**Clinical Research Agreement**

THIS AGREEMENT is entered into by and between MATRIX PHARMACEUTICAL, INC., with its office and place of business at 1430 O'Brien Drive, Menlo Park, Ca. 94025 ("Sponsor") and The University of Texas \_\_\_\_\_\_\_, \_\_\_\_\_\_\_\_\_, \_\_\_\_\_\_\_\_\_\_\_\_, TX \_\_\_\_\_\_\_, ("Research Organization").

**Recitals**

A. Research Organization has expertise and facilities for clinical trials using \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

B. Sponsor desires that Research Organization undertake an evaluation of the safety and efficacy of the in accordance with the Research Study Protocol #\_\_\_\_\_\_ "                   " and any amendments thereto ("Research").

C. The performance of such research is of mutual interest to Sponsor and Research Organization and is consistent with the organizational purpose and research objectives of the Research Organization.

NOW THEREFORE, in consideration of the premises and mutual covenants herein contained, the parties hereto agree as follows:

**1. Statement of Work**

Research Organization agrees to use its best efforts to perform the Research as defined in the above referenced Research Study Protocol under the direction of \_\_\_\_\_\_\_\_\_\_ (the "Principal Investigator") in accordance with the instructions, timing and directions set forth therein. The Principal Investigator will be assisted by the following data managers responsible to him: \_\_\_\_\_\_\_\_\_\_. Completion of patient enrollment into the study on a population of \_\_\_\_\_\_\_ (            ) patients is anticipated by \_\_\_\_\_\_\_\_\_\_\_\_.

Research Organization understands and agrees that the Sponsor has enlisted Agreement in part because the Principal Investigator has represented to the best of his knowledge that he:

A. has read and understood the Research Protocol.

B. has adequate time and patient base to complete the study, given the magnitude of concurrent studies.

C. is fully acquainted with existing literature on the \_\_\_\_\_\_\_\_\_\_\_\_\_\_ to be evaluated and fully understand said product's investigational status.

Research Organization agrees to use its best efforts to assure that the Principal Investigator complies fully with the terms of the Agreement.

**2. Period of Performance**

This Agreement is effective for the period of one (1) year after execution by the last party to sign the Agreement or until the completion of the Research, whichever occurs later, and shall be extended only by written agreement signed by both parties. The conditions governing the rights and duties of the parties in any additional performance period shall be identical to those detailed herein, except the level of funding may be altered to reflect the agreed upon performance in the period over which the Agreement is extended.

**3. Independent Contractor**

Research Organization shall perform services hereunder only as an independent contractor without any right on the part of Sponsor to direct or control said services. Research Organization shall not be considered to be an employee or agent of Sponsor nor shall this Agreement constitute, create or in any way be interpreted as a joint venture, partnership or formal business organization of any kind.

**4. Consideration by Sponsor**

A. In consideration of Research Organization's performance under this Agreement, Sponsor shall pay Research Organization the maximum sum of $           for an estimated \_\_\_\_\_\_\_\_ patients in accordance with the Payment Schedule set forth in Exhibit B. The actual payments will also be adjusted on a pro rata basis for the actual number of patients enrolled, including any additional patients approved by Matrix in writing. Further, Sponsor shall fulfill its other obligations as defined in the Research. It is estimated that the amount defined above will be sufficient to support the costs of the Research, but Research Organization may submit to Sponsor, and Sponsor shall consider, a revised budget requesting additional funds when additional funding is necessary to support agreed upon changes in the Research or other reasons as may be described.

B. No payment will be made, or product shipped, without an identified data manager assigned to this study by the Principal Investigator.

**5. Reporting of Research Progress**

Research Organization shall make periodic reports to Sponsor, including a final written report on completion of the Research, on the performance of the Research under this Agreement, and shall promptly respond to Sponsor's reasonable inquiries regarding the status of the Research.

Research Organization understands and agrees that the Principal Investigator is required to:

A. keep, maintain, and return adequate records of all receipts and dispositions of the product, including dates, quantity, and use by the patients, as required by the Research or by federal, state and institutional regulations.

