**Clinical Trial Agreement**

[Date]

[Component Contact,

Component Address]

Dear [Component Contact]:

This is to confirm our agreement for work to be performed under the protocol entitled, [protocol], Study No. [study number], a copy of which has been previously given to The University of Texas [Component], and which is incorporated in its entirety by reference herein. [Principal Investigator], an employee of The University of Texas [Component], will be the principal investigator of this study. Other investigators, employed by The University of Texas [Component], may also work under [Principal Investigator] to perform this study and in such event each of them will be bound automatically by all of the terms and conditions of this Agreement as well as the above-described protocol.

The anticipated enrollment for this study is based on the number of eligible patients completing the [Organon Study Number]. Payments will be made in accordance with the payment schedule, attached hereto as Exhibit A and incorporated herein up to a maximum total cost of [Total Cost]. The maximum total cost is based on a projection of patient enrollment and retention for the long-term study. Patient enrollment and retention will be reviewed periodically. At your request, payments will be made payable to The University of Texas [Component], Tax ID #[tax ID number]. The initial payment shall be sent as soon as all pre-investigational tasks (preparation of clinical supplies, notification of FDA) have been completed and after Organon's review and approval of the IRB sanctioned patient consent form for this study. It is understood that any change in the designated payee must be supported by sufficient documentation as required by Organon Inc.

It is further understood that any contracts or obligations with other institutions or organizations with which The University of Texas [Component], Principal Investigator or any other investigator hereunder are now or may become associated during the course of this study shall not conflict with the work required to be performed under this study. It is further understood and agreed that no person debarred by the U.S. Food and Drug Administration will be used in any capacity to perform any services under this Agreement.

It is understood and agreed that all information and data concerning this study are confidential and/or proprietary, exclusive property of Organon Inc. to do with as it wishes. Such data and information shall not be used except as contemplated herein and shall not be disclosed by UNIVERSITY, PRINCIPAL INVESTIGATOR or anyone working on this study to any third party except as required to do so by law or court order.

UNIVERSITY may publish data resulting from this study in accordance with the terms and conditions provided herein this paragraph. Publication of data resulting from this study, including but not limited to any papers, abstracts and presentations (oral or written), may not be made without prior review and comment by ORGANON, which comments will not be unreasonably rejected. Before any such paper, abstract, or presentation is made to any third party, a complete copy of such paper, abstract or presentation shall be provided to ORGANON at least sixty (60) days prior to the proposed date of submission or publication to such third party.As this study is a multicenter investigation, it is understood and agreed that participation in the study involves a commitment to publish data from the study in a cooperative publication prior to publication or presentation of efficacy and safety results on an individual basis. It is agreed that UNIVERSITY will not publish individual results of this study prior to publication of the results achieved during the entire multicenter study. However, if no manuscript of the multicenter study results is submitted for publication within 18 months of the date that ORGANON has submitted the final clinical study report for the multicenter study to the U.S. Food and Drug Administration, then UNIVERSITY may publish or present its individual study results before publication of the multicenter study results.

It is further agreed that, upon ORGANON's receipt of a fully executed copy of this Agreement, ORGANON shall execute an indemnification commitment in favor of UNIVERSITY in the form attached hereto as Exhibit B.

UNIVERSITY's relationship with ORGANON under this Agreement shall be that of an independent contractor and nothing in this Agreement or the arrangements for which it is made shall constitute UNIVERSITY or anyone furnished or used by UNIVERSITY in the performance of the services contemplated by this Agreement, as an employee, joint venturer, partner or servant of ORGANON.

UNIVERSITY, PRINCIPAL INVESTIGATOR, as well as each investigator performing work hereunder has the knowledge, expertise and training to perform the work and services contemplated herein; and will comply with all federal, state and local statutes and regulations pertaining to this study; and will execute any and all documents pertaining to this study ORGANON may reasonably request for its anticipated filing(s) with governmental authorities including, but not limited to, written statements certifying that no individual debarred pursuant to 306(a) and 306(b) of the Generic Drug Enforcement Act of 1992 were used in any capacity to perform any services under this Agreement and statements certifying the accuracy of clinical reports that may be produced for this study.

Time is of the essence and this Agreement, including the protocol, must be strictly adhered to.

As with all clinical studies, ORGANON reserves the right to terminate the study, or any part thereof, upon written notice. In such event, payment will be made in accordance with Exhibit A for all work performed up to the time of termination.

Any modification, change, deletion or addition to this Agreement or any part thereof, shall be effective only after both parties prior written consent thereto.

This Agreement, dated [date], is the sole Agreement between the parties and supersedes any prior agreements or arrangements, whether oral or in writing, pertaining to the subject matter herein.

Please indicate agreement with and acceptance of the terms and conditions of this Agreement by signing both originals of this letter. Please return both signed originals to ORGANON INC. for execution, whereupon one fully executed original will be returned to your for your file.

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| University of Texas \_\_\_\_\_\_\_\_\_\_\_\_ By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_                                Name Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  | Organon, Inc. By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_                                Name Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  |

I have read this Agreement and understand
my obligations hereunder.

By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

Accepted and agreed:



**Exhibit A**

**Payment Schedule**



**Exhibit B**

[Contact at Component]

COMPONENT

Dear [Contact at Component]:

It is our understanding that The University of Texas [Component] ("UNIVERSITY") desires an indemnification commitment from Organon Inc. ("ORGANON") relative to [Protocol Study No.] being performed by UNIVERSITY ([Principal Investigator] - PRINCIPAL INVESTIGATOR.) We will provide UNIVERSITY with such commitment including defense of any claim or lawsuit in accordance with our insurance policy, in particular, by adding UNIVERSITY, The University of Texas System, their Regents, agents, officers and employees as additional insureds to our policy. We have requested a certificate from our insurance carrier indicating that UNIVERSITY, The University of Texas System, their Regents, agents, officers and employees are being added as additional insured and it will be sent to you under separate cover.

Sincerely,

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| --- | --- |
| University of Texas \_\_\_\_\_\_\_\_\_\_\_\_ By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_                                Name Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  | ORGANON INC. By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_                                Name Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  |