MEMORANDUM

| DATE:     | 6/25/07 |
| TO:       | Stacy Steenken  
            | IP Legal Administrative Assistant |
| FROM:     | Leann Frankel  
            | Senior Manager  
            | Research and Development Contract Administration |
| RE:       | Master Clinical Study Agreement |

Enclosed please find one fully executed original Master Clinical Study Agreement between Astellas Pharma US, Inc. and each of The University of Texas Health Science Center at San Antonio, The University of Texas MD Anderson Cancer Center, The University of Dallas, and The University of Texas Health Center at Tyler.

Thank you for your cooperation in the execution of this document.
MASTER CLINICAL STUDY AGREEMENT

This Master Clinical Study Agreement ("Agreement") dated this 18th day of April, 2007 ("Effective Date"), sets forth the understanding between Astellas Pharma US, Inc., an affiliate of Astellas US LLC, a Delaware corporation, with its principal place of business at Three Parkway North, Deerfield, IL 60015-2548 ("APUS") and each of The University of Texas at Austin, The University of Texas Health Science Center at Houston, The University of Texas Health Science Center at San Antonio, The University of Texas MD 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 Health Center at Tyler (each an “Institute” and, collectively, the “Institutes”), each with an office and place of business as set forth on Exhibit B attached hereto, and each a component institution 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"). APUS and Institute and/or Institutes are hereinafter collectively referred to as the “Parties” or individually as a “Party”.

RECITALS

WHEREAS, APUS conducts business in the research and development, manufacturing and marketing of pharmaceutical products; and

WHEREAS, each Institute possesses the requisite expertise in the conduct of clinical research studies with investigational pharmaceutical products and each Institute has the requisite experience with the requirements, processes and procedures related to such research and clinical studies; and

WHEREAS, the clinical studies contemplated by this Agreement are of mutual interest and benefit to APUS and Institutes and will further the Institutes’ instructional, basic science, clinical science and fundamental research objectives and missions.

NOW, THEREFORE, for and in consideration of the mutual covenants contained herein, the Parties agree to the following terms and conditions:

1. Definitions.

A. As used in this Agreement, the following terms shall have the following meanings:

(1) "Authorized Representatives" shall mean the individuals who have authority on behalf of APUS and Institute to sign this Agreement as well as any "Order" (as defined in Section 1.A.(4)). For purposes of this Agreement, (a) the Institutes’ Authorized Representatives shall be the President of the Institute and/ or his/her designees; and (b) the Authorized Representatives for APUS is the Senior Vice President, Research & Development,
or his designee. A change in Authorized Representatives by one Party shall be binding on the other Party upon the other Party's receipt of a written document stating such change.

(2) "Work Order" shall mean a written document signed by the Authorized Representatives of both Parties which will specify certain pre-clinical or clinical research services to be performed hereunder for APUS. Each Work Order shall include, at minimum, the "Protocol", as defined in Section 1.A(6), which shall include the methods and specifications of the "Study" as defined in Section 1.A(7), a term, payment amount and the like. A Work Order is not enforceable unless signed by Authorized Representatives of Institute and APUS. A sample Work Order is attached hereto and incorporated herein as Exhibit A.

(3) "Change Order" shall mean a written document signed by the Authorized Representatives of both Parties, changing or modifying the research services to be performed pursuant to a Work Order. A Change Order is not enforceable unless signed by Authorized Representatives of each Party and only applies to that one specific Work Order.

(4) "Order" shall collectively be referred to in this Agreement as the Work Order and its respective Change Order(s), if any.

(5) Principal Investigator" shall mean an employee of Institute, with assistance from associates and colleagues as may be required, who is the primary investigator supervising and conducting a Study at Institute. The Principal Investigator for each respective Study shall be named in the applicable Order.

(6) "Protocol" shall mean a particular clinical research protocol approved by APUS which describes the design of a particular clinical study.

(7) "Study" shall mean an individual clinical research study based on the applicable Protocol, and as more fully described on a Work Order.

(8) "Study Drug" shall mean, with respect to each Study, the drug that is the subject of such Study, identified by chemical compound or brand name and as set forth and described more particularly in the Protocol and the applicable Work Order.

2. Performance.

(A) The specific details for each Study conducted pursuant to this Agreement will be separately negotiated by the Parties and set forth in an Order and will be (i) specified in writing; (ii) on terms acceptable to the Parties; and (iii) in a form acceptable to the Parties. Each Order will include (i) the conduct of the Study as written by APUS in each Protocol; (ii) the name of the Principal Investigator; (iii) the projected time line for Study initiation and completion; (iv) the target and maximum subject enrollment numbers; and (v) the payment schedule for such Study. Institute agrees and shall cause Principal Investigator to conduct the Study as described in the Protocol and to comply with all of the terms and conditions of this Agreement. Institute shall remain

APUS-initiated; 7 yr. period of confidentiality
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responsible to APUS in connection with Principal Investigator’s performance under this Agreement and the applicable Order.

(B) Institute shall provide such Study services and personnel as needed to conduct the Study as described in each Order. The Study and the Protocol shall be conducted in a manner consistent with Good Clinical Practices ("GCP"), conforming to U.S. Food and Drug Administration standards as codified in the Code of Federal Regulations ("CFR"), including all applicable requirements of 21 CFR § 312, the Statement of Investigator Form 1572 signed by Principal Investigator and on file with APUS, and all other applicable rules, laws and regulations. Institute shall cause the Principal Investigator to have the Study approved by the Institute’s Institutional Review Board ("IRB") prior to Study commencement and shall promptly provide APUS with a copy of such approval.

