CONSENT AGENDA
ITEM NO. 34

CITY OF SAN ANTONIO
INTERDEPARTMENTAL MEMORANDUM
SAN ANTONIO METROPOLITAN HEALTH DISTRICT

TO: Mayor and City Council

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

THROUGH: Terry M. Brechtel, City Manager

COPIES: Frances A. Gonzalez, Assistant City Manager; City Attorney's Office; Office of Management and Budget; Finance Department; Project; File

SUBJECT: ORDINANCE AUTHORIZING AN AGREEMENT WITH AVENTIS PASTEUR, INC.

DATE: December 18, 2003

SUMMARY AND RECOMMENDATIONS

This ordinance authorizes the City Manager to accept and execute an agreement with Aventis Pasteur Inc. (Aventis) providing up to $143,250.00 for the period October 1, 2003 through September 30, 2005 for the San Antonio Metropolitan Health District (SAMHD) to participate in a clinical trial study of PENTACEL™, a vaccine that prevents the five childhood diseases of pertussis, diphtheria, tetanus, polio and haemophilus influenza b. This ordinance also establishes a fund, adopts the project budget, approves the personnel complement and authorizes payment of stipends to participating parents/guardians enrolled in the studies.

Staff recommends approval.

BACKGROUND INFORMATION

Pentacel™ is an FDA approved 5-component combination vaccine composed of Hybrid Pertussis, Diphtheria, Tetanus Toxoids Absorbed, Inactivated Poliomyelitis and Haemophilus influenzae type B. The objective of this study is to describe the antibody vaccine responses in children who receive Pentacel™ when given with Prevnar®, an FDA approved pneumococcal vaccine. Children in this study will be enrolled at two months of age and will receive all vaccines free of charge up to sixteen months of age. SAMHD will recruit up to 50 children for this study.

The personnel complement for the study is three (3) staff: a full-time Health Program Specialist 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; a full-time Health Program Supervisor to be the study coordinator and ensure compliance with study protocols; and a part-time (.50 FTE) Special Projects Coordinator to assist with study protocol and coordination, interviewing parents/guardians, enrolling eligible infants, ensuring that clients keep timely appointments and performing other duties as needed to make this program successful (See Attachment I). These personnel are currently City employees and will be shifted from other vaccine studies that are terminating.

Study project data collected will be provided to Aventis 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 $235.00 per parent/guardian of enrolled infants. Aventis will pay SAMHD up to $143,250.00 for participation in this study depending on patient enrollment, cooperation with the follow-up visits and telephone conferences. Payments up to $4,000.00 will also be made to the study's Institutional Review Board (IRB), Cheasapeake Research Review, as required of all research studies to ensure that ethical practices are maintained.

POLICY ANALYSIS

Acceptance of this agreement from Aventis 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 Aventis Pentacel Vaccine Study M5A07 Project will provide up to $143,250.00 for SAMHD study participation. Acceptance of this agreement 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 clinical trial agreement with Aventis Pasteur, Inc. The Finance Department has approved the proposed project budget.

SUPPLEMENTARY COMMENTS

Provisions of the Ethics Ordinance do not apply.

Attachments: Attachment I: Project Budget and Personnel Complement
Attachment II: Clinical Trial Agreement

Fernando A. Guerra, MD, MPH
Director of Health

Frances A. Gonzalez
Assistant City Manager

APPROVED BY:

Terry M. Brechtel
City Manager

ATTACHMENT I
Pentacel Vaccine Study M5A07
Fund and Project No. 26-012256
Budget for Period: 10/1/03 - 9/30/05

