**MASTER CLINICAL STUDY AGREEMENT**

THIS MASTER CLINICAL STUDY AGREEMENT (the “ Agreement”) is made and effective August 3, 2004 (the " Effective Date") between the following (and as further described in Exhibit B) component institutions of The University of Texas System ("System") located at 201 West 7th Street, Austin, Texas 78701, that is governed by its Board of Regents (“Board”): THE UNIVERSITY OF TEXAS HEALTH CENTER AT TYLER, THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON, THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT SAN ANTONIO, THE UNIVERSITY OF TEXAS M.D. ANDERSON CANCER CENTER, THE UNIVERSITY OF TEXAS MEDICAL BRANCH AT GALVESTON, THE UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER AT DALLAS AND THE UNIVERSITY OF TEXAS AT AUSTIN (hereinafter collectively referred to as " Institution") and InterMune, Inc., a Delaware corporation (" InterMune"), having the respective addresses as set forth below. Each of Institution and InterMune may be referred to individually herein as a “ Party,” and jointly as the “ Parties.”

**WHEREAS** , Institution possesses certain expertise in the field of pharmaceutical clinical and related research and evaluation of such research; and

**WHEREAS** , InterMune is interested in engaging Institution in order to obtain the benefit of such expertise with respect to certain research and development projects being conducted by InterMune into the clinical development, safety and efficacy of various pharmaceutical products and/or medical devices being developed by InterMune;

Therefore, in consideration of the premises and undertakings set forth herein, Institution and InterMune agree as follows:

**1. DEFINTIONS**

**1.1 “Authorization”** will have the meaning ascribed in section 7.2.

**1.2** **“CFR”** means the United States Code of Federal Regulations.

**1.3 “Consent Form”** will have the meaning ascribed in Section 7.1.

**1.4 “Data”** will have the meaning ascribed in Section 14.5.

**1.5 “FDA”** means the United States Food and Drug Administration.

**1.6 “FD&C Act”** means the United States Federal Food, Drug and Cosmetic Act, as may be amended from time to time.

**1.7 “GCP”** means the Guidelines for Good Clinical Practices promulgated by the ICH (defined below) and all federal, state and local laws applicable to the conduct of clinical trials.

**1.8 “ICH”** means the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.

**1.9 “IRB”** means an institutional review board as defined in 21 CFR 56.102 (g).

**1.10 “Investigator”** means the principal investigator for a Study (defined below), as specified in the applicable Work Order.

**1.11 “Materials”** means all substances, compounds, devices, computer hardware or software and/or materials provided to Institution by or on behalf of InterMune for use in the performance of a Study.

**1.12 “Privacy Board”** means a privacy board, as defined in 45 CFR 164.512(i)(1)(i)(B).

**1.13 “Product”** means a proprietary InterMune pharmaceutical product or investigational drug that is (are) the subject of a Study.

**1.14** **“Regulatory Authority”** means any governmental or regulatory authority, with jurisdiction over a Study or a Product, including without limitation the FDA, and any entity representing such an authority.

**1.15 “Proprietary Information”** means (a) all confidential information and Materials, including, but not limited to, know-how, data, trade secrets, technology, expertise or other information, whether or not patentable or copyrightable, that is disclosed or provided by or on behalf of InterMune to Institution in connection with this Agreement (including without limitation such information and Materials that are disclosed pursuant to the negotiation of a potential Work Order), (b) subject to the Texas Open Records Act, and other applicable laws and regulations, the terms of this Agreement and of any Work Order, and (c) any other information designated as “Proprietary Information” under this Agreement.

**1.16 “Protocol”** means the protocol for the conduct of a Study, as set forth in the relevant Work Order.

**1.17 “Study”** means one or more InterMune Sponsored clinical research studies requested by InterMune and agreed to by Institution as set forth in the relevant Work Order , which may be referred to collectively as the “Studies.”

**1.18** **“Work Order”** will have the meaning ascribed in Section 3.1.

**2. SCOPE OF THE AGREEMENT**

The Parties intend for this Agreement to allow them to contract for multiple InterMune Sponsored Studies through the issuance of Work Orders without having to re-negotiate the basic terms and conditions contained herein.

**3. WORK ORDERS**

**3.1** The specific details of each Study under this Agreement will be separately negotiated by the Parties and specified in writing, on terms and in a form acceptable to the Parties (each such writing, a " Work Order"). Each Work Order will include the Protocol, time line and payment schedule for such Study. A sample Work Order is attached hereto as Exhibit A. InterMune will have no obligations hereunder with respect to any Study performed by Institution unless such Study is covered by an executed Work Order, or otherwise agreed to in writing by the Parties.

**3.2** Institution will conduct each Study covered by each executed Work Order in accordance with the terms and conditions of such Work Order (including without limitation, the Protocol and time line) within the amounts budgeted. Each executed Work Order will be deemed to be a part of this Agreement; *provided that* to the extent any terms or provisions of a Work Order conflict with the terms of this Agreement (exclusive of such Work Order), the terms of this Agreement will control, except to the limited extent that the applicable Work Order expressly and specifically states an intent to supersede this Agreement on a specific matter. Notwithstanding any other provision of this Article 3, this Agreement will not be deemed to be amended or modified in any manner by any provision of any Work Order.

**4.** **INVESTIGATORS’ QUALIFICATIONS**

**4.1** Each Work Order will identify the Investigator for the Study that is the subject of such Work Order (including, to the extent requested by InterMune, detailed *curriculum vitae*, certificates of training, current medical license and description of proposed responsibilities and time commitment).

