**PFIZER INC.**

**CLINICAL STUDY AGREEMENT**

This Clinical Study shall establish the following terms of your contract with Pfizer Inc:

1. The University of Texas , hereinafter referred to as "INSTITUTION," with its employee , M.D. as "INVESTIGATOR", located at \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ ,\_\_\_\_\_\_\_\_\_\_ , TX \_\_\_\_\_\_, agree to conduct a clinical study of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ hereinafter referred to as "DRUG", in accordance with the provisions of protocol number \_\_\_\_\_\_\_\_\_\_\_\_, entitled \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, Schedule A, attached hereto and made part hereof, which has been approved by the INSTITUTION, the INVESTIGATOR, the Institutional Review Board and Pfizer Inc, hereinafter referred to as "Pfizer".

2.

a) The approved payment rate for the study is $\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ per "completed" patient (as defined in paragraph 3) with a maximum approved contract price of $\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. In the case of partially completed patients, the payment will be proportional to the work performed.

b) The first payment of $\_\_\_\_\_\_\_\_\_\_\_\_\_ represents an advance payment against payments which are anticipated to be due to the INSTITUTION as a result of work performed under this Agreement. This amount shall be payable at the time this Agreement is signed by both parties. Subsequent payments will be disbursed according to the provisions of Schedule B attached hereto and made a part hereof.

c) All amounts due under this Agreement shall be paid to The University of Texas \_\_\_\_\_\_\_\_\_\_\_\_\_, Attn:\_\_\_\_\_\_\_\_\_\_\_\_ , hereinafter referred to as "PAYEE", Tax ID #\_\_\_\_\_\_\_\_\_.

3. A patient shall be considered "completed" for the purpose of this Agreement when all of the following criteria are met.

a) Receipt of Pfizer of complete and legible (either handwritten in black ballpoint pen or typed) case report forms representing all forms provided to the INVESTIGATOR by Pfizer for each patient entered in the study.

b) Completion of the full course of medication and/or participation through the course of the study with appropriate recording on case report forms of all the test assessments contained in the protocol.

c) Compliance with all other aspects of the protocol.

4. The study may be terminated by written notice from Pfizer to the INSTITUTION and the INVESTIGATOR for any of the following reasons:

a) Notification to Pfizer from Federal or State Regulatory Authorities to terminate said study.

b) Determination by Pfizer that the INVESTIGATOR is not performing the study as required in the protocol and/or is not meeting the agreed upon enrollment schedule of two (2) patients per month.

c) Failure of the INVESTIGATOR and/or the INSTITUTION to provide access by Pfizer representatives to any and all original medical records necessary to verify entries on study case report forms.

d) Failure of the INVESTIGATOR, associates or any other person engaged in this study (excluding patients) to be available, upon reasonable notice by Pfizer, to meet with Pfizer representatives during the course of the study as necessary to discuss information relevant to the study.

e) Failure of the INVESTIGATOR to comply with all regulatory requirements as delineated in Form FDA-1572 signed by the INVESTIGATOR.

f) Change of the INVESTIGATOR.

g) Determination by Pfizer that scientific or business considerations require termination.

5. In the event that Pfizer wishes to exercise its right to terminate this study, written notice of its decision to exercise such right shall be given by registered mail delivered to the INSTITUTION and the INVESTIGATOR.

6. Immediately upon receipt of any notice of termination, the INVESTIGATOR shall stop entering patients into the study and shall cease treatment with the DRUG, to the extent medically permissible, on patients already entered in the study.

7. In the event of termination, the sum payable under this Agreement shall be prorated based on actual work properly performed pursuant to the protocol. Any funds not due under this calculation but already paid shall be returned to Pfizer.

8. Notwithstanding any of the above, if during the life of this agreement the DRUG is approved by the Food and Drug Administration, or information becomes available which places the safety or efficacy of the DRUG in doubt, the parties agree to negotiate in good faith with the objective being the modification of the contract to reduce the number of patients to be studied and/or similarly modify any other relevant requirement.

