

CLINICAL TRIAL AGREEMENT

This Agreement is entered into on _____, 201_, by and between PharmaCo, Inc., _____, State, Zip Code, a _____ Corporation ("PharmaCo"), and _____, _____, a _____ corporation (the "Study Center").

WITNESSETH

WHEREAS, PharmaCo will supply specified funds and Investigational New Drug, New Drug(TM), to Study Center for a clinical trial which will be conducted under the oversight and in the clinic of Investigator;

WHEREAS, this is a double-blind, placebo-controlled, registrational clinical trial, and the results of this trial will be submitted for review and approval by the U.S. Food and Drug Administration;

WHEREAS, PharmaCo has developed the Investigational New Drug (as hereinafter defined) as a vaccine for the prevention of _____;

WHEREAS, in order to comply with certain regulatory approval obligations, PharmaCo intends to conduct a multi-center clinical trial with respect to the Investigational New Drug, of which the Study (as hereinafter defined) is a part;

WHEREAS, the Study Center is qualified to perform the Study and such performance would further the Study Center's instructional and research objectives;

WHEREAS, PharmaCo desires the Study Center to perform, and the Study Center desires to so perform, the Study on the terms set forth herein;

NOW THEREFORE, in consideration of the promises and the mutual covenants and conditions hereinafter recited, the parties do hereby agree as follows:

1.0 DEFINITIONS.

For purposes of this Agreement:

1.1 "CFR" means the United States Code of Federal Regulations.

1.2 "CRFs" means "Case Report Forms" as that term is defined in the Protocol.

1.3 "Confidential Information" has the meaning set forth in Section 10.2.

1.4 "Discoveries" has the meaning set forth in Section 13.1.

1.5 "Effective Period" has the meaning set forth in Section 2.3.

1.6 "FDA" means the United States Food and Drug Administration.

- 1.7 "_____ Laws" has the meaning set forth in Section 8.2.
- 1.8 "Informed Consent" has the meaning set forth in Section 5.1.
- 1.9 "Informed Consent Forms" has the meaning set forth in Section 5.1.
- 1.10 "Investigational New Drug" means "NEW DRUG(TM)", a vaccine consisting of one or more gp120 antigens plus the adjuvant alum or placebo containing adjuvant alum.
- 1.11 "Investigator" means the Principal Investigator, who is the real person expressly engaged to directly perform or supervise the Study.
- 1.12 "Investigator Brochure" means the written document summarizing the manufacturing, preclinical and clinical testing pertaining to the Investigational New Drug.
- 1.13 "IRB" means the Study Center's Institutional Review Board.
- 1.14 "Protocol" has the meaning set forth in Section 2.1.
- 1.15 "Researchers" means the Investigator and any real persons who shall, under the supervision of the Investigator or the Study Center, assist the Study Center and the Investigator in performing the Study in accordance with this Agreement.
- 1.16 "Rights" has the meaning set forth in Section 13.1.
- 1.17 "Study" means the clinical research trial to be performed by the Investigator and any other Researchers at the Study Center in accordance with this Agreement and the Protocol.
- 1.18 "Subject" means a human being who participates in the Study.
- 1.19 "PharmaCo Property" means all property in which PharmaCo has a proprietary interest, including, but not limited to, (1) the Confidential Information; (2) the Discoveries; (3) statistical data, evaluations, analyses and specimens generated or collected by the Study Center in connection with the conduct of the Study; (4) any quantities of the Investigational New Drug; (5) the Protocol; (6) the Investigator Brochure; (7) CRFs and Informed Consent Forms, whether or not completed; and (8) slides, study notes and other documents, research supplies and any other related materials that are furnished to the Study Center or the Researchers by or on behalf of PharmaCo.

2.0 STUDY PERFORMANCE.

2.1 The Study shall be performed by the Study Center in accordance with Protocol Number New Drug 004 entitled "A Phase III Trial to Determine the Efficacy of NEW DRUG(TM) B/B Vaccine in Adults _____ Infection in the United States," attached hereto as Exhibit A, and any subsequent amendments made thereto in accordance with Article 16.0 (the "Protocol"). The Protocol is subject to approval by the IRB. The Informed Consent is subject to approval by PharmaCo and the IRB. Any statement in the Protocol that is inconsistent with this Agreement shall be superseded by this Agreement.

2.2 The Study Center's Investigator shall be _____, M.D. The Investigator shall be responsible, either directly or through other Researchers, for the performance of the Study in accordance with the highest standards of medical and clinical research practice. If for any reason the Investigator is unable to continue to serve as Investigator and a successor, acceptable to both the Study Center and PharmaCo, is not available, this Agreement shall be terminated as provided by Section 14.2.

