A. Guerra, MD, MPH
Director of Health

Frances A. Gonzalez
Assistant City Manager

APPROVED:

Terry M. Brechtel
City Manager

ATTACHMENT I

Human Papillomavirus (HPV) Study Project
GSK Protocol 580299/007
Fund and Project No. 26-012257
Budget for Period: 01/01/04 - 12/31/05

INDEX	ESTIMATED REVENUES	OBJECT CODE	CURRENT BUDGET
015503	GlaxoSmithKline	00-008	$ 50,868
	Total Estimated Revenues		50,868
	APPROPRIATIONS		
471870	Regular Salaries and Wages	01-010	26,316
472712	Overtime Salaries and Wages	01-011	0
473447	Social Security	01-030	2,013
474098	TMRS	01-040	3,005
474809	Flexible Benefits Contribution	01-050	4,908
476085	Life Insurance	01-051	47
477380	Communications: Telephones	02-110	200
477570	Pagers/Mobile Phones	02-112	500
477851	Mail and Parcel Post Service	02-113	2,000
477992	Car Expense Allowance	02-130	300
478545	Fees to Professional Contractors	02-160	0
478735	Temporary Services	02-161	0
481887	Automatic Data Processing Services	02-172	500
482752	Advertising and Publication	02-175	0
484436	Other Contractual Services	02-193	6,300
485037	Food	03-216	0
485318	Office Supplies	03-210	1,200
485532	Chemicals, Medical & Drugs	03-228	1,200
485995	Indirect Cost	04-280	2,379
486811	Machinery & Equipment - Other	05-373	0
487272	Computer Equipment	05-360	0
	Total Appropriations		$ 50,868

Fund Only Index: 000922
Organization Code: 36-07-17

CLASS		CURRENT POSITIONS
0282	Health Program Specialist	2
	Total:	2

ATTACHMENT II

CLINICAL STUDY AGREEMENT

This CLINICAL STUDY AGREEMENT (this "Agreement") is effective 01-January-2004 (the "Effective Date") between San Antonio Metro Health Dist. ("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.

"Inventions" means all discoveries, developments, inventions (whether patentable or not), improvements, works of authorship, formulas, processes, compositions of matter, formulations, methods of use or delivery, specifications, computer programs or models and related documentation, know-how or trade secrets, that are made solely or jointly 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: Protocol 580299/007, a phase IIb, blinded, multi-center, long-term follow-up study of the efficacy of candidate HPV-16/18 VLP vaccine in the prevention of HPV-16 and/or HPV-18 cervical infection in adolescent and young adult women in North America and Brazil vaccinated in primary study 580299/001.
INVESTIGATOR'S NAME: Fernando A. Guerra, MD, MPH
TOTAL ENROLLMENT TARGET AT ALL STUDY SITES: 1006 subjects.
Within 10 days of receiving the initiation package, please return all Regulatory Documents to the Sponsor (Attn: Susan Stultz)
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 Study enrollment plan will apply to the Study:

i. It is anticipated that the Principal Investigator will enroll as many subjects as possible from the original co-hort at the site and any possible transfer subjects. Enrollment shall be completed on or before 15-February-2004. No payments shall be made for subjects enrolled over the Site Maximum without the agreement of GSK.

ii. Notwithstanding whether the Site Maximum has been reached, the Principal Investigator agrees to immediately cease enrolling subjects upon receipt of notice from GSK that, in the sole determination of GSK either:

(1.) GSK's target enrollment for the study has been achieved; or
(2.) the rate of enrollment at the site has fallen below an acceptable rate, which will be monitored on an ongoing basis.

In no event shall Institution or Investigator enroll a number of subjects into the Study which exceeds the then-current target number set by the enrollment plan without the written agreement of GSK.

(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) In accordance with mutually agreed time periods, Institution shall resolve all data queries from GSK and shall deliver to GSK complete and accurate case report forms (electronic or paper, as applicable) throughout the Study, with final delivery of case report forms after Study conclusion, and any other Study-related deliverables identified in writing by GSK and agreed to by Investigator/Institution.

(e) 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.

(f) 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.

3. COMPENSATION

(a) In consideration for conducting the Study, GSK shall pay Institution as described below.