INDEX	ESTIMATED REVENUES	OBJECT CODE	CURRENT BUDGET
057257	Aventis Pasteur Inc.		$ 143,250
	Total Estimated Revenues		143,250
	APPROPRIATIONS		
759985	Regular Salaries and Wages	01-010	76,698
760272	Overtime Salaries and Wages	01-011	0
760413	Social Security	01-030	5,867
760652	TMRS	01-040	8,759
760876	Flexible Benefits Contribution	01-050	12,270
761015	Life Insurance	01-051	138
761213	Communications: Telephones	02-110	500
761353	Pagers/Mobile Phones	02-112	500
761510	Mail and Parcel Post Service	02-113	4,460
761783	Car Expense Allowance	02-130	300
761924	Fees to Professional Contractors	02-160	4,000
762088	Temporary Services	02-161	0
762245	Automatic Data Processing Services	02-172	1,000
762419	Advertising and Publication	02-175	2,000
762575	Other Contractual Services	02-193	11,750
762724	Food	03-216	400
763128	Office Supplies	03-210	4,000
763896	Chemicals, Medical & Drugs	03-228	3,000
764431	Indirect Cost	04-280	7,608
767574	Machinery & Equipment - Other	05-373	0
769430	Computer Equipment	05-360	0
	Total Appropriations		$ 143,250

Fund Only Index: 000464
Organization Code: 36-07-43

CLASS		CURRENT POSITIONS
0282	Health Program Specialist	1
0284	Health Program Supervisor	1
0870	Special Projects Coordinator (.50 FTE)	1
		3

CLINICAL TRIAL RESEARCH AGREEMENT

This Agreement is entered into as of the last date on the signature page hereof, by and between the City of San Antonio, through the San Antonio Metropolitan Health District, having its place of business at 332 West Commerce, Suite 307, San Antonio, TX 78205, hereinafter called "Institution," and Aventis Pasteur Inc., a Delaware corporation with its office and place of business located at Discovery Drive, Swiftwater, Pennsylvania 18370-0187, hereinafter called "Sponsor."

Sponsor desires Institution to study the Immunogenicity of Pentacel™ (Hybrid Pertussis Vaccine in combination with Diphtheria and Tetanus Toxoids Adsorbed and Inactivated Poliomyelitis grown on MRC-5 cells used to reconstitute lyophilized *Haemophilus influenzae* Type b Tetanus Toxoid Conjugate Vaccine ($HCP_{20/20/5/3}$DT-mIPV//PRP-T), (the "Study Drug") when given at different times or concurrently with a Pneumococcal Conjugate Vaccine and Institution is willing to perform certain clinical trial research (the "Study"). The parties hereto agree as follows:

1. Scope of Work

The Study to be performed under this Agreement shall be performed in accordance with the terms of the final protocol, including as it may be amended in accordance with the terms of this Agreement, for the Study entitled "Immunogenicity Assessment of Pentacel™ (Hybrid $CP_{20/20/5/3}$DT-mIPV//PRP-T) when Given at Different Times from or Concurrently with a Pneumococcal Conjugate Vaccine", #M5A07, (the "Protocol") which is attached as Exhibit A and incorporated herein by reference. The Budget for the Study is attached as Exhibit B.

Institution certifies that, to its best knowledge, its facilities and population are adequate to perform the Study contemplated by this Agreement and the Protocol. Institution and Principal Investigator (named in Article 2 below) agree that all aspects of the Study will be conducted in a competent and professional manner, in conformity with the current state of Good Clinical Practices, the Protocol, and all applicable federal, state and local laws and regulations, including those FDA requirements set forth at 21 C.F.R. Part 312, Subpart D. Institution agrees not to conduct any research activities with the Study Drug which are contrary to the provisions of the Protocol or outside the scope of the Protocol. Institute will be required to further certify that it will maintain the facilities and population sufficiently to perform the study contemplated by the Agreement and the Protocol.

2. Principal Investigator

Institution's principal investigator is Fernando Guerra, MD, (who with any sub-investigators shall be collectively referred to as "Principal Investigator"). Additionally, the Principal Investigator shall conduct the Study in conformance with generally accepted standards of good clinical practice and in compliance with all laws and regulations pertaining to the transportation, storage, use, administration and disposal of

drugs, vaccines/biologicals, and the conduct of clinical investigations including, but not limited to the Public Health Service Act, the Food, Drug and Cosmetic Act, and the Code of Federal Regulations of the United States. Principal Investigator will be responsible for the direction and supervision of all Study efforts in accordance with applicable Institution policies, the Protocol and this Agreement. In the event that the Principal Investigator who signs either the Protocol and/or this Agreement leaves or is removed from the Institution, then Institution shall, within ten (10) days of such departure by Principal Investigator, provide written notice of such event to Sponsor. Any successor to Principal Investigator must be approved, in writing, by Sponsor and such successor shall be required to agree to all the terms and conditions of the Protocol and this Agreement and to sign each such document as evidence of such agreement (although failure to so sign will not relieve such successor from abiding with all the terms and conditions of the Protocol and this Agreement).

