**NON-GOVERNMENTAL CLINICAL STUDY AGREEMENT
("Clinical Trials")**

THIS AGREEMENT is made this \_\_\_\_\_\_\_\_\_\_\_\_\_ of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, 19 \_\_\_\_\_\_\_\_\_\_\_, between The University of Texas \_\_\_\_\_\_\_\_, \_\_\_\_\_\_\_\_\_ , \_\_\_\_\_\_\_\_\_, Texas \_\_\_\_\_, ("INSTITUTION"), a component of The University of Texas System ("SYSTEM"), and Marion Merrell Dow Inc., Kansas City, Missouri, ("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 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_described in Exhibit I as 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 the drug materials, protocol, case report forms, and statistical services for the conduct of the STUDY. Such drug materials shall be used by INSTITUTION solely for the purposes of completing the STUDY pursuant to this Agreement.

1.3. In performance of his duties, Investigator will at all times exercise his independent medical judgment as to the compatibility of each patient with the protocol requirements. Investigator will promptly notify SPONSOR and the IRB of any deviations from the protocol. INSTITUTION agrees that the Investigator or sub-investigators as listed on the Form 1572 will personally review all case report forms for completeness and accuracy, and that all data will be submitted in a timely manner.

**2. AWARD**

2.1. In consideration for performance of the STUDY by INSTITUTION, SPONSOR shall pay INSTITUTION a grant of\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ $\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ for each patient completing the STUDY, and a total of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ $\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ for the \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (\_\_\_\_\_\_\_\_\_\_\_\_\_\_) patients to be included in the STUDY. Payments will coincide with study initiation and completion of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, and \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ acceptable case report forms for procedurally correct patients, respectively. The first installment is payable within \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (\_\_\_\_\_\_\_\_\_\_) days of the date set forth hereinabove.

2.2 Payments made according to this Agreement are made in reliance upon completion of the scheduled case report forms. In the event that reports are not being completed substantially as scheduled, INSTITUTION will promptly refund, as requested by SPONSOR, a ratable portion of the payments made hereunder which were properly allocated to the reports scheduled but uncompleted. Reports of cases failing to meet protocol requirements will not be reimbursed unless otherwise specified by SPONSOR on a case-by-case basis.

2.3. SPONSOR recognizes that a certain number of patients participating in this STUDY will be lost to follow-up for numerous reasons. Funding for these patients will be accepted by SPONSOR in an amount commensurate with the percentage of study activities completed by these patients. The amount of this payment will be computed on an individual basis and added to the final payment.

2.4. All funds due to INSTITUTION hereunder will be paid to:

The University of Texas

Taxpayer Identification No.

**3. TERM**

3.1. This Agreement shall continue in force until completion of the STUDY as mutually agreed upon by the parties, or may be terminated by either party giving thirty (30) days advance notice of termination to the other. It is expected that case report forms for \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ patients are to be completed by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

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 invoice for same.

3.3. In the event \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_,designated as Investigator herein becomes unavailable and thereby unable to complete the STUDY, this Agreement may be terminated. INSTITUTION will return to SPONSOR any monies received but not yet encumbered as of the date upon which Investigator becomes unavailable. SPONSOR shall reimburse INSTITUTION for all expenses encumbered in the performance of the STUDY through the date of unavailability; provided, however, that SPONSOR and INSTITUTION may mutually agree to a substitute investigator, in which event this Agreement shall be amended and shall continue in full force and effect.

3.4. Upon termination of this Agreement, INSTITUTION shall return SPONSOR'S materials to SPONSOR.

**4. INDEMNIFICATION**

4.1 INSTITUTION shall, to the extent authorized under the Texas Constitution and the Texas Tort Claims Act, TEX. CIV. PRAC. & REM. CODE ANN., Title 5, 101 et. seq., 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 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 from any liability or loss resulting from judgments or claims for personal injury or death 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:

a. that the STUDY is conducted in accordance with the protocol, all written instructions delivered by SPONSOR concerning administration of the study drug and control drug, regulations as set forth in FDA Form 1572, 21 CFR Part 50 and Part 56, and such other requirements as may be published by FDA from time to time, and in the exercise of Investigator's own medical judgment;

b. that SPONSOR is notified promptly but in no event later than thirty (30) working days after receipt of notice of the injury or claim of suit, with same identified so as to advise INSTITUTION that it is related to the STUDY; and

c. that, to the extent to which SPONSOR is required hereunder to provide an indemnification for any claim or suit, to the extent permitted by law, and subject to the statutory duties of the Texas Attorney General, SPONSOR shall have the right to select defense counsel and to direct the defense or settlement of any such claim or suit.

