**NOTE: Concept of Biological Samples \*not\* included in this Master CSA. Contact OGC if your Pfizer Protocol includes us sending biological samples to Pfizer.**

Study Number \_\_\_\_\_\_

**MASTER CLINICAL STUDY AGREEMENT  
PFIZER INITIATED STUDY (NY)**

This Agreement shall establish the following terms between \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, ("CRO"), located at \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, and \_\_\_\_\_\_\_\_\_\_\_ ("INSTITUTION"), one of the following component institutions (collectively "INSTITUTIONS") of The University of Texas System ("SYSTEM") located at 201 West 7th Street, Austin, TX, 78701, which is governed by its Board of Regents ("BOARD"):

The University of Texas Health Science Center at San Antonio,  
The University of Texas Health Science Center at Houston,  
The University of Texas MD Anderson Cancer Center,  
The University of Texas Health Center at Tyler,  
The University of Texas Medical Branch at Galveston, and  
The University of Texas Southwestern Medical Center at Dallas.

INSTITUTION and CRO will be referred to individually as a "party," and jointly as "parties."

**1. Services:**

INSTITUTION, located at the address set forth in Exhibit C, agrees to conduct a clinical study sponsored by Pfizer Inc ("PFIZER"), using the drug named \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ ("Drug"), in accordance with the provisions of protocol number \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ ("Protocol"), entitled \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ ("Study"), which has been approved by the INSTITUTION, its Institutional Review Board and PFIZER. The Protocol is attached as Exhibit A. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, M.D., an employee of INSTITUTION, will serve as principal investigator ("INVESTIGATOR") for this Study. If, during this Study, INVESTIGATOR becomes unavailable or leaves INSTITUTION, then INSTITUTION will select an alternate INVESTIGATOR upon PFIZER'S written approval, such approval will not be unreasonably withheld, or, CRO may terminate this Agreement with INSTITUTION upon direction or instruction from PFIZER, as set forth in Article 4, if a suitable replacement is not found.

**2. Fees and Expenses:**

a. The approved payment rate for the Study is $ \_\_\_\_\_\_\_\_\_\_\_\_ for each of \_\_\_\_\_ "completed patients" (as defined in Paragraph 3), with an approved amount of $ \_\_\_\_\_\_\_\_\_\_\_\_. The Budget for this Study is attached as Exhibit B.

In addition, the following support costs will be reimbursed upon PFIZER'S receipt of supporting documents:

The maximum aggregate amount payable under this Agreement is $ \_\_\_\_\_\_\_\_\_\_\_\_. Payment for partially completed patients will be proportional to the work performed. INSTITUTION will be reimbursed for up to a maximum of \_\_\_\_\_\_ screen failures for every \_\_\_\_\_\_\_ patients randomized, at $ \_\_\_\_\_\_\_\_\_\_\_\_ per screen failure. This INSTITUTION may be a part of a multi-center Study, and as such, PFIZER reserves the right to terminate enrollment when the number of evaluable patients reaches the level specified in the Protocol.

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 the Agreement. This amount shall be payable at the time this Agreement is signed by all parties. Subsequent payments will be made based upon patient progress verified by the CRO monitor.

c. All amounts due under this Agreement are to be mailed to the contact person listed in Exhibit C which names a contact person and his/her relevant information for each INSTITUTION.

**3. Completed Patient:**

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

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

b. Compliance with all aspects of the Protocol.

c. 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 tests and assessments contained in the Protocol.

**4. Termination:**

4.1 The Study may be terminated by thirty (30) days written notice from CRO to the INSTITUTION and the INVESTIGATOR upon direction or instruction from PFIZER. Immediately upon receipt of any notice of termination, the INVESTIGATOR understands that he/she will stop entering patients into the Study and shall cease treatment with the Drug, to the extent medically permissible, on patients already entered into the Study. In the event of termination, the payments under this Agreement shall be prorated based on actual work properly performed in accordance with the Protocol. Any funds not due under this calculation but already paid shall be returned to PFIZER.

4.2 This Agreement may be terminated by INSTITUTION either (i) if it believes such termination is necessary to protect the best interests of the Study subjects, or (ii) for a breach of material provision hereof by CRO and/or PFIZER, which breach is not cured by CRO and/or PFIZER within thirty (30) days following receipt of written notice thereof from INSTITUTION.

4.3 Termination of this Agreement by either party shall not affect the rights and obligations of the parties accrued prior to the termination date. The rights and duties under Articles 7 (Publications), 8 (Confidentiality), 10 (Use of Name), 11 (Ownership of Property and Data), and 16 (Indemnification) herein shall survive the cancellation or termination of this Agreement regardless of the cause.

