## 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:

October 24, 2002

## **SUMMARY AND RECOMMENDATIONS**

This ordinance authorizes the City Manager to accept and execute an Investigator Agreement with GlaxoSmithKline Pharmaceuticals (GSK) for the participation of the San Antonio Metropolitan Health District (SAMHD) in a follow-on clinical research study of the prevention of hepatitis A in children. GSK will provide SAMHD up to \$800.00 in cash to conduct the study from August 15, 2002 through November 21, 2002.

Staff recommends approval.

### **BACKGROUND**

From October 1, 1999 to December 31, 2000, SAMHD participated in a clinical trial study to administer the Havrix® vaccine, a product developed to prevent hepatitis A, to children between the ages of 11 months to 25 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.

The analysis showed that some children still tested positive to hepatitis A. GSK decided that a follow-on study was needed to evaluate a booster dose of Havrix® to be given to those children.

The additional visits will be used for participant follow-ups through November 21, 2002. There is no change to the personnel complement.

#### **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 \$800.00. 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

Assistant to the City Manager

PPROVED BY

Terry M. Brechtel

City Manager