(C) Institute represents that it has all of the necessary licenses, permits and registrations to conduct each Study as required herein and shall maintain same, current and in good standing, during the term hereof. Institute further represents that each Principal Investigator (as well as all other individuals serving as Clinical Investigators for the Study, as the term Clinical Investigators is defined in the CFR) has all of the necessary licenses, permits and/or registrations to practice medicine in the appropriate jurisdiction where each Study takes place, and shall maintain same, current and in good standing, during the term hereof.

(D) Institute shall cause all Clinical Investigators performing Study services to complete a certification and disclosure of financial interests form as required under 21 CFR Part 54, "Financial Disclosure by Clinical Investigators" and promptly provide same to APUS.

(E) The number of subjects APUS expects to enroll across all sites participating in each Study is set forth in a separate Work Order. Institute’s specific enrollment rate depends on the rate and number of subjects enrolled at the other participating sites. APUS shall inform such Principal Investigator when subject enrollment is complete and no additional subjects are to be enrolled. Prior to enrolling any patients in a Study, Institute’s IRB shall have approved in writing the terms and conditions of such Study, including the informed consent; related instructions for use of the Study Drug; the Protocol; and the participation of Institute and its personnel in the Study. Institute shall, and Institute shall cause Principal Investigator to, obtain from each patient, at the time of enrollment, written authorization, or waiver of authorization, as may be necessary to permit APUS to have access to and use of patients’ Protected Health Information, as defined by the Health Insurance Portability and Accountability Act of 1996.
3. **Payment Terms.**

   (A) APUS shall pay Institute as set forth in the applicable Work Order.

   (B) APUS shall make all checks payable to the applicable Institute listed in the applicable Work Order. All payments shall be mailed to Institute at the address detailed in the applicable Work Order. Institute acknowledges and agrees that it shall be solely responsible for paying any and all federal, state and local taxes with respect to all amounts paid to Institute pursuant to this Agreement, and that APUS shall have no responsibility whatsoever for withholding or paying any such taxes for or on behalf of Institute.

   (C) Upon termination or expiration of this Agreement, Work Order(s) and/or Study(ies), APUS shall pay monies owed to Institute within thirty (30) days of such termination so long as said Study(ies) is performed in accordance with this Agreement, the applicable Order, and any other written instructions provided by APUS.

   (D) The Parties acknowledge and agree that the compensation set forth in the applicable Work Order represents the fair market value for the Study, has not been determined in a manner that takes into account the volume or value of any business otherwise generated between the Parties, and shall not obligate Institute and/or Principal Investigator to purchase, use, recommend, or arrange for the use of any products developed, manufactured, and/or marketed by APUS or any of its affiliates or business collaborators, or the formulary status of any products of APUS or any of its affiliates or business collaborators.

   (E) The “Per Subject Fee” (as defined in the applicable Order) is intended to compensate Institute for the time and materials, supplies and resources utilized by the Institute in carrying out the Protocol. Institute will not seek or accept reimbursement or other payment from any third-party payor, including any government entity, insurance plan or other third party, for any items or services, including without limitation any treatment, evaluation, procedure or supply and including any Study Drug, furnished to a Study subject where (i) APUS has paid for the item or service as part of the Per Subject Fee or any other fee detailed in Exhibit A or (ii) the item or service is furnished for the Study subject by or through APUS at no cost to the Institute.

4. **Regulatory Application.**

   APUS, as well as its affiliates and other business collaborators, may use all information resulting from a Study to develop and make regulatory applications to commercialize Study Drug, as that term is defined in each Work Order, to develop drug educational materials, and for related research and development purposes. Institute shall, and Institute shall cause
Principal Investigator to, reasonably cooperate with APUS and shall cause all other individuals involved in Study conduct to do the same, in answering questions from regulatory agencies concerning the Study. Institute shall cooperate and allow APUS, during normal business hours and upon prior written notice, to directly contact the individuals conducting the Study to request further information about the Study.

5. **Maintenance of Records.**

Institute agrees, and shall cause Principal Investigator, to keep proper records of the Study and its progress, including payment history records relevant hereto. Institute and/or Principal Investigator shall make these records reasonably available for review by APUS, or its designee, during such period of time that Institute is required by applicable law, rule or regulation to retain such records. Such review shall occur during normal business hours and upon prior written notice. At APUS’s written request and reasonable expense, Institute and/or Principal Investigator shall promptly provide copies of all or any part of such records, including, but not limited to, source data/documents to APUS, but excluding patient medical records. Prior to any necessary copying of records, APUS, or its designee, will redact all patient identifying information.

6. **Reports.**

As set forth in each Order, Institute shall cause Principal Investigator to provide APUS with updates and reports regarding the Study as APUS may periodically request in writing during the term hereof; such updates and reports shall include such information as APUS may reasonably request.

7. **Confidential Information.**

(A) “Confidential Information” means (i) any and all information arising out of or resulting from the conduct of the Study, except to the extent that such information is published or presented in a manner that strictly conforms to Institute's publication policies as well as the provisions of Section 9 herein, and (ii) any and all information furnished to Institute and/or Principal Investigator by APUS, an affiliate of APUS, or any agent or representative of APUS, that relates to the Study, Study Drug (and/or any analog thereof owned by or licensed to APUS or an affiliate of APUS) and/or other proprietary information of APUS, its affiliates, predecessors, successors or permitted assigns and/or business collaborators, including, without limitation, inventions; innovations; ideas; data; software and other copyrightable materials; specifications; processes; techniques; methods; formulas; manufacturing, marketing and research and development procedures, strategies or information; customers; and plans and programs related to its business and/or operations.

APUS-initiated; 7 yr. period of confidentiality
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(B) Institute shall not disclose, in whole or in part, directly or indirectly, any of the Confidential Information to any person or entity other than to its employees, agents, representatives and contractors performing Study services (including the Principal Investigator and members of the IRB) who have a need to know such Confidential Information to further this Agreement and/or the Study. Institute and the aforementioned employees, agents, representatives and contractors (including Principal Investigator and IRB members) shall not use, in whole or in part, directly or indirectly, any of the Confidential Information except in furtherance of the Study and this Agreement. Confidential Information shall remain the sole and exclusive property of APUS, its affiliates, predecessors, successors or permitted assigns and/or business collaborators, as the case may be. Disclosure of Confidential Information that is required to be disclosed pursuant to a subpoena or order of court of competent jurisdiction or applicable law or regulation shall not be a breach of this Agreement provided that Institute provides timely notice of such requirement to APUS, and reasonably cooperates with APUS, so that APUS can file a motion for a protective order or otherwise seek whatever legal relief it deems desirable or appropriate to protect its interests in the Confidential Information. Notwithstanding the above, the information described in Section 7(A)(i) shall no longer be deemed to be confidential when published in accordance with Section 9 herein.

(C) Institute shall advise its employees, agents, representatives and contractors (including Principal Investigator and IRB members) permitted to receive and use Confidential Information as contemplated above, of the obligations and shall cause the same to comply with the confidentiality obligations hereunder. Institute and Principal Investigator shall protect and safeguard Confidential Information in at least the same manner as their own confidential information, but in no event shall less than reasonable care be used.

(D) Confidential Information shall exclude information that: (i) at the time of disclosure hereunder, was in the public domain; (ii) after disclosure hereunder, becomes part of the public domain by publication or otherwise, other than by breach of this Agreement by Institute; (iii) was rightfully received before or after disclosure hereunder, from a third party not in violation of any nondisclosure obligation owed to APUS, its affiliates, predecessors, successors, permitted assigns and/or business collaborators, as evidenced by written records; or (iv) was developed independently by Institute without any reference to, incorporation of, or other use of any Confidential Information, as demonstrated by written records.

(E) Notwithstanding any other provision of this Section 7 or Section 9 herein, nothing herein shall be deemed to prevent Institute's right to publish or present data generated at their specific Study site and directly resulting from Study conduct so long as such
publication/presentation strictly conforms to Institute's publication policies as well as the provisions of Section 9 herein.

(F) Unless specifically agreed to in writing by the Parties in a Work Order, the obligations described in this Section 7 shall survive the expiration or earlier termination of each Study or Work Order, as the case may be, under this Agreement for a period of seven (7) years after its termination or expiration.

8. **Intellectual Property.**

(A) Institute shall ensure that Study Drug shall only be used for the purpose of conducting the Study hereunder.

(B) Ownership of discoveries, inventions, innovations, ideas, formulations, methods, techniques, technological developments, enhancements, modifications or improvements and works of authorship existing as of the Effective Date hereof, and all patents, copyrights, trade secret rights and other intellectual property rights therein (collectively, "**Pre-existing Intellectual Property**"), is not affected by this Agreement, and no Party shall have any claims to or rights in any Pre-existing Intellectual Property of any other Party, except as may be otherwise expressly provided in any other written agreement between two or more Parties.

(C) Astellas US LLC ("AUS"), an affiliate of APUS, shall own all rights, title and interest in and to (i) any inventions, technologies, know-how, ideas, processes, techniques, algorithms, discoveries, improvements, devices, products, concepts, designs, prototypes, samples, models, technical information, materials, drawings and specifications that are conceived, first reduced to practice or created pursuant to this Agreement or otherwise directly related to Confidential Information, whether by APUS, Institute or its personnel, individually or jointly ("**Inventions**") and (ii) subject to Institute’s publication rights as set forth in Section 9 herein, all records, reports and other data required to be delivered to APUS pursuant to the Protocol (including, without limitation, case report forms) and all information regarding inventories and dispositions of the Study Drug ("**Trial Data**") (Inventions and Trial Data shall be collectively referred to as "**Research Results**"). Institute shall cause its personnel to promptly and fully disclose all Inventions to APUS in writing. Institute, on behalf of itself and its personnel, hereby assigns (a) all of their respective right, title and interest in and to the Research Results to AUS, including all patents, copyrights which Institute may own and other intellectual property and proprietary rights; and (b) all rights of action and claims for damages and benefits arising due to past and present infringement of said rights. Institute shall reasonably cooperate and assist AUS to execute and shall cause all personnel to execute all documents
reasonably necessary for AUS to secure, perfect, effectuate and preserve AUS’s ownership rights in the Research Results.

(D) Institute shall cause its employees, agents, representatives and contractors, including Principal Investigator to comply with the terms and conditions of this Section 8. The obligations described in this Section 8 shall survive the expiration or earlier termination of this Agreement and/or an Order.

(E) APUS grants Institute the right to use data generated by Institute from a Study for Institute’s internal, non-commercial research, and educational purposes, and for purposes of publication in accordance with Section 9 herein, provided, that, Institute’s use of the data and results for such purposes are subject to Institute (a) complying with all applicable federal, state and local laws and regulations governing the confidentiality and privacy of personal health information, including, without limitation, the Standards of Privacy of Individually Identifiable Health Information under HIPAA, (b) using and disclosing “protected health information” (as that term is defined under HIPAA) only in accordance with HIPAA and the subject’s authorization; and (c) maintaining such information as confidential in accordance with Section 7 herein. APUS shall not be responsible in any way whatsoever for any claims, damages, losses, suits, expenses (including attorneys’ fees), or liabilities incurred by Institute resulting or arising from any use of the data by Institute.

9. **Publication.**

(A) Institute and/or Principal Investigator may publish or present data generated from a Study at their specific Study site; provided: (i) no Confidential Information of the type described in Section 7 is revealed and (ii) no data is presented and/or published prior to publication of the multi-center data from a Study, or until twelve (12) months have elapsed following completion of the multi-center Study data, whichever comes first. Any manuscript or communication of clinical research findings may represent an official summary for purposes of regulatory submissions. Institute shall provide APUS with a copy of any and all proposed publications and presentations at least thirty (30) days before the same is released for publication or presented. Within thirty (30) days of its receipt, APUS shall advise Institute and/or Principal Investigator, as the case may be, in writing of any information contained therein which is Confidential Information of the type described in Section 7(A) or which may impair APUS’s ability to obtain patent protection. APUS shall have the right to require Institute and/or Principal Investigator, as applicable, to remove specifically identified Confidential Information of the type described in Section 7(A) and/or to delay publication an additional sixty (60) days so that APUS may seek patent protection.
(B) Institute shall not, and shall ensure that its personnel do not, engage in interviews or other contacts with the media, including, but not limited to, newspapers, radio, television and the Internet, related to the Study, the Study Drug, Inventions or Trial Data without the prior written consent of APUS, which will not be unreasonably withheld. This provision does not prohibit publication or presentation of specific Study site data in compliance with Section 9(A).

(C) The obligations described in this Section 9 shall survive the expiration or earlier termination of this Agreement and/or an Order.

10. **Indemnification; Limitation of Liability; Insurance.**

(A) APUS shall defend, indemnify and hold harmless Institute, System, Board and their respective officers, agents and employees (including Principal Investigator) ("Institute Indemnities") from any and all third-party claims, demands, costs, expenses (including, without limitation, reasonable attorneys' fees), liabilities and/or losses (collectively referred to as "Losses") which may be asserted against Institute Indemnities arising from, resulting from or relating to: (i) the Study Drug; (ii) a procedure properly performed in accordance with the applicable Protocol; or (iii) APUS’s use of Institute’s results from a Study, provided that such results are not derived from falsified Study data. APUS’s indemnification obligations under this Section 10(A) shall not apply to the extent any Losses arise from, result from or relate to: (i) violation of applicable law, rule or regulation by any of Institute Indemnities; (ii) the negligence or willful misconduct of any of Institute Indemnites; or (iii) any unauthorized deviation by any of Institute Indemnities from the Protocol (except for any such deviation required as medical necessity).

(B) To the fullest extent authorized under the Constitution and laws of the State of Texas, Institute shall defend, indemnify and hold harmless APUS, its subsidiaries, affiliates, business collaborators, directors, officers, shareholders, employees, predecessors, successors and/or assigns ("APUS Indemnities") from any and all Losses related to (i) a violation of applicable law, rule, or regulation by any of Institute Indemnites; (ii) the negligence or willful misconduct of any of Institute Indemnites pertaining to the activities to be carried out pursuant to the obligations of this Agreement; or (iii) any unauthorized deviation by any of Institute Indemnites from the Protocol (except for any such deviation required as medical necessity). Institute’s indemnification obligations under this Section 10(B) shall not apply to the extent any Losses arise from, result from or relate to: (a) violation of applicable law, rule or regulation by any APUS Indemnites; (b) the negligence or willful malfeasance by any APUS Indemnites; or (c) any unauthorized deviation by any APUS Indemnites from the Protocol (except for any such deviation required as medical necessity).
(C) The Party against whom a claim that is subject to indemnification hereunder is brought (in this context, "Indemnified Party") shall promptly notify the indemnifying Party (in this context, "Indemnifying Party") in writing, of any claims asserted against Indemnified Party to which Indemnified Party is entitled to indemnification hereunder. Indemnified Party shall deliver to Indemnifying Party any appropriate court document or other document relative to or in relation to such claim. Indemnifying Party shall control the investigation, trial, defense and settlement of any such lawsuit or action and any appeal arising therefrom and shall employ or engage attorneys of its own choice. Indemnified Party may, at its own cost, participate in such investigation, trial and defense of such lawsuit or action and any appeal arising therefrom. Indemnified Party shall provide full reasonable cooperation to the Indemnifying Party at all times during the pendency of the claim or lawsuit including, without limitation, providing Indemnifying Party with access to all reasonable and relevant available information, personnel and documents concerning the claim. Indemnified Party shall not compromise or otherwise settle any such claim without Indemnifying Party's prior written consent. Indemnifying Party shall not enter into any settlement which admits fault by Indemnified Party without Indemnified Party's prior written consent, which consent shall not be unreasonably withheld. This Section 10(c), as applied to Institute, is subject to the statutory duties of the Texas Attorney General.

(D) In the event the State of Texas Attorney General determines that it is required to defend any Losses against any Institute Indemnitees, then APUS shall not be responsible or liable for any costs and expenses (including attorneys' fees) which may or can result in the defense of any such Losses filed against any of the Institute Indemnitees.

(E) NOTWITHSTANDING THE ABOVE, NEITHER PARTY, NOR, AS APPLICABLE, THEIR AFFILIATES, PREDECESORS, NOR ANY OF THEIR RESPECTIVE REGENTS, DIRECTORS, OFFICERS, EMPLOYEES, AGENTS OR CONTRACTORS SHALL BE LIABLE TO THE OTHER PARTY FOR ANY SPECIAL, INCIDENTAL, INDIRECT, OR CONSEQUENTIAL DAMAGES, INCLUDING, BUT NOT LIMITED TO, THE LOSS OF OPPORTUNITY, OR LOSS OF REVENUE OR PROFIT.

(F) Institute, 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 Medical Malpractice Coverage for certain Institutions subchapter A. Medical Professional Liability. During the term of this Agreement, Institute has and will maintain in force adequate insurance to cover its indemnification obligations hereunder.
(G) APUS shall maintain the following minimum levels of insurance or self-insurance: (i) Workers’ Compensation insurance within statutory limits; (ii) Employers Liability insurance with limits of not less than $2,000,000 per occurrence; (iii) Commercial General Liability insurance, including blanket contractual liability, with limits of not less than $2,000,000 per occurrence/$3,000,000 aggregate; and (iv) Product Liability insurance with limits of not less than $3,000,000 per occurrence/$5,000,000 aggregate.

(H) Upon written request, a Party shall provide the requesting Party with a certificate of insurance as evidence of the coverage required above.

(I) The obligations described in this Section 10 shall survive the expiration or earlier termination of this Agreement or a Work Order for a period of ten (10) years.

11. **Patient Injury Compensation.**

APUS agrees to reimburse Institute for the reasonable costs of medical treatment provided by Institute’s facilities/physicians in the event an Evaluate Subject (as defined in the applicable Work Order) is injured as a direct result of the use of the Study Drug, as determined jointly by APUS and the Principal Investigator. Such reimbursement will be provided only if the Study Drug has been used in accordance with the Protocol and any other written instructions provided to Institute by APUS. The obligations described in this Section 11 shall survive the expiration or earlier termination of this Agreement and or a Study.

12. **Non-Assignment; Independent Contractor; Non-Ability to Bind, Use of Affiliates.**

Institute may not subcontract the Study or any portion thereof. Neither Party shall be entitled to assign this Agreement or any of its rights and obligations hereunder without the express written consent of the other Party hereto, which consent shall not be unreasonably withheld; provided, however, that APUS may assign this Agreement and/or its rights and obligations hereunder without the consent of Institute to: (A) any affiliate; (B) an assignee or successor in interest (by merger, operation of law or otherwise); or (C) a purchaser of all or substantially all of APUS’s business. Institute acknowledges that Institute and Principal Investigator are conducting the Study as independent contractors and not as agents or employees of APUS. Nothing contained in this Agreement shall be construed as making the Parties joint venturers or partners or as granting to the other Party the authority to bind the other Party (financial or otherwise) or contract any obligations in the name of or on the account of the other Party or to make any representations, guarantees or warranties on behalf of the other Party. Institute agrees that the rights and obligations of APUS under this Agreement may be exercised or performed by one or more affiliates of APUS.
13. **Non-Exclusive Relationships.**

Nothing in this Agreement will limit or prohibit Institutes or any personnel, including Principal Investigator(s), from conducting any research or from performing research for or with any entity or person, including any other outside sponsors, provided, however, that such research does not create an actual conflict of interest with the Principal Investigator’s obligations under this Agreement or any Work Order hereof. APUS acknowledges that this provision is intended to ensure that Institutes and their faculty are not regarded as captive researchers for APUS.

14. **Use of Name.**

Except as required by law or government regulation, no party hereto shall use in advertising, publicity, news releases, reports or any promotional activities, whether oral or written, any name, trade name, trademark, or other designation of another Party hereto, including any contraction, abbreviation, or simulation of any of the foregoing, without the express prior written permission of that Party whose name is to be disclosed.

15. **Term and Termination.**

(A) This Agreement shall begin on the Effective Date and shall continue for the longer of (a) five (5) years from the Effective Date or (b) until the obligations under all the Orders are fully performed, unless terminated sooner as provided for herein. In addition to other provisions for termination set forth herein, a Party may terminate this Agreement or any Order at any time by giving the other Party thirty (30) days prior written notice.

(B) APUS may terminate this Agreement or any Work Order immediately or as soon as medically practical in the event of a material breach by Institute including, without limitation, failure to follow GCPs and/or any other applicable law, rule or regulation.

(C) Institute reserves the right to terminate Agreement or any Work Order immediately upon written notification to APUS if requested to do so by the responsible IRB or if such termination is required to protect the health and welfare of Study subjects.

(D) Upon termination or expiration of this Agreement and/or any Order, Institute shall return to APUS any and all of the remaining Study Drug and other APUS property, including without limitation, Confidential Information. Institute may, however, retain one (1) copy of the Confidential Information in a secure location solely for the purposes of verifying compliance with this Agreement and maintaining regulatory compliance. Any such copy shall be maintained in accordance with the terms and conditions of Section 7.
16. **Notice.**

(A) All notices under this Agreement shall be in writing and either faxed to the other Party, deposited in the United States mail (registered or certified, return receipt requested), or sent overnight express courier, such as Federal Express (receipt confirmed), and addressed as follows:

To APUS: Astellas Pharma US, Inc.  
Attention: R&D Contracts Administration  
Three Parkway North  
Deerfield, Illinois 60015-2548  
cc: General Counsel  
Facsimile: 846-317-1251

To Institute: See Exhibit B  
With a copy to: The University of Texas System  
Attn: Office of General Counsel – IP Section  
201 West 7th Street  
Austin, Texas 78701  
512-499-4518  
Facsimile: 512-499-4523

(B) Notices shall be deemed effective as follows: (i) if by mail, on the fourth day after posting; (ii) if by facsimile or personal delivery, on the date of actual delivery or transmission (as the case may be), with evidence of transmission acceptance; and (iii) if by overnight express courier, on the next business day following the day such notice is delivered to the overnight express courier. A Party may change its address listed above by written notice to the other Party.

17. **Entire Agreement; Amendment; Severability.**

This Agreement, the Protocol and any and all exhibits, constitute the entire agreement of the Parties and will not be changed or affected by any previous agreements, whether oral or written, or any agreements of the same date. This Agreement supersedes all other agreements, whether written or oral between the Parties regarding the subject matter hereof. Notwithstanding the foregoing, however, any confidentiality agreement previously entered into between APUS, its affiliates, and/or its predecessors and Institute shall remain in effect in accordance with its terms. In the event of any conflict between the terms and conditions of this Agreement and any such confidentiality agreement, the terms and conditions of this Agreement shall govern and control. In the event of any conflict between the terms and conditions of this Agreement and those set forth in the Protocol or an exhibit, this
Agreement's terms and conditions shall govern and control. This Agreement may not be amended except by a writing signed by both Parties. Any provision of this Agreement which is found by a court of competent jurisdiction to be illegal or invalid shall be deemed severed from this Agreement and shall not affect the continuing legality or validity of the rest of this Agreement.

18. **Regulatory Requirements.**

   (A) Institute certifies to APUS that Institute, Principal Investigator and any other person performing services for a Study have neither been debarred nor are they otherwise subject to debarment proceedings pursuant to 21 U.S.C. §335a(a) or (b), and shall immediately notify APUS should the accuracy of the foregoing certification be compromised.

   (B) The Parties represent that they have not been excluded or debarred from participation in any Federal health care program as defined in 42 U.S.C 1320a-7b(f) ("Federal Health Care Program"). If either Party, or any employee, officer or director of the other Party, is excluded or debarred from participation in any Federal Health Care Program or other government payment program, or becomes otherwise ineligible to participate in any such program, that Party shall notify the other Party within three (3) business days after such event. Upon the occurrence of such event, whether or not such notice is given to the other Party, the other Party may immediately terminate the whole or any part of this Agreement.

19. **Waiver.**

A waiver of any term, condition or default of this Agreement shall not be construed as a waiver of any other term, condition or default.

20. **Captions and Headings.**

The captions and headings are inserted only for convenience and in no way define or limit the scope of this Agreement or the intent of any provision hereunder.
21. **Authorization.**

The Parties represent that the individuals signing this Agreement are Authorized Representatives and all necessary approvals and authorizations have been made prior to execution hereof.

**ASTELLAS PHARMA US, INC.**

By: [Signature]

Name: ___________

Title: Vice President, Research and Development

Date: ___________

**THE UNIVERSITY OF TEXAS HEALTH CENTER AT TYLER**

By: [Signature]

Name: Vernon Moore

Title: Chief Business and Finance Officer

Date: 4/23/07

**THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON**

By: ___________

Name: ___________

Title: ___________

Date: ___________

**THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT SAN ANTONIO**

By: ___________

Name: ___________

Title: ___________

Date: ___________
21. **Authorization.**

The Parties represent that the individuals signing this Agreement are Authorized Representatives and all necessary approvals and authorizations have been made prior to execution hereof.

**ASTELLAS PHARMA US, INC.**

By: ____________________________

Name: __________________________

Title: __________________________

Date: __________________________

**THE UNIVERSITY OF TEXAS HEALTH CENTER AT TYLER**

By: ____________________________

Name: Jodi S. Ogden

**Contracts Director**

**Office of Sponsored Projects**

Title: __________________________

Date: 4/23/07

**THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON**

By: ____________________________

Name: __________________________

Title: __________________________

Date: __________________________

**THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT SAN ANTONIO**

By: ____________________________

Name: __________________________

Title: __________________________

Date: __________________________
21. **Authorization.**

The Parties represent that the individuals signing this Agreement are Authorized Representatives and all necessary approvals and authorizations have been made prior to execution hereof.

**ASTELLAS PHARMA US, INC.**

By: ____________________________

Name: __________________________

Title: __________________________

Date: __________________________

**THE UNIVERSITY OF TEXAS HEALTH CENTER AT TYLER**

By: ____________________________

Name: __________________________

Title: __________________________

Date: __________________________

**THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON**

By: ____________________________

Name: __________________________

Title: __________________________

Date: __________________________

**THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT SAN ANTONIO**

By: ____________________________

Name: Jane A. Youngers

Title: Assistant Vice President for Research

Date: 5-14-07
THE UNIVERSITY OF TEXAS MEDICAL BRANCH AT GALVESTON

By: [Signature]

Name: Susan E. Ramsey

Title: Manager of Research Operations

Date: April 24, 2007

THE UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER AT DALLAS

By: [Signature]

Name: [Name]

Title: [Title]

Date: [Date]

THE UNIVERSITY OF TEXAS AT AUSTIN

By: [Signature]

Name: [Name]

Title: [Title]

Date: [Date]

THE UNIVERSITY OF TEXAS MD ANDERSON CANCER CENTER

By: [Signature]

Name: [Name]

Title: [Title]

Date: [Date]
THE UNIVERSITY OF TEXAS MEDICAL BRANCH AT GALVESTON

By: __________________________
Name: _________________________
Title: __________________________
Date: __________________________

THE UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER AT DALLAS

By: __________________________
Name: Perrie M. Adams, Ph.D.
Title: Associate Dean for Research
Date: 11/01/07

THE UNIVERSITY OF TEXAS AT AUSTIN

By: __________________________
Name: _________________________
Title: __________________________
Date: __________________________

THE UNIVERSITY OF TEXAS MD ANDERSON CANCER CENTER

By: __________________________
Name: _________________________
Title: __________________________
Date: __________________________
EXHIBIT A
SAMPLE WORK ORDER

WORK ORDER #_______

This Work Order is issued pursuant to the Master Clinical Study Agreement ("Agreement") between APUS and Institute, dated April 18, 2007, and is subject to all terms and conditions of this Agreement.

[ANY CHANGES TO THE MASTER CLINICAL STUDY AGREEMENT REGARDING THE LENGTH OF CONFIDENTIALITY MUST BE STATED HERE.]

1. **Definitions.** In addition to defined terms set forth in the Agreement, the terms below shall have the following meanings:

   1.1 “Acceptably Completed CRF” means a case report form ("CRF") for an “Evaluable Subject” (defined below) completed according to the Protocol, whose entries are complete, accurate, and without discrepancies.

   1.2 “Evaluable Subject” means a subject that participates in the Study according to the Protocol and complies with the following requirements: (i) has met the applicable inclusion and/or exclusion criteria required by the Protocol; (ii) has signed an informed consent/authorization; and (iii) [Select Option: has received at least one dose of Study Drug].

   1.3 “Screen Failure” means a subject that completes the pre-screening and screening procedures as defined by the Protocol, has not received the Study Drug, and for whatever reason chooses not to participate in the Study and/or is not eligible for participation in the Study after undertaking such procedures.

2. **Protocol Title and Number.**

3. **Principal Investigator’s Name, Address, and Institute (“Institute”).**

4. **APUS’s Contact for the Study.**

5. **Study Schedule.**

   5.1 **Study Initiation.**

   5.2 **Enrollment.** Institute shall not enroll more than _______ Evaluable Subjects
5.3. Study Documentation.

6. Payment Terms.

6.1 Per Subject Fee. The maximum per subject fee for this Study is [WRITE OUT DOLLAR AMOUNT] ($__________) per each Evaluatable Subject ("Per Subject Fee"). The Per Subject Fee is payable in installments depending upon each Evaluatable Subject’s progress through and completion of the Study visits and/or procedures according to the Protocol, in the amounts set forth below:

Visits/Procedures Completed: Payment:
The Per Subject Fee includes payment for time spent in preparation of CRFs. Institute and/or Principal Investigator shall have the CRFs available for monitoring and determination of acceptability by APUS or its designee within [state period] following each subject’s last Study visit in order for payment to be credited for that visit. The Per Patient Fee will not be paid if APUS does not receive an Acceptably Completed CRF for that visit.

6.2. Site-Related Costs. APUS shall also pay the Institute for reasonable and verifiable site-related costs incurred in support of the Study as follows ("Site-Related Costs"): IRB Fee. APUS shall provide reimbursement to Institute, on a pass through basis, for the actual and reasonable cost of any Study related IRB fees incurred by Institute provided such fees are approved in advance by APUS ("IRB Fees"). Institute shall provide APUS with all necessary documentation in support of the IRB Fees.

Advertising Fee. APUS shall provide reimbursement to Institute, on a pass-through basis for Study-related advertising fees provided such advertisements and fees are approved in advance, in writing, by APUS ("Advertising Fees"). Institute shall invoice APUS and provide APUS with all necessary documentation in support of the Advertising Fees.

Start-Up Fee. APUS shall pay Institute a non-refundable amount of [WRITE OUT DOLLAR AMOUNT] ($) for Study start-up costs ("Study Start-up Fee") incurred by Institute and related to this Study. The Study Start-up Fee shall consist of costs associated with, but shall not be limited to, time incurred for protocol review, preparation of IRB documentation, pharmacy set-up costs and other administrative activities associated with the initiation of the Study.

