

AN ORDINANCE 2009-02-12-0110

APPROVING A CONTRACT WITH NOVARTIS VACCINES AND DIAGNOSTICS, INC. FOR AN AMOUNT UP TO \$62,875.00 FOR THE SAN ANTONIO METROPOLITAN HEALTH DISTRICT TO CONDUCT A MENINGOCOCCAL CLINICAL VACCINE STUDY THROUGH JUNE 30, 2011.

* * * * *

WHEREAS, the San Antonio Metropolitan Health District (SAMHD) has collaborated with Novartis Vaccines and Diagnostics, Inc. (Novartis) for the past year in conducting a vaccine clinical trial; and

WHEREAS, Novartis has assisted the SAMHD in providing new and upcoming vaccines to the community; and

WHEREAS, the objective of this latest study is to evaluate the safety and tolerability of routine vaccines administered to healthy infants at 2 months of age through 12 months of age when administered at the same time with MenACWY conjugate vaccine and when administered by themselves (without MenACWY conjugate vaccine); and

WHEREAS, all study clients will additionally receive routine vaccines including diphtheria, tetanus, pertussis, inactivated poliovirus, haemophilus influenzae type b, pneumococcal conjugate, hepatitis B, rotavirus, measles, mumps, rubella, varicella, hepatitis A and influenza at no cost to them; and

WHEREAS, MenACWY is a new meningococcal vaccine not currently licensed in the United States, but has been administered to over 12,000 patients in previous Novartis studies; and

WHEREAS, meningococcal disease is a serious infection that can lead to inflammation of the membranes covering the brain and spinal cord; and

WHEREAS, bacterial infections of the meninges are extremely serious illnesses, and may result in death or brain damage, even if treated; and

WHEREAS, currently, there is no meningococcal vaccine presently licensed for the population aged less than 2 years of age in the United States and establishing effectiveness of this vaccine against invasive meningococcal disease in children aged less than 2 years of age would address an important public health need; and

WHEREAS, epidemiologic studies suggest that the most cost-effective approach to reducing the meningococcal disease is to vaccinate adolescents, as well as toddlers; and

WHEREAS, this clinical study agreement will allow the SAMHD to enroll a total of 30 children and provide up to \$62,875.00 to the SAMHD; and

WHEREAS, Novartis will pay the SAMHD the contracted budget amounts for participation in this study depending on patient enrollment and cooperation with the follow-up visits and telephone conferences; **NOW THEREFORE**:

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

SECTION 1. The City Manager or her designee, or the Director of the San Antonio Metropolitan Health District or his designee, is authorized to execute a contract with Novartis Vaccines and Diagnostics, Inc. (Novartis) for an amount up to \$62,875.00 for the San Antonio Metropolitan Health District to conduct a meningococcal clinical vaccine study through June 30, 2011. A copy of said contract in substantially final form is attached hereto and incorporated herein for all purposes as **Attachment I**.

SECTION 2. The City Manager or her designee or the Director of the San Antonio Metropolitan Health District or his designee, is further authorized to execute a contract amendment pertaining to this contract extending the clinical vaccine study period for one year.

SECTION 3. Fund 26012000 entitled "Misc. Grants" is hereby designated for use in the accounting for the fiscal transaction in the acceptance of this contract, and the sum of \$62,875.00 from Novartis will be appropriated in said fund.

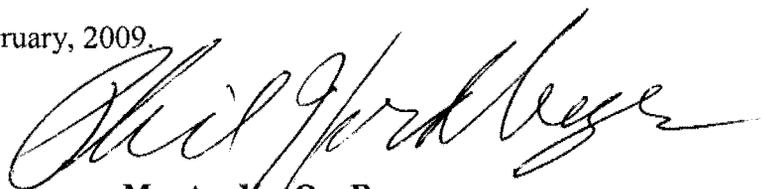
SECTION 4. The budget which is attached hereto and incorporated herein for all purposes as **Attachment II** is approved and adopted for entry in the City books.

SECTION 5. Payments of stipends to the participants or parent/guardians of the participants enrolled in the study are hereby authorized.

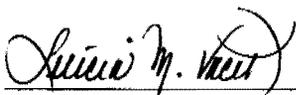
SECTION 6. The financial allocations in this Ordinance are subject to approval by the Director of Finance, City of San Antonio. The Director of Finance may, subject to concurrence by the City Manager or the City Manager's designee, correct allocations to specific SAP Fund Numbers, SAP Project Definitions, SAP WBS Elements, SAP Internal Orders, SAP Fund Centers, SAP Cost Centers, SAP Functional Areas, SAP Funds Reservation Document Numbers, and SAP GL Accounts as necessary to carry out the purpose of this Ordinance.

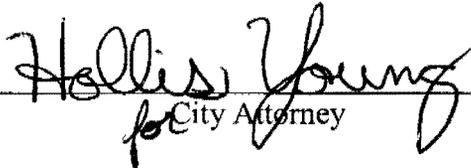
SECTION 7. This ordinance shall be effective on and after February 22, 2009.

PASSED AND APPROVED this 12th day of February, 2009.



M A Y O R
PHIL HARDBERGER

ATTEST: 
City Clerk

APPROVED AS TO FORM: 
City Attorney



NOVARTIS VACCINES AND DIAGNOSTICS, INC.

MASTER CLINICAL TRIAL AGREEMENT

for Institution

City of San Antonio on behalf of the San Antonio Metropolitan Health District

Effective Date: January 08, 2009

MASTER CLINICAL TRIAL AGREEMENT

for Institution

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Attachment A: Clinical Trial Request Form with Schedule A

MASTER CLINICAL TRIAL AGREEMENT

This Agreement is entered into by and between City of San Antonio on behalf of the San Antonio Metropolitan Health District, a Municipal Corporation with a place of business at 332 West Commerce, San Antonio, Texas 78205 hereinafter referred to as the "Institution"; and Novartis Vaccines and Diagnostics, Inc. with its principal place of business located at 350 Massachusetts Avenue, Cambridge, MA 02139 USA, hereinafter referred to as "Novartis V&D", the Institution and Novartis V&D each being a "Party" and hereinafter collectively referred to as the "Parties".

1. SCOPE OF WORK AND CLINICAL TRIAL REQUEST FORM

- A. The Institution shall exercise its best efforts to perform each clinical trial set forth in a protocol referenced in an executed Clinical Trial Request Form that references this Agreement (each a "Protocol"). Each such individual clinical trial is hereinafter referred to as a "Clinical Trial". Each Clinical Trial shall investigate the safety, efficacy and/or related properties of one or more active ingredients (each a "Study Drug"), alone or in comparison to a placebo and/or one or more other active ingredients (each a "Comparator Drug"). It is understood that various formulations of the Study Drug and Comparator Drug may be used in a Clinical Trial and, except where the contrary is clear from the context, the terms "Study Drug" and "Comparator Drug" mean each formulation actually used in a Clinical Trial and each active ingredient thereof. For the avoidance of doubt, when a Study Drug or a Comparator Drug is a combination of two or more active ingredients, except where the contrary is clear from the context, each active ingredient and each combination shall also be deemed to be a Study Drug or Comparator Drug, as the case may be.
- B. The terms and conditions of this Agreement shall apply to each Clinical Trial Request Form that references this Agreement except as expressly modified therein. The specific requirements for each Clinical Trial shall be set forth in the Clinical Trial Request Form for that Clinical Trial. Each Clinical Trial Request Form shall be substantially in the form of Attachment A hereto and shall include the information noted thereon, including all referenced schedules and other attachments.
- C. The Institution represents and warrants that its applicable policies are not inconsistent with this Agreement and that it will not enter into a Clinical Trial Request Form if it or the Protocol is inconsistent with its applicable policies.