**4.2** With respect to each Study, Institution will ensure that the applicable Investigator and subinvestigators will make the following representations to InterMune as part of each Work Order:

**(a)** Such person has no financial interests and/or arrangements with InterMune (or any development partner of InterMune for the applicable Product, if InterMune has identified such partner to Institution) that will require disclosure to FDA in accordance with 21 CFR Part 54;

**(b)** Such person has not been “debarred” by the FDA under the provisions of the Generic Drug Enforcement Act of 1992, 21 U.S.C. § 335a (a) and (b), nor have debarment proceedings been commenced against him or her;

**(c)** Such person is aware of and shall be bound by the terms of this Agreement (including without limitation Sections 6, 14 and 15 hereof) and of the Work Order covering such Study.

**4.3** With respect to each Study, Institution will also supply the following documents:

**(a)** A signed investigator statement (Form FDA-1572) and *curriculum vitae* for all individuals listed therein, and

**(b)** If any such individuals have been involved in an investigation or other research that has been terminated for cause, an explanation of the circumstances that led to such termination.

**5.** **FDA AND IRB APPROVAL**

For each Study to be conducted hereunder, InterMune will provide to the FDA and to the applicable Investigator for submission to the applicable IRB, adequate information (i.e. investigator's brochure, the Protocol, and sample informed consent form) for review and approval to begin such Study. If the IRB requires any modification of such informed consent form, Institution will promptly provide a copy of the form as modified to InterMune for its approval. Institution will provide InterMune with a copy of each IRB approval. Institution will promptly report any withdrawal of IRB approval to InterMune.

**6. CONDUCT OF STUDIES, GENERALLY**

**6.1** Institution will commence each Study as soon as possible following receipt of FDA and IRB written approval, or as otherwise agreed upon in writing with InterMune, and will follow any conditions of approval imposed by the FDA or the IRB. Study commencement will be subject to Institution’s receipt of the applicable Product and InterMune’s written authorization for initiation. Institution acknowledges that time is of the essence in completion of each Study.

**6.2** Institution and the applicable Investigator will conduct each Study in accordance with all applicable federal, state and local laws and regulations for protecting the rights, safety and welfare of human subjects and for the control of investigational drugs, including without limitation 21 CFR Parts 50 and 312 and all recognized medical and ethical standards for the conduct of clinical investigations, including without limitation GCP.

**6.3** Institution will ensure that all employees and agents of Institution who are to perform services under this Agreement are made aware of the obligations contained in this Agreement and the applicable Work Order and are bound by such obligations.

**6.4** Institution and the Investigator for each Study will use their best efforts and independent medical judgment to recruit only subjects likely to be eligible, per the Protocol, and sufficiently reliable to complete such Study in its entirety.

**6.5** Except in the case of a medical emergency or otherwise necessary for patient safety, neither Institution nor any Investigator will make any changes in, nor deviate from, the applicable Protocol without InterMune’ s prior written approval.

**6.6** InterMune or its designee will provide clinical monitoring for each Study. Institution and the applicable Investigator will cooperate fully with InterMune and/or its designee in the performance of its duties as clinical monitor.

**6.7** Any substitutions or replacements of an Investigator during the course of a Study must first be approved in writing by InterMune. If the Investigator for a Study becomes unable or unwilling to continue to perform his or her responsibilities under such Study, Institution will use its best efforts to provide a replacement acceptable to InterMune as promptly as possible. If Institution is unable to replace such Investigator to InterMune’ s reasonable satisfaction, InterMune will have the right to terminate such Study upon thirty (30) days written notice to Institution, as set forth in Section 6.8.

**6.8** InterMune reserves the right to terminate any Study at any time with or without cause upon notice to the Institution and the applicable Investigator. Any verbal notice of termination will be confirmed in writing within thirty (30) days. Upon receipt of initial notice of termination of a Study from InterMune, Institution and the applicable Investigator will cease the clinical investigation of the applicable Product and the enrollment of further subjects into such Study. Institution and the applicable Investigator will continue to collect Data and prepare case report forms for subjects who received such Product prior to such notice, as directed in writing by InterMune. Unless InterMune has terminated such Study or this Agreement for cause, Institution will be reimbursed by InterMune for (a) all fees incurred in its conduct of such Study through the effective date of such termination, and for any further Data and case report form processing as described above, in accordance with the payment schedule set forth in the applicable Work Order, and (b) any reasonable, non-cancelable costs resulting from the termination following InterMune’s receipt of an itemized invoice detailing such costs.

**6.9** Institution will promptly inform InterMune in writing of (a) any conflict or possible conflict that arises with respect to Institution’s and/or an Investigator’s obligations under this Agreement or any Work Order, or (b) any debarment or disqualification of Institution and/or an Investigator, or the commencement of any withdrawal of an Investigator's privileges or of any debarment, disqualification or like proceedings against Institution and/or an Investigator, or (c) of any financial interests and/or arrangements of Institution or an Investigator requiring disclosure to the FDA.

**7.** **INFORMED CONSENT/AUTHORIZATION/PRIVACY**

**7.1** For each Study to be conducted hereunder, and in accordance with 21 CFR Part 50 and 312.60, Institution will inform all subjects of such Study or their legal representatives that the applicable Product is being used for clinical investigation, and will obtain from these subjects or their legal representatives a signed written informed consent form that has been approved by the IRB and InterMune (a “ Consent Form”). Each subject will be provided a photocopy of his or her signed Consent Form, the original of which will be placed in the respective subject's investigational file.

**7.2** In accordance with the Health Insurance Portability & Accountability Act of 1996 and the regulations promulgated thereunder, and any other applicable federal, state or local law relating to the protection of patient health information (collectively, “ Privacy Regulations”), prior to administration of a Product in a Study, Institution will obtain from all Study subjects or their legal representatives a signed authorization to use and disclose such subject’s medical information that conforms to the Privacy Regulations and has been approved by InterMune and the Institution’s IRB (an “ Authorization”). Where permissible by applicable Laws, such Authorization may be incorporated into the Consent Form . Institution will provide to each subject a photocopy of his or her signed Authorization, the original of which Institution will place in the respective subject's investigational file. Institution will ensure that each Authorization will permit disclosure of such subject’s health information to and redisclosure among InterMune, its contractors and agents, other Study investigators and the appropriate Regulatory Authorities in connection with the applicable Study.

