**PFIZER INC.**

**STATEMENT OF AGREEMENT**

1. The University of Texas \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ and Pfizer Inc. agree to conduct a clinical study in \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ patients titled: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, Study # \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_,  according to the protocol attached herein as Exhibit A., which has been approved by The University of Texas \_\_\_\_\_\_\_\_\_
\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, its Institutional Review Board and Pfizer Central Research a division of Pfizer Inc. ("Pfizer"). In this undertaking Dr.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ , as principal investigator, will devote his/her best efforts in order to efficiently perform the work required under this agreement.

2. The approved reimbursement rate for the study to be conducted by Dr. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
\_\_\_\_\_\_\_\_\_\_ is $\_\_\_\_\_\_\_\_\_\_\_\_ (or $\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_/completed patient).

3. Any alteration in or amendment to the attached protocol or any additional clause in this agreement must be approved in writing by The University of Texas \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, the responsible Institute, its Institutional Review Board and Pfizer Inc. prior to such alteration or amendment becoming effective. The effective date of this agreement shall be from \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ through \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. However, this provision shall not preclude immediate modification in the patient inclusion criteria or management deemed clinically appropriate by the investigator and Pfizer Inc. provided such modification is subsequently documented in writing signed by the investigator and Pfizer Inc.

4. The study may be terminated by either party by giving 30 days advance written notice to the other party for any of the following reasons:

A. Notification to Pfizer Inc. from Federal or State Regulatory Authorities to terminate said study.

B. Determination by Pfizer Inc. that The University of Texas \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, after a reasonable opportunity, is unable (e.g. due to circumstances beyond its control) to satisfactorily perform the study as required in the protocol.

C. Case report forms provided to the principal investigator by Pfizer Inc. for use in this study, are not legibly completed and forwarded to Pfizer Inc. or its designated representative, as appropriate, within two weeks of each patient visit date.

D. The principal investigator and/or his or her organization The University of Texas \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, prevents access by Pfizer Inc. representatives to any and all original medical records necessary to verify entries on study case report forms.

E. The principal investigator, associates or any other person engaged in this study, excluding patients, are unavailable upon reasonable notice by Pfizer Inc., to meet with Pfizer Inc. representatives during the course of this investigation as necessary to discuss information relevant to the study.

F. The University of Texas \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ does not comply with all regulatory requirements as delineated in Form FD 1572/1573 signed by investigator.

5. In the event that either party wishes to exercise its right to terminate this study based on any of the enumerated grounds above, written notice of its decision to exercise such right shall be given by registered mail delivered thirty days before said termination.

6. Immediately upon receipt of a notice of termination, The University of Texas \_\_\_\_\_\_\_\_\_
\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ shall stop entering patients into the study and shall cease conducting procedures, to the extent medically permissible, on patients already entered into the investigational protocol.

7. In the event of termination, the sum payable under this agreement shall be limited to pro-rated fees based on actual work performed pursuant to the protocol. Any unexpended funds not due The University of Texas \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, under this calculation but already paid The University of Texas \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, shall be returned to Pfizer Inc.

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

9. It is agreed that payment of sums due under this agreement shall be made payable to: The University of Texas \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, Attention: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_,
\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ ,\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ ,\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ , Texas \_\_\_\_\_\_\_\_\_.

10. Payments are dependent upon the data as described in the protocol being submitted to Pfizer Inc. representatives in a timely and satisfactory manner on the case report form provided.

It is further agreed that, in general, payments of the sums due under this agreement shall be made according to the following schedule:

|  |  |  |
| --- | --- | --- |
|       Payment #  |           Amount   |            Study Status |
| 1   | $  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | prior to initiation of study |
| 2 | $  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | 25% of projected work              required under the protocol             submitted to Pfizer, Inc. |
| 3 | $  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | 50% of projected work             required under the protocol             submitted to Pfizer Inc. |
| 4 | $  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | 75% of projected work            required under the protocol            submitted to Pfizer Inc. |
| 5 | $  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | 100% of projected work             required under the protocol             submitted to Pfizer Inc. |

Any patient maintained in this trial who is found to be a protocol violator shall be compensated at 50% of the individual visit costs.