2. PRINCIPAL INVESTIGATOR

The Institution's principal investigator for a Clinical Trial shall be identified in the Clinical Trial Request Form ("Principal Investigator"). The Principal Investigator shall be responsible for the direction of the Clinical Trial in accordance with applicable Institution policies. If, for any reason, (s)he is unwilling or unable to continue to serve as the Principal Investigator and a successor, acceptable to both the Institution and Novartis V&D, is not available, the Clinical Trial may be terminated by Novartis V&D in accordance with the provisions of Paragraph A of Section 13. The Principal Investigator shall agree in writing to the terms of this Agreement and the Clinical Trial Request Form.

3. EFFECTIVE PERIOD

The effective period of this Agreement shall be from January 08, 2009 through January 07, 2014. In the event that a Clinical Trial is not completed within the effective period, Novartis V&D may extend the effective period by giving notice to the Institution.

4. RECORDKEEPING, REPORTING AND ACCESS

- A. The Institution and the Principal Investigator shall notify Novartis V&D of each Serious Adverse Event encountered in a Clinical Trial within twenty-four (24) hours of becoming aware of it in accordance with the instructions set forth in the Protocol. Each such notice shall be given by telefax on a Novartis V&D Serious Adverse Event Report form, whether or not notification was initially given by telephone. Paragraph D of this Section shall apply to both the original copy of

each Serious Adverse Event Report form and the telefax confirmation sheet reflecting its transmission to Novartis V&D.

- B. The Institution and the Principal Investigator shall, in a timely manner, prepare and maintain complete and accurate written and electronic records, reports and data of and/or resulting from and/or relating to the performance of each Clinical Trial (including, but not limited to, case report forms, other Source Documents and other Essential Documents as defined by the International Conference on Harmonization ("ICH") guidelines). The Institution and the Principal Investigator shall also transmit to Novartis V&D, in a timely manner, such complete and accurate written and electronic records, reports and data but, unless required by the Protocol or otherwise requested by Novartis V&D, need not transmit Source Documents and other Essential Documents. Any requirements relating thereto set forth in the Protocol or in a notice given to the Institution or the Principal Investigator, including, but not limited to, requirements for the preparation of case report forms, shall be followed.
- C. (a) Section 1.52 of the current ICH guidelines defines Source Documents as: "Original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate and complete, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories, and at medico-technical departments involved in the clinical trials)." (b) Section 1.51 of the current ICH guidelines defines Source Data as: "All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source Data are contained in Source Documents (original records or certified copies)." (c) Essential Documents are those documents (which may or may not be Source Documents) that individually and collectively permit evaluation of the performance of a clinical trial and the quality of the data resulting therefrom. These documents serve to demonstrate that the Principal Investigator, individuals working under the direction of the Principal Investigator, the sponsor of the clinical trial and others associated with the clinical trial and/or the resulting data have complied with the standards of Good Clinical Practice and with all applicable regulatory requirements.
- D. The Principal Investigator or the Institution shall retain the written and electronic records, reports and data of and/or resulting from and/or relating to the performance of each Clinical Trial for a period of not less than fifteen (15) years from the completion of the Clinical Trial unless, prior thereto, Novartis V&D provides written permission to dispose of them or, by notice given to the Institution, requires their retention for an additional period of time because of applicable laws, regulations and/or guidelines. Requests for permission to dispose of written and/or electronic records, reports and/or data shall be directed to the Novartis V&D contact for Clinical Trial Related Matters designated on the Clinical Trial Request Form. Novartis V&D shall promptly respond to such requests.
- E. (a) The Institution and the Principal Investigator may be subject to monitoring and audits by Novartis V&D and its representative(s) as well as inspections by the United States Food and Drug Administration ("FDA") and regulatory agencies of other countries and regions. During such monitoring, audits and inspections, (1) the Institution's facilities to be utilized, being utilized or utilized for the performance of a Clinical Trial may be examined and inspected, and (2) subject to applicable laws, any or all written and electronic records, reports and data of and/or resulting from and/or relating to the performance of a Clinical Trial may be inspected and copied. Such monitoring, audits and inspections may be conducted to verify that the Clinical Trial is being, or was, performed in accordance with the requirements of the Protocol, as well as in compliance with all applicable laws and regulations concerning clinical trials and the distribution and administration of Investigational New Drugs. To the extent possible, such monitoring, audits and inspections shall be conducted during regular business hours and arrangements for them shall be

made in advance with the Institution and/or the Principal Investigator. The Institution and the Principal Investigator shall cooperate with those rendering the monitoring, audits and inspections. (b) When the Institution or the Principal Investigator becomes aware that the FDA or a regulatory agency of any other country or region may conduct an inspection in connection with and/or relating to a Clinical Trial, the Institution or the Principal Investigator, as the case may be, shall notify Novartis V&D by telephone of the intended or possible inspection within twenty-four (24) hours of becoming aware of it; in addition, notice of the intended or possible inspection shall be sent to Novartis V&D within forty-eight (48) hours of the telephonic notification. The Institution and the Principal Investigator shall provide Novartis V&D with a copy of any report received in connection with, or as a result of, such inspection within three (3) days of its receipt.

5. COSTS AND PAYMENT

- A. The budget for a Clinical Trial, which shall include the payment schedule, shall be attached to the Clinical Trial Request Form as Schedule A. The total cost to Novartis V&D for the Clinical Trial shall not exceed the amount set forth in Schedule A. All costs set forth in Schedule A shall remain firm for the duration of the Clinical Trial, unless otherwise agreed to in writing by the Parties.
- B. Neither the Institution nor the Principal Investigator shall directly or indirectly seek or receive compensation from patients participating in a Clinical Trial ("Clinical Trial Subjects") or third-party payers for any material, treatment or service that is required by the Protocol and provided or paid for by Novartis V&D, including, but not limited to, Study Drug, Comparator Drug, Clinical Trial Subject screening, infusions, physician and nurse services, diagnostic tests and Study Drug and/or Comparator Drug administration.
- C. The costs of a Clinical Trial set forth on a Schedule A shall represent all costs of performing the Clinical Trial, including overhead. Neither the Institution nor the Principal Investigator shall use any additional funding that may jeopardize or adversely impact on the rights granted to Novartis V&D in Section 8 or any other section of this Agreement, such as a "funding agreement" (as defined in 35 USC 201) with the United States Government or a department or agency thereof, for any part of a Clinical Trial.