The schedule of payment is as follows:

- 5% of the total grant for subjects at Study Initiation. This advance payment must be returned if Study is terminated prior to Study Start or if payment exceeds per subject costs, pursuant to Section 5 (b) below.

- Interim payments will equal 80% of the total amount earned, less previous payments, with a minimum check amount of $ 3,000.00, provided that all eCRFs have been satisfactorily completed to the date of payment.

- The final payment (total earned less payments to date) will be made upon completion of all Qualified Subjects provided all completed eCRFs, laboratory specimens, and all resolved DRQ's have been submitted to GSK and are considered acceptable.

- We anticipate that some subjects may have relocated during the period between the HPV 001 end of study and the start of HPV 007. Should subjects transfer into your site, you will be compensated for the transfer subject at a rate equal to that of all other subjects.

The parties agree that such terms are consistent with the principles of fair market value payments for the performance of Study-related activities.

(b) GSK's payment obligation is conditioned upon Institution's compliance with standards identified in this Agreement. GSK will not make payments for work associated with a Study subject if that subject's data is not evaluable because of a violation of the Protocol by Investigator or Study Staff.

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.

(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. 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) 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 a GSK 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 agrees to indemnify, defend and hold harmless Institution, Investigators, Study Staff, and other Institution employees, agents, and subcontractors ("Institution Indemnitees") from and against any loss, expense, cost (including reasonable attorneys fees), liability, damage, or claim by third parties for personal injury, including death, that arises out of the conduct of the Study by Institution or that arises out of the negligence or willful misconduct of GSK ("Institution Claim"), provided that GSK shall not indemnify any Institution Indemnitee for any Institution Claim to the extent the Institution Claim arose out of:

(i) failure by Institution Indemnitees to conduct the Study in accordance with the Protocol, GCPs, GSK's written instructions, or applicable laws or regulations;

(ii) the negligence or willful misconduct of Institution Indemnitees; or

(iii) a breach by Institution Indemnitees of this Agreement.

(b) GSK's obligations under this Section with respect to an Institution Claim are conditioned on:

(i) Prompt written notification to GSK of the Institution Claim so that GSK's ability to defend or settle the Institution Claim is not adversely affected; and

(ii) Institution Indemnitees' agreement that GSK has sole control over the defense or settlement of the Institution Claim and to fully cooperate with GSK in the defense or settlement of the Institution Claim; provided, that, no Institution Indemnitee shall be required to admit fault or responsibility in connection with any settlement.

(c) Institution agrees to indemnify, defend and hold harmless GSK and its Affiliates, employees, agents, and subcontractors ("GSK Indemnitees") from and against any loss, expense, cost (including reasonable attorneys fees), liability, damage, or claim by third parties for personal injury, including death, that arises out of the negligence or willful misconduct of Institution, Investigators, or Study Staff with respect to conduct of the Study ("GSK Claim"), provided that Institution shall not indemnify any GSK Indemnitee for any GSK Claim to the extent the GSK Claim arose out of:

(i) the negligence or willful misconduct of GSK Indemnitees; or

(ii) a breach by GSK Indemnitees of this Agreement.

(d) Institution's obligations under this Section with respect to a GSK Claim are conditioned on:

(i) Prompt written notification to Institution of the GSK Claim so that Institution's ability to defend or settle the GSK Claim is not adversely affected; and

(ii) GSK Indemnitees' agreement that Institution has sole control over the defense or settlement of the GSK Claim and to fully cooperate with Institution in the defense or settlement of the GSK Claim; provided, that, no GSK Indemnitee shall be required to admit fault or responsibility in connection with any settlement.

(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, provide 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. 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:
Name: Sue Stultz

Address: 2301 Renaissance Blvd
King of Prussia, PA 19406
RN0220

If to Institution:

_____

_____

_____

_____

_____

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: _____

Name: Olivia Crayne

Title: Director, Vaccine Study Management

Date: _____

SAN ANTONIO METRO HEALTH DISTRICT

By: _____
Name: Frances A. Gonzalez
Title: Assistant City Manager

Date: _____

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

INVESTIGATOR'S NAME

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

Date: _____

ATTEST:

_____
Yolanda L. Ledesma
Acting City Clerk

APPROVED AS TO FORM:

_____
Andrew Martin
City Attorney