

**CITY OF SAN ANTONIO  
SAN ANTONIO METROPOLITAN HEALTH DISTRICT  
CITY COUNCIL AGENDA MEMORANDUM**

**TO:** Mayor and City Council

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

**SUBJECT:** ORDINANCE AUTHORIZING AN AMENDMENT TO A CLINICAL STUDY WITH GLAXOSMITHKLINE

**DATE:** August 11, 2005

**SUMMARY AND RECOMMENDATIONS**

This ordinance authorizes the City Manager to accept and execute an amendment to an agreement with SmithKlineBeecham Corporation, d/b/a/ GlaxoSmithKline (GSK), providing up to an additional \$143,640.00 from GSK for the San Antonio Metropolitan Health District (SAMHD) to continue participation in a clinical vaccine study. This ordinance will also revise the program budget, amend the personnel complement, and authorize the payment of stipends to the parents/guardians of participants enrolled in the study.

Staff recommends approval.

**BACKGROUND INFORMATION**

On October 20, 2003, City Council authorized the acceptance and execution of an agreement with GSK in the amount of \$47,880.00 for the San Antonio Metropolitan Health District to participate in the study of a new vaccine (HAVRIX®) for the prevention of hepatitis A. The reason for the study was to determine the safety and effectiveness of HAVRIX® when administered to young children along with a combination vaccine for measles, mumps and rubella and one for chickenpox. The project was to end on September 30, 2005.

Now GSK wishes to extend this agreement through September 30, 2007. The amendment to the clinical study agreement will allow SAMHD to enroll an additional 30 children (fifteen months of age) and provide up to an additional \$143,640.00 to the Health District. Part of these funds (\$14,500.00) will be provided to parents or guardians of the enrollees to offset transportation costs, leave from work and other expenses.

This ordinance will also add one Health Program Specialist position to the personnel complement to work with the existing Special Projects Coordinator.

**POLICY ANALYSIS**

Acceptance of this amendment to the agreement with GlaxoSmithKline will facilitate the effort to introduce newer, safer and more effective vaccines to the nation and it will allow local residents to receive these products at no cost.

### **FISCAL IMPACT**

This amendment to the clinical study agreement with GSK will provide up to an additional \$143,640.00 to the SAMHD and extend the project through September 30, 2007. It will place no demand on the City General Fund.

### **COORDINATION**

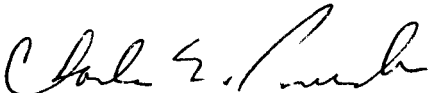
The City Attorney's Office and the Human Resources Department, Risk Management Division, have reviewed the amendment with GSK. The Office of Management and Budget and the Finance Department have approved the program budget.

### **SUPPLEMENTARY COMMENTS**

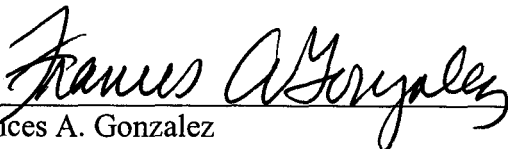
Provisions of the Ethics Ordinance do not apply.

Attachments:

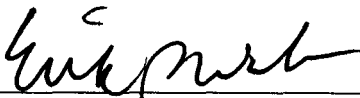
- Attachment I: GSK Protocol 208109/231 Vaccine Study Project Budget and Personnel Complement
- Attachment II: Amendment to Clinical Study Agreement



Fernando A. Guerra, MD, MPH  
Director of Health



Frances A. Gonzalez  
Assistant City Manager



J. Rolando Bono  
City Manager

ATTACHMENT I  
GSK Protocol 208109/231 Vaccine Study Project  
Fund and Project No. 26-012250  
Fund No. 26012000  
Funds Center 3607910000  
Budget for Period: October 1, 2003 through September 30, 2007

<u>ESTIMATED REVENUES</u>	SAP GL	PREVIOUS BUDGET	ADD (DEDUCT)	REVISED BUDGET
GlaxoSmithKline Agreement	4402100	\$ 47,880	0	47,880
Study Amendment	4402100	0	143,640	143,640
Total Estimated Revenues		<u>\$ 47,880</u>	<u>143,640</u>	<u>191,520</u>