2.3 The Study Center acknowledges that, with respect to the performance of the Study, time is of the essence. The effective period of this Agreement will commence on _____, 201_ and shall expire on September 30, 201_ (the "Effective Period"). In the event that the Study Center does not fulfill its obligations under this Agreement with respect to the Study during the Effective Period, PharmaCo may, at its sole option, extend the Effective Period by one-month periods.

2.4 The Study Center shall enroll one hundred fifty (150) Subjects in the Study. The Study Center shall use its best efforts to complete Subject enrollment by February 28, 201_. In the event the Study Center is unable to complete the enrollment by such date, PharmaCo may reassign the Study Center's enrollment slots, thereby reducing the number of Subjects the Study Center may enroll in the Study. The Study Center acknowledges that the Study is part of a multi-center clinical trial. When the enrollment goal of 5,000 subjects for the clinical trial as a whole is reached, enrollment will be closed at all sites, including the Study Center, regardless of whether the Study Center or any other site has reached its individual enrollment goal.

2.5 The Study Center shall utilize the following clinical facilities for the conduct of the Study:

_____.

3.0 PAYMENT AND PAYMENT SCHEDULE.

3.1 As consideration for performance under the terms of this Agreement, PharmaCo shall pay the Study Center according to the Clinical Study Payment Schedule attached hereto as Exhibit B. All payments outlined on Exhibit B shall remain firm for the duration of the Study, unless otherwise agreed in writing by the Study Center and PharmaCo. Such payments are inclusive of all associated costs, fees and charges, including any relevant or applicable overheads due any party, entity or institution.

3.2 Payments made pursuant to this Article 3.0 shall be paid to the Study Center, entity _____ (TAX ID) and sent to the following address:

Name
Entity
Address
City, State ZIP

3.3 Payment as set forth in this Section 3 shall constitute full payment for the Study and PharmaCo shall have no other payment obligations hereunder.

4.0 INVESTIGATIONAL NEW DRUG AND SPECIMENS.

4.1 PharmaCo shall provide the Study Center with the Investigational New Drug to be used solely for purposes of the performance of the Study by the Study Center. The Study Center agrees to limit access to the Investigational New Drug to only those individuals engaged in conducting [or participating in] the Study. The Study Center shall not transfer the Investigational New Drug to any third party. The Study Center shall maintain complete and accurate records of all quantities of Investigational New Drug received and dispersed

by the Study Center, as indicated in Section 6.2 below.

4.2 The Investigational New Drug shall be shipped to the Study Center in containers marked in accordance with 21 C.F.R Section 312.6. All used containers of the Investigational New Drug shall be destroyed or otherwise disposed of in accordance with the Study Center's Standard Operating Procedures. Written certification of such destruction or disposal shall be provided to PharmaCo by the Study Center. All expired or unused Investigational New Drug shall be returned to PharmaCo at the completion of the Study or termination of this Agreement, whichever occurs first.

4.3 The Study Center shall not collect specimens or use the Investigational New Drug for use in any research without the prior written permission of PharmaCo. All specimens collected by the Study Center shall be delivered to PharmaCo by the Study Center in a timely manner throughout the performance of this Study in accordance with the Protocol or as otherwise provided by PharmaCo, and in no event later than five (5) working days after the date of termination of this Agreement or on which PharmaCo otherwise requests delivery of the specimens.

5.0 SUBJECTS.

5.1 Informed consent of each of the Subjects participating in the Study shall be obtained in accordance with 21 C.F.R. Sections 50 and 56, including completion of the PharmaCo-approved Informed Consent Form, which has been approved by the IRB (such activities to be referred to collectively as "Informed Consent"). The Study Center shall administer the Investigational New Drug only to Subjects from whom Informed Consent has been properly obtained by the Study Center under this Section 5.0. The Study Center shall maintain adequate documentation of its obtainment of the Informed Consent of each Subject.

5.2 The Study Center shall monitor the Subjects in accordance with the Protocol. The Study Center shall require the Investigator to promptly report to PharmaCo all serious adverse experiences that may be associated with the administration of the Investigational New Drug that occur during the course of the Study. For purposes of this Section, "promptly" shall mean within twenty-four (24) hours of the occurrence of any such serious adverse experience. Failure to comply with this Section shall constitute reasonable grounds for PharmaCo to terminate this Agreement as provided in Section 14.2.

5.3 PharmaCo agrees to assume responsibility for the direct reasonable and necessary costs of treatment of any adverse reaction or injury to a Subject that is a vaccine induced reaction to the Investigational New Drug that has been administered in accordance with this Agreement, the Protocol and any other written instructions of PharmaCo, and are in no way attributable to the negligence or misconduct of any agent or employee of the Study Center. PharmaCo shall not be responsible for costs incurred for the treatment of _____ infection.

