**RESEARCH AND STUDY AGREEMENT**

This Agreement, entered into this \_\_\_\_ day of \_\_\_\_\_\_\_\_, 1991, by and between Fujisawa Pharmaceutical Company, a Division of Fujisawa USA, Inc., a Delaware Corporation with its principal place of business at Parkway North Center, Three Parkway North, Deerfield, Illinois 60015 (hereinafter "FUSA"), The University of Texas \_\_\_\_\_\_\_\_, with its principal place of business at \_\_\_\_\_\_\_, \_\_\_\_\_\_\_\_, Texas 75235, (hereinafter "Hospital"), a component of the University of Texas System (hereinafter "System"). \_\_\_\_\_\_\_\_\_\_\_\_\_\_ shall be "Principal Investigator" hereunder.

WHEREAS, the parties have prepared a protocol (hereinafter "Protocol") for research and study and a budget (hereinafter "Budget"), on \_\_\_\_\_\_\_\_\_; and

WHEREAS, the parties wish to provide for the orderly implementation of the research and study outlined in the Protocol and the Budget, copies of which are attached hereto and incorporated herein as Exhibits "A" and "B", respectively; and

WHEREAS, the parties agree that the studies and research to be performed is very important and of great value; and

WHEREAS, the parties agree that the studies and research to be performed must be performed in a timely and careful manner.

NOW, THEREFORE, the parties have agreed as follows:

1. Performance The Hospital and Principal Investigator will perform, or cause to be performed, the research and study described in the Protocol and Budget ("Study"). All Exhibits shall become an integral and essential part of this Agreement. Such Study will be performed as soon as possible, but in no event later than three (3) months after Hospital receives the necessary supplies from FUSA. Principal Investigator agrees to direct the overall implementation of the Study in a careful, accurate and diligent manner. Such procedures and techniques used by the Hospital and the Principal Investigator shall conform with all U.S. Food and Drug Administration standards, and regulations as well as generally accepted clinical standards. Hospital and Principal Investigator agree to use their best reasonable efforts to conform with not only the letter of the Protocol but the spirit as well. To this end Hospital and Principal Investigator will attempt to have a continuity of personnel administering the Protocol. The Principal Investigator shall not be removed or replaced without the prior consent of FUSA. In the event a new Principal Investigator cannot be mutually agreed upon, this Agreement may be terminated by either party.

2. Payment The total fee to be paid to Hospital is \_\_\_\_\_\_\_\_\_\_. This sum shall be paid in three equal installments as follows:

- One-third of the total shall be paid within ten (10) days of the execution hereof;

- One-third of the total shall be paid when Hospital has completed and filed reports on two-thirds or more of the research to be performed hereunder;

- One-third of the total shall be paid at the conclusion of the Study when all completed reports are received by FUSA in a form completed in a good and workmanlike order.

3. New Drug Application The parties recognize that the information produced by the Study under this Agreement will be used by FUSA to apply for a New Drug Application ("NDA") with the U.S. Food and Drug Administration ("FDA"). The parties also recognize that the FDA will routinely have follow-up questions regarding the NDA. Because FUSA will require the continuing assistance of the Hospital and the Principal Investigator to respond to such questions, Hospital and Principal Investigator agree to:

(a) continue to assist FUSA to prepare the NDA;

(b) respond to such FDA follow-up questions;

(c) explain and provide background on the Study performed;

(d) allow FUSA to review their files and results at any time; and

(e) work with FUSA to reasonably resolve any disputes in the administration of the Study.

4. Proprietary Information All data directly resulting from performance of the Protocol under this Agreement shall become the property of FUSA. Because of the highly secretive and valuable nature of this research, FUSA, the Hospital and Principal Investigator shall require all persons involved in the Study to be restricted by the obligation to maintain confidentiality of information as set forth in paragraph 9 of this Agreement.

5. Accounting The money paid by FUSA to Hospital shall be expended only for the work under this Agreement in a manner to be reasonably determined by Hospital in accordance with the Budget. At FUSA's request, Hospital will provide FUSA with an accounting of funds supplied by FUSA and spent by Hospital. Hospital agrees that FUSA shall be allowed to audit the accounting records pertaining to the performance of this Study during the term of the Agreement and for up to two (2) years following the Study close-out during ordinary business hours and at reasonable times.