**5. Relationship with CRO and Pfizer:**

In undertaking to perform professional services for CRO, it is understood that the INSTITUTION and the INVESTIGATOR shall be considered independent contractors and shall not be construed for any purpose as the partner, agent, employee or representative of CRO or PFIZER. Accordingly, payments to the INSTITUTION for services rendered under this Agreement shall be made in full at the agreed rate without any deductions for taxes. 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, if any, when due.

**6. Final Payment:**

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

**7. Publications:**

Subject to the INSTITUTION'S right to publish the results of the Study in accordance with this Article 7, PFIZER shall retain ownership of all original case report forms, data, analyses and reports that result from the Study. Notwithstanding the foregoing, the INVESTIGATOR understands that participation in the Study may involve a commitment to publish the data from the Study in a cooperative publication with other investigators prior to publication or presentation of individual investigator results. The INVESTIGATOR may publish the results of the Study after such cooperative publication, or eighteen (18) months after PFIZER'S final evaluation of all Study data from all sites, whichever occurs first. INVESTIGATOR shall provide the intended manuscript to PFIZER for review at least forty-five (45) days prior to submission for publication or presentation. Manuscript approval by PFIZER is not implied by this provision. INVESTIGATOR understands that he/she will delete any information that may be confidential or proprietary.

**8. Confidentiality:**

a. Subject to INSTITUTION'S publication rights as set forth in Article 7, all written and/or verbal information disclosed by CRO and/or PFIZER to INSTITUTION, INVESTIGATOR and/or associated staff, or developed hereunder by the INSTITUTION and/or the INVESTIGATOR and/or associated staff is confidential ("Confidential Information") and is subject to the following provisions:

(1) Each party will use reasonable efforts to prevent the disclosure of any of the other party's Confidential Information to third parties throughout the term of this Agreement and for a period of five (5) years from the commencement of the Study or until completion of the Study, whichever is longer, provided that the recipient party's obligation shall not apply to information that:

(a) is already in the recipient party's possession at the time of disclosure thereof as evidenced by contemporaneous written documentation;  
(b) is not disclosed in writing or reduced to writing and marked with an appropriate confidentiality legend within 30 days of the disclosure;  
(c) is or later becomes part of the public domain through no fault of the recipient party;  
(d) is received from a third party having no obligations of confidentiality to the disclosing party;  
(e) is independently developed by the recipient party as evidenced by written documentation; or  
(f) is required by law or regulation to be disclosed.

(2) Neither the INSTITUTION, the INVESTIGATOR, or associated staff shall use PFIZER'S Confidential Information for any purpose other than the conduct of the Study.

(3) In handling a Study subject's medical records, PFIZER, the CRO, the INSTITUTION, the INVESTIGATOR and associated staff shall hold in strict confidence the identity of the patient, and shall comply fully with any and all applicable laws regarding the confidentiality of such records.

b. Nothing herein shall be construed as preventing the INSTITUTION and the INVESTIGATOR from publishing the data generated from the Study, as provided in Article 7. INSTITUTION may retain and use copies of any information generated hereunder for internal, non-commercial, educational, and research purposes only.

**9. Protected Health Information:**

Data collected in the Study may include Protected Health Information ("PHI") as that term is defined in the privacy rule enacted pursuant to the Health Insurance Portability and Accountability Act of 1996 ("HIPAA Privacy Rule"). If INSTITUTION and/or INVESTIGATOR is a covered entity under the HIPAA Privacy Rule, INSTITUTION will, and INVESTIGATOR understands he/she will comply with the HIPPA Privacy Rule in its conduct and reporting of the Study. PFIZER and/or CRO will take appropriate measures to protect the confidentiality and security of all PHI that they receive from INVESTIGATOR in connection with the Study.

**10. Use of Name:**

No party hereto shall use the name of another party hereto either expressly or by implication in any news or publicity release, policy recommendation or commercial fashion without the express written approval of that party. Either party may use the name of the other party as required by state and/or federal law or regulation. INSTITUTION may use PFIZER's name for INSTITUTION'S internal administrative reporting requirements. Nothing herein shall be construed as prohibiting PFIZER from reporting on this Study to a governmental agency and to other investigators studying the Drug, or of INSTITUTION exercising its publication rights under Article 7.

**11. Ownership of Property and Data:**

PFIZER shall have sole ownership and rights to any inventions or discoveries directly relating to the Study Drug, whether patentable or not, made in the performance of work conducted under this Agreement using the Study Drug in accordance with the Protocol.