Institution represents and warrants that it will not use in any capacity, in connection with any services to be performed under this Agreement, any individual who has been debarred pursuant to the Federal Food, Drug and Cosmetic Act.

Institution agrees to immediately inform Sponsor in writing if any person, including but not limited to the Principal Investigator, who is performing services hereunder is debarred or if any action, suit, claim, investigation or legal or administrative proceeding is pending, or, to the best of Institution's knowledge, is threatened, relating to the debarment of Institution or any person performing services hereunder.

3. **Project Monitoring, Auditing and Inspection Rights**

It is agreed that the project monitor(s) and others designated by Sponsor may, at mutually agreeable times during the Study and for a reasonable time after completion or early termination of the Study, arrange with principal Investigator or his/her designee:

(i) to examine and inspect, at regular business hours, Institution facilities required for performance of the Study; and

(ii) subject to applicable patient confidentiality considerations, to inspect, audit, and to copy or have copied, all data and work product relating to the Study conducted under this Agreement and to inspect and make copies of all data necessary for Sponsor to confirm that the Study is being conducted in conformance with the Protocol and in compliance with all applicable legal and regulatory requirements, including without limitation, any applicable requirements of the United States Food and Drug Administration ("FDA").

Institution agrees to assist Sponsor, to the extent deemed reasonable by Sponsor, in order to facilitate Sponsor's representatives' examination, inspection, auditing and copying of materials relating to the Study and in order to enforce the rights granted to Sponsor in this Article 3.

4. **Clinical Trial Approvals**

A. Institution shall be responsible for and required to obtain the following:

(i) approval of the Protocol, the informed consent relating to the Study and advertisement, if any, pertaining to the enrollment of subjects in the Study by the appropriate Institutional Review Board ("IRB") prior to beginning any Study on human subjects; and

(ii) an informed consent form as set forth in the Protocol which complies with all applicable federal, state, and local laws and regulations signed by or on behalf of each human subject prior to the subject's participating in the Study.

B. In the event Institution's IRB requires changes in the Protocol or informed consent form, Sponsor shall be advised in advance and all modifications to the Protocol and informed consent form must be approved in advance by Sponsor. Institution and Principal Investigator shall not modify the Study described in the Protocol once finalized and after approval by the IRB without the prior written approval of Sponsor.

5. **Term of Agreement**

It is anticipated that the Study shall begin in October 2003, and shall continue until the Study is completed and all final Study documentation and specimens required to be provided under the Protocol is received and accepted by Sponsor. If, at any time, Institution or Principal Investigator have reason to believe that the Study will not be initiated or completed as per the schedule initially anticipated and agreed upon by the parties, Sponsor will be advised, in writing, of the reason(s) and length of additional time required to commence or complete work, and this Agreement may be terminated by Sponsor as provided in Article 6.

6. **Termination and Enrollment Cap**

A. Sponsor may terminate this Agreement by giving thirty (30) days written notice to Institution. In the event thirty (30) days is determined by Institution to be insufficient notice based upon evaluation of risks to enrolled research subject(s) then receiving the Study Drug, the parties will cooperate to safely withdraw subjects from the vaccine over a mutually agreeable period of time but in no event shall Sponsor's obligation to supply Study Drug hereunder extend beyond a reasonable period. Notwithstanding the foregoing, in the event Sponsor believes that immediate termination is necessary due to its evaluation of risks to

enrolled research subject(s), Sponsor may terminate this Agreement immediately.

B. Notwithstanding any other provision hereof, Sponsor shall be entitled to terminate this Agreement for any Material Breach which shall be defined as:

(i) Institution's failure to comply with its obligations, responsibilities and the terms and conditions of this Agreement or the Protocol;

(ii) Institution's failure to comply with: (a) its obligations for keeping Sponsor informed of all necessary and relevant information in connection with the Protocol; (b) any applicable law, rule or regulation relevant to the Study; or (c) the work to be performed under this Agreement.