6. CONFIDENTIAL INFORMATION

- A. To the extent permitted by law neither the Institution nor the Principal Investigator shall disclose or use for any purpose other than the performance of a Clinical Trial any and all trade secrets, privileged records and other confidential or proprietary information disclosed to the Institution and/or the Principal Investigator by or on behalf of Novartis V&D (including, but not limited to, the Protocol) whether disclosed prior to or during the effective period of this Agreement ("Novartis V&D-disclosed Information") or developed and/or discovered by the Institution and/or the Principal Investigator as a result of the performance of a Clinical Trial or using Novartis V&D-disclosed Information, including, but not limited to, all written and electronic records, reports and data of and/or resulting from and/or relating to the performance of a Clinical Trial ("Institution Information"). Novartis V&D-disclosed Information and Institution Information are hereinafter collectively referred to as "Information". This obligation of non-disclosure and non-use shall not apply to any:
 - (1) Information that is or becomes publicly available through no fault of the Institution or the Principal Investigator (including presentation or publication in accordance with the provisions of Section 7);
 - (2) Information that is already independently known to the Institution or the Principal Investigator as shown by prior written records, provided that the Institution or the Principal Investigator advises Novartis V&D of this promptly upon the discovery that the Information is already independently known to it, him or her;
 - (3) Information that is disclosed to the Institution or the Principal Investigator on a non-confidential basis by a third-party with the legal right to do so;

- (4) Information required to be released by any governmental entity with jurisdiction, provided that the Institution or the Principal Investigator, as the case may be, gives notice to Novartis V&D at least ten (10) days (if reasonably possible, and, if not, as many days as is reasonably possible) prior to making such release of Information; and
 - (5) Information independently developed and/or discovered by Institution personnel other than the Principal Investigator and other Institution personnel participating in the performance of the Clinical Trial without reference to and/or use of Information, as evidenced by written contemporaneous documentation.
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- B. In the event that the Institution or the Principal Investigator finds it necessary to disclose Information to a proper authority in order to defend its, his or her research against an allegation of fraud, the Institution or the Principal Investigator shall provide notice of this to Novartis V&D, and Novartis V&D and the Institution or the Principal Investigator, as the case may be, shall then agree on a mutually satisfactory method of disclosing such Information as necessary for this limited purpose.
 - C. Notwithstanding any other provision of this Section, the presentation and publication of the results of each Clinical Trial (i.e., a summary of the data of and/or resulting from the performance of the Clinical Trial) in accordance with the provisions of Section 7 is permissible, and the written and electronic records, reports and data of and/or resulting from and/or relating to the performance of a Clinical Trial may be used in accordance with the provisions of Section 8.
 - D. In the event that Novartis V&D comes into contact with any Clinical Trial Subject's medical records, Novartis V&D shall hold in confidence the identity of the Clinical Trial Subject and shall comply with all applicable laws and regulations regarding the confidentiality of such records.
 - E. The Institution hereby represents, warrants and agrees that, as of the date of enrollment of each individual participating as a Clinical Trial Subject, it will obtain from each such individual an authorization that meets the requirements of the privacy rule issued under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA Privacy Rule") set forth at 45 CFR 164.508(b) and (c). Such authorization shall permit (i) all necessary uses of the individual's "protected health information", as that term is defined in the HIPAA Privacy Rule, 45 CFR 164.501, by the Institution and the Principal Investigator as part of the Clinical Trial and (ii) all disclosures of such protected health information by the Institution and the Principal Investigator to Novartis V&D and its authorized agents and the Clinical Trial team and other professionals involved in the Clinical Trial for purposes relating to the Clinical Trial and for all other purposes permitted by law.
 - F. The obligations of the Institution and the Principal Investigator under this Section shall survive the termination or expiration of this Agreement for a period of five (5) years or, in the case of data of and/or resulting from the performance of a Clinical Trial, ten (10) years from the completion or termination of the Clinical Trial.

7. PRESENTATIONS AND PUBLICATIONS

- A. The presentation and publication of the results of each Clinical Trial (i.e., a summary of the data of and/or resulting from the performance of each Clinical Trial) in accordance with the provisions of this Section is permissible.
- B. Unless otherwise required by the authorship guidelines or requirements of the meeting or other forum at which the presentation will be made or the journal in which the publication will appear, authorship should reflect a substantial contribution to (1) the conception, design and/or conduct of the Clinical Trial, (2) the acquisition, evaluation and/or interpretation of the results of the Clinical Trial and/or (3) the drafting and revising of the manuscript and its final approval. Depending upon his or her level of participation in the performance of the Clinical Trial, the contribution of each participant should be recognized appropriately in all resulting presentations and publications, either as a named author or contributor or in an acknowledgement. The final determination shall be made by mutual agreement of the Parties.

- C. A manuscript of each proposed presentation or publication of the results of a Clinical Trial shall be submitted to Novartis V&D for review prior to submission to anyone who is not employed by the Institution and under an obligation of non-disclosure and non-use at least substantially identical to that imposed on the Principal Investigator by this Agreement in order to permit Novartis V&D to (1) evaluate the manuscript for accuracy, (2) ascertain whether information (other than the results of the Clinical Trial) is being improperly disclosed, (3) provide information which may not have yet been made available by Novartis V&D, (4) provide input for consideration regarding the content and/or conclusion(s) of the manuscript and (5) determine whether the manuscript discloses any potentially patentable invention(s). ~~Novartis V&D shall be afforded a~~ review period of fifteen (15) Working Days for manuscripts not exceeding two (2) double-spaced pages in length (or the equivalent thereof) and forty-five (45) Working Days for all other manuscripts. A Working Day is any day other than a Saturday, Sunday or Federal holiday. Upon receipt of Novartis V&D's notification that the manuscript may be released or, if later, upon the conclusion of the review period with no request, input or notification pursuant to Paragraph D and/or Paragraph E of this Section having been received from Novartis V&D, the manuscript may be submitted to anyone.
- D. At the request of Novartis V&D, any information (other than the results of the Clinical Trial) contained therein shall be excised from the manuscript and reasonable consideration to all other input received from Novartis V&D shall be given. The author(s) shall make all final decisions regarding the presentation or publication of the results of the Clinical Trial except as relates to the improper disclosure of information.
- E. If Novartis V&D determines that any manuscript submitted to it for review in accordance with this Section contains or describes one or more potentially patentable inventions that should be made the subject of one or more patent applications, Novartis V&D shall provide notice to the Institution and the Principal Investigator (who shall immediately notify all other authors) of this determination prior to the expiration of the review period. At the time such notice is provided or as promptly thereafter as is possible, Novartis V&D shall request that the Principal Investigator provide any additional information in his or her possession, in the possession of any other author or in the possession of the Institution which Novartis V&D deems necessary to file such patent application(s). Novartis V&D shall have four (4) months from its receipt of such additional information to file such patent application(s). Neither the Institution nor the Principal Investigator shall submit the manuscript to anyone who is not employed by the Institution and under an obligation of non-disclosure and non-use at least substantially identical to that imposed on the Principal Investigator by this Agreement until each such patent application has been filed by Novartis V&D or the conclusion of the four (4) month period of this Paragraph, whichever occurs first, or until the information on the potentially patentable invention(s) is excised from the manuscript.
- F. (a) If a Clinical Trial is part of a multi-center clinical trial, the data of and/or resulting from the performance of the Clinical Trial shall be pooled with the data from other centers (final pooled dataset) and analyzed as stipulated in the Protocol. Without the consent of the steering committee of the multi-center clinical trial, no presentation or publication of the results obtained from datasets other than the final pooled dataset (either of data from one center alone or of data from more than one but less than all of the centers) shall be made prior to the presentation or publication based on the final pooled dataset. Thereafter, should results obtained from datasets other than the final pooled dataset be presented or published for sound scientific reasons, adequate reference shall be made to the primary presentation or publication. (b) In no event shall the Institution or the Principal Investigator be restricted from presenting or publishing independently after the expiration of eighteen (18) months from the completion of the Clinical Trial (completion of Clinical Trial being defined as database lock), provided that all other provisions of this Section have been satisfied and provided that the presentation or publication adequately describes the results as obtained from a dataset other than the final pooled dataset, if that is the case.