**12. Record Retention and Site Audits:**

a. The INSTITUTION and the INVESTIGATOR shall retain all records and documents pertaining to the Study for a period in accordance with FDA regulations.

b. CRO, PFIZER and/or its designees may monitor and audit the INSTITUTION'S and the INVESTIGATOR'S performance of any work relating to services provided in connection with a Study during regular business hours with reasonable notice to INSTITUTION. Such audits, as they relate to the Study under this Agreement, may, as CRO and/or PFIZER so elect, comprise: (a) inspection of the INSTITUTION'S and the INVESTIGATOR'S facilities and records relating to the rendering of services to or for PFIZER; (b) review of the INSTITUTION'S and the INVESTIGATOR'S compliance with applicable federal, state and other licensures and certifications; and (c) the INSTITUTION and the INVESTIGATOR'S adherence to relevant laws, regulations and codes of practice including in particular, but without limitation, Good Clinical Practice, ICH and/or Food and Drug Administration regulations and all applicable regional/local standards and recommendations. As it relates to the Study under this Agreement, the INSTITUTION and the INVESTIGATOR will inform CRO and/or PFIZER within 24 hours of being notified of an FDA or other regulatory agency audit (if advance notice is given by the FDA or other applicable regulatory agency) or within 24 hours of the beginning of an FDA or other applicable regulatory agency audit (if no advance notice is given by the FDA or other applicable regulatory agency). As it relates to the Study under this Agreement, the INSTITUTION and the INVESTIGATOR shall provide CRO and/or PFIZER with a copy of all Study specific observations made during a regulatory body inspection at the INSTITUTION'S and the INVESTIGATOR'S facilities, immediately upon receipt of such information. As it relates to the Study under this Agreement, the INSTITUTION agrees and the INVESTIGATOR understands that he/she will cooperate with CRO and/or PFIZER in any such investigation, and in the implementation of appropriate action plans for such observations.

**13. Authorization to Use and Disclose Health Information:**

If INSTITUTION and/or INVESTIGATOR is a covered entity under the HIPAA Privacy Rule, INSTITUTION and/or INVESTIGATOR will obtain a written authorization ("HIPAA Authorization") for each Study patient. The HIPAA Authorization may be incorporated into the informed consent form or handled as a separate document. INSTITUTION and/or INVESTIGATOR will provide PFIZER an opportunity to review and approve the content of the HIPAA Authorization (including any revisions made during the course of the Study) before its use.

**14. Individually Identifiable Health Information:**

If, in connection with this Study or the terms of this Agreement, PFIZER and/or CRO come into contact with individually identifiable health information relating to patients who are not Study subjects, PFIZER and CRO agree to maintain the confidentiality of such information and not to use it for any unauthorized purpose.

**15. Safety Reporting:**

a. A "Serious Adverse Event" ("SAE") includes all adverse experiences which are defined as serious in accordance with FDA regulations 21 CFR 312.32 and 21 CFR 314.80, ICH guidelines and any applicable PFIZER guidelines and/or procedures.

b. The INVESTIGATOR is responsible for the identification and documentation of any and all adverse events in participating subjects (including all SAE'S).

c. The INVESTIGATOR is responsible for reporting all SAE'S immediately after knowledge of such SAE to PFIZER or the CRO Medical Monitor, as directed in the Protocol. The INVESTIGATOR will act reasonably to provide PFIZER or CRO with at least the minimum essential information about an SAE, as identified in PFIZER Standard Operating Procedures (SOPs) and training materials, which CRO or PFIZER will provide to the INVESTIGATOR. The INVESTIGATOR understands that as soon as minimum essential information about an SAE becomes available to INVESTIGATOR, INVESTIGATOR will immediately report that information to PFIZER CRO. The INVESTIGATOR understands that he/she will not postpone reporting said information to PFIZER or CRO irrespective of whether more detailed information may become available at a later time, or because the available information is not yet confirmed.

d. The INVESTIGATOR understands that he/she is responsible for making available any and all other safety information, as directed by PFIZER or the CRO, in accordance with regulatory standards, the Protocol, and PFIZER SOPs.

e. Upon written request by CRO or PFIZER, INVESTIGATOR understands that he/she will provide CRO or PFIZER with all information reasonably needed for PFIZER'S use in the clinical sections of regulatory submissions to the FDA, including but not limited to, the IND annual report and the NDA safety update, as well as regulatory submissions to other such agencies.