(iii) Institution and Principal Investigator shall deem a breach of the confidentiality provisions by its Agents a Material Breach of this Agreement.

C. In the event of any termination:

(i) Institution shall return to Sponsor all unused materials, including but not limited to, Study Drug and clinical supplies (unless written authorization to retain or destroy them is given by Sponsor in which case Institution shall comply with the applicable provisions of Article 11 hereof);

(ii) except in the event of termination because of a Material Breach by Institution, and unless otherwise specified in writing between the parties, the total sums payable by Sponsor pursuant to this Agreement shall be equitably pro-rated for actual work performed in accordance with the Protocol to date of notice of termination with any unexpended portion of funds previously paid by Sponsor to Institution being refunded to Sponsor;

(iii) in the event of termination as a result of a Material Breach, the parties agree to make a good faith effort to reach agreement to compensate Institution for actual work performed in accordance with the Protocol to date of notice of termination; and

(iv) Principal Investigator shall return to Sponsor all Confidential Information (as defined in Article 9 hereof) owned or controlled by Sponsor and in the possession of Institution.

D. The termination of this Agreement shall not relieve either party of its obligation to the other in respect of:

(i) retaining in confidence all Confidential Information (as defined in Article 9 hereof);

(ii) complying with record keeping and reporting obligation (under Article 7 hereof);

(iii) obtaining written approval and consents for any publications (under Article 10 hereof) and publicity and promotional purposes (under Article 17 hereof);

(iv) compensation for services performed to date of notice of termination, except as set forth in Article 6.C (iii) hereof;

(v) complying with obligations relating to clinical supplies (under Article 11 hereof);

(vi) indemnification and insurance obligations (under Article 12 hereof);

(vii) inspection rights (under Article 3 hereof); and

(viii) obligation to assist in obtaining patent protection (under Articles 10.E and 13 hereof)

all of which obligations are binding on the appropriate party and shall remain in full force and effect as set forth in this Agreement.

E. Sponsor reserves the right to limit enrollment by giving written notice, or by giving notice by telephone followed by written notice, to Institution and Principal Investigator to cease further enrollment in the Study ("Enrollment Cap"). Upon receipt of such notice, Institution and Principal Investigator agree to enroll no further patients in the Study. Unless otherwise specified in writing between the parties, in the event of such a notice to cease further enrollment, the total sums payable by Sponsor pursuant to this Agreement shall be equitably pro-rated for the number of patients enrolled to the date of such notice, with any funds for patients beyond the Enrollment Cap previously paid by Sponsor to Institution being refunded to Sponsor.

7. Records and Reports

A. Principal Investigator and Institution shall have the following record keeping and reporting obligations:

(i) preparation and maintenance of complete, accurately written records, accounts, notes, reports and data relating to the Study under this Agreement; and

(ii) preparation and submission to Sponsor (in a periodic and timely manner during the term of this Agreement) of all raw data and other material called for in the Protocol in the form of properly completed patient case report forms ("Case Report Forms") or into an electronic database (i.e., remote data entry) supplied by Sponsor for each patient as provided in the Protocol. Case Report Forms and the electronic database shall be the exclusive property of Sponsor.

B. Principal Investigator and Institution agree to notify Sponsor within twenty-four (24) hours after learning of any serious adverse drug reaction affecting any patient in the Study. Principal Investigator and Institution further agree to follow up such notification of adverse drug reaction with appropriate reports in compliance with the Protocol and all applicable legal and regulatory requirements.

C. Principal Investigator and Institution further agree to conduct the Study and maintain records and data during and after the terms or early termination of this Agreement in compliance with all applicable legal and regulatory requirements, including without limitation, any applicable requirements of the FDA. Principal Investigator and Institution further agree to permit Sponsor or Sponsor's representatives to examine and audit all records and reports, with prior written notification from Sponsor and during normal business hours (subject to applicable patient confidentiality considerations). Principal Investigator and Institution agree to take any action necessary, as reasonably requested by Sponsor, to properly correct or address any deficiencies noted during any audit and agree to cooperate with Sponsor with respect to any action taken to address any such deficiencies.

