**NON-GOVERNMENTAL CLINICAL STUDY AGREEMENT**

**("Clinical Trials")**

**(AS REVISED)**

THIS AGREEMENT is made this \_\_\_\_\_ day of \_\_\_\_\_\_\_\_\_\_\_\_\_\_, \_\_\_\_\_\_ between The University of Texas \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  at \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ ("INSTITUTE"), a component institution of  The University of Texas System ("SYSTEM"), and Warner-Lambert Company, 2800 Plymouth Road, Ann Arbor, MI 48105 ("SPONSOR"), INSTITUTION and SPONSOR agree as follows:

**I.    PROTOCOL**

1.1    INSTITUTION agrees to use its best efforts to complete the STUDY in an efficient and timely manner, as an independent contractor, in accordance with INSTITUTIONAL policy, applicable laws and regulations and the Protocol \_\_\_\_\_\_\_\_\_\_ described in Exhibit A as attached hereto and incorporated herein (the "Protocol").   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 is conduct the STUDY and further agrees to provide at no cost to INSTITUTION the drug for the conduct of the STUDY.

1.3    INSTITUTION agrees to provide SPONSOR periodically and in a timely manner during the term of this Agreement with the data called for in the Protocol on properly completed case reporting forms.  INSTITUTION agrees to notify SPONSOR at the earliest time possible after learning of an adverse drug reaction of any patient in the STUDY.

1.4    During the term of this Agreement, INSTITUTION agrees to permit representatives of SPONSOR to examine at any reasonable time during normal business hours (i) the facilities where the STUDY is being conducted, (ii) raw study data and (iii) any other relevant information (and to make copies) necessary for SPONSOR to confirm that the STUDY is being conducted in conformance with the Protocol and in compliance with applicable laws and regulations.  Notwithstanding the foregoing, SPONSOR shall not be granted access to any patient identifying information.

**2.  FINANCIAL CONSIDERATION AND PAYMENT SCHEDULE**

2.1    The total payments which Warner will be obligated to make or cause to be made to INSTITUTION to complete the Study with the number of patients specified in the protocol is as set forth in Exhibit B attached hereto and incorporated herein (the "Budget Agreement").  If fewer than the anticipated number of patients complete the Study, then the aforementioned payment will be prorated in an equitable manner.  Payments will be made according to the schedule set forth in the Budget Agreement with the final payment to be made at the time 1) the Study has been completed, 2) all unused experimental drug has been accounted for utilizing Warner accounting procedures, 3) all inquiries by Warner with respect to the  Study have been satisfactorily answered, and 4) all case reporting forms have been properly completed and supplied to Warner.

**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 by either party giving thirty (30) days advance notice of termination.  INSTITUTION may only terminate the STUDY early if such termination is a result of significant patient safety concerns or for other material and significant reasons.  Upon the receipt of giving of notice, as the case may be, INSTITUTION agrees to promptly terminate conduct of the STUDY to the extent medically permissible for any patients.

3.2    Upon early termination of this Agreement other than as a result of a material breach of this Agreement by INSTITUTION, the total sums payable by SPONSOR pursuant to this Agreement shall be equitably pro-rated for actual work performed to the date of termination, with any unexpended funds previously paid by SPONSOR to INSTITUTION being refunded to SPONSOR.  SPONSOR shall pay INSTITUTION for any remaining amounts owed within thirty (30) days of receipt of an invoice for same.

3.3.    Upon termination of this Agreement, INSTITUTION shall return SPONSOR'S drug to SPONSOR.

**4.    INDEMNIFICATION**

4.1    INSTITUTION shall, to the extent authorized under the Constitution and laws of the State of Texas, hold SPONSOR, its affiliates and their successors, assigns, directors and employees 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 of SPONSOR, its officers, agents, or any person or entity not subject to INSTITUTION supervision or control.