**16. Indemnification:**

PFIZER shall indemnify INSTITUTION as set forth in the Agreement of Indemnification attached hereto as Exhibit D and incorporated herein by reference and made a part of this Agreement.

**17. Debarment:**

a. INSTITUTION represents that to the best of its knowledge, it has never been, and that neither the INVESTIGATOR nor any other individual who will be rendering services to PFIZER under this Agreement 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 this Agreement, INSTITUTION agrees 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 written 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 Paragraph 17.

**18. Financial Disclosure:**

Pursuant to United States regulatory requirements, INSTITUTION shall cause the INVESTIGATOR and sub investigators directly involved in this Study to promptly return to CRO or PFIZER a financial disclosure form that has been completed and signed by INVESTIGATOR and sub investigators. Such form shall disclose any applicable interests/investments held by INVESTIGATOR and sub investigators, or their spouses or dependent children, prior to the commencement of the Study. PFIZER may withhold payments if it does not receive a completed form from INVESTIGATOR and sub investigators. INSITUTION will inform INVESTIGATOR and sub investigators that all such forms need to be promptly updated, as needed to maintain their accuracy and completeness during the Study and for one year after its completion. The INSTITUTION acknowledges that the completed forms may be subject to review by governmental and/or regulatory agencies, as well as CRO or PFIZER, and that the INSTITUTION hereby expressly consents to any and all such reviews.

**19. Informed Consent:**

INSTITUTION and/or INVESTIGATOR shall ensure that all appropriate informed consent forms have been obtained in compliance with 21 CFR Part 50 and that such informed consent forms have been signed by all Study subjects as necessary for their participation in the Study, in accordance with the Protocol. INSTITUTION confirms that IRB approval of the informed consent form approved by PFIZER has been obtained or shall be obtained prior to any use thereof. To the extent the IRB approval required under the preceding sentence has not been obtained upon the date hereof, INSTITUTION and/or INVESTIGATOR shall advise CRO or PFIZER promptly upon receipt of such approval.

**20. Assignment:**

This Agreement may be assigned by CRO to PFIZER or an affiliate of PFIZER, upon advance written notice to the INVESTIGATOR and the INSTITUTION by PFIZER and CRO.

**21. Miscellaneous:**

21.1 This Agreement shall be governed by the laws of the State of Texas in all respects of validity, construction and performance thereof.

21.2 This Agreement, together with the attached Exhibits, sets forth the entire Agreement and understanding among 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.

21.3 This Agreement shall not be amended or modified except in a written instrument signed by the parties hereof.

21.4 This Agreement cannot be assigned to another INVESTIGATOR nor moved to another INSTITUTION without the prior written consent of PFIZER via CRO.

21.5 CRO, PFIZER, INSTITUTION and the appropriate Institutional Review Board must approve any amendment to the Protocol in writing.

21.6 In the event of any inconsistency between this Agreement and the Protocol and/or Study attached hereto, the terms of this Agreement shall govern regarding financial and business issues, and the terms of the Protocol shall govern clinical issues.

21.7 INSTITUTION hereby represents that it has all power and authority (corporate or other) to execute and deliver this Agreement and to perform its obligations hereunder and, further, that INSTITUTION'S execution and delivery of, and performance under, this Agreement have been duly and validly authorized by all necessary action of INSTITUTION.

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

CRO   
\_\_\_\_\_\_\_\_\_\_\_[insert name]\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
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INSTITUTION - THE UNIVERSITY OF TEXAS   
\_\_\_\_\_\_\_\_\_\_[insert institution name]\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
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READ AND UNDERSTOOD:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
Investigator