D. Principal Investigator agrees to notify Sponsor within twenty-four (24) hours in the event that the FDA or any other regulatory authority notifies the Study site of a pending inspection/audit. In addition, Principal Investigator will forward to Sponsor any written communication received as a result of the inspection/audit within twenty-four (24) hours of receipt of such communication and agrees to allow Sponsor to assist in responding to any citations. Such responses shall be made within ten (10) business days of issuance of any citations or within any earlier deadline set by the issuing regulatory authority. Principal Investigator shall also provide to Sponsor copies of any documents provided to any inspector or auditor. In the event the FDA or other regulatory authority requests or requires any action to be taken to address any citations, Principal Investigator and Institution agree, after consultation with Sponsor, to take such action as necessary to address such citations, and agree to cooperate with Sponsor with respect to any such citation and/or action taken with respect thereto.

8. **Cost and Payment**

The budget for the Study will be contained on a separate form which will be signed by the Institution and which shall be deemed to be incorporated by reference into this Agreement. The payment(s) set forth in such budget are acknowledged by the parties hereto to be adequate consideration for the work undertaken hereunder.

A. Payment Terms - Initial down payment due upon receipt of signed "Clinical Trial Research Agreement". Balance payable Net 30 from date of completed milestone(s).

B. Tax Identification Number: 1746002070 .

9. **Confidential Information**

A. During and for a period of ten (10) years after the term or early termination of this Agreement, Institution and Principal Investigator shall retain in confidence all test articles and proprietary data and/or information obtained from Sponsor or generated pursuant to the Study including, but not limited to, the Protocol, the investigator's brochure, interim results and any other information or material disclosed under secrecy agreements previously entered into between the parties ("Confidential Information"). This restriction shall not apply to Confidential Information:

(i) which is or becomes public knowledge (through no fault of Institution, Principal Investigator, trustees, officers, agents, subcontractors, and employees of the Institution and Principal Investigator.);

(ii) which is lawfully made available to Institution or Principal Investigator by an independent third party owing no obligation of confidentiality to Sponsor with regard thereto (and such lawful right can be properly demonstrated by Institution or Principal Investigator);

(iii) which is already in Institution's or Principal Investigator's possession at the time of receipt from Sponsor (and such prior possession can be properly demonstrated by Institution or Principal Investigator);

(iv) published in accordance with the express terms of this Agreement; or

(v) which is required by law, regulation, rule, act or order of any governmental authority or agency to be disclosed by Institution.

B. To permit Sponsor an opportunity to intervene by seeking a protective order or other similar order, in order to limit or prevent disclosures of Confidential Information, Institution or Principal Investigator shall immediately notify Sponsor, in writing, if it is requested by a court order, a governmental agency, or any other entity to disclose Confidential Information in Institution's or Principal Investigator's possession and thereafter Institution or Principal Investigator shall disclose only the minimum Confidential Information required to be disclosed in order to comply, whether or not a protective order or other similar order is obtained by Sponsor.

C. Subject to applicable federal, state or local legal and regulatory requirements, Institution and Principal Investigator agree to return to Sponsor, upon its request and within thirty (30) days, all Confidential Information obtained from Sponsor or belonging to Sponsor pursuant to this Agreement; provided, however, that Institution's legal counsel may retain one copy of Confidential Information in a secure location for purposes of identifying Institution's obligations under these confidentiality provisions.

D. Institution and Principal Investigator shall limit disclosure of Confidential Information received hereunder to only those of its representatives, agents, officers and employees (collectively, "Agents") who are directly involved with the Study and only on a need to know basis. Institution and Principal Investigator shall advise its Agents upon disclosure to them of any Confidential Information of the proprietary nature thereof and the terms and conditions of this Agreement and shall use all reasonable safeguards to prevent unauthorized disclosure by such Agents. Institution and Principal Investigator shall be responsible for any breach of these confidentiality provisions by its Agents. A breach of the confidentiality provisions by its Agents shall be deemed a Material Breach of this Agreement by Institution and Principal Investigator.