**7.3** Each Party will comply with all Privacy Regulations applicable to its performance under this Agreement.

**8. SUPERVISING USE**

In accordance with 21 CFR Part 312.61, Institution will permit each Product to be used only by subjects under the applicable Investigator's supervision, or under the supervision of the associates listed on the applicable Form FDA-1572. Institution will not supply the Product to any person other than those authorized under this Agreement. Neither Institution nor any Investigator will undertake any procedures with any Product other than those set forth in the applicable Protocol on the enrolled subjects without the prior written approval of InterMune (and the IRB when necessary). Institution will not supply such Product, nor permit such Product to be supplied, to any third party (including, without limitation, any other individual except the above-referenced associates) or laboratory or any clinic for use in humans or for *in vitro* or *in vivo* laboratory research, or any other use, without InterMune’s prior written approval.

As specified in a Protocol, all specimens collected for a specific Study by the Institution shall be delivered to InterMune or its designee, at InterMune’s expense, in accordance with the Protocol or InterMune’s written instructions. The Institution shall not collect specimens derived from a specific Study for use in any other research without the prior written permission from InterMune.

**9.** **RECORDS**

**9.1** Institution will maintain the following accurate, complete and current records with respect to each Study, and, to the extent allowed by law or regulation, will make such records available to InterMune and its authorized representatives promptly upon written request:

**(a)** Any and all correspondence with InterMune, the IRB, the Privacy Board and/or any Regulatory Authority.

**(b)** In accordance with 21 CFR 312.6, records of receipt, use or disposition of the Product that is the subject of such Study including without limitation:

**(i)** The date of receipt, type, quantity, lot number and other identifying marks of such Product;

**(ii)** The names of all persons who received, used or disposed of each unit of such Product;

**(iii)** An explanation of the reasons why any Product was returned to InterMune (excluding the routine return of such Product upon completion or other termination of such Study).

**(c)** In accordance with 21 CFR 312.62, source records of each subject's case history and exposure to such Product. The records will:

**(i)** Include copies of signed Consent Forms and Authorizations (if separate from Consent Form);

**(ii)** Except with respect to Consent Forms and Authorizations (if separate from Consent Form), be transcribed onto InterMune-supplied case report forms and be completed at times indicated by InterMune;

**(iii)** Include all observations, and other data and records pertinent to such Study, and all records concerning adverse events.

**(d)** The applicable Protocol, and any amendments thereto, with documents showing the dates of and reasons for each deviation from such Protocol.

**9.2** Institution will review, sign and date the case report forms for each subject enrolled in a Study. Institution will make available upon written request all source documents, including without limitation each patient’s medical records and x-ray, laboratory and pathology reports, for review as needed by InterMune or its representatives to audit or correct Study case report forms or to respond to a Regulatory Authority. Prior to any necessary copying of source documents, InterMune’s representatives shall redact any patient identifying information. The foregoing source documents and records will be made available upon written request for review at pre-Study and routine clinical monitoring visits. Institution will cooperate with InterMune or its representatives during monitoring visits or for the resolution of questions regarding records or clinical data generated throughout the performance of this Agreement.

**9.3** Institution will retain the records in accordance with 21 CFR 312.62 and with ICH GCP 4.9.5, which provides in pertinent part that:

Essential documents should be retained until at least 2 years after the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applications in an ICH region or at least 2 years have elapsed since the formal discontinuation of clinical development of the investigational product.

InterMune will inform Institution as to when these documents no longer need to be retained.

**9.4** Neither Institution nor any Investigator will divulge the names of subjects on any case report forms or otherwise. Institution will maintain a detailed list identifying the subjects of each Study.

**10.** **REPORTS**

**10.1** Institution will prepare and submit to InterMune or its designee the following complete, accurate and timely reports with respect to each Study:

**(a)** **Case Report Forms:** Institution will submit completed case report forms as required in the applicable Protocol or as otherwise requested in writing by InterMune. In the event subject follow-up is not possible for any reason, Institution will document this fact and the circumstances thereof on a case report form and promptly submit such form.

**(b) Adverse Events:** Institution will report any serious adverse events that occur in connection with such Study to InterMune, and to the IRB if required by federal regulations (including without limitation 21 CFR 312), as soon as possible, but in no event later than twenty-four (24) hours following receipt of such information.

**(c) Withdrawal of IRB Approval:** Institution will notify InterMune promptly in writing the IRB’s withdrawal of approval of the Institution's or applicable Investigator's participation in a Study immediately following receipt of such notice from the IRB.

**(d) Deviations from the Protocol:** Institution will promptly notify InterMune in writing of any deviation from the Protocol.

**(e) Informed Consent:** Institution will promptly notify InterMune and the IRB of any failure to obtain informed consent or an Authorization from a subject in accordance with Article 7 prior to such subject’s participation in a Study, but in any event within five (5) working days after discovery of such failure occurs.

**10.2** Institution will provide to InterMune (i) periodic written progress reports for each Study, and (ii) a final written report for such Study, in each case as described in the applicable Work Order.

**10.3** InterMune will prepare all reports required for submission of to any Regulatory Authority. Upon written request by InterMune, Institution will conduct a complete, accurate and timely review and provide comments on any such report prior to its submission to such Regulatory Authority.

**11. COMPENSATION**

**11.1** InterMune will compensate Institution for its conduct of each Study in accordance with the payment terms and fee schedule set forth in the applicable Work Order. Unless otherwise agreed in writing by the Parties, such payment amount is inclusive of any and all applicable fees, personnel costs, overhead and the like.

**11.2** Institution's payments will be made payable to the name and address set forth in the applicable Work Order.

**11.3** It will be Institution’s sole responsibility to report all payments received under this Agreement. InterMune may also report any payments made to Institution under this Agreement, and withhold from such payments any required amounts for remittance to the applicable authority, solely to the extent required by applicable federal, state or local laws or regulations.

