

**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:** May 8, 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 a combined immunization for the prevention of hepatitis A and hepatitis B in healthy adults 18 years of age or older. GSK will provide SAMHD up to \$64,350.00 in cash to conduct the study during the period March 28, 2003 through March 27, 2005.

Staff recommends approval.

**BACKGROUND**

Between October 1, 1999 and December 30, 2000, SAMHD participated in a clinical trial study that administered the HAVRIX® vaccine to children to protect against hepatitis A. Now GSK has developed a combined hepatitis A and hepatitis B vaccine, TWINRIX®, which will be given on an accelerated schedule compared to separate vaccinations for hepatitis A and hepatitis B. The hepatitis A vaccine requires two injections in six months and the hepatitis B vaccine requires three injections in four months, for a total of five injections. By using the TWINRIX® vaccine the number of injections is reduced from five to three for the same protection.

The standard primary course of vaccination consists of three doses, the first dose administered at the elected date, the second dose one month later and the third dose six months after the first dose. In this study, SAMHD will enroll thirty (30) healthy adults 18 years of age or older. This study will consist of three (3) visits to receive the doses and five (5) follow-up monitor visits. Adults enrolled in this study will receive all vaccines free of charge and will be reimbursed \$25.00 upon completion of each visit. This compensation is for travel expenses, childcare and/or leave from work.

The personnel complement for this project is one (1) part-time Health Program Supervisor and one (1) part-time Public Health Nurse. Both positions are being utilized with concurrent GSK projects.

### **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**

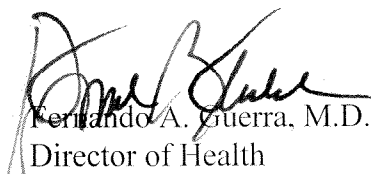
The total project budget for this agreement is \$64,350.00. This project will place no demands on the City General Fund.


### **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.

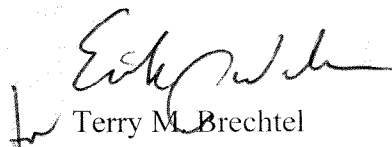
### **SUPPLEMENTARY COMMENTS**

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 208127/121 Vaccine Study Project

Fund No. 26-012242

Budget for Period: March 28, 2003 through March 27, 2005

INDEX	ESTIMATED REVENUES	OBJECT CODE	CURRENT BUDGET
081844	GlaxoSmithKline Agreement - Cash		\$ 64,350
	Total Estimated Revenues		<u>64,350</u>
<b>APPROPRIATIONS</b>			
462051	REGULAR SALARIES AND WAGES	01-110	30,168
462077	OVERTIME SALARIES AND WAGES	01-011	5,000
462085	SOCIAL SECURITY	01-030	2,308
462168	TMRS	01-040	3,508
462671	FLEX BENEFITS CONTRIBUTION	01-050	4,350
462689	LIFE INSURANCE	01-051	70
463257	COMMUNICATIONS: TELEPHONES	02-110	50
463265	PAGERS/MOBILE PHONES	02-112	30
463273	MAIL AND PARCEL POST	02-113	2,008
463281	TRAVEL-OFFICIAL	02-124	500
463307	CAR EXPENSE ALLOWANCE	02-130	100
463315	FEES TO PROFESSIONAL CONTRACTORS	02-160	0
463323	TEMPORARY SERVICES	02-161	0
463331	ADP	02-172	0
463349	ADVERTISING AND PUBLICATION	02-175	1,500
463539	BINDING, PRINTING AND REPRODUCTION	02-181	0
463554	OTHER CONTRACTUAL SERVICES	02-193	6,500
463562	OFFICE SUPPLIES	03-210	4,000
463570	FOOD	03-216	250
463596	CHEMICALS, MEDICAL, DRUGS	03-228	1,000
463604	COMPUTER SOFTWARE	03-243	0
463638	INDIRECT COST	04-280	1,508
463646	COMPUTER EQUIPMENT	05-360	1,500
463653	MACHINERY & EQUIPMENT - OTHER	05-373	0
463661	FURNITURE & FIXTURES	05-375	0
	Total Appropriations		<u>\$ 64,350</u>

Fund Only Index: 007239

Organization Code: 36-07-88

**PERSONNEL COMPLEMENT**

	Activity 36-07-88	# of positions
0246	Public Health Nurse (P/T)	1
0284	Health Program Supervisor (P/T)	1
	Total:	<u>2</u>