8. INTELLECTUAL PROPERTY

- A. (a) Notwithstanding any other provision of this Agreement, neither the Institution nor the Principal Investigator shall acquire any rights of any kind in any Study Drug, Comparator Drug or other drug, or any use thereof, as a result of the performance of a Clinical Trial other than the rights expressly granted in this Section. (b) Neither Party transfers to the other any rights to any inventions, patent applications, patents, trademark applications, trademarks, copyright applications, copyrights or data or any other proprietary rights except as expressly set forth in this Agreement. (c) ~~Inventorship and when an invention is deemed to have been made shall be~~ determined in accordance with United States patent law. (d) Each Clinical Trial Invention shall be disclosed to Novartis V&D within six (6) months of the date that it was made.
- B. All Clinical Trial Inventions and patents covering Clinical Trial Inventions shall be owned by Novartis V&D and may be used and/or transferred by Novartis V&D for any lawful purpose with no further payment to the Institution and/or the Principal Investigator. Notwithstanding the foregoing, unless precluded by any other patent(s), the Institution and the Principal Investigator may use any Clinical Trial Inventions for their own internal educational, non-commercial research and patient care purposes and to comply with any applicable Federal, state and local government laws and regulations, without any payment to Novartis V&D.
- C. In the event that Novartis V&D decides to file one or more patent applications covering one or more Clinical Trial Inventions, the Institution, the Principal Investigator and other individuals under an obligation to assign Clinical Trial Inventions to the Institution, at the request and expense of Novartis V&D, shall assist Novartis V&D in the preparation and prosecution of such patent application(s) and shall execute all documents reasonably deemed necessary by Novartis V&D for the filing thereof and/or for the vesting in Novartis V&D of title thereto.
- D. All written and electronic records, reports and data of and/or resulting from and/or relating to the performance of a Clinical Trial (other than individual Clinical Trial Subject medical records) shall be the sole and exclusive property of Novartis V&D. However, the Institution and the Principal Investigator may (i) maintain copies of such written and electronic records, reports and data, (ii) use such written and electronic records, reports and data for their own internal educational, non-commercial research and patient care purposes and to comply with any applicable Federal, state and local government laws and regulations and (iii) prepare presentations and publications based on such written and electronic records, reports and data in accordance with the provisions of Section 7.
- E. Novartis V&D, its affiliates and all other corporations and other entities authorized to do so by Novartis V&D or an affiliate of Novartis V&D may incorporate the written and electronic records, reports and data of and/or resulting from and/or relating to the performance of a Clinical Trial in regulatory filings in the United States and all other countries and regions for one or more Study Drugs, Comparator Drugs and/or other drugs. Neither the Institution nor the Principal Investigator shall have any ownership, license or access rights in, or to, any regulatory filing or any Study Drug, Comparator Drug or such other drug based upon the inclusion of such written and electronic records, reports and/or data in any regulatory filing(s).
- F. The Institution warrants and represents that: (i) The Principal Investigator and all other individuals participating in the performance of a Clinical Trial (other than any individuals under an obligation to assign inventions to Novartis V&D) shall be under an obligation to assign all Clinical Trial Inventions and written and electronic records, reports and data of and/or resulting from and/or relating to the performance of the Clinical Trial to the Institution; and (ii) It has the authority to grant all of the rights granted in this Section.
- G. As used in this Agreement: (a) The term "patents" includes United States and foreign patents (including reissue patents), extensions thereof and Supplemental Protection Certificates based thereon, the term "patent applications" includes applications for all of the foregoing, the terms "trademark applications" and "trademarks" include, respectively, United States and foreign

trademark applications and trademarks, the term "copyright applications" includes applications for United States and foreign copyrights, and the term "copyrights" includes United States, foreign and common law copyrights. (b) The term "Clinical Trial Inventions" means inventions resulting from the performance of a Clinical Trial made by the Principal Investigator and/or one or more other individuals under an obligation to assign inventions to the Institution, alone or jointly with one or more others, including, but not limited to, inventions made with biological samples collected during and/or as a result of the performance of a Clinical Trial (e.g., as part of the initial screening of potential Clinical Trial Subjects).

9. PUBLICITY

- A. (a) The Institution shall not use Novartis V&D' name nor issue any public statement about this Agreement without the prior written permission of Novartis V&D, except as required by law and/or regulation (and, in such case, only with ten (10) days prior notice to Novartis V&D (if reasonably possible, and, if not, as many days as is reasonably possible). The preceding sentence shall not apply to presentations and publications in accordance with the provisions of Section 7 or obligations Institution may have as a municipal corporation. In order for the Institution to satisfy its reporting obligations, it may identify Novartis V&D as the sponsor of a Clinical Trial and disclose the amount of funding received from Novartis V&D for the Clinical Trial, but to the extent permitted by law shall not include in any such report any information which identifies any Study Drug by name or the therapeutic area(s) involved in the Clinical Trial. (b) Novartis V&D shall not use the Institution's name without the prior written permission of the Institution, except as required by law and/or regulation (and, in such case, only with ten (10) days prior notice to the Institution (if reasonably possible, and, if not, as many days as is reasonably possible). (c) Such permission shall not be unreasonably withheld by either Party.
- B. All advertising of a Clinical Trial must be reviewed and approved by Novartis V&D prior to use.
- C. As part of the registration of a Clinical Trial on www.ClinicalTrials.gov and/or other applicable clinical trial registries, Novartis V&D may disclose the Institution's name and contact information (including, but not limited to, the Institution's address and telephone number) and the name of the Principal Investigator.

10. APPLICABLE LAW

This Agreement shall be governed by the laws of the State of Texas without regard to any conflict of laws provisions.

11. NOTICE

- A. Any notice required or permitted by this Agreement shall be in writing and delivered by hand or sent by registered or certified mail, postage prepaid, return receipt requested, or by nationally recognized overnight delivery service, delivery charges prepaid, in each case addressed to the Party to receive such notice at the address set forth below or such other address as is subsequently specified in writing in accordance with this Section. Such notice shall be deemed given or provided as of the date of receipt. For the avoidance of doubt, a writing provided by E-mail shall not be deemed to comply with the notice requirements of this Agreement.

IF TO Novartis V&D Legal:
Novartis Vaccines and Diagnostics, Inc.
Antonio Metropolitan Health District
General Counsel - URGENT
San Antonio, TX 78205
350 Massachusetts Avenue
Cambridge MA 02139
617-871-7000 - (Tel)
617-871-8911- (Fax)

IF TO INSTITUTION:
City of San Antonio on behalf of the San
332 West Commerce, Suite 307
210-207-8731 - (Tel)
210-207-8999 - (Fax)

- B. Any notice relating to a Clinical Trial or a Clinical Trial Request Form shall be given as set forth in Section 2 of the Clinical Trial Request Form.
- C. Upon conclusion of a Clinical Trial, if the Institution is unable to communicate with and/or contact one of the Novartis V&D personnel referenced above or in the Clinical Trial Request Form, the Institution shall telephone 617-871-7000 to obtain the appropriate contact information.