**12. REGULATORY ISSUES; INSPECTIONS**

**12.1** Institution will be responsible for obtaining and maintaining, at its expense, all permits, licenses, approvals, authorizations and the like required for its performance under this Agreement.

**12.2** If any Regulatory Authority requests access to Institution’s records, facilities and/or personnel, or conducts an unannounced inspection, in each case relating to a Study, then Institution will promptly notify the contact set forth in the Work Order covering such Study by telephone followed by written confirmation. InterMune will have the right, but not the obligation, to be present at any audit or inspection by a Regulatory Authority that relates to a Study, and where time permits, to conduct a pre-inspection audit.

**12.3** Institution will promptly provide InterMune copies of all communications between Institution and any Regulatory Authority relating to any Study. Where Institution is required or intends to respond to any such communication, Institution will provide InterMune with a copy of such communication and Institution’s proposed response sufficiently in advance of the date that such response is to be submitted, in order to permit InterMune to review and comment upon such response. To the extent permitted by law, Institution will incorporate all such InterMune comments into such response prior to submission.

**12.4** Institution will permit InterMune’s representatives to examine or audit the work performed pursuant to any Study and the facilities at which the Study is conducted, upon reasonable advance written notice during regular business hours, to determine that Institution is conducting Study in accordance with the terms of this Agreement and the applicable Work Order and regulatory requirements, and that Institution is providing adequate facilities and staffing.

**12.5** InterMune’s failure to exercise its rights to conduct audits under this Article 12 will not represent a waiver of any future exercise of this or any other right hereunder, nor does it represent acceptance of any past or present conditions that might exist.

**13.** **DISPOSING OF CLINICAL SUPPLIES**

In accordance with 21 CFR 312.59, upon the earlier of completion or termination of each Study or at InterMune’s written request and expense, Institution will return to InterMune any remaining Product (including investigational devices, if any) and other Materials from such Study, or, if so instructed by InterMune, destroy any such remaining Product in accordance with the written instructions provided by InterMune and consistent with applicable local, state and federal guidelines and will supply InterMune with a written statement of such destruction.

**14. INTELLECTUAL PROPERTY/CONFIDENTIALITY**

**14.1** Institution hereby agrees for a period of five (5) years from the expiration or termination of the applicable Study.

**(a)** not to use any Proprietary Information except for the purpose of conducting the applicable Study or as otherwise expressly authorized in this Agreement or in writing by InterMune, and

**(b)** not to disclose or transfer Proprietary Information to any person or entity, other than to those employees or agents (including, without limitation, Investigators, IRB and Privacy Board members) who require same for the purpose hereof and who are bound by similar obligations to protect such Proprietary Information, without the express written permission of InterMune.

**14.2** The obligations set forth in Section 14.1 will not apply to any Proprietary Information that Institution can demonstrate by written evidence:

**(a)** was known to Institution prior to its disclosure or creation hereunder or was already in Institution’s possession at time of request, unless such information came to be in Institution’s possession under obligations of confidentiality;

**(b)** is now or later becomes publicly available other than by breach of this Agreement;

**(c)** is lawfully disclosed to Institution on a non-confidential basis by a third party who is not obligated to InterMune or any other party to retain such Proprietary Information in confidence;

**(d)** is independently developed by Institution and/or Investigator without the use or benefit of Proprietary Information.

**14.3** Nothing in this Agreement will prevent Institution from disclosing Proprietary Information that is duly required to be disclosed by law or regulation, order of a court, government agency or the like having competent jurisdiction; *provided that* Institution will (a) promptly notify InterMune in writing of such requirement reasonably in advance of such disclosure, (b) disclose only such portion of the Proprietary Information as is required to be so disclosed, and (c) cooperate with InterMune at InterMune’s expense in seeking a protective order or injunctive relief to protect the confidentiality of the Proprietary Information.

**14.4** The furnishing of Proprietary Information under this Agreement will not constitute any grant, option or license to the Institution under any patent or other rights now or hereafter held by InterMune. Institution will not acquire any rights of any kind whatsoever with respect to any Product or intellectual property right of InterMune as a result of this Agreement.

**14.5** All data, information and results resulting from the performance of this Agreement (" Data") will be and is the sole and exclusive property of InterMune, and Institution hereby assigns, and automatically will be deemed to have assigned, to InterMune all right, title and interest of Institution in and to such Data. All Data will be delivered to InterMune in a timely fashion, and in no event later than fifteen (15) business days after the earlier of: (a) any date provided in the applicable Protocol, (b) receipt of InterMune’s written request for such Data, (c) termination or expiration of the applicable Study or (d) termination or expiration of this Agreement. All Data will be deemed “Proprietary Information.” Notwithstanding the foregoing, Institution shall have the right to publish Institution’s individual results subject to Article 15 of this Agreement.

**14.6** Any inventions, discoveries and the like relating to a Product, whether patentable or not, conceived of and/or reduced to practice by Institution and/or Investigator, whether solely or jointly with others, as a result of performance of a Study or of any disclosure of Proprietary Information under this Agreement, and all intellectual property rights therein and thereto (collectively, "Inventions") will be and remain at all times the sole and exclusive property of InterMune. Institution hereby assigns, and automatically will be deemed to have assigned, to interMune all right, title and interest in and to all inventions. Institution will promptly disclose all Inventions to InterMune. Institution, without further compensation other than reimbursement of its reasonable documented costs directly relating thereto, will perform any and all acts necessary to assist InterMune in preparing, filing any patent applications and enforcing any patents covering the Inventions, or in otherwise perfecting its rights thereto. All Inventions will be deemed "Proprietary Information."