4.2    SPONSOR shall indemnify and hold harmless SYSTEM, INSTITUTION, their regents, officers, agents and employees (together, "INDEMNITEE(S)") from any liability or loss resulting from judgements 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 failure of any INDEMNITEE to comply with any applicable governmental requirements or to adhere to the terms of the protocol or to adhere to written recommendations and written instructions delivered to such INDEMNITEE by or on behalf of SPONSOR concerning the administration and use of any drug substances, including placebo, involved in the STUDY; or

    b.    the negligence or willful malfeasance by any INDEMNITEE

    c.    negligent failure of any INDEMNITEE to evaluate or properly interpret available information that is relevant to he STUDY and for independent decisions made as a result of such failure; or

    d.    negligent failure of any INDEMNITEE to render professional service or to conduct the STUDY in a normal, prudent manner.

A condition of this indemnity obligation is that, whenever an INDEMNITEE has information from which it may reasonably conclude an incident of bodily injury, sickness, disease, or death has occurred that arises from the performance of this STUDY, such INDEMNITEE shall immediately give notice to SPONSOR of all pertinent data surrounding such incident, and in the event claim is made or suit is brought, such INDEMNITEE shall assist SPONSOR and cooperate in the gathering of information with respect to the time, place, and circumstances and in obtaining the names and addresses of the injured parties and available witnesses.

No INDEMNITEE shall, except as its own cost, voluntarily make any payment or incur any expense in connection with any such claim or suit without the prior written consent of SPONSOR.

**5.    PUBLICATION, CONFIDENTIALITY AND OWNERSHIP**

5.1    INSTITUTION reserves the right to publish or otherwise make public the data or other results of the STUDY.   In this even, INSTITUTION shall submit any such manuscript or release to SPONSOR for comment prior to publication or release at least forty-five (45) days in advance of submission for publication.  If the parties disagree concerning the appropriateness of the data analysis and presentation, INSTITUTION agrees to meet with SPONSOR'S representatives for the purpose of making good faith efforts to discuss and resolve any issue or disagreement.

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 said approval shall not be unreasonably withheld.

5.3    INSTITUTION shall hold in confidence during the term of this Agreement and for six (6) years after the termination or expiration of this Agreement any information identified as proprietary or confidential obtained from SPONSOR during the course of the STUDY.  Not in any limitation of Section 5.1, INSTITUTION also agrees to hold confidential during the term of this Agreement and for six (6) years after the termination or expiration of this Agreement, research data which is generated by SPONSOR as a result of the STUDY.  INSTITUTION agrees to return SPONSOR'S confidential information to SPONSOR, and all copies thereof, at the conclusion of the STUDY or at an earlier date at the request of SPONSOR, except with respect to raw research study data where original data will be retained in accordance with FDA regulations.  This obligation to maintain confidentiality shall not be extended to data which is in the public domain or comes within the public domain through no fault of or action by INSTITUTION, which is received from a third party which is lawfully in possession of such information and not in violation of any contractual or legal obligation with respect to such information, which was already in INSTITUTION'S possession, at the time of disclosure by SPONSOR, as evidenced by its written records, which is independently developed by INSTITUTION by persons without access to SPONSOR'S confidential information under this Agreement, or which the INSTITUTION is required by law to disclose; provided that if INSTITUTION is required by law to disclose any of the information, it is agreed that INSTITUTION will provide SPONSOR with prompt notice of such request so that SPONSOR may (a) seek an appropriate protective order, or (b) consult with the INSTITUTION on the advisability of  taking steps to resist or narrow such request, and the INSTITUTION will cooperate with SPONSOR, to the extent legally permissible, in any attempt it makes to avoid or limit such disclosure.  The provisions of this paragraph 5.3 shall survive termination or expiration of this Agreement.