12. INDEMNIFICATION AND INSURANCE

A. Novartis V&D covenants and agrees to **FULLY INDEMNIFY, DEFEND and HOLD HARMLESS**, the Institution, Principal Investigator, and the elected officials, employees, officers, directors, volunteers and representatives of the Institution, individually and collectively, from and against any and all costs, claims, liens, damages, losses, expenses, fees, fines, penalties, proceedings, actions, demands, causes of action, liability and suits of any kind and nature, including but not limited to, personal or bodily injury, death and property damage, made upon the Institution directly or indirectly arising out of, resulting from or related to Novartis V&D's activities under this Agreement, including any acts or omissions of Novartis V&D, any agent, officer, director, representative, employee, consultant or subcontractor of Novartis V&D, and their respective officers, agents employees, directors and representatives while in the exercise of the rights or performance of the duties under this Agreement. The indemnity provided for in this paragraph shall not apply to any liability resulting from the negligence of Institution, its officers or employees, in instances where such negligence causes personal injury, death, or property damage. **IN THE EVENT NOVARTIS V&D AND INSTITUTION ARE FOUND JOINTLY LIABLE BY A COURT OF COMPETENT JURISDICTION, LIABILITY SHALL BE APPORTIONED COMPARATIVELY IN ACCORDANCE WITH THE LAWS FOR THE STATE OF TEXAS, WITHOUT, HOWEVER, WAIVING ANY GOVERNMENTAL IMMUNITY AVAILABLE TO THE INSTITUTION UNDER TEXAS LAW AND WITHOUT WAIVING ANY DEFENSES OF THE PARTIES UNDER TEXAS LAW.**

The provisions of this INDEMNITY are solely for the benefit of the parties hereto and not intended to create or grant any rights, contractual or otherwise, to any other person or entity. Novartis V&D shall advise the Institution in writing within 24 hours of any claim or demand against the Institution or Novartis V&D known to Novartis V&D related to or arising out of Novartis V&D's activities under this AGREEMENT and shall see to the investigation and defense of such claim or demand at Novartis V&D's cost. The Institution shall have the right, at its option and at its own expense, to participate in such defense without relieving Novartis V&D of any of its obligations under this paragraph.

Defense Counsel - Institution shall have the right to select or to approve defense counsel to be retained by Novartis V&D in fulfilling its obligation hereunder to defend and indemnify Institution, unless such right is expressly waived by Institution in writing. Novartis V&D shall retain Institution approved defense counsel within seven (7) business days of Institution's written notice that Institution is invoking its right to indemnification under this Agreement. If Novartis V&D fails to retain Counsel within such time period, Institution shall have the right to retain defense counsel on its own behalf, and Novartis V&D shall be liable for all costs incurred by Institution. Institution shall also have the right, at its option, to be represented by advisory counsel of its own selection and at its own expense, without waiving the foregoing.

Employee Litigation – In any and all claims against any party indemnified hereunder by any employee of Novartis V&D, any subcontractor, anyone directly or indirectly employed by any of them or anyone for whose acts any of them may be liable, the indemnification obligation herein provided shall not be limited in any way by any limitation on the amount or type of damages, compensation or benefits payable by or for Novartis V&D or any subcontractor under worker's compensation or other employee benefit acts.

- B. Deviations from the terms of a Protocol that may arise out of necessity do not constitute negligence or willful malfeasance provided that the Institution promptly provides notice to Novartis V&D of any such deviations.
- C. Novartis V&D warrants that it maintains a policy or program of insurance or self-insurance at levels sufficient to support the indemnification obligations assumed herein. Upon request, Novartis V&D shall provide evidence of such insurance.
- D. The Institution shall maintain during the term of this Agreement the following insurance or self-insurance in amounts not less than that specified for each type:
 - (1) General liability insurance with combined limits of \$2,000,000 per occurrence and \$2,000,000 per accident for bodily injury, including death, and property damage;
 - (2) Workers' compensation insurance in the amount required by the law of the state in which the Institution's employees are located and employer's liability insurance with limits of \$2,000,000 per occurrence;
 - (3) In the event that the use of a motor vehicle is required in the performance of this Agreement, motor vehicle liability insurance with combined limits of \$2,000,000 per occurrence and \$2,000,000 per accident for bodily injury, including death, and property damage; and
 - (4) Medical professional liability insurance with a limit of \$2,000,000 per person and \$3,000,000 in the aggregate.
- E. The Institution shall provide to Novartis V&D, upon request, evidence of its insurance of the types specified in Paragraph D of this Section or self-insurance and, unless the Institution is self-insured, shall name Novartis V&D as an additional insured party under its insurance policies of Types (1), (3) and (4) and shall provide to Novartis V&D thirty (30) days prior notice of any change in, or cancellation of, its insurance policies of said four (4) types.

13. TERMINATION

- A. (a) A Clinical Trial may be terminated by either Party by notice given to the other Party (i) for any safety and/or efficacy concerns or (ii) in the event that any Institutional Review Board, FDA or other Federal or state agency required approval is terminated, withdrawn, suspended or expires. (b) A Clinical Trial may be terminated by Novartis V&D by notice given to the Institution if, for any reason, the Principal Investigator is unwilling or unable to continue to serve as such and a successor, acceptable to both Parties, is not available. (c) The effective date of any termination in accordance with this Paragraph shall be ten (10) days from the date the notice is given unless a later date is specified in the notice.
- B. A Clinical Trial may be terminated by Novartis V&D or Institution with or without cause, other than those specified in Paragraph A of this Section, by notice given to the Institution. The effective date of the termination shall be thirty (30) days from the date the notice is given unless a later date is specified in the notice.

- C. (a) Immediately upon receipt of a notice of termination, the Institution and the Principal Investigator shall cease entering patients into the Clinical Trial. (b) Upon the effective date of the termination, the Institution and the Principal Investigator shall cease the treatment, in accordance with the Protocol, of all Clinical Trial Subjects already entered into the Clinical Trial unless further treatment is medically necessary.
- D. In the event that a Clinical Trial is terminated by Novartis V&D, (i) Novartis V&D shall pay the Institution for non-cancelable commitments incurred, in accordance with Schedule A, prior to the receipt of the notice of termination, and (ii) Novartis V&D shall pay the Institution for all other costs set forth in Schedule A incurred prior to the effective date of the termination but shall not be responsible for any other costs set forth in Schedule A incurred on or after the effective date of the termination.
- E. Within sixty (60) days of the effective date of the termination of a Clinical Trial, the Institution shall return to Novartis V&D any funds paid by Novartis V&D that were not earned or irrevocably committed by the Institution prior to said date.
- F. Termination of a Clinical Trial shall not affect the rights and obligations of the Parties accrued prior to the effective date of the termination and shall not affect any other Clinical Trial. The rights and obligations under Sections 4, 6-13 and 17-19 (i) insofar as they relate to a specific Clinical Trial, shall survive the termination of that Clinical Trial and (ii) shall survive the expiration of this Agreement.

14. ENTIRE AGREEMENT AND SEVERABILITY

- A. This Agreement represents the entire understanding of the Parties with respect to the subject matter hereof. In the event of any inconsistency between this Agreement and a Clinical Trial Request Form, the terms of the Clinical Trial Request Form shall govern, and in the event of any inconsistency between this Agreement or a Clinical Trial Request Form and the Protocol, the terms of this Agreement or the Clinical Trial Request Form, as the case may be, shall govern.
- B. The invalidity or unenforceability of any term or provision of this Agreement or a Clinical Trial Request Form shall not affect the validity or enforceability of any other term or provision of either this Agreement or the Clinical Trial Request Form.

