**CLINICAL TRIAL RESEARCH AGREEMENT**

This Agreement is entered into this \_\_\_\_ day of \_\_\_\_\_\_, 1993, by and between The University of Texas \_\_\_\_\_\_\_\_\_, hereinafter called "Institution," and SCHERING-PLOUGH RESEARCH INSTITUTE, a Delaware corporation with its office and place of business at 2015 Galloping Hill Road, Kenilworth, New Jersey 07033, hereinafter called "Sponsor."

Sponsor desires Institution to study the safety and/or efficacy of **[DRUG]** (the "Study Drug") 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 "                 " (the "Protocol") which is attached as Exhibit A and incorporated into this Agreement by reference. The Protocol includes a suggested informed consent form (the "Informed Consent"). 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 conformity with all applicable federal, state and local laws and regulations. Institution further 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.

**2. Principal Investigator**

Institution's Principal Investigator is \_\_\_\_\_\_\_\_\_\_\_\_, (who with any sub-investigators shall be collectively referred to as "Principal Investigator"). 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.

**3. Project Monitor**

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 the Principal Investigator or his/her designee:

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

**4. Clinical Trial Approvals**

A. Institution shall be responsible for obtaining the following:

(i) approval of the Protocol, any 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 begining any study on human subjects.

(ii) an informed consent which complyies with all applicable federal, state, and local laws and regulations signed by or on behalf of each human subject prior to the subjects participating in the Study.

B. In the event Institution's IRB requires changes in the Protocol or informed consent, Sponsor shall be advised in advance and all modifications to the Protocol and informed consent must be approved in advance by Sponsor. Institution and the 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 on \_\_\_\_\_\_\_\_\_, and shall continue until the Study is completed and all final Study documentation 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 reasonably 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 drug treatment 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 material obligations, responsibilities and the material terms and conditions of this Agreement and the Protocol;

C. In the event of 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 obligations (under Article 7 hereof);

(iii) obtaining review of any publications (under Article 10 hereof) and approval of publicity and promotional statements (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 Article 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. 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 subject to Institution's right to publish the results as set forth in Article 10.

B. Institution agrees to notify Sponsor within twenty-four (24) hours after learning of any serious and/or unexpected adverse drug reaction affecting any patient in the Study. Institution further agrees 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. Institution further agrees to conduct the Study and maintain records and data during and after the term or early termination of this Agreement in compliance with all applicable legal and regulatory requirements, including without limitation, any applicable requirements of the FDA. Institution further agrees 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).

D. Institution agrees to notify Sponsor promptly or at most within three (3) days in the event that the FDA or any other regulatory authority notifies the Study site of a pending inspection/audit. In addition, Institution will promptly forward to Sponsor any written communication received as a result of the inspection/audit and agrees to allow Sponsor to assist in responding to any citations. Such responses shall be made within two (2) weeks of issuance of any citations or within any earlier deadline set by the issuing regulatory authority. Institution shall also provide to Sponsor copies of any documents provided to any inspector or auditor.

**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.

**9. Confidential Information**

A. During and for a period of five (5) years after the term or early termination of this Agreement, Institution 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 or Principal Investigator);

(ii) which is lawfully made available to Institution 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 possession at the time of receipt from Sponsor (and such prior possession can be properly demonstrated by Institution);

(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 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 agrees to promptly return to Sponsor, upon its request, all Confidential Information obtained from Sponsor or belonging to Sponsor pursuant to this Agreement; provided, however, that Institution may retain one copy of Confidential Information in a secure location for purposes of identifying Institution's obligations under these confidentiality provisions.

D. Institution 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 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 shall be responsible for any breach of these confidentiality provisions by its Agents.

**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. Institution agrees that all research data and results generated during the course of the study shall be the property of Sponsor, subject to Institution's right to publish the results. Institution further agrees 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. Institution further agrees to provide thirty (30) 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, including without limitation interim results, arising out of the Study. Sponsor shall have 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.

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 or until the passage of eighteen (18) months from the completion of Institution's performance of the Study. 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 s 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 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.

