CONSENT AGENDA
ITEM NO. 22

CITY OF SAN ANTONIO

SAN ANTONIO METROPOLITAN HEALTH DISTRICT

INTERDEPARTMENTAL CORRESPONDENCE SHEET

TO: Mayor and City Council

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

THROUGH Terry M. Brechtel, City Manager

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

SUBJECT: ORDINANCE ACCEPTING AN INVESTIGATOR AGREEMENT WITH GLAXOSMITHKLINE PHARMACEUTICALS

DATE: March 13, 2003

SUMMARY AND RECOMMENDATIONS

This ordinance authorizes the City Manager to accept and execute an Investigator Agreement with GlaxoSmithKline Pharmaceuticals (GSK) for the San Antonio Metropolitan Health District (SAMHD) to participate in a follow-on clinical research study of an immunization booster for the prevention of diphtheria, tetanus and pertussis in children 15 to 18 months of age. GSK will provide SAMHD up to $15,390.00 in cash to conduct the study during the period January 31, 2003 through January 23, 2004.

Staff recommends approval.

BACKGROUND

Between January 1, 2002 and February 28, 2003, SAMHD participated in a clinical trial study that administered a combination vaccine to protect against the childhood diseases of diphtheria, tetanus and pertussis to infants between the ages of 2 months to 6 months. This vaccine was co-administered with other routine childhood vaccines to determine the immune responses of these children. The results were recorded, compared by groups and provided to GSK for analysis.

Now these same infants are toddlers 15 to 18 months of age and ready for their routine boosters. GSK determined that a follow-on study was needed to evaluate a booster dose of Infanrix® for

diphtheria, tetanus and pertussis. The additional visits will be used for participant follow-ups through January 23, 2004. The personnel complement for this project is one (1) part-time Health Program Supervisor which is a carryover from the previous project

POLICY ANALYSIS

Acceptance of this agreement from GlaxoSmithKline Pharmaceuticals 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.

FINANCIAL IMPACT

The total project budget for this agreement is $15,390.00. This project 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 proposed project budget.

SUPPLEMENTARY COMMENTS

Provisions of the Ethics Ordinance do not apply.

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

Frances A. Gonzalez
Assistant to the City Manager

APPROVED BY:

Terry M. Brechtel
City Manager

ATTACHMENT I

GSK Protocol 208355/125 Vaccine Study Project

Fund and Project No. 26-012239

Budget for Period: January 31, 2003 through January 23, 2004

INDEX	ESTIMATED REVENUES	OBJECT CODE	CURRENT BUDGET
081703	GlaxoSmithKline Agreement - Cash		$ 15,390
	Total Estimated Revenues		15,390
	APPROPRIATIONS		
616714	Regular Salaries and Wages	01-110	9,050
616722	Social Security	01-030	692
616730	TMRS	01-040	1,053
616755	Flexible Benefits Contribution	01-050	1,305
617043	Life Insurance	01-051	21
617050	Communications: Telephones	02-110	50
617068	Pagers/Mobile Phones	02-112	30
617076	Mail and Parcel Post Service	02-113	100
617084	Car Expense Allowance	02-130	50
617092	Other Contractual Services	02-193	475
617100	Office Supplies	03-210	425
617878	Food	03-216	200
618363	Chemicals. Medical and Drugs	03-228	400
618405	Indirect Cost	04-280	1,539
	Total Appropriations		$ 15,390

Fund Only Index: 002922

Organization Code: 36-07-87

PERSONNEL COMPLEMENT

	Activity 36-07-87	# of positions
0284	Health Program Supervisor (P/T)	1

INVESTIGATOR AGREEMENT

Project/Protocol:	208355/125
Principal Investigator Name:	Fernando Guerra, M.D.
Principal Investigator Address:	San Antonio Metropolitan Health District 332 West Commerce Street Suite 202 San Antonio, TX 78205
Principal Investigator Telephone Number:	210-224-4661
Principal Investigator FAX Number:	210-224-8801

WHEREAS, SmithKline Beecham Corporation, d/b/a/ GlaxoSmithKline (the "Company"), and the City of San Antonio (the "City") through the San Antonio Metropolitan Health District (SAMHD), have agreed that the Company will sponsor a study to be conducted by the Principal Investigator of the drug identified in the protocol named herein; that Fernando Guerra, M.D. shall be named as the Principal Investigator (the "Principal Investigator") for this study; and the Principal Investigator(s) has the personnel and facilities to undertake the study; NOW, THEREFORE, the parties agree as follows:

I. Scope of Work

The Principal Investigator(s) shall conduct the study of 208355/125 (the "Study Drug") entitled, "A phase III, open, multicenter study of the safety of Infanrix® when administered as a booster dose at 15 to 18 months of age following primary immunization in studies 217744/084 and 217744/085 (Subjects from DTaP-HepB-IPV-084 and DTaP-HepB-IPV-085)" (the "Protocol"), including any subsequent amendments, which are hereby incorporated into this Agreement by reference. The Principal Investigator(s) shall exercise due care in conducting the study in compliance with all applicable Food and Drug Administration ("FDA") regulations, as reflected on FDA Form 1572, and in accordance with the Protocol, without changes, except as agreed to and approved in writing by the Company and, where required, the Principal Investigator(s)'s research Institutional Review Board ("IRB").

II. Study Schedule

A. Study Initiation

1. All contractual and regulatory documentation, including a fully completed Federal Tax Form W-9, must be received by Company no later than 23 January 2003.

2. The study shall be initiated between 31 January 2003 and 17 March 2003.

B. Enrollment

1. It is anticipated that the Principal Investigator will enroll 23 subjects into the study ("Site Maximum"), determined from the pool of subjects who have completed Protocol

217744/084 and/or 217744/085. Subject enrollment shall be completed on or before 23 January 2004. Enrollment of each subject over the Site Maximum requires agreement of the Company. No payments shall be made for subjects enrolled over the Site Maximum without the agreement of the Company.

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

(i) the Company's target enrollment for the study has been achieved; or

(ii) the rate of enrollment at the site has fallen below an acceptable rate, which will be monitored on an ongoing basis.

C. Study Documentation

1. Electronic case report forms ("ECRFs") must be satisfactorily completed within 7 days of the subject's visit and receipt of the subject's test results, if required.

2. Data Resolution Queries ("DRQs") must be completed and returned to Company within one week of receipt during the active phase of the trial. DRQs received at study-end (after notification of enrollment completion), must be completed and returned to Company within 24 hours of receipt.

D. Study Completion

1. Based on a recruitment time of 10 months, and an interval of 31 to 48 days between Visit 1 and Telephone Contact 2, all subject visits for the active phase will be completed no later than 10 March 2004.

2. All final ECRF data will be completed no later than 25 March 2004.

III. Payment

A. Itemized Per Subject Budget

Payment of costs associated with the Protocol shall be made pursuant to an itemized Per Subject Budget. Payment for "Qualified Subjects" enrolled into the study will be based on a per subject budget attached hereto and incorporated herein. Payments shall be made only for the actual number of subject visits, up to the maximum per subject budget. "Qualified Subjects" are defined as evaluable subjects who have satisfied all protocol requirements, including compliance with dosing regimen and visit schedule, and can be included in the statistical analysis for the study.

B. Additional Costs Outside Per Subject Budget

Payment for any costs outside of the per subject budget must be approved in advance by the Company Associate Director.

C. Payments are subject to the following terms:

1. A payment will not be made for any subject who is not qualified to participate in the Protocol based on the inclusion and exclusion criteria contained in the Protocol. Questions pertaining to a subject's eligibility must be addressed to and resolved by the

Company Medical Monitor identified in the Protocol prior to that subject's entry into the study.

2. Payment will not be made for any subject who is not evaluable due to failure to comply with the Protocol.

3. With the exception of the payment made at study initiation, all payments are conditional upon satisfactory completion of ECRFs up to the date of the request for payment.

4. Payments for Qualified Subjects dropped from the Protocol will be based on actual costs as defined in the budget, for the number of visits actually completed prior to drop out, provided that complete documentation is submitted.

D. Payment Schedule:

The schedule of payment is as follows:

- 10% 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 VIII.D 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 and Laboratory Data have been submitted to the Company and are considered acceptable.

E. Payment for Subjects Enrolled Over Site Maximum:

Payment for subjects enrolled over the Site Maximum shall be the same as the interim and final payments set forth in Paragraph D. above. Payments are conditional upon Company's agreement to accept such subjects into the study.

