**NON-GOVERNMENTAL CLINICAL STUDY AGREEMENT**

**(“Clinical Trials”)**

**THIS** Agreement is made this day of , 199 , between (Name of Institution) (“Institution”), a component of The University of Texas System (“System”), and (Company Name), (Company’s address) (“Sponsor”), to conduct a clinical study and evaluation (“Study”). Institution and Sponsor agree as follows:

**1. PROTOCOL**

1.1 Institution agrees to use its best efforts to conduct the Study as an independent contractor, in accordance with Institutional policy, applicable laws and regulations and the Protocol/Project (#) , “(Study title) “, as described in Exhibit A (“Protocol”). The Study will be supervised by (name of Principal Investigator) (“Principal Investigator”) at Institution with assistance from associates and colleagues as required.

1.2 Sponsor agrees to engage the services of Institution to conduct the Study and further agrees to provide at no cost to Institution the (drug, materials, or equipment) for the conduct of the Study.

**2. AWARD**

2.1 In consideration for performance of the Study by Institution, Sponsor shall pay Institution Dollars ($ ) for Study expenses for the clinical study of approximately (number) ( # ) patients and other related costs. This amount, shown by approximate category of expense in Exhibit B, is payable in (number) ( # ) installments of Dollars ($ ) each by Sponsor to Institution. The first installment is payable within thirty (30) days of the date set forth above, and subsequent installments are payable on a quarterly basis upon receipt by Sponsor of interim case reports for: (a) one- third (1/3) of the final patient enrollment; (b) two-thirds (2/3) of the final patient enrollment; and © the remaining patient enrollment and Study close out, or as otherwise agreed upon by both parties and as set forth in Exhibit C.

**3. TERM**

3.1 This Agreement shall continue in force until the earlier of completion of the Study as mutually agreed upon by the parties , or (number) ( # ) month(s) from the date set forth above; provided, however that either party may terminate the Agreement by giving thirty (30) days advance notice to the other.

3.2 Upon early termination of this Agreement, Sponsor shall be liable for all reasonable costs incurred or obligated by Institution at the time of such termination, subject to the maximum amount specified in Article 2. Sponsor shall pay Institution for such costs within thirty (30) days of receipt of an invoice for same.

3.3 Upon termination of this Agreement, Institution shall return Sponsor’s materials and equipment to Sponsor.

**4. INDEMNIFICATION**

4.1 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.

4.2 Sponsor shall indemnify and hold harmless System, Institution, their Regents, officers, agents and employees from any liability or loss resulting from judgments or claims against them arising out of the activities to be carried out pursuant to the obligation of this Agreement, including but not limited to the use by Sponsor of the results of the Study; provided however, that the following is excluded from Sponsor’s obligation to indemnify and hold harmless:

a. the negligent failure of Institution to comply with any applicable governmental requirements or to adhere to the terms of the Protocol; or

b. the negligence or willful malfeasance by a Regent, officer, agent, or employee of Institution or System.

**5. PUBLICATION AND CONFIDENTIALITY**

5.1 The parties reserve the right to publish or otherwise make public the data resulting from the Study. The party wishing to publish or make public shall submit any such manuscript or release to the other party for comment prior to publication or release.

5.2 Except as otherwise required by law or regulation, neither party 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 such approval shall not be unreasonably withheld.

5.3 The parties may wish, from time to time, in connection with work contemplated under this Agreement, to disclose confidential information to each other ("Confidential Information"). Each party will use reasonable efforts to prevent the disclosure of any of the other party's Confidential Information to third parties for a period of three (3) years after the termination of this Agreement, provided that the recipient party's obligation shall not apply to information that:

a. is not disclosed in writing or reduced to writing and so marked with an appropriate confidentiality legend within thirty (30) days of disclosure;  
b. is already in the recipient party's possession at the time of disclosure thereof;  
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; or  
f. is required by law or regulation to be disclosed.

