**CLINICAL STUDY AGREEMENT**

1. **This Agreement** is between The University of Texas [*component*], a component of The University of Texas System, ("Institution") and Janssen Pharmaceutica Inc. ("Janssen"), to conduct a medical research study entitled, [*title of protocol*], ("Protocol"), protocol number [*number*] and all subsequent protocol amendments. The Institution agrees that the principal investigator(s) for the study will be [*investigator*] ("Investigator").

2. **The Investigator** has signed the Protocol Agreement Sheet and acknowledges that the Study is to be conducted in accordance with the Protocol and the conditions specified in each Investigator's Statement of Investigator Form (FDA 1572), and in compliance with all applicable federal, state, and local laws.

3. **The Institution** agrees that the protocol will not be revised without the written agreement of Janssen and the Institutional Review Board (IRB).

4. **The Institution** agrees that the Informed Consent Form approved by the IRB responsible for the Study and by Janssen is the only Informed Consent Form that will be used.

5. **The Institution** agrees to the performance measures and/or incentives specified in the payment schedule.

6. **Janssen** agrees to a grant, according to the attached payment schedule, for completed records for up to \_\_\_\_\_ valid subjects. ***A valid subject is defined as a subject who meets eligibility requirements to enroll int he study and does not have significant protocol violations that would exclude his/her data from analysis.*** Subjects not completing the trial will be paid for on a prorated basis according to the number of completed visits. All payments will be made for subject visits according to the attached payment schedule. No payment will be made for any subject excluded from analysis because of protocol violations that were within the study personnel's control. Reimbursement for expenses related to screening failures will be made according to the payment schedule.

7. **The Institution** agrees that Janssen will have access to any source documents from which case record forms have been generated.

8. **The Institution** conducting a blinded trial agrees to maintain the blinding of the drug. The Investigator understands that the randomization codes will be released upon completion of the study and finalization of the database by Janssen. For multi-center studies, data from all centers are required before the study is considered completed. Should a medical emergency occur requiring the Investigator to break the code for a specific patient, the Investigator agrees to notify Janssen immediately.

9. **The Institution** agrees that no subject in this study may participate concurrently in any ancillary study (technique, procedure, questionnaire, or observation other than those set forth in the protocol) without prior approval in writing from Janssen. In this instance, the Investigator agrees that all such ancillary studies will be conducted according to federal and state regulations, including IRB approval and subject informed consent.

10. **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 from receipt thereof, provided that the recipient party's obligation shall not apply to information that:

1. is not disclosed in writing or reduced to writing and so marked with an appropriate confidentiality legend within thirty (30) days of disclosure;

2. is already in the recipient party's possession at the time of disclosure thereof;

3. is or later becomes part of the public domain through no fault of the recipient party;

4. is received from a third party having no obligations of confidentiality to the disclosing party;

5. is independently developed by the recipient party; or

6. is required by law or regulation to be disclosed.

In the event that information is required to be disclosed pursuant to subsection 6, 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.

Janssen agrees that scientific data developed from the study may be published, provided the manuscript is sent to Janssen thirty (30) days prior to submission for publication.

11. **Janssen** will indemnify and defend the Institution, System, their Regents, officers, agents and employees, clinical investigators approved by Janssen, and personnel working under their direct supervision against any claim or suit brought against any of them resulting from the activities to be carried out pursuant to the obligations of this Agreement, including but not limited to the use by Janssen of the results of this study; provided that said use of the product and the conduct of the investigation were in accordance with the protocol for the clinical investigation and any other written information, instructions, or warnings furnished by Janssen, and also provided that IRB approval is obtained when required by law and that the informed patient consent form complies with Federal, State, and Municipal Regulations.

For this indemnification to apply, Institution must promptly notify Janssen upon receipt of notice of any claim or lawsuit and, subject to the statutory duties of the Texas Attorney General, must permit Janssen's attorneys and personnel, at Janssen's discretion and cost, to handle and control the defense to such claims or suits. Institution cannot settle any such claims or suits without prior written consent of Janssen. Institution will agree, subject to the statuary duties of the Texas Attorney General, to fully cooperate and aid in such defense.

Institution understands that the sole liability of Janssen to the Institution and those employees engaged in conducting the investigations at the request of Janssen will be the indemnification described above.

Notwithstanding the foregoing, Janssen does not agree to indemnify, defend, or hold harmless any person or institution against any claim or suit due to the negligence or willful malfeasance of the Institution.

12. **Janssen** is a wholly-owned subsidiary of Johnson & Johnson and is insured for its liabilities hereunder in an amount of at least $1 million per occurrence through a Johnson & Johnson self-insurance program. Written evidence of the Johnson & Johnson self-insurance coverage will be supplied upon request.

13. **The Institution** shall not employ, contract with or retain any person directly or indirectly to perform services under this agreement if such person is debarred by the U.S. Food and Drug Administration under 21 U.S.C. §355a (Federal Food and Drug and Cosmetic Act §306). Upon written request from Janssen, the Investigator and Institution shall, promptly but no later than thirty (30) days, provide written confirmation that it has compiled with the foregoing obligation.

14. **The Investigator** understands that, if there is any suspicion of misconduct or fraud, Janssen will report this to the FDA and will cooperate fully with governmental agencies in any ensuing investigation.

15. **The Study** may be terminated at any time by Janssen or the FDA. The Study may be terminated by Institution for subject safety concerns or if the Investigator leaves the Institution and a suitable replacement cannot be found. If the Study is terminated, all enrolled subjects will be paid for on a prorated basis according to the number of visits completed.

16. **This Agreement** shall be governed by the laws of the State of Texas.

17. **IN WITNESS WHEREOF,** the undersigned agrees to the terms and conditions of this Agreement and the attached payment schedule.

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| University of Texas \_\_\_\_\_\_\_\_\_\_\_\_  By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_                                 Name  Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Janssen Pharmaceutica Inc.  By:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_                                 Name  Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

I have read this Agreement and understand  
my obligations hereunder.

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

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