15. ASSIGNMENTS AND SUBCONTRACTS BY THE INSTITUTION

Neither this Agreement nor any Clinical Trial Request Form nor any rights and obligations under either may be assigned or subcontracted by the Institution without the written consent of Novartis V&D; such consent will not be unreasonably withheld.

16. CHANGES TO A PROTOCOL

Novartis V&D may at any time modify a Protocol by notice given to the Institution, with the approval of the Principal Investigator and, if required, the Institutional Review Board. No financial adjustments shall be made because of such modification unless the Parties amend the Clinical Trial Request Form accordingly.

17. DELIVERY TO NOVARTIS V&D OR DESTRUCTION OF UNUSED MATERIALS

Within thirty (30) days following completion or termination of a Clinical Trial, all unused Study Drug(s), Comparator Drug(s), devices and other materials that were furnished to the Institution by or on behalf of Novartis V&D shall, at Novartis V&D' expense, be returned to Novartis V&D or, if Novartis V&D so directs, destroyed.

18. CONFORMANCE WITH LAW, REGULATIONS AND ACCEPTED PRACTICE

- A. The Institution shall perform each Clinical Trial in conformance with all applicable Federal, state and local government laws and regulations, including, but not limited to, the Federal Food, Drug

and Cosmetic Act, the Health Insurance Portability and Accountability Act of 1996 and regulations of the FDA and other Federal agencies, generally accepted standards of Good Clinical Practice, the Protocol and ICH guidelines governing the performance of clinical trials.

- B. (a) If the Institution, or any Independent Institutional Review Board utilized by the Institution, commences an investigation of, or takes any action against, the Principal Investigator in connection with the performance of a Clinical Trial or any other clinical trial, whether or not for Novartis V&D, the Institution shall notify Novartis V&D within forty-eight (48) hours of the commencement of the investigation or the taking of action or, in the case of an investigation or action taken by an Institutional Review Board, within forty-eight (48) hours of becoming aware of the commencement of the investigation or the action taken. (b) If the FDA or a regulatory agency of any other country or region commences an investigation of, or takes any action against, the Institution and/or the Principal Investigator in connection with the performance of any Clinical Trial or any other clinical trial, whether or not for Novartis V&D, the Institution and/or the Principal Investigator shall notify Novartis V&D within forty-eight (48) hours of becoming aware of the commencement of the investigation or the action taken.
- C. All shipments of diagnostic specimens obtained as the result of the performance of a Clinical Trial shall comply with all applicable Federal regulations including, but not limited to, 49 CFR Part 173, such as 49 CFR 173.199 (if applicable), and the Institution shall execute any declarations required in connection therewith on forms provided, or approved, by Novartis V&D.
- D. **Corporate Citizenship.** Novartis V&D gives preference to Third Parties who share its societal and environmental values, as set forth in the Novartis V&D Corporate Citizenship hereto attached as Exhibit B. Accordingly, Consultant represents and warrants that this Agreement will be performed in material compliance with all applicable laws and regulations, including without limitation, laws and regulation relating to health, safety and the environment, fair labor practices and unlawful discrimination.

None

<http://www.Novartis V&D.com/downloads/about-Novartis V&D/Novartis V&D TP Code.pdf>

19. DEBARMENT

The Institution hereby certifies that (i) it has not been debarred under Subsection (a) or (b) of Section 306 of the Federal Food, Drug and Cosmetic Act (21 USC 335a) and no person who has been debarred under Subsection (a) or (b) of Section 306 of said Act will participate in the performance of any Clinical Trial or in any other work to be performed for or on behalf of Novartis V&D, and (ii) no person on any of the following FDA Clinical Investigator Restriction Lists - Disqualified/Totally Restricted List, Restricted List and Adequate Assurances List - will participate in the performance of any Clinical Trial. The Institution further certifies that if, at any time after execution of this Agreement, it becomes aware that it or any person who participated, or is participating, in the performance of a Clinical Trial or any other clinical trial for Novartis V&D is on, or is being added to, the FDA Debarment List or any of the three (3) FDA Clinical Investigator Restriction Lists, it will provide notice of this to Novartis V&D within forty-eight (48) hours of its becoming aware of this.

20. DATA PRIVACY

The Principle Investigator acknowledges that Novartis V&D Vaccines & Diagnostics, Inc. will hold personal information about him/her, including details of name, address, qualifications and clinical trials experience, financial information relating to, among other matters, compensation and reimbursement payments and other personal data for administrative purposes in connection with his/her appointment as investigator of this clinical trial. This information will be processed both by computer and manually. The Principle Investigator consents to the following:

- A. Understand that I will not be eligible for appointment as a clinical investigator in connection with the clinical trial if I do not consent to the collection of this information about me.
- B. Understand and expressly agree that this information may, if necessary for these purposes, be made available to ethics committees, government authorities or Affiliates located both in the country in which the relevant trial will be carried out, in other countries in the European Economic Area (EEA) and in or otherwise as required by law or any applicable regulation.
- C. Understand that some of the (non-EEA) countries to which my data may be transferred may not offer an adequate level of protection of privacy of personal data.
- D. Understand that personal information held about me may if necessary be transferred to government authorities in the European Economic Area (EEA) and/or in the United States for compliance with the requirements of Title 21, Part 54 of the Code of Federal Regulations on Financial Disclosure to Clinical Investigators, as amended from time to time. I further agree that personal information held about me may be disclosed in connection with Good Clinical Practice audits or similar requirements either in the EEA.
- E. The collection, use, processing, and disclosure of the information provided by me in this form in accordance with the terms of the above paragraphs and to the transfer of such data. I understand that I have (i) a right of access to information held about me, (ii) a right to correct inaccurate data, and (iii) a right to know who the recipients or categories of recipients are.
- F. Please address any questions that you may have about the processing and use of personal information relating to you or requests to exercise any rights that you may have with respect to such information in writing to:

Address: Integrity & Compliance
Novartis Vaccines and Diagnostics, Inc.
350 Massachusetts Avenue
Cambridge, MA 02139

email: NVD.IntegrityCompliance@Novartis.V&D.com

[THIS PAGE INTENTIONALLY LEFT BLANK. SIGNATURE PAGE TO FOLLOW]

IN WITNESS WHEREOF, the Parties have executed this Agreement in duplicate by proper persons thereunto duly authorized.

NOVARTIS VACCINES AND DIAGNOSTICS, INC.

CITY OF SAN ANTONIO ON BEHALF OF THE
SAN ANTONIO METROPOLITAN HEALTH
DISTRICT

By: *Niranjan Kanesa-thasan*
(signature)

By: _____
(signature)

Niranjan Kanesa-thasan
Chief Medical Officer Americas

Fernando A. Guerra, MD, MPH

Title: JAN 26 2009

Title: Director of Health

Date: _____

Date: _____

ATTEST

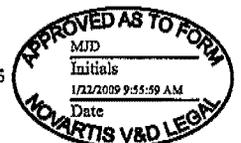
Leticia M. Vacek, City Clerk

Date: _____

APPROVED AS TO FORM

Michael D. Bernard, City Attorney

Date: _____





ATTACHMENT A: Clinical Trial Request Form

City of San Antonio on behalf of the San Antonio Metropolitan Health District

This Clinical Trial Request Form shall be binding upon the undersigned upon its execution by the duly authorized representatives of the Parties and the Principal Investigator as of the day and year last written below. It is subject to the terms of the Master Clinical Trial Agreement dated January 08, 2009 entered into by the Parties.

i3 research, a division of Ingenix Pharmaceutical Services, Inc. ("i3 Research"), a contract research organization, has entered into an agreement with Novartis V&D to provide clinical research services relating to this Clinical Trial.