9. In undertaking to perform professional services for Pfizer it is understood that the INSTITUTION is doing so as an independent contractor and not as an employee of Pfizer. As an independent contractor the INSTITUTION's fees will be limited to those stated above. No employee of the INSTITUTION performing the agreed study will participate in any Pfizer employee benefit plans or receive any other compensation from Pfizer beyond that stated.

10. Payments to the INSTITUTION for services rendered under this Agreement shall be made in full at the agreed rate without any deductions for taxes of any kind whatsoever, this being in conformity with non-employee status. Any taxes that may be due and payable as a result of the payments herein specified by Pfizer to the INSTITUTION shall be entirely the recipient's responsibility. It is understood that, as part of this Agreement, the INSTITUTION undertakes to pay all taxes on such payments for which it may be liable when due.

11. Upon completion or termination of the study, the INSTITUTION agrees to provide written acknowledgement that all work requested under this Agreement has been completed and all monies due have been received.

12. Pfizer shall retain ownership of all original case report forms which result from the study. Notwithstanding the foregoing, the INVESTIGATOR may publish the results generated from this study provided such manuscript is submitted to Pfizer for review prior to submission for publication. INVESTIGATOR will consider any comments timely received; however, INVESTIGATOR shall retain final editorial control over any INVESTIGATOR publication. Should the INVESTIGATOR decide not to publish such study, which decision shall be evidenced by the failure to provide Pfizer with a manuscript within six (6) months of study completion, Pfizer shall have the right to publish the results. If the results of the study are part of a multi-site investigation, Pfizer may publish the pooled results from all sites comprising the multi-site investigation.

13. The INSTITUTION and its employees will hold all information disclosed to it by Pfizer or developed by Pfizer with regard to the DRUG, which information is not already in the public domain, in confidence and will not disclose the same to any third party without the written permission of Pfizer. Nothing herein shall be construed as preventing the INSTITUTION and the INVESTIGATOR from publishing the data generated from this study as provided in Section 12 above.

14. Except as otherwise required by law or regulation, neither party to the Agreement shall release or distribute any materials or information containing the name of the other party or any of its employees without prior written approval by an authorized representative of the non-releasing party, but said approval shall not be unreasonably withheld.

15. The sole and exclusive right to any inventions or discoveries relating to the DRUG, whether patentable or not, made by Pfizer in the performance of work under this Agreement shall be the property of Pfizer. All other inventions or discoveries under this Agreement shall be the property of the INSTITUTION and handled in accordance with The University of Texas System Intellectual Property Policy. The INSTITUTION hereby grants Pfizer an option to negotiate an exclusive, royalty-bearing license to any invention or discovery arising out of research conducted under this Agreement and conceived and reduced to practice during the course of this study or arising out of research conducted under this Agreement and reduced to practice within six (6) months of completion of work under this Agreement. The INSTITUTION shall promptly disclose to Pfizer in writing and marked confidential any such inventions or discoveries arising from research conducted under this Agreement, and Pfizer shall advise the INSTITUTION in writing within ninety (90) days of disclosure to Pfizer whether or not it wishes to secure a commercial license. If Pfizer elects not to secure a license, or if Pfizer and the INSTITUTION fail to enter into a license agreement within one hundred eighty (180) days from the date of election by Pfizer to secure such a license, or such reasonable time period to which the parties may later agree in writing, then the rights to such inventions and discoveries disclosed hereunder shall be disposed of in accordance with the INSTITUTION's policies with no further obligation to Pfizer. In the exercise of the option right granted hereunder, the parties shall negotiate in good faith concerning the terms and conditions of a license agreement.