5.4 PharmaCo, the Study Center and the Researchers shall hold in confidence the identity of the Subjects and shall comply with all applicable laws regarding the confidentiality of their identities and their individual medical records.

6.0 RECORDKEEPING, REPORTING AND ACCESS TO RECORDS.

6.1 PharmaCo or its authorized representatives, and regulatory authorities to the extent permitted by law, may, during regular business hours:

- (1) Examine and inspect the Study Center's facilities used in performance of the Study, including

storage or use of the Investigational New Drug;

(2) Observe conduct of the Study;

(3) Inspect and copy all data and work products relating to the Study or the IRB, including CRFs, Subject medical records and Informed Consent Forms and other Informed Consent documentation, required licenses, certificates and accreditation; and

(4) Interview the Investigator, other Researchers and Study Center or IRB personnel.

The Study Center shall, and shall cause the Investigator and any other Researcher to, cooperate with any such inspection and shall ensure timely access to requested records and data.

6.2 The Study Center, including the Investigator and any other Researchers, shall perform the recordkeeping and reporting obligations described in the Protocol and this Agreement and shall do so in accordance with all applicable local, State and federal laws, regulations and guidelines. Such recordkeeping shall be complete, current, accurate, organized and legible, and shall be performed in a manner acceptable for the collection of data for submission to, or review by, the FDA and in full compliance with such laws, regulations, guidelines and in full compliance with the Protocol. These recordkeeping and reporting obligations include, but are not limited to, the following:

(1) maintaining written records, accounts, notes, reports and data relating to the Study, including full case histories, as described in 21 CFR Section 312.62;

(2) completing original, authorized Informed Consent Forms and CRFs for each Subject on a per visit basis;

(3) maintaining adequate documentation of the obtainment of Informed Consent from each Subject;

(4) preparing and submitting all safety, progress, interim and final reports;

(5) maintaining records of the receipt, use and disposition of the Investigational New Drug;

(6) maintaining copies of all correspondence with PharmaCo, the IRB and the FDA; and

(7) maintaining other documents indicated by the Protocol or specified by PharmaCo.

All such records shall be submitted to PharmaCo upon request or upon completion of the Study or as otherwise directed by PharmaCo. All reports provided to PharmaCo by the Study Center must be in accordance with the Protocol and FDA requirements or as otherwise instructed by PharmaCo. Notwithstanding the foregoing, Study Center may retain one copy of the records for archival purposes.

6.3 The Study Center agrees to maintain all records required by this Agreement and resulting from the Study for the time required by applicable Federal, State and local laws and regulations and shall allow for inspections of all such records by PharmaCo or its authorized representatives during such period of retention.

7.0 FDA ASSISTANCE.

7.1 At the request and expense of PharmaCo, the Study Center shall, and shall cause the Investigator to:

(1) assist PharmaCo in the preparation and submission of investigational new drug applications, and any other premarket applications relating to the Study as may be required by the FDA; and

(2) attend meetings with the FDA and other regulatory agencies regarding such applications and the associated approvals as requested by PharmaCo.

7.2 The Study Center shall promptly inform PharmaCo of any effort or request by the FDA or other persons to contact the Study Center, the Investigator or any other Researcher regarding the Study. The Study Center shall promptly notify PharmaCo in the event that the FDA or any other governmental agency, either state or federal, issues the Study Center, the IRB, the Investigator or any other Researcher any Notice of Inspectional Observations, Warning Letters or other comparable documents citing allegedly improper or inadequate research practices with respect to any activity of the Study Center, the Investigator, other Researchers or the IRB. For purposes of this section, "promptly" shall mean within three (3) business days of the receipt of any such documents, efforts or requests by the Study Center, the Investigator or any other Researcher.

8.0 COMPLIANCE WITH STATUTES.

8.1 The Study Center shall ensure that the Study is performed in conformance with the standards of Good Clinical Practice acceptable to the FDA, with the Protocol and other Written instructions provided by PharmaCo, and with all applicable local, State and Federal laws, regulations and guidelines, including, but not limited to 21 CFR parts 312, 50 and 56.

8.2 In connection with any testing or other activity undertaken pursuant to the Study with respect to determining the ____ virus (_____)status of any Subject or potential Subject, the Study Center agrees to assume full responsibility for complying with all federal, State, and local laws, rules, and regulations as amended from time to time, directed to the status of such individuals, including, without limitation, laws covering informed consent, screening, testing, counseling, reporting, confidentiality, disclosure and record keeping.