1. CLINICAL TRIAL INFORMATION

Site No.:	050
Principal Investigator:	Fernando Guerra, M.D.
Study No.:	V59P23
Brief Description of the Clinical Trial [Protocol Title]:	A Phase 3b, Open-Label, Randomized, Parallel-Group, Multi-Center Study to Evaluate the Safety of Novartis MenACWY Conjugate Vaccine when Administered with Routine Infant Vaccinations to Healthy Infants
Is this Clinical Trial part of a Multi-center Study? [Yes or No]	Yes
Effective Period	January 08, 2009
Start Date:	June 30, 2011
Termination Date:	
Number of Patients to be Enrolled:	30

2. NOTICE

- A. Any notice required or permitted by this Clinical Trial Request Form shall be in writing and delivered by hand or sent by registered or certified mail, postage prepaid, return receipt requested, or by nationally recognized overnight delivery service, delivery charges prepaid, in each case addressed to the Party to receive such notice at the address set forth below or such other address as is subsequently specified in writing in accordance with this Section. Such notice shall be deemed given or provided as of the date of receipt. For the avoidance of doubt, a writing provided by E-mail shall not be deemed to comply with the notice requirements of this Clinical Trial Request Form.

IF TO Novartis V&D:

All payment queries and all invoices must include the following information (refer to Schedule A):

1. Project (Study Drug)
2. Protocol number
3. Principal Investigator's name
4. Center number
5. PO number (if available)

For Agreement Matters copy to Legal:

Novartis Vaccines and Diagnostics, Inc.
General Counsel - URGENT
350 Massachusetts Avenue
Cambridge MA 02139
617-871-7000 - (Tel)
617-871-8911- (Fax)

For Clinical Trial Matters at i3 Research:

Vicky Leamy, MPH
Project Manager II
i3 Research
512-347-2617 - (Tel)
512-347-2655 - (Fax)
Vicky.Leamy@i3research.com

For Clinical Trial Matters at Novartis V&D:

Dina Mirpuri Berdieva, MPH
Manager, Clinical Programs
Novartis Vaccines & Diagnostics, Inc.
617 871 8108 - (Tel)
617 871 8914 - (Fax)
Dina.Berdieva@Novartis.com

For Payment Matters to i3 Research:

Attn: Finance Department
i3 Research
131 Morristown Road
Basking Ridge, NJ 07920

IF TO INSTITUTION:

For Technical Matters:

City of San Antonio on behalf of the
San Antonio Metropolitan Health District
Attention: Dr. Fernando Guerra
332 West Commerce, Suite 307
San Antonio, TX 78205
210-207-8731 - (Tel)
210-207-8999 - (Fax)

For Administrative Matters:

City of San Antonio on behalf of the
San Antonio Metropolitan Health District
Attention: Dr. Fernando Guerra
332 West Commerce, Suite 307
San Antonio, TX 78205
210-207-8731 - (Tel)
210-207-8999 - (Fax)

- B. Upon conclusion of the Clinical Trial, if the Institution is unable to communicate with and/or contact one of the appropriate personnel referenced above, the Institution shall telephone 617-871-7000 to obtain the appropriate contact information.

3. MODIFICATIONS AND ADDITIONAL TERMS FOR THIS CLINICAL TRIAL

[CAUTION: The provisions of this Section supersede any conflicting provisions of the Master Clinical Trial Agreement.]

If this Clinical Trial Request Form requires the Clinical Trial to be performed beyond the expiration or termination date of the Master Clinical Trial Agreement, then the terms of the Master Clinical Trial Agreement that would otherwise expire shall remain in effect until the expiration or termination of this Clinical Trial Request Form.

The Institution and the Principal Investigator shall contact both Novartis V&D and i3 Research, according to the terms specified in the Master Clinical Trial Agreement, regarding the following occurrences:

- A. Obtain prior written approval prior to a substitution of the Principal Investigator.

- B. Provide notice of each Serious Adverse Event encountered in the Clinical Trial.
- C. Transmit complete and accurate written and electronic records, reports and data related to the performance of this Clinical Trial, unless required by the Protocol or otherwise requested by Novartis V&D and I3 Research.
- D. Provide notice of any intended or possible inspection and a copy of any report in connection with such inspection.
- E. Provide notice upon becoming aware of any person who participated, or is participating, in the performance of a Clinical Trial or any other clinical trial for Novartis V&D is on, or is being added to, the FDA Debarment List or any of the three (3) FDA Clinical Investigator Restriction Lists.
- F. Obtain prior written permission of I3 Research prior to using I3 Research's name or issuing any public statement about the Master Clinical Trial Agreement.

The terms and conditions of the Master Clinical Trial Agreement shall supersede and replace any existing Confidentiality Disclosure Agreement between the parties. Novartis V&D-disclosed Information, I3 Research-disclosed Information and Institution Information are herein collectively referred to as "Information". Any and all notices regarding the use and/or disclosure of Information during the course of the Clinical Trial, the Institution and Principal Investigator shall provide notice to both Novartis V&D and I3 Research.

I3 Research expressly disclaims any liability for any claim arising out of a condition caused by or allegedly caused by the administration of the Study Drug, Comparator Drug, or a placebo. Novartis V&D, the Institution and the Principal Investigator expressly acknowledge and agree that I3 Research shall have no liability whatsoever to the Institution or the Principal Investigator with respect to such claims.

4. LIST OF ATTACHMENTS AND PROTOCOL

Protocol: V59P23 "A Phase 3b, Open-Label, Randomized, Parallel-Group, Multi-Center Study to Evaluate the Safety of Novartis MenACWY Conjugate Vaccine when Administered with Routine Infant Vaccinations to Healthy Infants"

Schedule A – Attached, Copy of Master Clinical Trial Agreement – On file at the Institution, Novartis V&D and I3 Research

5. COSTS AND PAYMENT

5.1. Payments will be made payable to: City of San Antonio, Texas ("Payee") with Tax ID # 74-6002070, and sent to P.O. Box 839966, San Antonio, TX 78283.

5.2. A non-refundable start-up payment of One Thousand Dollars (\$1000.00) will be paid to Payee within thirty (30) days of receipt by I3 Research of a fully executed copy of this Agreement, receipt of copies of all regulatory documents necessary to start the Study, and the initiation of the Study at Site.

5.3. A document storage fee of One Thousand Dollars (\$1000.00) will be paid at the time of study closure upon receipt of invoice.

5.4. Central IRB Fees will be paid directly to the IRB by I3 Research.

5.5. Costs associated with the recruitment of subjects (advertising, screening/health fairs, seminars, etc.) must be pre-approved by Sponsor in writing and will then be reimbursed upon submission of invoice up to Two Thousand Dollars (\$2,000).

Invoices should be submitted to I3 Research for reimbursement at the following address:

Attn: Finance Dept.
I3 Research
131 Morristown Road
Basking Ridge, NJ 07920

5.6. Subsequent payments will be made based upon actual procedures and visits performed as evidenced by eCRFs per the Schedule A attached hereto and made a part of this Exhibit.