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**EXHIBIT A**

Protocol

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**EXHIBIT B**

Budget

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**EXHIBIT C**

ADDRESSES AND RELEVANT CONTACT INFORMATION   
FOR EACH U.T. SYSTEM HEALTH COMPONENT INSTITUTION

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| --- | --- |
| **For Contract Information Only**  (no payments may be sent to this address):  Melinda Mathis, MPA Director Sponsored Programs and Compliance Office of Research Administration UT M.D. Anderson Cancer Center 1515 Holcombe Boulevard, Unit 307 Room B8.4453 Houston, TX 77030  phone: 713-745-3468 fax: 713-794-4535 email: mmathis@mdanderson.org  **For Payments Only:**  UT M. D. Anderson Cancer Center P.O. Box 297402 Attn: Grants & Contracts Accounting Houston, TX 77297 Tax ID: 74-6001118 | **For Contract Information Only** (no payments may be sent to this address):  Perrie M. Adams, Ph.D. Assoc. Dean for Research The University of Texas Southwestern Medical Center at Dallas 5323 Harry Hines Blvd., B1.204 Dallas, TX 75390-9016  phone: 214-648-6449 fax: 214-648-3362 email: perrie.adams@utsouthwestern.edu  **For Payments Only:**  Checks should be made payable to:  The University of Texas Southwestern Medical Center at Dallas Tax ID: 75-6002868 Checks should reference the Principal Investigator's name and protocol number, and be sent as follows:  if sent via U.S. Mail:   UT Southwestern Clinical Trials  P.O. Box 842265 Dallas, TX 75284-2265   if sent via FedEx or Other Courier:   Bank of America 1401 Elm Street, 5th floor Attn: Lockbox #842265 Dallas, TX 75202 |
| Ms. Susan E. Ramsey  Contract Administrator The University of Texas Health Science Center at Houston P. O. Box 20036 Houston, TX 77225  Overnight address:  The University of Texas Health Science Center at Houston 7000 Fannin Street, Suite 1460 Houston, TX 77030  phone: 713-500-3268 fax: 713-500-3275 email: susan.e.ramsey@uth.tmc.edu Tax ID: 74-1761309 | Mr. Rick Hefner Vice President for Finance and Administration  The University of Texas Health Center at Tyler 11937 U.S. Hwy. 271 Tyler, TX 75708  phone: 903-877-7720 fax: 903-877-7899 email: rick.hefner@uthct.edu Tax ID: 75-600-1354 |
| Mr. Lively Williams Clinical Trial Specialist  The University of Texas Medical Branchat Galveston Office of Clinical Research 301 University Boulevard 2.234 Gail Bordon Galveston, TX 77555-0671  phone: 409-747-1538 fax: 409-747-3793 email: hlwillia@utmb.edu Tax ID: 74-6000949 | Ms. Jane A. Youngers Director, Grants Management The University of Texas Health Science Center at San Antonio 7703 Floyd Curl Drive, Mail Code 7828 San Antonio, TX 78229-3900  phone: 210-567-2333 fax: 210-567-2344 email: youngers@uthscsa.edu Tax ID: 74-1586031 |

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**EXHIBIT D**

Agreement of Indemnification to be Attached to the Above Referenced Master Clinical Study Agreement

The "Indemnified Parties" shall mean, \_\_\_[Investigator]\_\_\_\_\_\_\_, \_\_\_\_[Institution]\_\_\_\_\_, The University of Texas System and its Board of Regents, their officers, agents, and employees.

PFIZER will indemnify the Indemnified Parties against and will assume the defense of any and all claims, demands, costs or judgments for damages, losses or liability they may suffer arising out of the activities to be carried out pursuant to this Agreement, including but not limited to PFIZER's use of the study results, pursuant to the clinical research protocol [number], entitled: " [title] ", except to the extent that such damages are the result of (i) any Indemnified Party breaching or acting outside the scope of this Agreement; (ii) negligence or willful misconduct by an Indemnified Party; (iii) the failure of an Indemnified Party to adhere to the terms of the Protocol or PFIZER's written instructions; or (iv) the failure of an Indemnified Party to comply with any applicable FDA or other governmental requirements.

Indemnified Parties agree (i) to notify PFIZER of a claim that is subject to PFIZER's indemnification obligation under this Agreement as soon as reasonably practicable, (ii) to authorize PFIZER and/or its insurers to carry out the sole management and defense of the claim, including without limitation the settlement thereof at the sole option of PFIZER and/or its insurers and (iii) to cooperate in the management and the defense by PFIZER and/or its insurers of the claim. The Indemnified Parties agree that no Indemnified Party will compromise or settle any claim that is subject to its indemnification obligation under this Agreement without the prior written approval of PFIZER.

The foregoing rights and obligations of the Indemnified 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.

PFIZER shall pay for the cost of providing any reasonably necessary medical diagnoses and treatment to a Study subject for any injuries directly resulting from the Study Drug or research procedures required and conducted in accordance with the Protocol, and provided that such injury is not caused in any way by the negligence or willful misconduct of the Indemnified Parties. Payments for patients' lost wages will not be made available by PFIZER.

This agreement shall be governed and interpreted in accordance with the laws of the State of Texas and the United States of America.

To indicate your agreement with and approval of the above, please sign and return to the undersigned the enclosed copy of this letter agreement.

|  |  |
| --- | --- |
| AGREED AND APPROVED  PFIZER INC    By \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Institution    By \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |