**SPONSORED CLINICAL STUDY AGREEMENT**

THIS AGREEMENT is made this \_\_\_\_\_\_\_ day of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 19\_\_\_, between The University of Texas \_\_\_\_\_\_\_, whose address is \_\_\_\_\_\_\_\_\_("INSTITUTION"), a component institution of The University of Texas System ("SYSTEM"), and Abbott Laboratories whose address is One Abbott Park Road, Abbott Park, Illinois 60064 ("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 in accordance with INSTITUTION policy, applicable laws and Protocols entitled \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ described in Exhibits I and II attached hereto and incorporated herein. The STUDY will be supervised by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 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 a sufficient quantity of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (collectively "Study Drug") to conduct the STUDY, as well as case report forms for use in the STUDY and any other materials as SPONSOR deems necessary or useful for the conduct of the STUDY and desires to provide for the conduct of the STUDY.

1.3 INSTITUTION agrees to use reasonable efforts to complete the STUDY within \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (\_\_\_\_\_\_\_\_\_\_\_\_\_) months of its receipt of the clinical materials needed to commence the STUDY as described in Section 1.2 herein.

1.4 Within thirty (30) days following completion of the STUDY, INSTITUTION will furnish SPONSOR with written case report forms completed in such reasonable detail as SPONSOR may specify, setting forth the results of the STUDY, including the data generated by the STUDY. Not in any limitation of the provisions of Section 5.1, the case report forms and the data contained therein shall be the property of SPONSOR. INSTITUTION may keep a copy of the case report forms and data for its records.

**2. GRANT**

2.1 In consideration for performance of the STUDY by INSTITUTION, SPONSOR agrees to pay INSTITUTION an amount not to exceed \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ ($\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_) and NO/100 DOLLARS for STUDY expenses and other related costs. This fee, shown by approximate category of expense in Exhibit III attached hereto is payable as follows:

$\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ upon the execution of this Agreement

$\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ at the completion and close out of the STUDY.

As used herein, a case report form is "acceptable" if it is completed, accurate, and verifiable. A pro rata portion of the per patient cost of $\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ as reflected on the attached Budget (Exhibit III), shall be paid for patients who withdraw prior to completing the STUDY based upon data available for analysis up through date of withdrawal as determined by SPONSOR. However, no partial payment will be made for patients who are withdrawn from the STUDY because of violations of the Protocol. In addition, SPONSOR shall pay for the costs of emergency care or additional diagnostic procedures associated with adverse reactions suffered by the STUDY subject directly due to the Study Drug or the performance of the Study Protocols, except where the adverse reaction is due to the negligence or willful malfeasance of INSTITUTION, its employees, or its agents.

**3. INDEMNIFICATION**

3.1 INSTITUTION shall, to the extent authorized under the Constitution and the laws of the State of Texas, 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 negligence of SPONSOR, its officers, agents or any person or entity not subject to INSTITUTION supervision or control.

3.2 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 obligations 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 Protocols attached hereto as Exhibit I; or

b. the negligence by a regent, officer, agent or employee of INSTITUTION or SYSTEM.

3.3 SPONSOR'S indemnity is conditioned upon SYSTEM'S and INSTITUTION'S obligation to: (i) advise SPONSOR (Abbott Laboratories, Abbott Park, North Chicago, Illinois 60064, Attention: Risk Management, D-317) of any claim or lawsuit, in writing within such a time frame as not to materially prejudice the rights of SPONSOR after SYSTEM or INSTITUTION has received notice of said claim or lawsuit and (ii) subject to the statutory duty of The Texas Attorney General, assist SPONSOR and its representatives in the investigation and defense of any lawsuit and/or claim for which indemnification is provided.

**4. TERM**

4.1 This Agreement shall begin \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ and continue in force through \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ or upon completion of the STUDY, whichever is later, unless earlier terminated by either party by giving thirty (30) days advance written notice of termination.

4.2 In the event of premature termination of this agreement, SPONSOR shall be liable for all reasonable costs and noncancelable commitments incurred by INSTITUTION at the time of termination. SPONSOR agrees to pay INSTITUTION for such costs within thirty (30) days of receipt of an invoice for same.

4.3 Upon termination of this Agreement, INSTITUTION agrees to return SPONSOR'S materials and equipment to SPONSOR, including all unused Study Drug, used and unused case reports forms, and data and information which is the property of SPONSOR.

**5. PUBLICATION AND CONFIDENTIALITY, AND INVENTORSHIP**

5.1 INSTITUTION reserves the right to publish the results of the STUDY, with due regard to the protection of SPONSOR'S confidential information. INSTITUTION will submit the manuscript to SPONSOR for comments at least thirty (30) days prior to publication, and shall permit delay of publication, upon SPONSOR'S request, up to sixty (60) additional days to enable SPONSOR to secure adequate intellectual property protection on SPONSOR'S intellectual property that would be affected by said publication.

5.2 Except as required by applicable laws or government regulation, the parties agree not to 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, said approval not to be unreasonably withheld.

5.3 Each party agrees to hold in confidence for five (5) years after the termination of this Agreement any confidential information identified as proprietary or confidential obtained from the other party during the course of this STUDY. This obligation of confidentiality shall not apply to any information which is:

a. published or becomes part of the public domain through no fault of the receiving party;

b. disclosed to the receiving party by a third party lawfully entitled to make such a disclosure;

c. already known to the receiving party as of the date hereof, as evidenced by such party's written records;

d. independently developed by the receiving party, which in the case of INSTITUTION shall include but not be limited to other component institutions of the SYSTEM; or

e. required by law to be disclosed, including but not limited to requirements of any Governmental Regulatory Agency or Authority.

In addition, nothing herein shall prevent INSTITUTION or any other component of SYSTEM from using any information generated hereunder for the ordinary research and educational purposes of a university.

5.4 "Materials" as used herein, shall refer to all the instruments and related software and all reagents and disposables that are provided by SPONSOR. INSTITUTION agrees that Materials are and shall remain the sole property of SPONSOR. INSTITUTION disclaims any rights to the Materials and agrees that INSTITUTION will assert no claim, patent or otherwise, to them, and INSTITUTION further agrees to use them for research purposes only and not to employ them for any commercial purposes. INSTITUTION will use Materials solely for the STUDY and will not give them to any third party without SPONSOR'S prior written consent. INSTITUTION agrees to return or destroy any unused Materials at the completion of the STUDY or at SPONSOR'S request.

**6. GENERAL**

6.1 This Agreement constitutes the entire and only agreement between the parties relating to the STUDY; and all prior negotiations, representations, agreements and understandings are hereby superseded. No agreements altering or supplementing the terms hereof, including Exhibit I, may be made except by means of a written document signed by the duly authorized representatives of each of the parties.

6.2 Proceeding hereunder is not inconsistent with contractual relationships INSTITUTION may have with third parties.

6.3 INSTITUTION'S status under this Agreement shall be that of an independent contractor. INSTITUTION may not assign this Agreement or subcontract the performance of its obligations hereunder to any third party.

6.4 Any conflicts between the Protocols and this Agreement are controlled by this Agreement.

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

IN WITNESS HEREOF, INSTITUTION AND SPONSOR hereby enter into this Agreement effective as of the date first hereinabove written and execute three (3) original counterparts.

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| University of Texas \_\_\_\_\_\_\_\_\_\_\_\_  By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_                                 Name  Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Abbott Laboratories  By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_                                 Name  Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

I have read this Agreement and understand  
my obligations hereunder.

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

**ABBOTT.DIA  
Revised \_\_\_\_\_\_\_\_**