- a) Payments will be made quarterly for each visit completed in the payment period.
- b) Early termination expenses will be reimbursed at the time of the final payment.
- c) Payments will be made for each Completed Subject that has been confirmed by the completion of eCRFs.

5.7. Final payment for all completed visits will be made contingent upon completion of the following:

- a) satisfactorily completed eCRFs for all Study subjects;
- b) Resolution of any queries or requests for clarification concerning Study data or records;
- c) Return receipt or proof of destruction of Study Drug supplies and materials; and
- d) Receipt of a copy of the Investigator final report.

5.8. Payment will not be made for procedures, completed visits, expenses or other charges without receipt by I3 Research of proper documentation. I3 Research shall not be responsible for payments requested by Payee for documentation presented after the closing of the Study

5.9. All payments may be pro-rated at any time based on work performed. Screen Failures will not be reimbursed.

5.10. Compensation will not be provided to Payee for Study subjects who are withdrawn due to a Protocol violation, if such violation compromises the evaluability of Study subjects.

5.11. Any procedures, visits, or other charges performed apart from those scheduled by the Protocol are subject to prior written approval of I3 Research. Payment for all approved extra visits and procedures will be made at the time of the final payment.

5.12. Payee will reimburse I3 Research under the following condition: if the Study is closed out by I3 Research, Payee will reimburse all monies received from I3 Research in excess of the pro rata amount due for actual Study subjects visits performed as of closing of the Study.

5.13. Site acknowledges and agrees that it shall be solely responsible for paying the appropriate amount of all taxes including, without limitation, Value Added Tax with respect to all compensation paid pursuant to this Agreement, and that I3 Research shall have no responsibility whatsoever for withholding or payment of any such taxes for or on behalf of Payee.

NA

IN WITNESS WHEREOF, the Parties have executed this Clinical Trial Request Form in duplicate by proper persons thereunto duly authorized.

NOVARTIS VACCINES AND DIAGNOSTICS, INC.

CITY OF SAN ANTONIO
SAN ANTONIO METROPOLITAN HEALTH
DISTRICT

By: _____

(signature)

By: _____

(signature)

Niranjan Kanasa-thasan
Chief Medical Officer Americas
(print or type name)

(print or type name)

Title: JAN 26 2009

Title: _____

Date: _____

Date: _____

PRINCIPAL INVESTIGATOR

I have read this Clinical Trial Request Form and the Master Clinical Trial Agreement, and I understand and accept my obligations hereunder.

(signature)

Fernando Guerra, M.D.

Title: Director of Health

Date: _____

ATTEST

Leticia M. Vacek, City Clerk

Date: _____

APPROVED AS TO FORM

Michael D. Bernard, City Attorney

Date: _____

Schedule A

Novartis V&D Study Details

Drug / Compound: Novartis MenACWY Conjugate Vaccine
Study #: V59P23
Title: A Phase 3b, Open-Label, Randomized, Parallel-Group, Multi-Center Study to Evaluate the Safety of Novartis MenACWY Conjugate Vaccine when Administered with Routine Infant Vaccinations to Healthy Infants
Phase: 3b
Patient Type: Healthy Infants
Single Patient Duration: 16 months
Visits: 4 visits + 3 phone calls
Payment Terms: *details provided in contract agreement*
Indications: **Vaccination; Meningococcal**

Total Subjects: 1
Visits: 4
 Fernando Guerra, MD/Site 050/ City of San Antonio on behalf of the San Antonio Metropolitan Health District

Site: Antonio Metropolitan Health District
Patients Per Site: 30
Overhead: 25%

Subject Costs - Procedures

Procedure	Enter Qty	Overhead	Enter Cost (USD \$)	Total
Informed consent	1.0	X	75	75
Initial Physical assessment and history: Includes a medical history, physical assessment, vital signs and review of Inclusion/Exclusion. Typically, 60 minutes are spent performing or supervising the visit.	1.0	X	200	200
Vaccination preparation and administration	4.0	X	50	200
Check 15-mins post-injection: Includes temperature and IM site assessment. Typically, 15 minutes are spent performing or supervising these services.	4.0	X	30	120
Worksheet Instruction, Collection, Monitoring and Review	4.0	X	40	160
Physical Assessment, vital signs and confirmation of continued eligibility. Typically, 20 minutes are spent performing or supervising this visit.	3.0	X	60	180
Telephone call: review of Worksheet	3.0	X	30	90
eCRF Completion and electronic resolution of queries	7.0		25	175
Clinical research team: Investigator, Study Coordinator, Study Nurse - study oversight, GCP requirements, etc.	throughout	X	250	250
Procedures Sub Total				1,450

Subject Costs - Non Procedures

Non Procedure	Qty	OH	Cost	Total
Patient Reimbursement, Expenses, Patient Travel	4.0	X	30	120

Non Procedures Sub Total 120

sum of procedures and non-procedures 1,570

Overhead 25% 393

Total Cost Per Subject 1,963

Number of Subjects 1

sum of study subject costs (1): 1,963

Site Costs

Site Cost	Qty	OH	Cost	Budget	Total
Initial IRB review and approval fee	1	X			0
IRB Renewal Fee	1	X			0
IRB Amendment Fee	1	X			0
Study Start-Up Fee/Site Set-Up Fee	1	X	1,000		1,000
Document Storage	1	X	1,000		1,000
Advertising - if needed, submit a budget proposal and advertising plan for discussion.	1	tbd	2,000		2,000

Site Costs Sub Total 4,000

sum of site costs 4,000

Total anticipated subject enrollment

30

Total site costs for expected subjects

62,875

Novartis Protocol V59P23 Vaccine Study Project

Fund and Project No.

Fund No.

Funds Center

Budget for Period:

<u>ESTIMATED REVENUES</u>	SAP GL	PREVIOUS BUDGET
Novartis Agreement		\$ 62,875
Total Estimated Revenues		<u>\$ 62,875</u>

APPROPRIATIONS

Cost Center		
Internal Order		
Activity		
Regular Salaries and Wages	5101010	27,000
Temporary Salaries	5101015	9,000
Social Security	5103005	1,500
Temporary FICA	5103007	1,000
TMRS	5105010	2,359
Flexible Benefits Contribution	5104030	3,252
Life Insurance	5103010	28
Language Skills Pay	5101050	600
Communications: Telephones	5403010	1,000
Pagers/Mobile Phones	5403030	1,000
Mail and Parcel Post	5205010	300
Car Expense Allowance	5103055	0
Transportation Allowance	5103056	100
Travel official	5207010	50
Automatic Data Processing Services	5403520	100
Advertising and Publication	5203040	2,000
Other Contractual Services	5202025	3,600
Food	5304010	103
Office Supplies	5302010	2,241
Chemicals, Medical, Drugs	5304040	500
Computer Equipment	5501000	20
Machinery & Equipment - Other	5709060	0
Other Commodities	5304080	100
Indirect Cost	5406530	7,022
Total Appropriations		<u>\$ 62,875</u>

PERSONNEL COMPLEMENT

Cost Center		
Internal Order		
Activity		CURRENT POSITION
284 Community Services Supervisor		<u>1</u> 1

**Salary is calculated at 50% for one year

**This position is current and filled with an employee, it is not a new position to be created.