9.0 WARRANTIES.

9.1 The Study Center warrants that the Study Center, the Investigator and each of the other Researchers have all training, information, licenses, approvals or certifications necessary for safely, adequately and lawfully performing the Study, and the Study Center shall ensure that all such training, licenses, approvals or certifications are properly maintained throughout the course of the Study. The Study Center further warrants to the best of its knowledge that it, the Investigator and the other Researchers are not subject to any conflicting obligation or legal impediment that might interfere with the performance of the Study or that might impair the acceptance of data resulting from the Study by the FDA, and that no such obligations or conflicts will be incurred or permitted in the future without the prior written approval of PharmaCo.

9.2 The Study Center warrants that none of the Study Center, the Investigator or the other Researchers have been or may be subject to debarment under the provisions of the Generic Drug Enforcement Act of 1992, 21 U.S.C. 306(a) or (b), or have otherwise been disqualified or suspended from performing the Study or otherwise subject to any restrictions or sanctions by the FDA or any other governmental agency

or professional body with respect to the performance of scientific or clinical investigations. In the event that the Study Center or any of the Researchers (1) becomes debarred; or (2) receives notice of action or threat of action with respect to such debarment during the term of this Agreement, the Study Center shall notify PharmaCo immediately. In the event that the Study Center or any of the Researchers become debarred during the term of this Agreement, or the Study Center receives notice of any action or threat of action as set forth in clause (2), PharmaCo may, at its sole option, automatically terminate the Agreement without any further action or notice by either party.

9.3 The Study Center hereby certifies that it has not and will not use in any capacity the services of any individual, corporation, partnership, or association which has been debarred under 21 U.S.C. 306(a) or (b). In the event that Study Center becomes aware of the debarment or threatened debarment of any individual, corporation, partnership, or association providing services to Study Center which directly or indirectly relate to Study Center's activities under this Agreement, Study Center shall notify PharmaCo immediately. PharmaCo shall have the right to terminate this Agreement immediately upon receipt of such notice.

9.4 The Study Center warrants that the Investigator or other Researchers has not entered, and will not enter, into any contractual agreement or relationship that would in any way conflict with or compromise any PharmaCo Property at the time of the execution of this Agreement or arising out of or related to the performance thereunder.

9.5 The Investigational New Drug provided under this Agreement is not for commercial use. PharmaCo makes no representations or warranties, express or implied, related to the Investigational New Drug, including without limitation any warranty of merchantability or fitness for a particular purpose, or that the use of the Investigational New Drug for purposes other than specified in this Agreement will not infringe any patent or other proprietary right.

9.6 Any specimens collected by the Study Center and provided to PharmaCo in accordance with this Agreement shall be "as is" and the Study Center makes no representation or warranty (express or implied) that the specimens are free from harmful biological or infectious agents or organisms and are otherwise merchantable or fit for a particular purpose or use.

10.0 CONFIDENTIALITY; PROTECTION OF PHARMACO PROPERTY.

10.1 The Study Center agrees that the Study Center and the Researchers shall protect PharmaCo Property from unauthorized use, access, duplication, disclosure, loss or damage. In protecting PharmaCo Property, the Study Center will take adequate measures, including but not limited to the following:

(1) limit access and use of PharmaCo Property to authorized Researchers for whom such access and use are required for performance of the Study;

(2) use PharmaCo Property only for the purposes described in the Protocol or other purposes as approved by PharmaCo in writing;

(3) prevent transfer or disclosure of PharmaCo Property to any other person or entity without PharmaCo's written approval;

(4) prevent any unauthorized duplication of PharmaCo Property in written or electronic form and any decompilation or modification of the Investigational New Drug;

(5) use at least the same degree of care and discretion it uses in maintaining the confidentiality of its own Confidential Information;

(6) upon completion or termination of the Study, or on PharmaCo's written request, return to PharmaCo all PharmaCo Property and all written material that incorporates any PharmaCo Property and, if so requested, provide a written inventory showing the disposition of all PharmaCo Property received or developed by the Investigator. Return of PharmaCo Property shall include permanent removal of all PharmaCo Property from all computer or other electronic storage media that is not returned to PharmaCo, except as otherwise required by the FDA and/or local, state and federal laws, regulations and guidelines or other governmental agencies.