F. Payment Recipient and Mailing Address:

1. All checks shall be made payable to the entity/person identified on the Federal Tax Form W-9, which is attached hereto. The Principal Investigator warrants and represents that the institution or entity identified on the Form W-9 is the appropriate entity to receive such payments.

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

_____

_____

G. The Principal Investigator(s) acknowledges that Medicare, Medicaid, and certain private payors will only pay for testing and/or services that are medically necessary for the diagnosis and treatment of a particular subject. It is the Principal Investigator(s) obligation to determine which tests and/or services he or she orders are medically necessary (as defined by the applicable payor), and therefore properly billable, and which are not. Any tests and/or services ordered for purposes of the treatment and care of a subject are to be billed by the Principal Investigator(s) to the

appropriate payor in accordance with all applicable billing requirements. The Principal Investigator(s) agrees that any tests and/or services required to be performed under the protocol but not medically necessary for the diagnosis and treatment of the subject are intended to be included within the per subject budget negotiated with the Company and will not be billed to Medicare or Medicaid (or any other applicable payor) in accordance with such payor's billing requirements.

IV. Confidentiality and Publication

A. All unpublished information given to the Principal Investigator(s) by the Company in connection with this Agreement or the conduct of the Protocol is confidential and/or proprietary to the Company and shall not be published or disclosed to a third-party without the prior written consent of the Company. This paragraph shall not apply to information which:

- at the time of receipt by the Principal Investigator is in the public domain; or
- after its receipt by the Principal Investigator is made public by a third party, unless such publication was improper; or
- was in the possession of the Principal Investigator before receipt from the Company and was developed independently or acquired directly or indirectly from a source wholly independent of the Company; or
- is the subject of a valid subpoena or is otherwise required by law to be disclosed, provided that prompt notice is given to the Company of the requirement of such disclosure.

B. The obligation of this paragraph pertaining to confidentiality shall survive the termination of the Agreement.

C. The Principal Investigator(s) shall have the right to publish and/or disclose publicly information and/or data arising from the Protocol, provided, however, that the text of any such publication and/or public disclosure shall be submitted to the Company to review for confidential or proprietary information and for comment at least thirty (30) days prior to submission for publication or other disclosure and further provided that, at the Company's request, such submission shall be deferred for a further period not exceeding one hundred eighty (180) days to enable the Company to protect its rights in such confidential or proprietary information.

V. Inventions & Discoveries

All patentable inventions and discoveries made or conceived in the course of or as a result of the study shall be solely owned by the Company. Whenever requested to do so by Company, Institution will at Company's expense, execute any and all documents or other instruments and give testimony which Company shall deem necessary to apply for and obtain patent(s) in any country or to otherwise protect Company's interest therein. These obligations shall continue beyond the termination of this Agreement and shall be binding upon the Institution's assigns, administrators and other legal representatives.

VI. Indemnification

Except as set forth below, the Company agrees to defend, indemnify and hold harmless the Principal Investigator(s) and/or the City of San Antonio, its elected officials, officers, agents and employees from any

liability, loss, damage and expense, including attorneys' fees and costs, in connection with any claim or lawsuit, regardless of merit, brought against the Principal Investigator(s) for personal injuries (including death) or property damage allegedly arising from the Protocol. The Company shall have the exclusive right to manage claims and control litigation, including compromise or settlement. The Company's obligations under this paragraph shall survive the termination of this Agreement.

Notwithstanding the foregoing, the Company shall have no obligations pursuant to this Agreement to defend or indemnify the Principal Investigator(s) from liability, loss, damage or expense arising from: (1) the negligence or willful misconduct of the Principal Investigator(s) (2) the Principal Investigator(s)'s failure to adhere to the terms of the Protocol or the Company's written instructions with respect to the Protocol; or (3) the Principal Investigator(s)'s failure to comply with state or federal regulations, including FDA regulations. In addition, the Company shall have no obligations under this Article unless the Principal Investigator(s) (1) gives the Company reasonably prompt notice of any claim or lawsuit for which it seeks to be indemnified under this Agreement; and (2) cooperates fully with the Company and its agents in defense of the claim or lawsuit. Slight deviations which arise out of necessity and which do not contribute to any injury shall not constitute failure to adhere to the Protocol or Company's written instructions.

