

AN ORDINANCE **98371**

AUTHORIZING THE ACCEPTANCE OF TWO (2) CLINICAL STUDY AGREEMENTS WITH SMITHKLINE BEECHAM CORPORATION, D/B/A GLAXOSMITHKLINE (GSK), FOR THE PERIOD OCTOBER 1, 2003 THROUGH SEPTEMBER 30, 2005 FOR THE SAN ANTONIO METROPOLITAN HEALTH DISTRICT TO PARTICIPATE IN TWO (2) STUDIES OF A VACCINE ADMINISTERED TO CHILDREN FIFTEEN (15) MONTHS OF AGE AS FOLLOWS: ACCEPTING \$46,284.00 TO STUDY THE EFFECTIVENESS AND SAFETY OF GSK'S INACTIVATED HEPATITIS A VACCINE WHEN CO-ADMINISTERED WITH PNEUMOCOCCAL VACCINE AND ACCEPTING \$47,880.00 TO STUDY THE EFFECTIVENESS AND SAFETY OF GSK'S INACTIVATED HEPATITIS A VACCINE WHEN CO-ADMINISTERED WITH MEASLES-MUMPS-RUBELLA VACCINE AND VARICELLA VACCINE; AUTHORIZING THE EXECUTION OF THE TWO (2) CLINICAL STUDY AGREEMENTS; ESTABLISHING FUNDS; ADOPTING PROGRAM BUDGETS; APPROVING PERSONNEL COMPLEMENTS; AND AUTHORIZING PAYMENTS FOR CONTRACTUAL SERVICES.

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WHEREAS, GlaxoSmithKline (GSK), one of the world's leading pharmaceutical and healthcare companies, has offered two (2) Clinical Study Agreements to the San Antonio Metropolitan Health District (SAMHD) for the period October 1, 2003 through September 30, 2005; and

WHEREAS, Clinical Study Agreement Protocol 208109/220 will provide up to \$46,284.00 for the SAMHD to study the effectiveness and safety of GSK's inactivated hepatitis A vaccine (HAVRIX®) when co-administered to children fifteen (15) months of age with pneumococcal vaccine (PREVNAR™); and

WHEREAS, Clinical Study Agreement Protocol 208109/231 will provide up to \$47,880.00 for the SAMHD to study the effectiveness and safety of GSK's inactivated hepatitis A vaccine (HAVRIX®) when co-administered to children fifteen (15) months of age with measles-mumps-rubella vaccine (M-M-R®) and varicella vaccine (VARIVAX®); and

WHEREAS, SAMHD desires to participate in these studies that will facilitate the introduction of a new vaccine for hepatitis A and provide enrollees with childhood vaccines free of charge; and

WHEREAS, the SAMHD desires to reimburse the families of children enrolled in the study for any expenses that may be incurred through their participation in these projects; and

WHEREAS, it is now necessary to authorize the acceptance and execution of these agreements with GSK, establish the funds, adopt the program budgets, approve the personnel complements and approve the payment of stipends of up to \$145.00 to the participating parent or guardian in the studies; **NOW THEREFORE:**

BE IT ORDAINED BY THE CITY COUNCIL OF THE CITY OF SAN ANTONIO:

SECTION 1. The City Manager, or her designee, is hereby authorized to accept and execute Clinical Study Agreement Protocol 208109/220 with GlaxoSmithKline (GSK) for the period October 1, 2003 through September 30, 2005 and to accept up to \$46,284.00 for the San Antonio Metropolitan Health District to participate in a vaccine study of children fifteen (15) months of age receiving GSK inactivated hepatitis A vaccine (HAVRIX®) when administered with pneumococcal conjugate vaccine (PREVNAR™). A copy of this agreement, in substantially correct form, is set out as Attachment III and incorporated herein for all purposes.

SECTION 2. Fund 26-012249 entitled “GSK Protocol 208109/220 Vaccine Study Project” is designated for use in accounting for this project.

SECTION 3. The sum of \$46,284.00 is hereby appropriated in Fund 26-012249 for the GSK Protocol 208109/220 Vaccine Study Project, and the budget attached hereto and incorporated herein as Attachment I is approved and adopted for entry on the City books.

SECTION 4. The two (2) personnel positions set out in Attachment I are hereby authorized for the GSK Protocol 208109/220 Vaccine Study Project.

SECTION 5. Payments in an aggregate amount not to exceed \$4,100.00 are authorized to be paid out as stipends of up to \$145.00 to each participating parent/guardian in the vaccine study. Payment will be made from Fund 26-012249, Activity Code 36-07-90, Index No. 784223.

SECTION 6. The City Manager, or her designee, is hereby authorized to accept and execute Clinical Study Agreement Protocol 208109/231 with GlaxoSmithKline (GSK) for the period October 1, 2003 through September 30, 2005 and to accept up to \$47,880.00 for the San Antonio Metropolitan Health District to participate in a vaccine study of children fifteen (15) months of age receiving GSK inactivated hepatitis A vaccine (HAVRIX®) when administered with measles-mumps-rubella vaccine (M-M-R®) and varicella vaccine (VARIVAX®). A copy of this agreement, in substantially correct form, is set out as Attachment III and incorporated herein for all purposes.

SECTION 7. The sum of \$47,880.00 is hereby appropriated in Fund 26-012250 for the GSK Protocol 208109/231 Vaccine Study Project, and the budget attached hereto and incorporated herein as Attachment II is approved and adopted for entry on the City books.

SECTION 6. The one (1) personnel position set out in Attachment II is hereby authorized for the GSK Protocol 208109/231 Vaccine Study Project.

SECTION 8. Payments in an aggregate amount not to exceed \$4,500.00 are authorized to be paid out as stipends of up to \$145.00 to each participating parent/guardian in the vaccine study. Payment will be made from Fund 26-012250, Activity Code 36-07-91, Index No. 785774.

SECTION 9. The Director of Finance may, subject to concurrence by the City Manager or the City Manager's designee, correct allocation to specific index codes and fund numbers as necessary to carry out the purpose of this ordinance.

SECTION 10. Should the clinical study agreements offered be in an amount other than that budgeted for, or should the agreements contain terms and conditions different than those currently existing, acceptance of the agreements, budget and corresponding personnel complement will be subject to subsequent City Council ordinance.

SECTION 11. This ordinance shall be effective on and after the tenth day after passage hereof.

PASSED AND APPROVED this 30th day of October, 2003.



M A Y O R

EDWARD D. GARZA

ATTEST: 
City Clerk

APPROVED AS TO FORM: 

City Attorney