

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

**TO:** Sheryl Sculley, City Manager

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

**SUBJECT:** An Agreement with GlaxoSmithKline

**DATE:** April 20, 2006

**SUMMARY AND RECOMMENDATIONS**

This ordinance authorizes the City Manager to accept and execute an agreement with GlaxoSmithKline (GSK) providing up to \$99,000.00 for the period December 27, 2005 through December 31, 2007 for the San Antonio Metropolitan Health District (SAMHD) to participate in a clinical trial study of Hib-MenCY-TT, a vaccine that prevents pertussis, diphtheria, and tetanus diseases in children. This ordinance also adopts the project budget, and approves the personnel complement.

Staff recommends approval.

**BACKGROUND INFORMATION**

The objective of this study is to demonstrate the safety and effectiveness of various combination vaccines. These vaccines prevent diphtheria, tetanus, pertussis and poliovirus, and may be combined with a vaccine against *Haemophilus influenzae* type b (HIB). Children in this study will be enrolled at six to eight weeks of age and will be participating in the study for approximately nineteen months. They will receive all vaccines free of charge. SAMHD will recruit up to 50 children for this study.

The personnel complement for the study is two (2) staff: a part-time Health Program Supervisor responsible for interviewing parents/guardians, enrolling eligible infants, ensuring that clients keep timely appointments, and performing other duties as needed to make this program successful to assist with recruitment, conduct study visits, maintain study documents and perform data entry; and a part-time Special Projects Coordinator to be the study coordinator and ensure compliance with study protocol, carry out all Institutional Review Board requirements and complete mandatory documents. These personnel are currently City employees and will be assigned from other vaccine studies that are terminating.

Study data collected from this project will be provided to the manufacturer for analysis. Parents/guardians of enrolled infants will receive stipends throughout the study to cover their time and travel to the clinic. Payments will be made up to \$100.00 per parent/guardian of enrolled infants. GSK will pay SAMHD up to \$99,000.00 for participation in this study depending on patient enrollment and their cooperation with the follow-up visits and telephone conferences.

## **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 these childhood vaccinations to be offered free of charge to study enrollees.

## **FISCAL IMPACT**

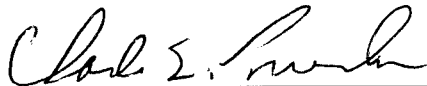
The Hib-MenCY-TT Vaccine Study Project will provide up to \$99,000.00 for SAMHD study participation.

## **COORDINATION**

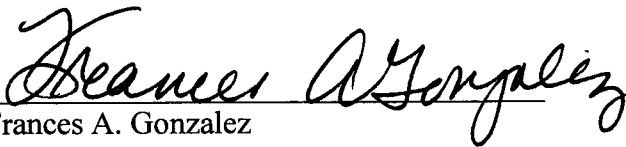
The City Attorney's Office and the Human Resources Department, Risk Management Division, have reviewed and approved the clinical trial agreement with GSK. The SAMHD has coordinated this item with the Office of Management and Budget and the Finance Department.

## **SUPPLEMENTARY COMMENTS**

Provisions of the Ethics Ordinance do not apply.

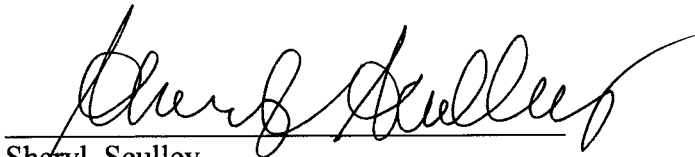


1 Fernando A. Guerra, MD, MPH  
Director of Health, San Antonio Metropolitan Health District



Frances A. Gonzalez  
Assistant City Manager

Approved for Council Consideration:



Sheryl Sculley  
City Manager