B. on the suspension, termination, discontinuation, or completion of the study, return any unused supply of the product to the Sponsor.

C. take adequate precautions to limit access to the product, including the maintenance of locked storage in accordance with applicable federal, state, and institutional regulations.

D. keep, maintain and retain patient records and other records as required by the Research or by applicable federal, state, and institutional regulations.

E. prepare, submit, and retain copies of case reports on forms provided by Sponsor, a final report, and special reports as required by the Research or by applicable federal, state and institutional regulations.

F. permit Sponsor, or Sponsor's Monitor, reasonable access to records kept, maintained and retained in connection with this study, to facilities used in this study and to the Principal Investigator and Sub-Investigators, subject to applicable laws and regulations.

G. permit FDA reasonable access to all records, facilities and investigators as required by FDA regulations.

**6. Patents and Inventions**

To the extent permitted by existing Research Organization policies and regulations, Sponsor shall be given the first right of refusal to obtain a royalty-bearing, world-wide, exclusive license to any patentable inventions made by the Research Organization in carrying out the Research. The previously stated right of first refusal must be exercised no later than one hundred eighty (180) days after Sponsor has been notified of the option by Research Organization. This license shall contain reasonable terms based on industry standards in agreements relating to similar products and technology, Sponsor's financial and technical contribution, and any other relevant facts.

**7. Publication**

Research Organization shall have the right to publish any material resulting from Research under this Agreement. In this regard, Research Organization shall furnish Sponsor with a copy of any proposed publication at least thirty (30) days in advance of the proposed submission date. Within this thirty day period, Sponsor shall review said proposed publication for technical content, including patentable inventions, and for the disclosure of any proprietary information which Sponsor may have furnished to facilitate Research under this Agreement, and the Sponsor shall inform Research Organization in writing of the location and content of specific Proprietary Information (Proprietary Information is defined as it is in the Confidential Disclosure Agreement, attached hereto as Exhibit C) contained in the proposed publication and of potentially patentable inventions which are disclosed in the proposed publication. Upon receiving the appropriate written notification from Sponsor, Research Organization shall consider Sponsor's request to remove Sponsor's Proprietary Information, and if such Proprietary Information has been previously marked and identified as such to Research Organization, Research Organization will delete such Proprietary Information and shall delay submission thirty (30) days until the appropriate patent application(s) can be filed by Research Organization. Sponsor shall have the option of receiving an acknowledgement on the publication of its sponsorship of the Research.

**8. Representations by Research Organization**

Research Organization represents that it will obtain from all individuals subject to treatment according to the Research, a properly executed Informed Consent. Moreover, Research Organization represents that this Informed Consent form complies with all applicable federal and state laws and regulations. Research Organization understands and agrees that Principal Investigator is required to:

A. obtain Institutional Review Board (IRB) approval of the Research and associated Informed Consent material prior to enrolling patients or implementing the Research.

B. obtain IRB approval of any changes to the Research and associated Informed Consent material prior to implementing such changes.

C. respond promptly and fully to IRB inquires.

D. comply with IRB requirements and applicable federal, state, and institutional regulations concerning periodic review of the study by the IRB and submission of reports to the IRB.

E. conduct the study in compliance with the Research and with applicable federal, state, and institutional regulations.

F. obtain proper Informed Consent prior to enrolling any patient into the study.

G. exercise such care as required by the industry in performing the tasks called for under the Research and this Agreement.

H. permit only himself as Principal Investigator, Sub-Investigator(s), or trained staff under direct supervision of the Principal Investigator to dispense, administer or dispose of the \_\_\_\_\_\_\_\_\_\_\_\_\_ under study in accordance with the Research Protocol.

I. terminate the study of an individual patient whenever the patient so requests, the Principal Investigator so decides, or the Sponsor or U.S. Food and Drug Administration so directs.

J. terminate the entire study if the Principal Investigator, the IRB, the Sponsor, or the U.S. Food and Drug Administration so advises.

