**SPONSORED CLINICAL STUDY AGREEMENT**

THIS AGREEMENT is made this \_\_\_\_\_\_\_ day of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 20\_\_\_, 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 Upon the SPONSOR'S reasonable request, INSTITUTION shall submit oral and/or written reports on the progress of the STUDY. Completed case report forms shall be delivered to SPONSOR by INSTITUTION as may be provided in the PROTOCOL. Within thirty (30) days following completion of the STUDY, INSTITUTION will furnish SPONSOR with all remaining 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.

1.5 INSTITUTION shall permit SPONSOR and/or SPONSOR'S designees such access to STUDY site(s) as is reasonably necessary to monitor the conduct of the STUDY, as well as to audit records, case report forms, source documents, and any other data relating to the STUDY, in compliance with FDA rules and regulations.

**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 verified and demonstrates adherence to the PROTOCOL. All patient visits will be reimbursed by SPONSOR, but if patients withdraw prior to completing the STUDY, only visits made prior to their withdrawing will be reimbursable. However, no partial payment will be made for patients who are withdrawn from the STUDY because of violations of the PROTOCOL. In addition, except to the extend covered by a patient's medical or hospital insurance or governmental programs providing such coverage, 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, except where the adverse reaction is due to the negligence or willful malfeasance of INSTITUTION, its employees, or its agents, or their failure to adhere to the terms of this Agreement, the PROTOCOL or applicable law.

**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 (or intentional, if permitted by law) 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 performance of the STUDY pursuant to the obligations of this Agreement, as well as arising out of 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 or intentional failure of INSTITUTION or SYSTEM to comply with any applicable laws, governmental regulations or FDA published guidelines relating to the conduct of the STUDY or to adhere to the terms of the PROTOCOL attached hereto as Exhibit I; or

b. the negligence or willful misconduct of the INSTITUTION or SYSTEM, or of 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; (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; and (iii) not settle or otherwise compromise any lawsuit or claim which is subject to indemnity hereunder without SPONSOR'S prior written consent.

**4. TERM**

4.1 This Agreement shall begin \_\_\_\_\_\_\_\_\_ and continue in force through \_\_\_\_\_\_\_\_\_ or until 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 by SPONSOR for reasons other than breach by INSTITUTION or SYSTEM, SPONSOR shall be liable for all reasonable costs and noncancelable commitments incurred by INSTITUTION at the time of termination, provided that SPONSOR'S liability therefor (inclusive of amounts paid pursuant to Section 2.1) shall not exceed the maximum budgeted amount set forth in Section 2.1. SPONSOR agrees to pay INSTITUTION for such costs within thirty (30) days of receipt of an invoice for same and SPONSOR'S receipt of the items discussed in Paragraph 4.3 below.

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 of the proposed publication to SPONSOR at least thirty (30) days prior to publication, and SPONSOR shall have the right to review and comment upon the publication in order to protect SPONSOR'S confidential information. Upon SPONSOR'S request, publication will be delayed 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.

[IF MULTI-CENTER STUDY] INSTITUTION acknowledges that the STUDY is part of a multi-center study, and an independent, joint publication is anticipated to be authored by investigators in the multi-center study, including INSTITUTION'S investigator. Therefore, INSTITUTION agrees not to independently publish the results of the STUDY before the publication of the multi-center investigator paper; but in no event shall INSTITUTION be so restricted after the expiration of twelve (12) months from completion of INSTITUTION'S performance of the STUDY.

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.

5.3 Each party agrees to hold in confidence for during the term of this Agreement and for five (5) years after the termination of this Agreement any confidential information identified in writing as "proprietary" or "confidential," or if orally disclosed, reduced to writing within thirty (30) days and marked "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 in a nonconfidential manner 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 without obligation of confidentiality to another, 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) without reference to the disclosing party's confidential information, as evidence by the receiving party's records; or

(e) required by law to be disclosed.

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 All inventions or discoveries made by INSTITUTION under this Agreement shall be the property of INSTITUTION and handled in accordance with the University of Texas System Intellectual Property Policy. INSTITUTION hereby grants SPONSOR an option to negotiate an exclusive royalty-bearing license with a royalty not to exceed six percent (6%) of net sales of licensed products, or in the alternative, a non-exclusive royalty-bearing license with a royalty rate not to exceed three percent (3%) of net sales of licensed products to any invention or discovery made by INSTITUTION arising out of research conducted under this Agreement and conceived or reduced to practice during the course of the STUDY. INSTITUTION shall promptly disclose to SPONSOR in writing and marked "confidential" any such inventions or discoveries arising from research conducted under this Agreement, and SPONSOR shall advise INSTITUTION in writing within forty-five (45) days of disclosure to SPONSOR whether it wishes to secure a commercial license. If SPONSOR elects not to secure a license, or if SPONSOR and INSTITUTION fail to enter into a license agreement within one hundred twenty (120) days from the date of election by SPONSOR 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 INSTITUTION'S policies with no further obligation to SPONSOR. 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.

**6. GENERAL**

6.1 This Agreement, including its exhibits, 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 Each party hereto represents and warrants that it has the power and authority to enter into this Agreement, and covenants that proceeding hereunder is not inconsistent with contractual relationships or legal obligations it 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 PROTOCOL 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.

6.6 INSTITUTION represents that the Principal Investigator and all other investigators that may perform services hereunder are its employees and shall abide by the terms and conditions of this Agreement as if each were a party hereto.

6.7 INSTITUTION warrants and represents that INSTITUTION has never been, is not currently, and, during the term of this Agreement, will not become a corporation, partnership or association that has been debarred by the FDA pursuant to 21 U.S.C. §335a (a) or (b) ("Debarred Entity") from submitting or assisting in the submission of any abbreviated drug application.

INSTITUTION further warrants and represents that, to the best of its knowledge after reasonable inquiry, none of its employees, agents or subcontractors performing services related to this Agreement is an individual who has been debarred by the FDA pursuant to 21 U.S.C. §335a (a) or (b) ("Debarred Individual") from providing services in any capacity to a person that has an approved or pending drug product application.

INSTITUTION further warrants and represents that, to the best of its knowledge after reasonable inquiry, no Debarred Individual or Debarred Entity has performed or rendered, or will perform or render, any services or assistance relating to activities taken pursuant to this Agreement. INSTITUTION further warrants and represents that INSTITUTION has no knowledge of any circumstances which may affect the accuracy of the foregoing warranties and representations, including, but not limited to, FDA investigations of, or debarment proceedings against, INSTITUTION or any person or entity performing services or rendering assistance relating to activities taken pursuant to this Agreement, and INSTITUTION will immediately notify SPONSOR if INSTITUTION becomes aware of any such circumstances during the term of this Agreement.

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:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  | Licensee: By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_                               Name Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  |

I have read this Agreement and understand
my obligations hereunder.

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

**ABBOTT.PHA
Revised 5/9/94**