6. Records Hospital shall cause individuals conducting research under this Agreement to keep complete and systematic written records of all work performed and data developed. Hospital shall make all such records available for inspection by an authorized representative of FUSA and/or FDA during Hospital's regular working hours. At FUSA's request, Hospital shall furnish copies of all, or any part, of such records to FUSA.

7. Consultation During the term of this Agreement, FUSA representatives may consult personally, by correspondence or by telephone with Hospital representatives regarding the work to be performed under this Agreement. FUSA may also work closely with the Hospital on the work to be performed under this Agreement.

8. Reporting Hospital shall make bi-monthly reports to FUSA of the research conducted under this Agreement as FUSA shall direct. Such reports shall include without limitation the results of such research, including a description of all inventions made, a brief description of scientific progress to date including attainment of objectives established for the complete period, problems encountered and plans for the forthcoming period. Upon completion of the Study or termination of this Agreement, whichever is earlier, Hospital shall submit a brief final, report including Study results, supporting data, etc. This final report shall be due within sixty (60) days after completion of such Study. FUSA shall treat all invention disclosures made hereunder as Confidential Information.

9. Confidentiality Except as otherwise required by law or regulation, FUSA, the Hospital, the Principal Investigator, and all hospital personnel assigned to this project agree or shall agree to keep confidential and secret all information relating to performance of the Study received in writing from the other party, including the data generated by performance of the Protocol ("Confidential Information"). No System employee other than those of Hospital will have access to or use FUSA's Confidential Information without written consent of FUSA. The obligation to keep information confidential shall not apply to:

(a) information which can be shown to have been in the possession of the receiving party prior to being produced hereunder;

(b) information which is now, or later becomes, generally available to the public without breach hereof; and,

(c) information which is received from a third party who has the right to disclose such information without restrictions; or

(d) information which is required by law to be disclosed or which is independently developed by personnel of the recipient party without access to the information.

Hospital and Principal Investigator shall be allowed to publish findings of the research under the conditions set forth herein.

All publications resulting from the research and study or publications resulting from the collaborative effort must be in a form which does not reveal the Confidential Information of the other party, except that Hospital publications may contain analysis of data resulting from the performance of the Study. A draft of a manuscript proposed for publication will be submitted to FUSA by Hospital thirty (30) days before submission of the final form to any journal, scientific conference and/or symposium. FUSA will then promptly inform Hospital of any changes or deletions in such manuscripts necessary to preserve FUSA's Confidential Information before the expiration of the thirty (30) day period. If the parties disagree concerning the appropriateness of the data analysis and presentation, Hospital agrees to meet with FUSA's representatives for the purpose of making good faith efforts to discuss and resolve any issues or disagreement.

Nothing herein however shall prevent the Hospital or any other component of the System from using information generated or published in accordance with the terms of this Agreement for ordinary research and educational purposes of a university.

10. Subcontract The Hospital may not subcontract or assign any portion of the Study contemplated hereunder without the prior written consent of FUSA. If it is necessary for Hospital to subcontract a portion of the Study contemplated hereunder and FUSA gives prior written authorization, any third party to whom information is disclosed in connection with the subcontracting of such Study is subject to the confidentiality requirements and invention requirements outlined in paragraph 9 of this Agreement, and will be required to execute a Nondisclosure Agreement with FUSA to that effect.

11. Liability The Hospital agrees, to the extent authorized under the constitution and laws of the State of Texas, to hold FUSA harmless from liability whatsoever for damages, or claims for damages or other relief, resulting from the negligent acts of Hospital's employees, agents or faculty in the performance of any research or study not specifically authorized by the Study or performed in accordance with the Study, but in a negligent manner. FUSA will cooperate with Hospital in its efforts to defend against any such claims. FUSA expressly agrees to indemnify and hold the Hospital, System, their Regents, officers, agents and employees, and the Principal Investigator harmless from and against any claim that may arise against them from their faithful performance of the Protocol.

12. Independent Contractor In performing the services under this Agreement, both Hospital and Principal Investigator acknowledge that they are acting as independent contractors and not as agents or employees of FUSA. Hospital and Principal Investigator shall have no authority to make any representations, or to take any action, which shall be binding upon FUSA except as is provided for herein or as is otherwise authorized in writing by FUSA.