**9. Indemnification**

A. Research Organization shall, to the extent authorized under the Constitution and laws of the State of Texas, hold Sponsor harmless from liability resulting from the negligent acts or omissions of Research Organization, its agents or employees pertaining to the activities to be carried out pursuant to the obligations of this Agreement; provided, however, that Research Organization shall not hold Sponsor harmless from claims arising out of the negligence or willful malfeasance of Sponsor, its officers, agents, or employees, or any person or entity not subject to Research Organization's supervision or control.

B. Sponsor shall indemnify and hold harmless The University of Texas System, Research Organization, their regents, officers, agents and employees from any liability or loss resulting from judgments or claims against them arising out of the activities to be carried out pursuant to the obligations of this Agreement, including but not limited to the use by Sponsor of the results of the Research; provided, however, that the following is excluded from Sponsor's obligation to indemnify and hold harmless:

a. the negligent failure of Research Organization to comply with any applicable governmental requirements or to adhere to the terms of the Research Study Protocol; or

b. the negligence or willful malfeasance by a regent, officer, agent, or employee of Research Organization or The University of Texas System.

C. Sponsor's obligation hereunder shall be conditioned upon Research Organization notifying Sponsor within thirty (30) days of any claim made against Research Organization as a result of this Research and Research Organization fully cooperating with Sponsor in defending any such claim, subject to the statutory duties of the Texas Attorney General.

**10. Notices**

Any notices given under this Agreement shall be in writing and delivered by first-class mail, postage prepaid, or by facsimile transmission addressed to the parties as follows:

|  |  |
| --- | --- |
| Research Organization | The University of Texas \_\_\_\_\_\_\_\_ |
|  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, TX \_\_\_\_\_\_\_\_\_\_\_ |
|  | Attn: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  |  |
| Sponsor | Matrix Pharmaceutical, Inc.1430 O'Brien DriveMenlo Park, CA 94025 Attn: Andrew Korey, Ph.D.  |
|  | Vice President Medical and Regulatory Affairs |

**11. Headlines**

The paragraph headings herein are for convenience only and shall not affect the construction or interpretation of this Agreement.

**12. Entire Agreement**

This Agreement and its Exhibits, which are made part of this Agreement, contain the entire agreement between the parties. No amendments or changes to this Agreement shall be effective unless made in writing and signed by authorized representatives of Research Organization and Sponsor.

**13. Governing Law**

This Agreement shall be governed by the laws of the State of Texas.

Both parties agree to comply with all applicable state and federal laws and regulations.

**14. Effective Date**

This Agreement shall be effective on the last date indicated below by which all parties have executed this document.

**15. Authority**

A. The undersigned representative of Sponsor acknowledges that he has complete and unconditional authority to execute this Agreement on behalf of Sponsor and that such Agreement has been executed following applicable procedural requirements of Sponsor.

B. The undersigned representative of Research Organization acknowledges that he has authority, subject to approval by The University of Texas System Board of Regents, to execute this Agreement in behalf of Research Organization and that such Agreement has been executed following applicable procedure requirements of Research Organization.

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

|  |  |
| --- | --- |
| University of Texas \_\_\_\_\_\_\_\_\_\_\_\_ By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_                                Name Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  | Matrix Pharmaceutical, Inc. By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_                                Name Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  |

I have read this Agreement and understand
my obligations hereunder.

By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
                   (Principal Investigator)

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Attachments:     Exhibit A = General Terms and Conditions
                        Exhibit B = Research Project Budget and Payment Schedule
                        Exhibit C = Confidential Disclosure Agreement



**EXHIBIT A**

GENERAL TERMS AND CONDITIONS

Research Protocol # \_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**1. Independent Research**

Nothing in this Agreement shall be construed as to limit the freedom of individuals participating in this work, whether paid under this Agreement or not, to engage in similar inquiries made independently under other grants, contracts or agreements with parties other than Sponsor.

**2. Publicity**

Neither party shall use the name of the other in connection with any products, promotions, or advertising without the prior written permission of the other party.

**3. Termination**

This Research may be terminated for any reason by the Research Organization or Sponsor when in their independent and sole judgment or that of the Principal Investigator or the Food and Drug Administration, it is inappropriate, impractical, or inadvisable to continue. Upon termination initiated hereunder, the Research Organization shall be reimbursed for its costs incurred to the date of notification of the decision to terminate in accordance with the Notices article and Payment Schedule (Exhibit B).