**14.7** All writings, reports, records (exclusive of Study subject medical records) and documentation generated pursuant to any Study, whether in written, electronic or other form or media, (collectively, “ Documentation”) will be owned exclusively by InterMune. Institution hereby assigns, and automatically will be deemed to have assigned, to InterMune all right, title and interest in and to all Documentation. To the extent permitted by applicable law or regulation, InterMune will have the unrestricted right to reproduce, modify, distribute, publish and use all such Documentation. Notwithstanding the foregoing, all original Study subject records are the sole and exclusive property of the respective subjects, to be retained by Institution as required by applicable law and regulations. All Documentation will be deemed “Proprietary Information.” Notwithstanding the foregoing, Institution shall have the right to publish Institution’s individual results subject to Article 15 of this Agreement.

**14.8** Institution understands and acknowledges that the United States securities laws prohibit any person who has material non-public ("inside") information about a company from purchasing or selling securities of such company, and prohibits communicating such material non-public information to any other person under circumstances where it is reasonably foreseeable that such person is likely to purchase or sell securities of such company. Institution further acknowledges that the Proprietary Information, including without limitation Data, reports and information concerning the progress of a Study, can constitute such material non-public information, and will comply with all United States Securities laws with respect to such Proprietary Information.

**14.9** Upon written request of InterMune, at the completion or earlier termination of a Study, all tangible copies of Proprietary Information relating to such Study and any copies thereof will be returned to InterMune at InterMune’s expense, except that one record copy may be retained in Institution's or the applicable Investigator's legal files solely for purposes of determining future compliance with the terms of this Agreement or for other purposes as allowed in this Agreement.

**14.10** Institution acknowledges that the promises or agreements contained in this Agreement relating to confidentiality and/or intellectual property are necessary and reasonable in order to protect InterMune and its business, and Institution expressly agrees that monetary damages would be inadequate to compensate InterMune for the breach thereof, and that any such violation or threatened violation will cause irreparable injury to InterMune. Accordingly, in addition to any other remedies that may be available, in law, in equity or otherwise, InterMune shall be entitled to obtain injunctive relief against the breach or threatened breach by Institution of such obligations, as soon as such breach or threatened breach is discovered.

**15.** **PUBLICATION OF RESULTS**

**15.1** Institution understands that InterMune intends, for each Study, to have a committee comprised of investigators responsible for such Study at multiple centers prepare and publish a multicenter publication with respect to such Study (the “ Primary Publication”). Institution therefore agrees not to publish, present or otherwise disseminate any information relating to such Study, except as permitted under Section 15.2.

**15.2** If no Primary Publication for a Study has been submitted for publication within eighteen months (18) of InterMune’s receipt of all Data from such Study from all Study sites, then Institution or the applicable Investigator may publish and/or otherwise present the Institution's individual Study results in any form, including but not limited to lectures, slides, abstracts, posters and the like, subject to subsections (a) and (b) below.

**(a)** If Institution or such Investigator wishes to make such a presentation or a submission for publication, Institution and/or such Investigator first must submit all such materials to InterMune for review and comment at least thirty (30) days prior to the date on which such presentation or submission is proposed to be made.

**(b)** Institution and Investigator will give due consideration to all reasonable comments received from InterMune on such presentation or submission. Institution will delay the presentation or submission for up to forty-five (45) additional days if, upon review of the presentation or submission, InterMune reasonably determines and notifies the Institution in writing within the initial thirty-day period that the presentation or submission contains patentable material and/or Proprietary Information. At InterMune’s expense, Institution agrees to provide to InterMune and its representatives such assistance in the preparation and filing of any patent application(s) as InterMune may reasonably request and to cooperate with InterMune with regard to such measures as are reasonably necessary to protect such Proprietary Information and, upon InterMune’s written request, to delete any Proprietary Information other than Institution’s individual Study results.

**16. REPRESENTATIONS AND CERTIFICATIONS**

**16.1** Institution hereby represents and certifies that:

**(a)** It is under no obligation to any third party, and will not during the term of this Agreement assume any obligation to any third party, that would conflict with, prohibit or otherwise interfere with its performance of its obligations under this Agreement;

**(b)** all Investigators that perform any Study under this Agreement will be qualified by training and experience as appropriate experts to conduct such Study, as required under 21 CFR 312.53;

**(c)** it has no financial interests and/or arrangements with InterMune that will require disclosure to the FDA in accordance with 21 CFR Part 54;

**(d)** it has not been debarred under 21 U.S.C. § 335a(a) or 335a(b) and will not use the services of any persons debarred under 21 U.S.C. § 335a(a) or 335a(b) in any capacity in connection with the performance of its obligations under this Agreement;

**(e)** neither Institution nor any Institution official or employee has been convicted of a felony under Federal law for conduct (i) relating to the development or approval, including the process for development or approval, of any drug, product, medical device, NDA, abbreviated NDA, PMA, 510(k) or IND; or (ii) otherwise relating to the regulation of any drug product or medical device under the FD&C Act;

**(f)** all Investigators and other Institution employees or agents that perform any work under this Agreement are under a written obligation to assign all intellectual property arising during the course of such work to Institution ; and

**(g)** it will obtain from each Study subject sufficient written Authorization, consistent with all applicable Privacy Regulations, to permit disclosure of such subject’s health information to and redisclosure among InterMune, its contractors and agents, other Study investigators and the appropriate Regulatory Authorities in connection with the applicable Study.

**17.** **INDEMNIFICATION**

**17.1** InterMune will indemnify, defend and hold harmless Institution, System, their Regents, officers, agents and employees, including Investigators and associated staff, (collectively, the “Institution Indemnitees”) from any and all liability, loss or damage, including without limitation reasonable attorneys' fees, they may suffer as the result of any third party claims, demands, costs or judgments against them arising out of (i) the procedures required by the applicable Protocol; (ii) InterMune’s negligence, recklessness or willful malfeasance in connection with this Agreement; (iii) any defect, use or administration of a Product that is the subject of a Study in accordance with the applicable Protocol; or (iv) the use by InterMune of the results of the Study. Notwithstanding the foregoing, InterMune will have no obligations under this Section 17.1 to the extent that any such liability, loss, or damage arises as a direct result of any third party products or materials or from any Institution Indemnitee’s (a) failure to adhere to the terms of such Protocol or InterMune’s other reasonable written instructions with respect to the use of such Product; (b) failure to comply with any applicable FDA or other governmental requirements; (c) improper or unauthorized use of any Product or Materials; or (d) negligence, recklessness, malfeasance related to this Agreement.