The final payment will be adjusted to reflect the data collected on the actual number of qualified patients entered, numbers of patients screened, and the work completed on those patients as determined by review of the case reports received against the protocol requirements.

This final payment will only be made after an accounting of all experimental drug has been made using Pfizer Inc. procedures.

11. Pfizer Inc. shall retain ownership of all original case report forms which result from this study. However, The University of Texas \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ shall have publication privileges provided such manuscript is submitted to Pfizer Inc. for review prior to submission for publication. No right of manuscript approval by Pfizer Inc. is implied by this provision. Should Dr. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ decide not to publish, which decision shall be evidenced by his/her failure to provide Pfizer Inc. with a final study report in manuscript form within six months of study completion, Pfizer Inc. shall have the right, by mutual agreement between Pfizer Inc. and Dr. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ to publish the study.

12. The University of Texas \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ agrees to hold all information disclosed to it by Pfizer Inc. or developed hereunder by Pfizer with regard to\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_,
which information is not already in the public domain and is trade secret information of Pfizer Inc., in the strictest of confidence and will not disclose the same to any third party without the express permission of Pfizer Inc. Nothing herein shall be construed as preventing The University of Texas \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ from publishing the clinical data generated from this study in scientific journals.

13. Pfizer Inc. shall not use the name of The University of Texas \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, either expressly or by implication in any news or publicity release, without the express written approval of The University of Texas \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. However, nothing herein shall be construed as prohibiting Pfizer Inc. from reporting on this study to a governmental agency, or from exercising its publication rights under (11) above.

14. The sole and exclusive right to any inventions or discoveries relating to the formulation or use of the study 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 University of Texas \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ and handled in accordance with The University of Texas System Intellectual Property Policy. The University of Texas \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 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. The University of Texas \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 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 University of Texas \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ in writing within ninety (90) days of disclosures 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 University of Texas \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 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 University of Texas \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
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.

15. Pfizer Inc. undertakes to indemnify and hold harmless Dr. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ and The University of Texas \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, UT 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 designated as \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, 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 instructions relative to use of the investigational drug,

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

(iii) negligence or willful malfeasance by Dr. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ or The University of Texas \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, their regents, officers, agents and employees is excluded from this agreement to indemnify and hold harmless.

Dr. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ and The University of Texas \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
agree to notify Pfizer Inc. as soon as they become aware of a claim or action and subject to the statutory duty of the Texas Attorney General to cooperate with and to authorize Pfizer Inc. to carry out the sole management and defense of such claim or action. Pfizer Inc. agrees, at its own expense, to provide attorneys to defend against any actions brought or filed against Dr.\_\_\_\_\_\_\_\_\_\_\_ , The University of Texas \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ , UT 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.

Neither The University of Texas \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, nor its regents, officers, agents or employees shall compromise or settle any claim or action without the prior written approval of Pfizer Inc.

16. In undertaking to perform professional services for Pfizer Inc. it is understood that The University of Texas \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ is doing so as an independent contractor and not as an employee of Pfizer Inc. As an independent contractor, The University of Texas \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ fees will be limited to those stated above. Neither Dr. \_\_\_\_\_\_\_\_\_
nor any associated staff performing the agreed-to investigation will participate in any Pfizer Inc. employee benefit plans nor receive any other compensation beyond that stated above.

17. It is understood that payments to The University of Texas \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 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. It is understood that any taxes that may be due and payable as a result of the payments herein specified by Pfizer Inc. to The University of Texas \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, shall be entirely the recipient's responsibility. It is understood that, as part of this agreement, the recipient undertakes to pay all taxes on such payments for which it may be liable when due.

18. Upon completion or termination of the study The University of Texas \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, agrees to provide written acknowledgement that all work requested under this agreement has been completed and all monies due have been received.

19. This agreement shall be interpreted and enforced under the laws of the State of Texas.

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

ACCEPTED AND AGREED:

|  |  |
| --- | --- |
| 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: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_