**4. Warranties**

Other than specifically provided hereinbefore, neither party makes any warranties, express or implied, as to the merchantability or fitness for a particular purpose of any Research results.

**5. Force Majeure**

The Research Organization and Sponsor shall be excused for any failure to perform as required by this Agreement, only to the extent such failure to perform is caused by any labor disturbances or labor disputes of any kind, accidents, failure of any governmental aggression, floods, earthquakes, acts of God, energy or other conservation measures, explosion, failure of utilities, mechanical breakdowns, material shortages, disease, or other such occurrences, which are not within Research Organization's control and, the happening of which is not due to any fault or negligence on the part of Research Organization. Such excuse shall be valid so long as the condition or event preventing the performance continues to exist.

**6. Nondiscrimination**

The Research Organization shall not discriminate against any employee or applicant for employment because of race, religion, national origin, sex, age or physical limitation, except where sex, age, or physical limitation is a bona fide occupational qualification.

**7. Assignment**

Neither party shall assign this Agreement to another without the prior written consent of the other party, which consent shall not be unreasonably withheld; provided, however that Sponsor may assign this Agreement to a successor in ownership of all or substantially all its business assets relating to . Such successor shall expressly assume in writing the obligation to perform in accordance with the terms and conditions of this Agreement. Any other purported assignment shall be void.

**8. Severability**

In the event a court of competent jurisdiction holds any provision of this Agreement to be invalid, such holding shall have no effect on the remaining provisions of this Agreement, and they shall continue in full force and effect.



**EXHIBIT B**

RESEARCH PROJECT BUDGET AND PAYMENT SCHEDULE

Research Protocol #

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
(Principal Investigator)

I. PRO RATA SCHEDULE PER PATIENT

|  |  |
| --- | --- |
| A. Screening, Treatment Phase and Follow-up Week 7    | $        |
|     | (dollar amount)  |
| B. Follow-up Month 1    | $        |
|     | (dollar amount)  |
| C. Follow-up Month 2    | $        |
|     | (dollar amount)  |
| D. Follow-up Month 3    | $        |
|     | (dollar amount)  |
| **TOTAL MAXIMUM PER PATIENT**    | $        |
|     | (dollar amount)  |
| Total number of patients    | x         |  |
|  | **(total #of patients)**  |  |
| **TOTAL PAYMENT** | $\_\_\_\_  |  |

In the event of premature termination of this study, payments will be prorated in accordance with the schedule as outlined above. Payment will be made based on completed case report forms received by Matrix Pharmaceutical, Inc. No payment will be made before conditions listed below.

II. PAYMENT SCHEDULE

Payments will be made according to the following schedule:

A. Fully executed contract and enrollment of the first patient              $

B. Quarterly thereafter, based on payment for completed patients, beginning with study completion of the \_\_\_\_ patient.

The Research Organization is responsible for all fees and charges incurred in the conduct of this study including but not limited to charges for use of facilities, nursing, laboratory, pharmacy and other services.

III. PAYMENTS

|  |  |
| --- | --- |
| Checks made out to:    | The University of Texas \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Address:   | c/o \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  |
|  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, Texas \_\_\_\_\_\_\_\_  |

ATTN:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
              Federal ID Number:

EXHIBIT C

CONFIDENTIAL DISCLOSURE AGREEMENT

Research Protocol # \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
(Principal Investigator)

1. Receiver agrees to the extent authorized by the Constitution and the laws of the State of Texas to hold harmless Matrix from any loss or harm caused by any negligent breach of Receiver's obligations hereunder, including any negligent and unauthorized disclosure or use of the Proprietary Information. Receiver agrees to notify Matrix immediately upon any occurrence of such breach or unauthorized use or disclosure and shall assist Matrix in mitigating the consequences thereof.

2. This Agreement shall be governed by and construed in accordance with the internal laws of the State of Texas without regard to the conflicts of law provisions thereof.