F. Institution is granted the right, subject to the provisions of this Agreement, to use the results of work 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 teaching and research purposes. Institution agrees, on behalf of itself and its employees, officers, trustees, and agents, not to cause said results to be knowingly used for any commercial purpose whatsoever except as set forth in Section 13 below.

**11. Clinical Supplies**

Sponsor shall make available sufficient quantities of Study Drug to carry out the Study, it being understood that Institution and the 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 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.

**12. Indemnification and Insurance**

A. Sponsor shall indemnify, defend and hold harmless Institution, the University of Texas System, their Regents, 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, or damage to property, arising out of or connected with the performance of the activities to be carried out pursuant to the Protocol including, without limitation, the use by Sponsor of the results of the study.

B. Notwithstanding the foregoing, Sponsor shall have no indemnification obligation or liability for loss or damage resulting from:

(i) failure of Institution 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 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 to render professional service or to conduct the study in a normal, prudent manner or

(iv) negligent act or omission or willful malfeasance by 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. Subject to the statutory duties of the Texas Attorney General, Principal Investigator and Institution agree to cooperate with and to authorize Sponsor to carry out sole 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, to the extent authorized under the Constitution and laws of the State of Texas, indemnify and hold Sponsor harmless from liability resulting from the negligent acts or omissions of Institution, its agents or employees pertaining to the activities to be carried out pursuant to the obligations of this Agreement; provided, however, that Institution 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 Institution's supervision or control.

E. Each component of The University of Texas System is self-insured pursuant to The University of Texas System Professional Medical Malpractice Self-Insurance Plan, under the authority of Section 59.01, Texas Education Code. The University/Institution has and will maintain in force during the term of its agreements with third parties adequate insurance to cover its indemnification obligations.

F. Sponsor, as with most major pharmaceutical companies, is largely self-insured for its liability exposures. Sponsor's assets are sufficient to cover any contemplated self-insured liability assumed by Sponsor under this Agreement.

**13. Inventions and Patents**

**[This paragraph is for use in clinical trials where the Protocol is Sponsor's.]**

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 and Study under this Agreement and using Study funds or otherwise arising out of use of the Study Drug (the "Inventions" shall be the property of the Sponsor. Institution will promptly notify Sponsor in writing of any such Inventions, and at Sponsor's request, and expense, Institution 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:

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| To Institution: | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Attn.: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| To Sponsor: | Schering-Plough Research Institute2015 Galloping Hill RoadKenilworth, New Jersey 07033Attn: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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 the 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. Applicable Law**

This Agreement shall be construed in accordance with Texas law.

**17. Publicity**

Neither party shall make reference to the other in a press release or any other written statement in connection with work performed under this Agreement, if it is intended for use in the public media, except as required by the Texas Public Information Act or other law or regulation. Institution, however, shall have the right to acknowledge Sponsor's support of the investigations under this Agreement in scientific or academic publications and other scientific or academic communications, without Sponsor's prior approval. In any such statements, the parties shall describe the scope and nature of their participation accurately and appropriately.

**18. Independent Contractor**

It is agreed by the parties that Institution is acting in the capacity of independent contractor hereunder and not as employee or agent or joint venturer of or with Sponsor. Institution does not have any authority to represent, bind or act on behalf of Sponsor.

**19. Agreement Modifications**

Neither this Agreement nor the Protocol may not be altered, amended or modified except by written document signed by both parties.

**20. 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.

**21. 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.

**22. 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 it best efforts to cause the event of such force majeure to terminate, be cured or otherwise ended.

**23. Employee Obligations to Perform Services**

Institution represents that the Principal Investigator and all other investigators that may perform services hereunder are its employees and shall abide by the terms and conditions of this Agreement as if each were a party hereto.

**24. 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 respect of the subject matter hereof. In the event of any inconsistency between this Agreement and the attached Protocol (Exhibit A), 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 hereto.

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

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| --- | --- |
| University of Texas \_\_\_\_\_\_\_\_\_\_\_\_ By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_                                Name Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  | Schering-Plough Research Institute By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_                                Name Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  |

I have read this Agreement and understand
my obligations hereunder.

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

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



**EXHIBIT A**



SCHERING
Revised 3/4/96