13. Notice Notice and communication under this Agreement shall be in writing and shall be deemed sufficiently given if sent by certified or registered mail, postage prepaid, to the parties at the following addresses, or to such other addresses as shall be designated in writing by either party:

To Hospital:      University of \_\_\_\_\_\_\_\_  
                         \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
                         \_\_\_\_\_\_\_\_\_\_\_\_, Texas   
                         Attn: \_\_\_\_\_\_\_\_\_\_\_\_\_\_

To FUSA:        Fujisawa Pharmaceutical Company,  
                        Division Fujisawa USA, Inc.  
                        Parkway North Center  
                        Three Parkway North  
                        Deerfield, Illinois 60015  
                        Attn: General Counsel

14. Assignment FUSA may sell, transfer or assign its rights under this Agreement to a third party with the consent of Hospital. This Agreement shall be binding and inure to the benefit of the parties hereto and their successors, assigns, heirs and legal representatives.

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

16. Terms Services of the Hospital are to commence as of the first service performed hereunder, and shall continue until all services contemplated by this Agreement have been fully performed. FUSA shall, however, have the right to terminate this Agreement at its discretion with written notice to the Hospital and Principal Investigator, but shall be liable for all payments accrued prior to the date of termination according to Exhibit "B". Hospital shall, however, have the right to terminate this Agreement at its discretion with written notice to FUSA and Principal Investigator.

17. Breach Upon the material breach of the Hospital or Principal Investigators of any of the respective obligations under this Agreement, FUSA shall have the absolute and unqualified right to terminate this Agreement.

18. Severability The invalidity or unenforceability of any non-material particular word, phrase, sentence, paragraph or provision of this Agreement shall not affect the other words, phrases, sentences, paragraphs or provisions hereof, and this Agreement shall be construed in all respects as if such invalid or unenforceable provisions were omitted and the remainder construed so as to give them meaningful and valid effect. It is the intention of the parties that if any particular provision of this Agreement is capable of two constructions, one of which would render the provision void, the other of which would render the provision valid, the provision shall have the meaning which renders it valid.

19. Authority The Agreement constitutes the entire Agreement between the parties. It supersedes all prior and contemporaneous communications, representations or agreements whether oral or written with respect to the subject matter thereof and has been induced by no representations, statements or Agreements other than those herein expressed. No agreement hereafter made between the parties shall be binding on either party unless reduced to writing and signed by an authorized officer of the party sought to be bound thereby.

20. Waiver No failure of either party to exercise any of the rights and options granted hereunder, or to insist upon strict compliance, and no custom or practice of the parties at variation with the terms hereof shall constitute any waiver of either parties right to demand exact compliance with the terms hereof. A waiver by either of any specific default shall not affect or impair the right of the other party with respect to any subsequent default of the same or different nature, nor shall any delay or omission to exercise any rights arising from a default affect or impair rights of either party to such default or any subsequent default.

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first stated above.

|  |  |
| --- | --- |
| AGREED TO AND ACCEPTED:  UNIVERSITY OF TEXAS \_\_\_\_\_\_\_\_    By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | AGREED TO AND ACCEPTED:  FUJISAWA PHARMACEUTICAL COMPANY DIVISION FUJISAWA USA, INC. A DELAWARE CORPORATION  By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

I have read this agreement and   
understand my obligations  
hereunder:

By:                                   
      Principal Investigator

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

horizontal rule

**EXHIBIT B**

**RESEARCH AND STUDY AGREEMENT**

**BETWEEN**

**THE UNIVERSITY OF TEXAS**

**AND**

**FUJISAWA PHARMACEUTICAL COMPANY**

**"\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_"**

The approximate distribution of expenses related to the STUDY described in the covering Agreement is as follows:

|  |  |
| --- | --- |
| Salaries (including fringe benefits)  Data Management Costs  Supplies and Other Miscellaneous  Indirect Costs (institutional overhead)                                          TOTAL | $        .00            .00            .00            .00  $        .00 |

Such expenses are provided for information only. INSTITUTION reserves the right to modify the distribution of such expenses as necessary in the circumstances, provided that the stipulated total cost of $    .00 and the line item for total indirect overhead cost of $    .00 are not exceeded.

**FUJISAWA  
Revised \_\_\_\_\_\_**