E. Institution and Principal Investigator acknowledge and expressly agree that any disclosure of Confidential Information in violation of this Agreement would be detrimental to Sponsor's business and cause it irreparable harm and damage. In accordance with applicable law and in addition to any other rights and remedies provided herein, Sponsor shall be entitled to secure equitable relief by way of injunction or otherwise.

10. Data, Publications and Other Rights

In recognition of the importance of disseminating information relating to any novel or important observations or results arising from the Study and understanding that such need must be balanced with Sponsor's obligations to maintain control over Confidential

Information as well as to comply with appropriate rules and regulations of the FDA, the parties hereby agree to the following:

A. Principal Investigator and Institution agree that all research data and results generated during the course of or as a result of the Study shall be the property of Sponsor. Principal Investigator and Institution further agree to execute any documents or undertake any further actions if requested by Sponsor to evidence transfer of title to such data.

B. Subject to the terms and conditions of this Agreement, Institution and Principal Investigator have the right to publish or publicly present the results of the Study. Principal Investigator and Institution agree not to publish or publicly present any interim results of the Study without prior review by Sponsor, as provided below. Principal Investigator and Institution further agree to provide ninety (90) days written notice to Sponsor prior to submission for publication or presentation to permit Sponsor to review drafts of abstracts and manuscripts for publication (including slides and texts of oral or other public presentations, collectively or individually a "Public Presentation") which report any results arising out of the Study. Sponsor shall have editorial rights with respect to a Public Presentation and the right to review and comment on the data analysis and presentation to:

(i) ensure that Confidential Information is protected by the provisions contained in Article 10D below;

(ii) ensure the accuracy of the information contained in the Public Presentation; and

(iii) ensure that the Public Presentation is fairly balanced and in compliance with FDA regulations regarding labeling and promotional materials.

If the parties disagree concerning the accuracy and appropriateness of the data analysis and presentation, and/or confidentiality of Sponsor's Confidential Information, Institution agrees to meet with Sponsor's representatives at the clinical Study site or as otherwise agreed, prior to submission of a Public Presentation, for the purpose of making good faith efforts to discuss and resolve any such issues or disagreement.

C. To the extent that the Institution's participation in the Protocol is a part of a multi-center study, Institution and Principal Investigator agree that an initial Public Presentation of their results shall occur only together with the other sites unless specific written permission is obtained in advance from Sponsor for Public Presentation of separate results. Sponsor shall advise as to the implications of timing of any Public Presentation in the event clinical trials are still in progress at sites other than the Institution's and

any Institution participating in a multi-center study shall follow the Public Presentation review procedures set forth in Article 10B above.

D. No Public Presentation shall contain any Confidential Information of Sponsor (as defined in Article 9) and shall be confined to new discoveries and interpretations of scientific fact. At Sponsor's request, Sponsor shall be acknowledged as one of many or as the sole financial Sponsor, as the case may be, of the Study reported in the Public Presentation.

E. If Sponsor believes there is a patentable subject matter contained in any public presentation submitted for review, Sponsor shall promptly identify such subject matter to Institution. If Sponsor requests and at Sponsor's expense, Institution shall use its best efforts to assist Sponsor to file a patent application covering such subject matter with the United States Patent and Trademark Office or through the Patent Cooperation Treaty prior to any publication.

Furthermore, in the event that the review of the proposed publications or other public disclosure results in a determination that potential patentable subject matter would be disclosed, and that such disclosure would be prejudicial to perfecting intellectual property rights, Sponsor may delay the publication or public disclosure for an additional 30 days to allow for filing the necessary patent applications.

F. Institution is granted the right, subject to the provisions of this Agreement, to use the results of the Study provided by Institution under this Agreement, including but not limited to, the results of tests and any raw data and statistical data generated therefrom, for its own internal teaching and research purposes.