APPROPRIATIONS

Cost Center 3607910001  
Internal Order 136000000033  
Activity 36-07-91

Regular Salaries and Wages	5101010	26,214	80,954	107,168
Social Security	5103005	1,546	6,653	8,199
TMRS	5105010	2,308	9,931	12,239
Flexible Benefits Contribution	5405040	2,454	12,270	14,724
Life Insurance	5103010	36	157	193
Language Skills Pay	5101050	0	1,500	1,500
Communications: Telephones	5403010	500	1,000	1,500
Pagers/Mobile Phones	5403030	30	970	1,000
Mail and Parcel Post	5205010	2,500	(1,000)	1,500
Car Expense Allowance	5103055	30	970	1,000
Automatic Data Processing Services	5403520	141	859	1,000
Advertising and Publication	5203040	1,000	0	1,000
Other Contractual Services	5202025	4,500	14,500	19,000
Food	5304010	0	1,000	1,000
Office Supplies	5302010	2,000	2,000	4,000
Chemicals, Medical, Drugs	5304040	2,000	2,000	4,000
Other Commodities	5304080	0	1,780	1,780
Indirect Cost	5406530	2,621	8,096	10,717
Total Appropriations		<u>\$ 47,880</u>	<u>143,640</u>	<u>191,520</u>

PERSONNEL COMPLEMENT

Cost Center 3607910001  
Internal Order 136000000033  
Activity 36-07-91

	PREVIOUS POSITIONS	ADD (DEDUCT)	REVISED POSITIONS
0282 Health Program Specialist	0	1	1
0870 Special Projects Coordinator	1	0	1
	<u>1</u>	<u>1</u>	<u>2</u>

AMENDMENT TO CLINICAL STUDY AGREEMENT

This AMENDMENT is entered into this 1<sup>st</sup> day of July, 2005, and amends the Clinical Study Agreement entered into by SAMHD ("Institution") and SmithKline Beecham Corporation, doing business as GlaxoSmithKline ("GSK") which was effective the 1st day of October, 2003 for GSK Study 208109/231.

Pursuant to **Section 1 THE STUDY** of the above Clinical Study Agreement, the parties hereby agree to amend the Clinical Study Agreement as follows:

ORIGINAL ENROLLMENT MAXIMUM INITIALLY SET FOR INSTITUTION: 30 subjects  
CURRENT ENROLLMENT AT INSTITUTION: 66 subjects  
INCREASE IN ENROLLMENT MAXIMUM FOR INSTITUTION: 54 subjects  
ENROLLMENT MAXIMUM SET FOR INSTITUTION: 120

Pursuant to Section 2(b)(i) of the above Clinical Study Agreement, the parties hereby agree to amend the Clinical Study Agreement as follows:

i. Enrollment is competitive. It is anticipated that the Principal Investigator will enroll 30 subjects. GSK will notify the sites when Enrollment for the study is met. No payments shall be made for subjects enrolled over the Site Maximum without the agreement of GSK.

Pursuant to Sections 10 (c) and (d) of the above Clinical Study Agreement, the parties hereby agree to amend the Clinical Study Agreement as follows:

(c) For the Study performed under this Agreement, GSK will offer Study patients compensation for Study-related injuries, through the Study's informed consent process. If Institution provides a Study patient 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 patient's authorization, to pay Institution directly on the Study patient's behalf for the care provided.

(d) Intentionally deleted.

If any provision of this Amendment is inconsistent with the terms of the Clinical Study Agreement, the terms of this Amendment shall prevail. Other than the modifications provided herein, the remaining terms of the Clinical Study Agreement remain in full force and effect.

IN WITNESS WHEREOF, the parties have acknowledged their consent to this

Amendment by executing it as of the day and year above written.

SMITHKLINE BEECHAM  
D/b/a GLAXOSMITHKLINE

CITY OF SAN ANTONIO

By Olivia Crayne  
Olivia Crayne  
Director, Vaccine Study Management

By \_\_\_\_\_  
Frances A Gonzalez  
Assistant City Manager

Date 25 Jun 2005

Date \_\_\_\_\_

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

INVESTIGATOR NAME

By: \_\_\_\_\_

Name: Fernando Guerra, MD  
Director of Health

Date: \_\_\_\_\_

ATTEST:

\_\_\_\_\_  
Leticia M. Vacek  
City Clerk

APPROVED AS TO FORM:

\_\_\_\_\_  
Martha G. Sepeda  
Acting City Attorney