10.2 The Study Center shall not, and shall obligate the Researchers not to, disclose or use for any purpose other than performance of the Study, any trade secret, privileged record or other confidential or proprietary information (collectively, the "Confidential Information") disclosed to or developed by the Study Center pursuant to this Agreement. Such Confidential Information includes but is not limited to all information received by the Study Center or the Investigator from PharmaCo, the Investigator Brochure and the Protocol, the Investigational New Drug and all information related to the Investigational New Drug, all information developed during the Study, the CRFs and safety and efficacy information, all data, results, reports, technical and economic information, the existence or terms of this or other research agreements with PharmaCo, commercialization and research strategies, trade secrets and know-how disclosed by PharmaCo to the Study Center or any Researcher directly or indirectly, whether in writing or orally, or developed under this Agreement. Such Confidential Information shall be disclosed to the Study Center by PharmaCo hereunder in writing or if disclosed orally or in other than documentary form, shall be reduced to writing within 30 days thereafter. Confidential Information that is not in oral or written form, such as, but not limited to data tapes, shall be designated in writing as confidential within thirty (30) days after disclosure. The obligation of non-disclosure shall not apply to information that:

(1) was known to Study Center or the Investigator, as evidenced by prior written records, prior to receiving such information either directly or indirectly from PharmaCo, or

(2) is generally known to the public or that becomes generally known to the public through no act or omission on the part of the Study Center or the Investigator, or

(3) is disclosed to the Study Center or the Investigator on a non-confidential basis at any time by a third party who has not obtained or disclosed such information through improper or unlawful means.

10.3 The Study is intended to be conducted as a blind trial. The Study Center shall not perform any independent assays for the purpose of unblinding treatment assignment.

10.4 In the event the Study Center or the Investigator is ordered to provide Confidential Information by a lawful judicial or government order, the Study Center shall promptly inform PharmaCo and shall permit PharmaCo to defend against such order of disclosure and shall assist in such defense to the extent permitted by law. In no other circumstances may the Study Center or the Investigator disclose information without the consultation and prior written consent of PharmaCo.

11.0 PUBLICATION AND ADVERTISING.

11.1 The Study is being conducted as part of a multi-center clinical trial. As stipulated in the Protocol,

data from all such centers shall be pooled and analyzed for publication in a final report (Primary Publication). Study Center agrees that the Primary Publication to be coordinated by PharmaCo will be the first publication to present the pooled Study results.

Following the Primary Publication, or if the Primary Publication is not published within one year of termination of this Agreement, the Study Center and the Investigator shall have the right and be encouraged to publish or present materials related to the Study. At least thirty (30) days prior to submission of any material for publication or presentation by the Study Center or the Investigator, the Study Center shall provide PharmaCo with such material for its review and comment. Expedited reviews of such materials may be arranged at PharmaCo's sole option. If requested in writing by PharmaCo, the Study Center shall withhold, or shall cause the Investigator to withhold, material from submission for publication or presentation an additional sixty (60) days to allow for the filing of a patent application, or the taking of such measures as PharmaCo deems appropriate, to establish and preserve its proprietary rights in the information in the material being submitted for publication.

11.2 In the event PharmaCo permits Study Center to conduct ancillary research as provided in Section 4.3, Study Center and Investigator shall not publish or make presentations with respect to the ancillary research until after the primary data obtained from conducting this Study is published or publicly presented.

11.3 PharmaCo and the Study Center shall obtain prior written permission from the other before using the name, insignia, symbol(s), trademarks or logotypes associated with such party in any form of publicity in connection with the Study; provided however that PharmaCo may use the name associated with the Study Center, or the names of the Researchers and Study Center employees to identify the Study Center as the site at which the Study was conducted and to identify those individuals responsible for conducting the Study. The disclosure restrictions contained in this Section shall not apply to the extent such disclosure is legally required.

11.4 PharmaCo shall not use, nor authorize others to use, the name, insignia, symbol(s), trademarks or logotypes of the Study Center or the Researchers in any advertising, promotional or publicity material or make any form of representation or statement in relation to the Study that would constitute any express or implied endorsement by the Study Center of the Investigational New Drug without prior written approval of the Study Center or the Researchers.

11.5 Nothing contained herein shall prevent immediate public disclosure of results by the Study Center or the Investigator to the extent necessary to prevent or mitigate a serious health hazard.

12.0 INDEMNIFICATION; LITIGATION.

12.1 PharmaCo agrees to indemnify, and hold harmless the Study Center, its officers, agents and employees, and each of the Researchers from any and all liability, loss (including attorney's fees), or damage they may suffer as the result of claims, demands, or judgments for bodily injury or death of a Subject caused by the use of the Investigational New Drug during the course of the Study, provided that:

(1) The Study was conducted in accordance with this Agreement, the Protocol and all written instructions of PharmaCo concerning the Study;

(2) Such claims, demands or judgments do not arise, in whole or in part, from the negligent or willful acts or omissions or any misuse of the Investigational New Drug by the Indemnitee, the Investigator or any other Researcher or by any other person on the Study Center's property, exclusive of PharmaCo's

employees;

(3) The Study was conducted in accordance with all applicable federal, state or local laws, regulations and guidelines, including all applicable laws, and in conformance with the practices of reasonable and prudent clinical investigators, physicians and medical institutions.