**17.2** To the extent authorized by the Constitution and laws of the State of Texas, Institution will indemnify, defend and hold harmless InterMune and its directors, officers, agents and employees (collectively, the “InterMune Indemnitees”) from any and all liability, loss or damage 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 indemnify, defend and hold harmless InterMune Indemnitees for claims arising out of the negligence, willful malfeasance or breach of this Agreement by InterMune Indemnitees, or any person or entity not subject to Institution’s supervision or control.

**17.3** If a Party (the "Indemnitee") intends to claim indemnification from the other Party (the "Indemnitor") under this Article 17, then the Parties will proceed as follows:

**(a)** The Indemnitee, subject to the statutory duties of the Texas Attorney General when Institution is Indemnitee, will promptly notify the Indemnitor in writing of any action, claim or other matter in respect of which the Indemnitee or any of its directors, officers, employees or agents, intend to claim such indemnification; *provided, however,* the failure to provide such notice within a reasonable period of time will not relieve the Indemnitor of any of its obligations hereunder except to the extent the Indemnitor is prejudiced by such failure.

**(b)** T he Indemnitee, subject to the statutory duties of the Texas Attorney General when Institution is Indemnitee, will permit, and will cause, as applicable, its directors, officers, employees and agents to permit, the Indemnitor at its discretion to settle any such action, claim or other matter, and the Indemnitee agrees to the complete control of such defense or settlement by the Indemnitor. Notwithstanding the foregoing, the Indemnitor will not enter into any settlement that would adversely affect the Indemnitee’s rights hereunder, or impose any obligations on the Indemnitee in addition to those set forth herein in order for it to exercise such rights, without Indemnitee’s prior written consent, which will not be unreasonably withheld or delayed.

**(c)** No such action, claim or other matter will be settled without the prior written consent of the Indemnitor, which will not be unreasonably withheld or delayed. The Indemnitee, subject to the statutory duties of the Texas Attorney General and, as applicable, its directors, officers, employees and agents will cooperate fully with the Indemnitor and its legal representatives in the investigation and defense of any action, claim or other matter covered by the indemnification obligations of this Article 17. The Indemnitee will have the right, but not the obligation, to be represented in such defense by counsel of its own selection and at its own expense. The Indemnitor will not be responsible for any attorneys’ fees or other costs incurred other than as provided herein.

**17.4** If a subject enrolled in a Study according to the applicable Protocol suffers a physical injury or adverse reaction as a direct result of (a) the Product that is the subject of such Study, administered in accordance with such Protocol and this Agreement and the applicable Work Order, or (b) research procedures required by and conducted in accordance with such Protocol and this Agreement and the applicable Work Order, and provided in each case that such injury is not caused in any way by an Investigator's or Institution's negligence, recklessness or malfeasance, then without any admission of wrongdoing on the part of InterMune, InterMune will pay all reasonable medical expenses engendered by the immediate and necessary medical treatment of such injury or adverse reaction. InterMune will not pay for the treatment of medical complications that are a part of the natural course of the primary disease or that are caused by any third party product or materials. No other compensation of any type will be provided by InterMune to any Study subject.

**17.5** InterMune shall maintain sufficient insurance coverage to cover its liabilities hereunder, in accordance with industry standards. InterMune will provide Institution with certification of such insurance upon written request.

**17.6** Institution, as a component of System, is an agency of the State of Texas and is self-insured pursuant to The University of Texas System Professional Medical Liability Benefit Plan, under the authority of Section 59.01, Texas Education Code. During the term of this Agreement, Institution has and will maintain in force adequate insurance to cover its indemnification obligations hereunder, and will provide InterMune with certification of such insurance upon written request.

**18. NOTICES**

All notices, requests, consents and other communications under this Agreement will be in writing and will be delivered by hand or mailed by first class, certified or registered mail, return receipt requested, postage prepaid, as follows (or to such other address as a Party hereto may notify the other in writing):

In the case of InterMune, addressed to:

InterMune, Inc.

3280 Bayshore Boulevard

Brisbane, CA 94005

when of a clinical nature or otherwise related to a particular Study, directed to the attention of InterMune’s clinical leader for such Study set forth in the applicable Work Order, and when of a business or other formal nature as provided under the Agreement, directed to the attention of General Counsel; and

In the case of Institution, addressed to the address indicated in Exhibit C and incorporated into this Agreement by reference, or at such other place or places as either party may designate in a written notice to the other.

**19.** **TERM AND TERMINATION**

**19.1** This Agreement will become effective as of the Effective Date, and will remain in force unless and until terminated as set forth in Section 19.2 or by written agreement of the Parties. Upon such termination, all currently on-going Studies will terminate with the effects set forth in Section 6.8.

**19.2** Either Party may terminate this Agreement, or at its election in its sole discretion, the affected Study only, if the other Party materially breaches this Agreement and such breaching Party fails to cure such breach within thirty (30) days from the receipt of written notice from the non-breaching Party of such material breach. Additionally, Institution may terminate this Agreement immediately in the event the Study is terminated by a government or regulatory authority, or if the Investigator believes continuation of the Protocol is detrimental to the health, safety and/or welfare of any Study subject.

**19.3** The following provisions will survive termination of this Agreement: Sections 6.2, 6.8, 6.9(c), 7.3, 8, 9, 10, 12, 13, 14, 15, 17, 18 and 20. Termination of this Agreement will not relieve either Party of any liability which accrued hereunder prior to the effective date of such termination, nor preclude either Party from pursuing all rights and remedies it may have hereunder or at law or in equity with respect to any breach of this Agreement, nor prejudice either Party’s right to obtain performance of any obligation.

**20.** **MISCELLANEOUS PROVISIONS**

**20.1** Institution will not assign, subcontract or otherwise transfer any of its rights or obligations hereunder, or any part hereof, without the prior written consent of InterMune. Any such assignment or transfer made without InterMune’s prior written consent will be null and void.

**20.2** Institution will, at all times, be an independent contractor, not an agent of InterMune, and will have no actual, apparent or implied authority to act or make representations for, or on behalf of, or to bind or commit InterMune in any manner or to any obligation whatsoever.

**20.3** Except as may be required by law or regulation, each Party will obtain prior written permission from the other Party before using the name, symbols and/or marks of such other Party or the names of such other Party’s employees in any form of publicity; *provided that* each Party may identify the other Party as a participant in a Study for enrollment purposes on its Study website or in its newsletter.

**20.4** EXCEPT TO THE EXTENT REQUIRED BY LAW, INTERMUNE MAKES NO WARRANTIES, EXPRESS OR IMPLIED, AS TO ANY MATTER WHATSOEVER.

**20.5.** The Parties of this Agreement will encourage the prompt and equitable settlement of all controversies or claims between the Parties.  The Parties agree to negotiate their differences directly and in good faith for a period of no less than thirty (30) days after receiving written notification of the existence of a dispute. If after negotiation, the dispute is not resolved, the Parties are free to exercise all other legal and equitable rights.

**20.6** Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement to the extent permitted by applicable law or regulation.

**20.7** Ambiguities, if any, in this Agreement will not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision.

**20.8** The remedies provided under this Agreement are cumulative, and are not exclusive of other remedies available to a Party in law or equity.

**20.9** Paragraph and section headings are included for convenience of reference only and form no part of the Agreement between the Parties.

**20.10** Any delay in enforcing a Party’s rights under this Agreement or any waiver as to a particular default or other matter will not constitute a waiver of such Party’s rights to the future enforcement of its rights under this Agreement, excepting only as to an express written and signed waiver as to a particular matter for a particular period of time.

**20.11** If any provision of this Agreement is or becomes or is deemed to be invalid, illegal, or unenforceable in any jurisdiction, then such provision will be deemed amended to conform to applicable laws of such jurisdiction so as to be valid and enforceable. If such provision cannot be so amended without materially altering the intention of the Parties, then it will be stricken. The validity, legality and enforceability of such provision will not in any way be affected or impaired thereby in any other jurisdiction, and the remainder of this Agreement will remain in full force and effect.

**20.12** This Agreement, and any Work Orders executed in connection herewith, set forth the complete, final and exclusive agreement between the Parties with respect to the subject matter hereof, and supersedes and terminates all prior agreements and understandings between the Parties with respect to such subject matter. There are no covenants, promises, agreements, certifications, representations, conditions or understandings, either oral or written, between the Parties with respect to such subject matter other than as are set forth herein and therein. In the event of any conflict or inconsistency between the terms and conditions of this Agreement and the terms and conditions of the Protocol, the terms and conditions of this Agreement shall govern, except in the case of matters relating directly to clinical procedures, with respect to which terms and conditions of the Protocol shall prevail. No subsequent alteration, amendment, change or addition to this Agreement will be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party.

**20.13** This Agreement may be executed in two or more counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument.

IN WITNESS THEREOF, the Parties have executed this Agreement by their duly authorized representatives as of the day set forth below.



 **EXHIBIT A**

**FORM OF WORK ORDER**

Work Order # \_\_\_\_\_\_\_\_\_\_\_\_\_\_

[Title]

This Work Order is issued pursuant to the Master Clinical Study Agreement, between InterMune, Inc. (“InterMune”) and **INSTITUTION** (“Institution”) effective as of **DATE** (the “ Agreement”), and is subject to all terms and conditions of the Agreement.

Any capitalized terms not otherwise defined herein will have the same meaning ascribed to them in the Agreement.

**Protocol Title and Number:** (the “ Study”).

A copy of the Protocol is attached hereto as Schedule 1 and incorporated herein by this reference.

**Principal Investigator(s) Name:** (“ Investigator(s)”).

**Investigator(s) Address:**

A copy of the Investigator’s Certification is attached hereto as Schedule 2, must be executed along with this Work Order and is incorporated herein by this reference.

**InterMune’s Medical Monitor:** InterMune, Inc.

Correspondence to InterMune’s Medical Monitor can be addressed to the address first listed above.

**Study Schedule:**

1. Study Initiation

All contractual and regulatory documentation must be completed, executed and received by InterMune prior to Study initiation. It is anticipated that Study initiation will begin on **DATE**. The Study will be considered completed \_\_\_\_\_\_\_ months following enrollment of the last patient **which is anticipated to be on (DATE)** (the “Study Completion Date”).

2. Enrollment

It is anticipated that the Investigator(s) will enroll up to **NUMBER(#)** patients into the Study (the “Site Maximum”). Patient enrollment is expected to be completed on or before **DATE.** If InterMune and the Investigator wish to increase the Site Maximum, this Work Order must be amended accordingly. No payments will be made for patients enrolled over the Site Maximum.

Notwithstanding whether the Site Maximum has been reached, the Investigator(s) shall immediately cease enrolling patients upon written notice from InterMune.

3. Study Documentation

(a) A "Completed Case Report Form" (“Completed CRF”) will mean a case report form (i) that has been completed by the Investigator in accordance with all FDA and Study requirements, (ii) for a patient who properly qualified, participated in and completed the Study in accordance with all Study requirements, and (iii) which InterMune determines can be used in all analyses of the Study results.