16. Pfizer undertakes to indemnify and hold harmless the INSTITUTION, the University of Texas System, their Regents, officers, agents and employees from any and all liability, loss or damage they may suffer as the result of claims, demands, costs, or judgments against them arising out of the activities to be carried out pursuant to the clinical research protocol; provided, however, that any such liability, loss, or damage resulting from

(i) a negligent failure to substantially adhere to the terms of the protocol or Pfizer's written instruction relative to use of the DRUG

(ii) a negligent failure to comply substantially with any applicable FDA or other governmental requirements or

(iii) negligence or willful malfeasance by the INVESTIGATOR, INSTITUTION, the University of Texas System, their Regents, officers, agents and employees is excluded from this agreement to indemnify and hold harmless.

The INSTITUTION agrees to notify Pfizer as soon as it becomes aware of a claim or action and, subject to the statutory duty of the Texas Attorney General, to cooperate with and to authorize Pfizer to carry out the sole management and defense of such claim or action. Pfizer agrees, at its own expense, to provide attorneys to defend against any actions brought or filed against the INSTITUTION, the University of Texas System, their Regents, officers, agents and employees with respect to the subject of indemnity contained herein, whether such claims or actions are rightfully brought or filed.

The foregoing rights and obligations of the parties are subject to the right or duty of the Texas Attorney General to defend the indemnified parties and to settle or compromise the portion of any claim that may result in liability on behalf of any indemnified party; provided, however, that Pfizer shall have no obligation hereunder to indemnify and hold harmless any indemnified party to the extent that party's claim or action is defended, settled or compromised by the Texas Attorney General on behalf of such indemnified party. For purposes of this Section 16, the Texas Attorney General's making an appearance, and/or agreeing to a settlement or compromise of a claim over which Pfizer has sole management of the defense pursuant to this Section 16 shall not relieve Pfizer of its obligations hereunder.

Notwithstanding any other provision, neither the Attorney General nor INSTITUTION shall compromise or settle any claim or action which is the subject of Pfizer's duty to defend and/or indemnify hereunder without the prior written approval of Pfizer.

17.

a) INSTITUTION represents that it has never been, and that, to the best of its knowledge after appropriate inquiry, neither the INVESTIGATOR nor any other individual who will be rendering services to PFIZER has ever been, (i) debarred or convicted of a crime for which a person can be debarred under 21 U.S.C. § 335(a), as amended ("§ 335(a)") nor (ii) threatened to be debarred or indicted for a crime or otherwise engaged in conduct for which a person can be debarred under § 335(a).

b) INSTITUTION and/or INVESTIGATOR shall promptly notify PFIZER in the event of any such debarment, conviction, threat or indictment occurring during the term of this Agreement, or the three (3) year period following the termination or expiration of this Agreement.

c) During the term of the Agreement, INSTITUTION and/or INVESTIGATOR agree not to employ or otherwise engage any individual who will be rendering services to PFIZER who has been (i) debarred or (ii) convicted of a crime for which a person can be debarred.

d) Upon PFIZER's request from time to time, INSTITUTION and/or INVESTIGATOR shall certify to PFIZER in writing INSTITUTION and/or INVESTIGATOR's compliance with the foregoing provisions of this Section 17.

18. This Agreement (a) shall be governed by the laws of the State of Texas in all respects of validity, construction and performance thereof; (b) sets forth (together with Schedules A, B, and C) the entire Agreement and understanding between the parties as to the subject matter hereof and has priority over all documents, verbal consents or understanding made between the parties with respect to the subject matter hereof; (c) shall not be amended or modified except in a written agreement signed by the parties hereof; and (d) cannot be assigned to another INVESTIGATOR nor moved to another INSTITUTION without the prior written consent of PFIZER. In addition, any amendment to the protocol must be approved in a written agreement by the authorized Institutional Review Bard.

If the foregoing terms are acceptable to you, please so indicate by signing and returning the enclosed copy of this agreement.

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| University of Texas \_\_\_\_\_\_\_\_\_\_\_\_ By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_                                Name Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  | Pfizer, Inc. By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_                                Name Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  |

I have read this Agreement and understand my obligations hereunder.

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

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