12.2 In the event that a claim or action is or may be asserted, the Study Center shall have the right to select and obtain representation by separate legal counsel. If the Study Center exercises such right, all costs and expenses incurred by the Study Center for such separate counsel shall be borne by the Study Center.

12.3 The Study Center agrees to indemnify and hold PharmaCo harmless from any and all liability, loss (including attorneys' fees), or damage it may suffer as the result of claims, demands, or judgments which are, or are alleged to be, arising out of:

(1) a failure to adhere to the terms of this Agreement, the Protocol, any other written instruction of PharmaCo;

(2) negligent or willful acts or omissions or any misuse of the Investigational New Drug by the Study Center, the Investigator or any other Researcher or by any other person on the Study Center's property, exclusive of PharmaCo's employees; or

(3) a breach of any applicable federal, state, or local laws, regulations, or guidelines, including any laws, by the Study Center, the Investigator or any other Researcher.

12.4 Each Party's agreement to indemnify and hold the other harmless is conditioned on the indemnified party (i) providing written notice to the indemnifying party of any claim, demand or action arising out of the indemnified activities within ten (10) days after the indemnified party has knowledge of such claim, demand or action, (ii) permitting the indemnifying party to assume full responsibility to investigate, prepare for and defend against any such claim or demand, (iii) assisting the indemnifying party, at the indemnifying party's reasonable expense, in the investigation of, preparation for and defense of any such claim or demand, and (iv) not compromising or settling such claim or demand without the indemnifying party's written consent.

12.5 PharmaCo agrees to assume the risk of all liability in connection with its use of any specimens delivered to it by the Study Center in connection with the Study and, further agrees to indemnify, defend and hold Study Center, its agents and employees harmless (including reasonable attorney's fees) arising as a result of any injury or damages relating to the shipment, handling, use, or subsequent transfer of the specimens by PharmaCo, its agents and employees.

12.6 Regardless of whether indemnification is sought under this Section 12.0, the Study Center shall inform PharmaCo of any allegation or threat of legal action that it receives pertaining to the Study.

12.7 Unless the Study Center is self-insured or unless other terms of insurance are required by law, the Study Center shall maintain during the performance of this Agreement [and for three (3) years after the termination of this Agreement], Commercial General Liability Insurance, including Products and Professional Liability coverage, in amounts not less than \$1,000,000 per occurrence and \$1,000,000 per accident for bodily injury and death and property damage liability insurance with limits of not less than \$1,000,000 per occurrence and \$1,000,000 per accident. Such insurance policies shall be issued

by insurers having an A.M. Best rating of at least A-VIII or be otherwise acceptable to PharmaCo. Upon request, the Study Center shall provide satisfactory evidence of its insurance or self-insurance and unless the Study Center is self-insured, shall provide to PharmaCo thirty (30) days prior written notice of any cancellation in its coverage. If other insurance is required by law, the Study Center shall inform PharmaCo of such legal requirements and shall certify in writing that it complies with these requirements.

13.0 INVENTIONS AND DATA.

13.1 PharmaCo shall exclusively own all rights, title and interests (collectively "Rights") in and to any inventions, data (including Study results and any clinical specimens or samples obtained from Subjects), discoveries, know-how, patents, copyrights, moral rights, trade and service marks, and trade secrets and other intellectual property, including but not limited to inventions, discoveries and technology relating to the Investigational New Drug or otherwise generated by the Study (collectively, the "Discoveries"). The Study Center and the Researchers hereby irrevocably transfer and assign any and all their Rights in any such Discoveries to PharmaCo. The Discoveries will be the sole property of PharmaCo and PharmaCo will have the right to determine the treatment of any Discoveries, including the right to keep them as trade secrets, to file and execute patent applications on it, to use and disclose it without prior patent application, to file copyright and trademark applications on it or its own name, or to follow any other procedure PharmaCo deems appropriate.

13.2 The Study Center and the Researchers agree: (1) to disclose promptly in writing to PharmaCo all Discoveries including but not limited to the surrender of all original lab books and other records; (2) to cooperate with and assist PharmaCo to apply for and to execute applications, assignments, affidavits, or other documents, reasonably necessary to obtain any patent, copyright, trademark or other statutory or other protection for Discoveries in PharmaCo's name as PharmaCo deems appropriate; and (3) to otherwise treat all Discoveries as Confidential Information.

13.3 Neither the Investigator nor the Study Center, including its employees or agents, shall acquire any rights of any kind whatsoever with respect to the Investigational New Drug as a result of performance under this Agreement or otherwise.