11. Clinical Supplies

Sponsor shall make available sufficient quantities of Study Drug to carry out the Study, it being understood that Institution and Principal Investigator shall take responsibility for and reasonable steps to maintain appropriate records and assure appropriate supply, handling, storage, distribution and usage of these materials in accordance with the Protocol and any applicable laws and regulations relating thereto. Clinical supplies provided by the Sponsor may not be used for any other purpose than that stated in the Protocol. All unused materials will be returned to Sponsor by Institution at the conclusion of the Study, or upon earlier termination of this Agreement, unless written authorization to destroy or retain them is given by Sponsor. If authorization to destroy unused material is given, Institution shall provide Sponsor with documentation of the method of destruction. Institution shall conform with all laws and regulations pertaining to the disposal of drugs, vaccines/biologicals, during any destruction of unused quantities of Study Drug.

12. Indemnification and Insurance

A. Sponsor shall indemnify, defend and hold harmless Institution, its trustees, officers, agents, employees and Principal Investigator, (and any named co-investigator) from and against any demands, claims, actions, proceedings or costs of judgments which may be made or instituted against any of them by reason of personal injury (including death) to any person, arising out of or connected with the performance of the activities to be carried out pursuant to the Protocol.

B. Notwithstanding the foregoing, Sponsor shall have no duty to indemnify, defend and/or hold harmless any person, individual, or entity pursuant to this Agreement from and against any demands, claims, actions, proceedings or costs of judgments arising out of or resulting from:

(i) failure of Institution or Principal Investigator to adhere to the terms and provisions of the Protocol or agreed amendments thereto or Sponsor's written recommendations and instructions relative to the administration and use of any drug substances involved in the Study, including, but not limited to, the Study drug, any comparative drug and any placebo;

(ii) failure of Institution or Principal Investigator to comply with any applicable FDA or other governmental or state requirements, law, rules or regulations applicable to the performance of its obligations under this Agreement;

(iii) failure of Institution or Principal Investigator to render professional service or to conduct the Study in accordance with good clinical practices and current medical practice; or

(iv) negligent act or omission or willful misconduct by Principal Investigator, Institution, its trustees, officers, agents or employees related to the performance of services under this Agreement.

C. A condition of Sponsor's indemnity obligation is that, whenever Principal Investigator and/or Institution has information from which it may reasonably conclude an incident of bodily injury or death has occurred, Institution shall immediately give notice to Sponsor of all pertinent data surrounding such incident. In addition, Principal Investigator and Institution shall comply with all of their obligations with regard to adverse event reporting procedures as set forth in this Agreement and the Protocol and any appendix or attachment thereto. In the event claim is made or suit is brought, Institution and Principal Investigator shall assist Sponsor and cooperate in the gathering of information with respect to the time, place, and circumstances and in obtaining the names and addresses of the injured parties and available witnesses. Principal Investigator and Institution agree to cooperate with and to authorize Sponsor to carry out principal management and defense of such claim or action. Neither

Principal Investigator nor Institution, its trustees, officers, agents or employees shall compromise or settle any claim or action without the prior written approval of Sponsor.

D. Institution shall secure and maintain in full force and effect through the performance of the Study (and following termination or early termination of the Study to cover any claims arising from the Study) insurance coverage for:

(i) medical professional and/or medical malpractice liability (including coverage of Principal Investigator);

(ii) general liability (including coverage for the Study site); to include, but not limited to, a self-insured liability fund, self-insured retention and excess liability, and

(iii) worker's compensation, each such insurance coverage or self-insured fund in amounts required by applicable federal and state laws and appropriate to the conduct of Institution's business activities and the services contemplated by the Study.

Upon request of Sponsor, copies of certificates evidencing such insurance coverage, or other instruments of validation, will be made available to Sponsor and Institution shall provide thirty (30) days' prior written notice to Sponsor in the event of cancellation or any material change in such insurance.

13. **Inventions and Patents**

The sole and exclusive right to any inventions, discoveries, or innovations, whether patentable or not, arising directly or indirectly, in the performance of the Protocol or Study under this Agreement or using Study funds or otherwise arising out of use of the Study Drug (the "Inventions") shall be the property of the Sponsor. Institution or Principal Investigator will promptly notify Sponsor in writing of any such inventions, and at Sponsor's request, and expense, Institution and Principal Investigator will cause to be assigned to Sponsor all right, title, and interest in and to any such Inventions and provide reasonable assistance to obtain patents including causing the execution of any invention assignment or other documents.