In the event that information is required to be disclosed pursuant to subsection f., the party required to make disclosure shall notify the other to allow that party to assert whatever exclusions or exemptions may be available to it under such law or regulation. Nothing herein shall prevent Institution or any other component of System from using any information generated hereunder for ordinary research and educational purposes of a university.

**6. INTELLECTUAL PROPERTY**

***[NOTE: Our Standard Agreement does not address Intellectual Property issues. If Sponsor does not raise ownership/licensing issues, we will not raise such issues either. If, however, Sponsor requests an allocation of rights or interests different from those set forth in this Section 6, this would be our standard response.]***

6.1 “Invention” shall mean any discovery, concept, or idea, whether or not patentable, made during the conduct of the Study, and arising directly from the performance of the Study, including but not limited to processes, methods, software, tangible research products, formulas and techniques, improvements thereto, and know-how related thereto.

6.2 Institution agrees that the Principal Investigator will promptly disclose to its Intellectual Property Committee and to Sponsor any Inventions made by the Institution and/or the Principal Investigator. It is agreed that all Inventions and any information with respect thereto shall be subject to confidentiality obligations commensurate with those set forth in Section \_\_\_ herein.

6.3 Any Inventions that originate solely with the Principal Investigator, or any other Institution agent or employee associated with this Study (jointly or severally referred to as “Inventor”) shall be the property of Institution. If Inventor is a co-inventor with Sponsor, its agents or employees, Institution and Sponsor shall jointly own the Invention. Any Inventions that originate solely with any agent or employee of Sponsor shall be the property of Sponsor. To the extent that Sponsor pays all patent expenses for an Invention, Institution does hereby grant to Sponsor an exclusive option to acquire an exclusive, worldwide royalty-bearing license to any Invention in which Institution has an ownership interest. Sponsor shall indicate its intention to exercise its option to license by notifying Institution in writing within forty-five (45) days of each Invention’s disclosure to Sponsor. If Sponsor decides to exercise its option, the terms shall be negotiated in good faith within one hundred twenty (120) days of the date the option is exercised, or within such time as the parties may mutually agree in writing.

6.4 If negotiations between Sponsor and the Institution terminate and the Institution thereafter negotiates a license agreement with a third party on substantially better terms than those last offered to Sponsor, Sponsor shall be given the first right to refuse such terms for a period of sixty (60) days from the date of Sponsor’s receipt of a draft of such license agreement from Institution.

**7. GENERAL**

7.1 This Agreement, including the attached Exhibits A and B, constitutes the entire and only Agreement between the parties relating to the Study, and all prior negotiations, representations, agreements, and understandings are superseded hereby. No agreements altering or supplementing the terms may be made except by a written document signed by the duly authorized representatives of the parties.

7.2 Any conflicts between the Protocol and this Agreement are controlled by this Agreement.

7.3 This Agreement shall be construed and enforced in accordance with the laws of the State of Texas.

7.4 This Agreement anticipates educational training and may involve health science postgraduates and other students of the Institution.

**SPONSOR**

By\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
Title:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**(U.T. Component Institution)**

By\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
Title:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

I have read this Agreement and understand my obligations hereunder.

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

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**EXHIBIT II**

NON-GOVERNMENTAL CLINICAL STUDY AGREEMENT (“Clinical Trials”) BETWEEN \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (UT Institution) AND SPONSOR - “STUDY TITLE”

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

Salaries (including fringe benefits) $.00  
Supplies .00  
Indirect Costs (institutional overhead) .00  
TOTAL COST $.00

These expenses are provided for information only. Institution reserves the right to modify the distribution of these expenses as necessary under the circumstances, provided that the stipulated total cost of $ is not exceeded. Further, the above data is based on the evaluation of (number) ( # ) patients; if the total number of evaluated parties is greater or less than said number, the parties may increase or decrease the grant amount accordingly by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Dollars ($ ) per patient.