6.3. Variable Subject Fees. APUS shall also pay Institute for the reasonable and verifiable subject-related fees not included in the Per Subject Fee that are incurred in
support of the Study ("Variable Subject Fees") as follows:
Screen Failure Fee. APUS shall pay for screen failures at a rate of [WRITE OUT DOLLAR AMOUNT] ($______) per subject, up to a maximum of [insert number] screen failures ("Screen Failure Fee"). The Screen Failure Fee shall not be prorated for partial completion of pre-screening and/or screening procedures.

End of Study Fee. APUS shall pay up to [WRITE OUT DOLLAR AMOUNT] ($______) per Evaluable Subject ("End of Study Fee") for the following end-of-Study activities: (i) resolution of any problems as described in any Request for Information ("RFI") issued in response to a CRF; and (ii) completion of all required Study close-out activities (as described in the Protocol), including the issuance of a final report to the applicable IRB.

Unscheduled Visit Fee. APUS shall pay up to [WRITE OUT DOLLAR AMOUNT] ($______) per visit for any Study-related unscheduled visits and/or procedures according to the Protocol ("Unscheduled Visit Fee"). Institute shall provide APUS with the appropriate documentation in support of Unscheduled Visit Fees.

7. Payments. Payments shall be made according to the following schedule:

7.1 A payment of [WRITE OUT DOLLAR AMOUNT] ($______) ("Initial Payment") following full execution of this Work Order, completion of all regulatory documents, and initiation of the Study at the site.

7.2 Further payments shall be calculated at the end of each calendar [state period, e.g., quarter/month] following the effective date of this Study. [State period] payments due for the Per Subject Fee shall be based on services completed in accordance with the terms of this Exhibit’s Section 2 and shall be made upon APUS’s verification of such services. Payments due for Site-Related Costs shall be based on services completed in accordance with the terms of this Exhibit’s Section 3 and shall be paid [state period] upon APUS’s receipt and acceptance of all supporting documentation required for payment (including, in the case of pass-through Site-Related Costs, copies of actual third-party invoices and receipts). Payments due for Variable Subject Fees shall be based on services completed in accordance with the terms of this Exhibit’s Section 6 and shall be paid [state period] upon APUS’s receipt and acceptance of all supporting documentation required for payment. Institute shall timely provide any additional documentation as APUS requests in order to verify any payments owed hereunder.

7.3 APUS shall make all checks payable to: Institute. All payments shall be mailed to Institute at the address of __________, unless otherwise specified in writing. Institute’s FEIN: [insert #].

APUS-initiated; 7 yr. period of confidentiality
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8. Upon the termination of this Agreement or the completion of the Study, any excess funds shall either be promptly paid by APUS (provided that the Study has been performed in accordance with this Agreement, the Protocol and any written instructions provided by APUS) or reimbursed by Institute as appropriate under the payment terms herein, no later than thirty (30) days after the effective date of termination. Reimbursement to APUS shall be made to the following: Astellas Pharma US, Inc., attention Research and Development Administration, Three Parkway North, Deerfield, Illinois 60015-2548.

This Work Order is entered into and made effective as of ________________ “Effective Date”. This Work Order shall begin on the Effective Date and end on __________, unless earlier terminated in accordance with the Agreement.

Accepted and agreed to by:

ASTELLAS PHARMA US, INC.

By: _________________
Date: ________________

INSTITUTE

By: _________________
Date: ________________

Read and understood:

PRINCIPAL INVESTIGATOR

By: _________________
Date: ________________
EXHIBIT B
CONTACT INFORMATION FOR EACH INSTITUTE

THE UNIVERSITY OF TEXAS AT AUSTIN
Office of Sponsored Projects
N. Adm. Bldg. 101 E. 27th St. Rm. 4.300
Austin, TX 78712
Phone: 512-471-6424
Fax: 512-471-6564
Tax ID: 74-6000203

THE UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER AT DALLAS
Research Administration
5323 Harry Hines Blvd., H1.108
Dallas, Texas 75390-9016
Phone: 214-648-6449
Fax: 214-648-3362
Tax ID: 75-6002868

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON
Contracts Director
Office Of Sponsored Projects
P.O. Box 20036
Houston, TX 77225
Phone: 713-500-3999
Fax: 713-500-0355
Tax ID: 74-176139

THE UNIVERSITY OF TEXAS HEALTH CENTER AT TYLER
Chief Business and Finance Officer,
Administration
11937 U.S. Hwy. 271
Tyler, TX 75708-3154
Phone: 903-877-7069
Fax: 903-877-7558
Tax ID: 75-600-1354

THE UNIVERSITY OF MEDICAL BRANCH AT GALVESTON
Manager of Research Operations
Office of Sponsored Programs
301 University Boulevard 2.240 Gail Borden
Galveston, TX 77555-0671
Phone: 409-772-0574
Fax: 409-747-3793
Tax ID: 74-6000949

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT SAN ANTONIO
Assistant Vice President for Research and
Sponsored Programs
Office of Sponsored Programs
7703 Floyd Curl Drive, Mail Code 7828
San Antonio, TX 78229-3900
Phone: 210-567-2333
Fax: 210-567-2344
Tax ID: 74-1586031

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