14. **Notice**

Whenever any notice is to be given hereunder, it shall be in writing and mailed postage prepaid by certified or registered mail, return receipt requested, or personally delivered to the appropriate party at the address indicated below, or at such other place or places as either party may designate in a written notice to the other:

To Institution: San Antonio Metropolitan Health District

332 West Commerce, Suite 307
San Antonio, TX 78205-2489
Attn.: Fernando Guerra, MD

To Sponsor: Aventis Pasteur Inc.
Discovery Drive
Swiftwater, Pennsylvania 18370

Attn.: Fernando Noriega, MD, MPH

Notice shall be deemed to have been received at the earlier of receipt or five (5) days from the date of mailing (in the case of a letter).

15. **Assignment**

This Agreement is not assignable by Institution and any attempted assignment or delegation in violation hereof shall be void. Sponsor may assign this Agreement to an affiliated company without the prior consent of Institution. Notwithstanding such assignment, Sponsor shall remain liable for all of its obligations under this Agreement.

16. **Publicity**

Neither party shall use the name of the other party (or the name of any of Sponsor's divisions or affiliated companies) for promotional purposes without the prior written consent of the party whose name is proposed to be used. No news release, publicity or other public announcement, either written or oral, regarding this Agreement or performance hereunder or results arising from the Study, shall be made by Institution or Principal Investigator without the prior written approval of Sponsor.

17. **Independent Contractor**

It is agreed by the parties that Institution and Principal Investigator are acting in the capacity of independent contractors hereunder and not as employees, agents or joint venturers of or with Sponsor. Neither Institution nor Principal Investigator shall have any authority to represent, bind or act on behalf of Sponsor.

18. **Agreement Modifications**

Neither this Agreement nor the Protocol may be altered, amended or modified except by written document signed by both parties.

19. **Severability**

If any term or condition of this Agreement, the deletion of which would not adversely affect the receipt of any material benefit by either party hereunder, shall be held illegal, invalid or unenforceable, the remaining terms and conditions of this Agreement shall not be affected thereby and such terms and conditions shall be valid and enforceable to the fullest extent permitted by law.

20. No Waiver

Failure on the part of Sponsor to exercise or enforce any right conferred upon it hereunder shall not be deemed to be a waiver of any such right nor operate to bar the exercise or enforcement thereof at any time or times thereafter.

21. Force Majeure

Noncompliance by either party with the obligations of this Agreement due to force majeure, (laws or regulations of any government, war, civil commotion, destruction of production facilities and materials, fire, flood, earthquake or storm, labor disturbances, shortage of materials, failure of public utilities or common carriers), or any other causes beyond the reasonable control of the applicable party, shall not constitute breach of this Agreement and such party shall be excused from performance hereunder to the extent and for the duration of such prevention, provided it first notifies the other party in writing of such prevention and that it uses its best efforts to cause the event of the force majeure to terminate, be cured or otherwise ended.

22. Entire Understanding

This Agreement, including any exhibits and schedules hereto, constitutes the entire agreement between the parties with respect to the subject matter hereof. This Agreement supersedes and cancels all previous agreements among the parties, written and oral in respect of the subject matter hereof. In the event of any inconsistency between this Agreement and the Protocol, the terms of this Agreement shall govern except with regard to adverse event reporting procedures which shall be governed by the Protocol and any appendix or attachment thereto.

23. Consent

Whenever a party's consent or permission is required under this Agreement, such consent or permission shall not be unreasonably withheld.

24. Use of Study Drug

The Institution and Principal Investigator agree that they will limit any use and/or evaluation of Study Drug submitted under this Agreement to activities directly related to the Protocol, unless prior written consent has been provided by Sponsor.

SIGNATURE PAGE FOLLOWS

IN WITNESS WHEREOF, the parties have caused this Agreement to be duly executed, by duly authorized representatives, as of the last date written below.

INSTITUTION	AVENTIS PASTEUR, INC.
Signature _____	Signature _____
Print Name _____	Print Name _____
Title _____	Title _____
Date _____	Date _____

AGREED AND ACCEPTED:

_____
Principal Investigator

Date _____