14.0 TERMINATION.

14.1 This Agreement may be terminated or suspended before the expiration of the Effective Period by the mutual written consent of the parties.

14.2 This Agreement may be terminated or suspended by either party upon immediate prior notice to the others if any of the following conditions occur:

(1) The authorization and approval to perform the Study in the United States is permanently withdrawn by the FDA or the IRB or any other lawful authority or authorization and is not restored within three months of suspension.

(2) PharmaCo deems termination appropriate upon reasonable grounds.

(3) The Investigator is unable to continue and an acceptable successor is not agreed upon.

14.3 In the event this Agreement is terminated for any reason prior to expiration of the Performance Period, the Study Center shall take all reasonable steps required by PharmaCo, including communicating

with the Subjects, to facilitate completion of the Study at an alternative clinical site designated by PharmaCo. In such event, PharmaCo will reimburse Study Center for its reasonable direct costs incurred in connection with such transfer, as well as for reasonable non-reimbursed costs incurred and non-cancelable commitments made prior to the receipt by the Study Center that the Agreement will be terminated.

14.4 Termination of this Agreement by either party shall not affect the rights and obligations of the parties that have accrued prior to the effective date of the termination.

15.0 CONFLICT OF INTEREST.

In order to avoid the potential for conflicts of interest as well as the appearance of such, the Study Center agrees that the Investigator, during the term of this Agreement, shall not hold any financial interest in PharmaCo, including but not limited to shares of stock of PharmaCo or options to purchase shares of stock of PharmaCo, without the prior written consent of PharmaCo, and that the Investigator shall not purchase or sell, whether for his own account or the account of any other person or entity, shares of PharmaCo stock. The Study Center shall ensure that the Investigator makes all other Researchers aware of this provision and shall make such provision fully applicable to them.

16.0 CHANGES TO PROTOCOL.

If at a future date changes to the Protocol are desired, such changes shall be made through prior written agreement between PharmaCo and the Study Center. If such changes affect the cost of the performance of the Study by the Study Center, the Study Center shall submit a written estimate of such cost to PharmaCo for prior approval. If in the course of performing this Agreement, however, generally accepted standards of clinical research and medical practice affecting the safety of the Subjects require a deviation from the Protocol, such standards shall be followed. In such case, the party aware of a need for a deviation shall immediately inform the other party of the facts necessitating the deviation. Any such changes or deviation from the Protocol shall be made in full compliance with all applicable laws, regulations and guidelines.

17.0 GENERAL PROVISIONS.

17.1 Entire Agreement.

This Agreement represents the entire understanding as of the date hereof between the parties with respect to the subject matter hereof, and supersedes all prior agreements, negotiations, understandings, representations, statements, and writings between the parties relating thereto. No modification, alteration, waiver, or change in any of the terms of this Agreement shall be valid or binding upon the parties hereto unless made in writing and duly executed by each of the parties hereto.

17.2 Headings.

Article and section headings contained in this Agreement are included for convenience only and form no part of the agreement between the parties.

17.3 Assignment.

(1) Study Center shall not assign this Agreement in whole or in part to any other party and shall not appoint any other person as Investigator without PharmaCo's written consent. PharmaCo may assign this Agreement in whole or in part to any corporate parent, affiliate or subsidiary of PharmaCo without Study Center's consent.

(2) The Agreement shall inure to the benefit of, and be binding upon, each party signatory hereto, its successors and permitted assigns. No assignment shall relieve either party of the performance of any accrued obligation which such party may at the time of assignment have under this Agreement.

17.4 Independent Contractors.

The Study Center, including its agents and employees, shall be an independent contractor at all times, and shall not be an agent of PharmaCo and shall have no actual, apparent or implied authority to bind PharmaCo in any manner or to any obligation whatsoever. The Investigator and the other Researchers shall not be deemed to be employees of PharmaCo and shall not be entitled to any benefits available to employees of PharmaCo.

17.5 Governing Law.

This Agreement is governed by the laws of the State of _____, not withstanding _____'s, or any other jurisdiction's, choice of law principles.

17.6 Notices.

All notices or other communications that are required or permitted hereunder shall be in writing and sufficient if delivered personally, sent by prepaid air courier, sent by mail, or sent by facsimile transmission, to the address set forth below or such other address as is subsequently specified in writing:

Study Center:	PharmaCo, Inc.:
Name	Name
Title	Title
Study Center	PharmaCo, Inc.
Address	Address
City, State ZIP	City, State, ZIP
000-000-0000 Telephone	000-000-0000 Telephone
000-000-0000 Facsimile	000-000-0000 Facsimile

Any such communication shall be deemed to have been given when delivered if personally delivered, on the business day after dispatch if sent by air courier, on the third business day following the date of mailing if sent by mail; and on the date of facsimile transmission if sent by facsimile transmission or electronic mail.