In addition to the foregoing obligations, the Company will be responsible for medical expenses not covered by other insurance or government programs, which are incurred by any Qualified Subject in the Protocol and which arise from his or her direct participation in the Protocol, unless a diagnostic work-up establishes that the condition giving rise to such expenses was unrelated to the Protocol, in which event the Company's responsibility shall be limited to medical expenses reasonably incurred in connection with the diagnostic work-up. Review and approval from the Medical Monitor is required in advance of such expenditures. No other compensation of any type will be provided by Company to any Qualified Subject in connection with adverse experiences occurring in connection with the study.

VII. Insurance

The Company 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, the Company shall provide the Principal Investigator with written evidence of its self-insurance program.

VIII. Termination

A. Immediate Termination: The Company may terminate this Agreement, in whole or in part, effective immediately, upon written notice to the Principal Investigator(s): (i) if the Company, in its sole discretion, deems that the safety of the subjects will be compromised by a delay; or (ii) for any violation of the Study Schedule set forth in paragraph 2; or (iii) prior to the shipment of study drug to the investigational site.

B. 30-Day Termination: The Company may terminate this Agreement, in whole or in part, upon thirty (30) days written notice to the Principal Investigator(s). Upon receipt of a notice of termination, no further subjects may be enrolled into the study, and Principal Investigator agrees to cooperate with Company in closing-out the study in an orderly manner.

C. Either party may immediately terminate this Agreement by written notice of breach by the other. Breach shall be defined as a failure to comply with any provision of this Agreement.

D. In the event that this Agreement is terminated, the Company shall reimburse the Principal Investigator(s) for all subject costs, compensable under the payment provisions of this Agreement,

incurred to the effective date of termination. If the amount the Company has previously paid to the Principal Investigator(s) exceeds the amount that is actually earned, the Principal Investigator(s) shall reimburse the balance to the Company within 30 days after he/she receives written notice of the final accounting.

IX. Independent Contractor

The Principal Investigator(s)'s relationship to the Company in the performance of this Agreement is that of an independent contractor.

X. Changes

This Agreement may be amended only by the further written agreement between authorized representatives of the parties.

XI. Order of Precedence

In any conflict between the terms of this Agreement and the documents incorporated herein, the terms of this Agreement shall take precedence.

XII. Notices

Any notice required or permitted under this Agreement shall be in writing and shall be sent by hand delivery, FAX, certified mail or private courier. Any such notice shall be effective upon receipt. Notices to the Principal Investigator shall be sent to the address noted on page 1 of this Agreement. Notices to Company shall be sent to the Medical Monitor for the study, at the address set forth in the Protocol.

XIII. Applicable Law

This Agreement shall be construed, interpreted and enforced under the laws of the Commonwealth of Pennsylvania.

XIV. Non-Waiver

Any failure by either party to enforce any term or condition of this Agreement shall not constitute a waiver by such party of the particular term or condition. Such a failure to enforce shall not affect or impair the right of such party to enforce the particular term at any other time.

XV. Assignment

The Principal Investigator(s) may not assign this Agreement without the prior written approval of the Company.

XVI. Institutional Signature

If the Principal Investigator (PI) is associated with an Institution (VA, Medical School, University, Hospital or other) where the study will be conducted (in whole or in part), and the policies of the Institution require approval of this Agreement, then a responsible representative of the Institution must sign below. **IF THE INSTITUTIONAL SIGNATURE LINE IS LEFT BLANK, THEN THE PI WARRANTS THAT NO SUCH APPROVAL IS REQUIRED BY HIS/HER INSTITUTION.**

ACCEPTED AND AGREED TO:

SmithKline Beecham Corporation
d/b/a/ GlaxoSmithKline

Olivia Crayne

Signature

Olivia Crayne, Director, Vaccine Study Management
Typed Name and Title

8 January, 2003
Date

Institutional Signature (if required)

Signature of Responsible Officer for Institution
Frances A. Gonzalez
Assistant to the City Manager
Typed Name and Title

Date

Yolanda L. Ledesma
Acting City Clerk

APPROVED AS TO FORM:

Andrew Martin
City Attorney

Principal Investigator(s)

Signature

Fernando Guerra, M.D.
Typed Name

Date