MASTER CLINICAL STUDY AGREEMENT
RESTATED AND AMENDED

This Master Clinical Study Agreement (Restated and Amended) (**"Agreement"**) dated this April 18, 2014 (**"Effective Date"**), sets forth the understanding between Astellas Pharma Global Development, Inc. a Delaware corporation with its principal place of business at 1 Astellas Way, Northbrook, IL, 60062 (**"SPONSOR"**) 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 Medical Branch at Galveston, The University of Texas Southwestern Medical Center, and The University of Texas Health Science 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 member 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"**). SPONSOR and Institute and/or Institutes are hereinafter collectively referred to as the **"Parties"** or individually as a **"Party"**.

RECITALS

WHEREAS, SPONSOR 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 SPONSOR and Institutes and will further the Institutes' instructional, basic science, clinical science and fundamental research objectives and missions.

WHEREAS, SPONSOR and Institutes have entered into a Master Clinical Study Agreement having an Effective Date of April 18, 2007 ("**Master Agreement**"), and SPONSOR and Institutes have amended the Master Agreement twice since the Effective Date to extend the term of the Master Agreement which ends April 18, 2014, or sooner, upon execution of this Agreement.

WHEREAS, SPONSOR and Institutes desire to restate and amend the Master Agreement to (a) extend the term for an additional seven (7) years, (b) revise specific sections, and (c) add several new sections under this restated Agreement.

WHEREAS, SPONSOR and Institutes agree that all Work Orders (as defined in the Master Agreement) executed pursuant to the Master Agreement and in effect as of the Effective Date above ("**Transferred Work Orders**") shall be attached to this Agreement as a Work Order in accordance with the terms hereof.

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

1. (A) **Definitions.**

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

(1) **"Agency"** shall mean any applicable regulatory authority.

(2) **"Authorized Representatives"** shall mean the individuals who have authority on behalf of SPONSOR and Institute to sign this Agreement as well as any "Order" (as defined in Section 1(A)(5)). 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 SPONSOR 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.

(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" (as defined in Section 1(A)(11)). A Change Order is not enforceable unless signed by Authorized Representatives of each Party and only applies to that one specific Work Order.

(4) **"Deliverables"** shall mean reports or other items to be delivered to SPONSOR by Institute. Specific Deliverables (if any) shall be identified and defined in each applicable Order.

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

(6) **"Personnel"** shall mean Institute's medical and professional staff, employees, agents, servants, representatives and contractors performing Study services hereunder, including the Principal Investigator (defined below).

(7) **"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 Work Order.

(8) **"Protocol"** shall mean a particular clinical research protocol approved by SPONSOR for research services performed under each Order. The Protocol shall detail the objectives, design, means and methods by which the services are performed.

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

(10) **"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 applicable thereto.

(11) **"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 SPONSOR or an affiliate of SPONSOR. Each Work Order shall include, at minimum, the Protocol, which shall include the methods and specifications of the Study , a term, payment amount and the like. A Work Order is not enforceable unless signed by Authorized Representatives of Institute and SPONSOR or an affiliate of SPONSOR. A sample Work Order is attached hereto and incorporated herein as Exhibit A.

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 SPONSOR 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 responsible to SPONSOR 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 SPONSOR, 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 SPONSOR 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 (as defined in the CFR) and/or Principal 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 SPONSOR or its designee.

(E) The number of subjects SPONSOR 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. SPONSOR 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 provide SPONSOR or its designee with a copy of such IRB Approval. 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 SPONSOR, its affiliates, business collaborators, designee and/or any or all other clinical trial service providers to have access to and use of patients' Protected Health Information, as defined by the Health Insurance Portability and Accountability Act of 1996. The informed consent and the written authorization, or waiver of authorization, are collectively referred to as the "**Authorization Documents**."

(F) SPONSOR may engage the services of a contract research organization (**"CRO"**) to assist in the monitoring of a Study. The terms and conditions of this Agreement and the applicable Work Order shall govern the conduct of any Study sponsored by SPONSOR or its affiliates and performed by Institute(s).

(G) SPONSOR will notify Institute of any Study subject safety issues in accordance with the applicable Protocol and all applicable laws, rules and regulations. In addition, SPONSOR will notify the Institute(s) and Principal Investigator of interim findings and post Study results that could affect the human subject

protections associated with the Study. Institute(s), through the Principal Investigator and/or IRB as appropriate, shall tell subjects of important information that may adversely affect the safety, well-being, medical care or health of a subject in accordance with its IRB policy, but only to the extent such disclosure is i) limited to safety information germane to the subject's condition, and ii) provided that such disclosure is minimized to the extent possible.