In the event that representation of indemnities and SPONSOR by the same counsel would be a conflict of interest for such counsel, indemnities may select independent counsel without relieving SPONSOR of its obligations of indemnification and defense as set forth above.

4.3 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 attached hereto as Exhibit I; or

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

**5. PUBLICATION AND CONFIDENTIALITY**

5.1. It is understood that this study is part of a multi-center trial and Investigator will be free to publish the results of his part of the STUDY in collaboration with the other investigators in this trial, but with due regard to confidential and proprietary information and materials of SPONSOR. Subsequent to the multi-center publication or eighteen (18) months after completion of the STUDY, whichever comes first, Investigator may publish the results of the STUDY, again with due regard to confidential and proprietary information of SPONSOR. To this end, Investigator will provide SPONSOR with a copy of any manuscript or abstract derived from the STUDY for review and comment at least sixty (60) days prior to its submission for publication. In the event SPONSOR asks Investigator to defer publication because said publication contains SPONSOR'S confidential information, Investigator shall not publish or otherwise disclose to any third party any of the information contained in the publication until Investigator has deleted SPONSOR'S confidential information.

5.2. Except as otherwise required by law or regulation, SPONSOR agrees that its use of INSTITUTION'S name and that of Investigator will be limited to identifying INSTITUTION as the research site and the Investigator as the director of the STUDY. Any other use of the names of INSTITUTION or its employees must be approved in writing by an authorized representative of INSTITUTION. SPONSOR agrees that it will not use the name of INSTITUTION or its employees for advertising or other promotional purposes without prior written approval by an authorized representative of INSTITUTION.

5.3 Neither party shall issue any press release or other third party communication relative to this Agreement without the prior written consent of the other party.

5.4. All clinical data (hereinafter "Data"), including case reports and similar information generated as a result of the STUDY, will be promptly and fully disclosed to SPONSOR upon request. The completed case report forms shall be the property of SPONSOR and all such Data may be used by SPONSOR in any manner whatsoever.

5.5. It is understood that the information and materials referred to in the Protocol attached hereto as Exhibit I and accompanying Clinical Brochure for Investigators are considered confidential by SPONSOR and that further confidential information and materials may be supplied to INSTITUTION by SPONSOR in the future. It is agreed that such information and materials are the property of SPONSOR and that INSTITUTION will use its best efforts not to disclose such information or materials to others for a period of five (5) years after completion of this STUDY without the prior written consent of SPONSOR. Such confidentiality, however, will not apply to information or materials which are publicly available; which become publicly available through no fault of INSTITUTION; which INSTITUTION receives from a third party not under obligation to SPONSOR respecting such information; which can be documented to have been independently developed by INSTITUTION or the component institutions of the SYSTEM; which INSTITUTION is required by law to disclose; or which can be documented to already be in INSTITUTION'S possession. Nothing herein, however, 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. 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.

6.5 The invalidity or unenforceability of any term or provision of this Agreement shall not affect the validity or enforceability of any other term or provision hereof.

6.6 Waiver by either party or the failure by either party to claim a breach of any provision of this Agreement shall not be deemed to constitute a waiver or estoppel with request to any subsequent breach of any provision hereof.

IN WITNESS WHEREOF, The University of Texas and Marion Laboratories, Inc. hereby enter into this Agreement, effective as of the date first hereinabove written and execute \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (\_\_\_\_\_\_\_\_) original counterparts.

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| University of Texas \_\_\_\_\_\_\_\_\_\_\_\_ By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_                                Name Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  | Marion Merrell Dow Inc. By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_                                Name Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  |

I have read this Agreement and understand
my obligations hereunder.

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

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