5.4    All clinical data, including raw data, case report forms and source documents generated as the result of the Warner-Lambert/Parke-Davis-sponsored study, will be promptly and fully disclosed to SPONSOR.  For purposes hereof, "source documents" means all SPONSOR-developed forms recording the subject's health status and related data.  All such data and information will become the property of SPONSOR and may be freely utilized by SPONSOR in any manner desired subject to the publication rights set out in paragraph 5.3  It is understood that the original raw research study data will be e retained by INSTITUTION in accordance with FDA regulations.

5.5    All rights to any invention conceived and reduced to practice in the performance of the work conducted under this Agreement and relating to any use of the Study drug shall belong to SPONSOR.  INSTITUTION agrees to assign to SPONSOR, at the request of SPONSOR, the sole and exclusive ownership thereto, upon payment of costs by SPONSOR, if any, incurred by INSTITUTION in the filing, prosecution, issuance and/or maintenance of any patent application or patent issuing thereon.  Further prosecution and costs, if any, shall thereafter be borne by SPONSOR.

5.6    All rights to inventions and discoveries arising from research conducted under this Agreement, other than as provided for above ("Other Inventions"), shall belong to INSTITUTION and shall be disposed of in accordance with INSTITUTION policy.  To the extent that SPONSOR pays all costs associated with filing, prosecution, issuance and maintenance of patent expense related thereto, SPONSOR is hereby granted the right to negotiate an exclusive, world-wide, royalty-bearing license to any Other Inventions conceived and reduced to practice during the course of the research project or conceived during the research project and reduced to practice within six (6) months thereafter.  Such license shall contain reasonable terms and royalties and shall require diligent pursuit by SPONSOR of the commercial development of such Other Inventions.  In the event Other Inventions are conceived but not actually reduced to practice during the course of this project, such license agreement may further include a provision for actual reduction to practice within a reasonable time by either SPONSOR or by INSTITUTION under funding provided by SPONSOR.

5.7    INSTITUTION shall promptly disclose SPONSOR on a confidential basis any Other Invention arising under this Agreement, and SPONSOR shall advise INSTITUTION in writing  within ninety (90) days after disclosure to SPONSOR whether it wishes to secure a commercial license to such Other Invention.  If SPONSOR elects not to secure such a license, rights to such Other Invention shall be disposed of in accordance with INSTITUTION policies, with no further obligation to SPONSOR.

**6.    GENERAL**

6.1    This Agreement constitutes the entire and only Agreement between the parties relating to the STUDY, and all prior negotiation, representations, agreements, and understandings are superseded hereby.  No agreements altering or supplementing the terms hereof, including the exhibits attached hereto, may be made except by a written document signed by the duly authorized representatives of the parties.

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

6.3    THIS AGREEMENT SHALL BE CONSTRUED AND ENFORCED IN ACCORDANCE WITH THE LAWS OF THE STATE OF TEXAS.

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

**7.    GENERIC DRUG ENFORCEMENT ACT OF 1992**

Institution represents that it has never been and, to the best of its knowledge after reasonable inquiry, its employees, affiliates, and agents have never been 1) debarred or 2) convicted of a crime for which a person can be debarred, under Section 306(a) or 306(b) of the Generic Drug Enforcement Act of 1992 ("Section 306(a) or (b)").   Institution represents that it has never been and, to the best of its knowledge, after our inquiry, none of its employees, affiliates, or agents has ever been 1) threatened to be debarred or 2) indicted for a crime or otherwise engaged in conduct for which a person can be debarred, under Section 306(a) or (b).  Institution agrees that it will promptly notify Warner in the event of any such debarment, conviction, threat, or indictment.  The terms of the preceding sentence shall survive the termination or expiration of this Agreement.

IN WITNESS WHEREOF The University of Texas \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
and Warner-Lambert Company hereby enter into this Agreement, effective as of the date first hereinabove written, and executed two (2) original counterparts.

|  |
| --- |
| **WARNER-LAMBERT COMPANY**By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Name:Title:  |
|   **THE UNIVERSITY OF TEXAS**By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Name: Title:  |

I have read this Agreement and understand
my obligations hereunder.

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

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_