17.7 Severability.

If any one or more of the provisions of this Agreement shall be held to be invalid, illegal or unenforceable, the validity, legality or enforceability of the remaining provisions of this Agreement shall not in any way be affected or impaired thereby.

17.8 Waiver.

The failure of any party hereto to insist upon strict performance of any provision of this Agreement or to exercise any right hereunder will not constitute a waiver of that provision or right.

17.9 Survival.

The rights and duties under Sections 1, 4.2, 5.3, 5.4, 7, 8, 9, 10, 11, 12, 13 and 17 shall survive the termination or expiration of this Agreement.

17.10 Integration.

Any Exhibits to this Agreement are incorporated into and made part of this Agreement by reference.

The persons executing this Agreement represent and warrant that they have the full power and authority to enter into this Agreement on behalf of the persons or entities for whom they are signing.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed in duplicate counterpart original by their duly authorized representatives to be effective as of the date of this Agreement.

Study Center:

PharmaCo, Inc.:

By: _____

By: _____

Print Name: _____

Print Name: _____

Title: _____

Title: _____

Date: _____

Date: _____

I, _____, M.D., named as Investigator in this Agreement, acknowledge that I have read this Agreement in its entirety and that I have reviewed the obligations the Study Center has undertaken on my behalf. I agree to use best efforts to assist the Study Center in meeting those obligations.

Investigator:

By: _____

Print Name: _____

Title: Principal Investigator

Date: _____

EXHIBIT B
 PHARMACO, INC.
 CLINICAL STUDY BUDGET AND PAYMENT SCHEDULE
 NEW DRUG 004

 <TABLE>

<S>	<C>
PROTOCOL NO:	New Drug 004
STUDY CENTER:	Name
INVESTIGATOR:	Investigator
COMMENCEMENT DATE:	Month, Day, 201_
ANTICIPATED COMPLETION DATE:	September 30, 201_
COST PER SUBJECT:	\$ _____.00
ANTICIPATED ENROLLMENT:	150
PROJECTED TOTAL REIMBURSEMENT:	\$ _____ .00

BREAKDOWN OF PAYMENTS

I. INITIATION PAYMENT \$ _____.00

The Initial Payment shall be made within thirty (30) days, once a signed copy of the Agreement is returned to PharmaCo, all regulatory documents have been received and approved by PharmaCo. The Initial Payment shall be credited against ten (10) Per Subject Payments.

II. PAYMENT PER SUBJECT (a "Per Subject Payment") \$ _____.00

Per Subject Payments shall be made for evaluable, eligible Subjects only. An evaluable Subject is one for whom 16 CRFs, representing all visits by a Subject for 36 months, have been completed in accordance with the Protocol, completed the appropriate study procedures as set forth in the Protocol, and undergone the evaluations required by the Protocol for assessment of efficacy and safety. An eligible Subject is one that meets the inclusion/exclusion requirements of the Protocol, that was enrolled by the Study Center and from whom Informed Consent has been obtained. Per Subject Payments shall become due for each Subject upon PharmaCo's satisfactory review of all study documentation, including completed CRFs and close-out audits. A completed CRF is one that is signed by the Investigator and contains all complete verified information in accordance with the procedures and scheduled assessments as stated in the Protocol.

Subsequent payments shall be made quarterly, upon PharmaCo's receipt and satisfactory review of completed

case report forms. Quarterly payments shall be determined by the total number of subject visits and case report forms received, reviewed and accepted by PharmaCo within the preceding three month period for each quarter ending March 31, June 30, September 30 and December 31 during the term of this Agreement.

An amount equal to fifteen percent (15%) of all payments made during this Agreement shall be withheld by PharmaCo until all case report forms required to be completed under the Protocol have been received by PharmaCo and all Data discrepancies have been resolved at the end of the trial. Once resolved, the final payment is due within (30) days.

In the event that there are less than 16 completed CRFs for a Subject, PharmaCo shall only be obligated to make payment for such Subject on a pro-rated, completed CRF basis contingent on the date of discontinuation from the Study in accordance with the Protocol. Each completed CRF for enrolled and randomized subjects who do not complete all study visits shall be reimbursed at a rate of \$234.38.

For those subjects who sero-convert during the course of the clinical trial, they will rollover into the study schedule for _____ infected subjects as identified in Exhibit B-2 of the Protocol. Each completed CRF for enrolled subjects who rollover into the study schedule for _____ infected subjects will be reimbursed at a rate of \$____.00.