(b) Completed CRFs must be faxed to InterMune within ten (10) business days of the end of each treatment week; within ten (10) business days of each follow up visit and within ten (10) business days of completion of the patient’s participation in the Study and receipt of patient’s test results, if any, but in no event later than the Study Completion Date.

(c) Any requests by or on behalf of InterMune for verification, clarification or correction of data on CRFs must be responded to and returned to InterMune within ten (10) business days of Institution’s receipt of such request.

(d) Institution will complete all CRFs and resolve all data discrepancies therein within one (1) month of the Study Completion Date. Institution will deliver hard copies of the original Completed CRFs as directed by InterMune. Institution will cooperate with InterMune or its designees should any further information or clarification be required.

**Payment Schedule:**

A copy of the budget for this Study (the “Budget”) is attached hereto as Schedule 3 and incorporated herein by this reference. Payment will be made for work actually performed, in accordance with the payment schedule set forth in the Budget. Institution herein acknowledges and agrees that the total compensation due Institution for full, complete, and satisfactory performance of Study in accordance with Protocol and the terms of the Agreement will in no event exceed **[$non-refundables + # x per patient amount + pass-through costs + screen failures = Maximum Compensation DOLLARS ($00.00)]** , inclusive of all associated costs, fees, and charges, including any relevant or applicable overheads due any party, entity or Investigator ("Maximum Compensation").

Screen failures will be reimbursed at the rate specified in the Budget up to a maximum of **DOLLARS ($00.00).** As used herein, “screen failure” means a potential Study patient who has had one or more screening procedures performed in accordance with the Protocol and, based on the results of such procedures, does not meet the entry criteria for the Study set forth in the Protocol.

InterMune will pay Institution an advance payment of **DOLLARS ($00.00)** comprising the following:

**LIST**

The foregoing advance payments will be non-refundable, except in the event of Institution’s breach.

The advance payments will be paid within thirty (30) days of InterMune’ receipt of this fully executed Work Order **{and Agreement, if applicable}** and IRB approval. Subsequent payments will be made within thirty (30) days of the end of each calendar quarter as applicable, upon InterMune’ receipt of the Completed CRFs for such quarter.

InterMune may withhold ten percent (10%) of the Maximum Compensation pending resolution of all data queries and completion of Study closeout procedures. Final payment of any outstanding amounts due under this Work Order will be made following the completion of Study closeout procedures.

Pass-Through Costs

**{*To be used where InterMune has agreed in writing to reimburse Institution for certain pass-through costs*}** InterMune will reimburse Institution for its actual, documented costs for the following **{procedures, ancillary materials, concomitant/comparator medications, etc. – specify}**, up to the following maximum possible reimbursement amounts:

item/maximum

item/maximum

Reimbursement for each such procedure will be due following InterMune’s receipt of Institution’s invoice and documentation of costs for such procedure, and will be made concurrently with the quarterly payment due for the calendar quarter in which InterMune received the applicable invoice and documentation. In no event will InterMune have any direct liability to any party other than Institution in connection with Institution’s conduct of the Study (including without limitation any third party vendor), unless otherwise agreed in writing by InterMune.

Invoices shall be sent to the following address:

The name and address of the payee for all payments due to Institution hereunder is:

Checks with invoice numbers will be made payable to:

Tax ID Number of the payee:

Contact Name: (Provide name of individual responsible for payments)

Phone Number:

This Work Order is entered into and made effective as of **DATE**. This Work Order will remain in effect until completion of all services described herein, unless earlier terminated in accordance with the Agreement.

**Accepted and Agreed to by:**

I have read the Agreement and Work Order and understand my obligations hereunder:

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

[Insert Principal Investigator’s name]

Principal Investigator

Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Schedule 1 to Work Order #**

**PROTOCOL**

**Schedule 2 to Work Order #**

**PRINCIPAL INVESTIGATOR'S CERTIFICATION**

I acknowledge that I have read this Work Order #**\_\_\_** and am aware of and understand its terms and conditions and the terms and conditions of the Agreement referred to therein. I shall comply with all the terms and conditions of the Work Order and the Agreement, both as an individual and as an employee of Institution. Without limiting the generality of the foregoing, I represent and certify that I will not use any information, data, case report forms and/or any other similar data and information, or any intellectual property, arising from or relating to the Study for any purpose other than as authorized by the terms of this Agreement.

I represent and certify that my entering into and participating in this Study will not conflict with or be a breach of any other agreement to which I am bound.

I represent and certify that the Institution or entity identified in the Work Order is the appropriate entity to receive payment(s) for this Study.

I represent and certify that I have no financial interests and/or arrangements with InterMune that will require disclosure to the federal Food and Drug Administration (“FDA”) in accordance with 21 CFR Part 54, and that I will promptly notify InterMune if any such interests or arrangement later arise.

I represent and certify that I have not been disqualified by the FDA or otherwise disqualified from serving as a Principal Investigator for this Study, and that I will conduct this Study in accordance with GCP and my independent medical judgment.

I represent and certify that I have not been debarred under the provisions of the Generic Drug Enforcement Act of 1992, 21 U.S.C. §335a(a) and (b). In the event that I: (i) become debarred; or (ii) receive notice of an action or threat of an action with respect to my debarment during the term of this Study, I agree to immediately notify InterMune and Institution and to immediately cease conducting this Study.

I understand that in the event InterMune receives notice or otherwise becomes aware that (i) I have been debarred (ii) a debarment action has been brought against me, or (iii) I have been threatened with a debarment action, InterMune will have the right, at its sole discretion, to (i) terminate immediately my participation in the Study, or (ii) agree with Institution to a substitute Principal Investigator who will assume full responsibility and perform all the remaining activities under this Study.

PRINCIPAL INVESTIGATOR

Print Name:

Signature:

Date:

**Schedule 3 to Work Order #**

**BUDGET**



**EXHIBIT B**

**Contact List**