(H) Institute covenants, represents and certifies that it shall cause all Personnel to comply with the terms of this Agreement. Institute shall be responsible for ensuring that all Personnel are bound by the obligations stated herein.

(I) SPONSOR's affiliates may participate in this Agreement by executing along with Institute their own separately numbered Work Order(s) and agreeing in such Work Order(s) to be bound by this Agreement. Each affiliate of SPONSOR that participates hereunder shall be severally and solely responsible for its own transactions, conduct, actions, inactions, and liabilities arising as a result of such affiliate's participation hereunder. Each SPONSOR affiliate executing an Order shall not be responsible for any transactions, conduct, actions, inactions or liabilities of any other participating affiliates of SPONSOR as a result of this Agreement. For the avoidance of doubt, any affiliate of SPONSOR who enters into an Order hereunder shall be defined as "SPONSOR" in lieu of "Astellas Pharma Global Development, Inc." for the purposes of such Order and shall enjoy the rights and assume the obligations set forth in this Agreement with respect to such Order.

3. **Payment Terms.**

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

(B) SPONSOR 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 SPONSOR 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), SPONSOR 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 SPONSOR or its designee.

(D) Institute shall provide a final invoice for reimbursable items not included in the Per Subject Fee (as defined below) for a Study to SPONSOR or its designee no later than six (6) months following the completion or early termination of such

Study at the Institute. SPONSOR shall not be responsible for making any payments beyond such six (6) month period.

(E) 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 SPONSOR or any of it affiliates or business collaborators, or the formulary status of any products of SPONSOR or any of its affiliates or business collaborators.

(F) 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) SPONSOR has paid for the item or service as part of the Per Subject Fee or any other fee detailed in a Work Order Exhibit A or (ii) the item or service is furnished for the Study subject by or through SPONSOR at no cost to the Institute.

4. **Regulatory Application.**

SPONSOR, 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 SPONSOR and shall cause all Personnel involved in Study conduct to do the same, in answering questions from regulatory agencies concerning the Study. Institute shall cooperate and allow SPONSOR or its designee, 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 SPONSOR, 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 SPONSOR'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

SPONSOR, but excluding patient medical records. Prior to any necessary copying of records, SPONSOR, or its designee, will redact all patient identifying information.

6. **Reports.**

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

7. **Equipment.**

(A) SPONSOR or its designee may provide certain equipment (collectively, the "**Equipment**") solely for use in performance of this Study. The Equipment (a description of which, as applicable, will be included in each Work Order) shall be deemed to be part of the consideration and budget for performing the Study. Title and ownership to the Equipment provided by SPONSOR for use in performing the Study shall be retained by SPONSOR, and Institute shall return the Equipment upon the earlier to occur of SPONSOR's or its designee's written request, or completion or termination of the Study. If the Study is completed or this Agreement is terminated prior to completion of the Study, Institute shall return the Equipment at SPONSOR's or its designee's expense and upon SPONSOR's or its designee's written request.

(B) During the Study, except where protected under manufacturer warranty or where due to the negligence or willful misconduct relating to use of the Equipment by Institute, SPONSOR shall be responsible for any repairs and maintenance to the Equipment. During this Study, Institute shall promptly notify SPONSOR or its designee of any malfunctioning Equipment and SPONSOR shall repair or replace any malfunctioning equipment, to the extent not protected under manufacturer warranty, and based on SPONSOR's assessment of the Study progress and Institute's facilities.

(C) Institute shall implement reasonable and appropriate administrative, physical and technical safeguards to protect the confidentiality, integrity and availability of all data on any electronic Equipment.

(D) The Equipment will be provided "as is". SPONSOR MAKES NO REPRESENTATIONS OR WARRANTIES OF ANY KIND CONCERNING THE EQUIPMENT, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION WARRANTIES OF MERCHANTABILITY, USE OR FITNESS FOR ANY PARTICULAR PURPOSE OR TITLE, the absence of latent or other defects to the Equipment, whether or not discoverable or that the Equipment will not infringe any patent, copyright, trademark or other right of a third party.

8. **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 10 herein, and (ii) any and all information furnished to Institute and/or Principal Investigator by SPONSOR, an affiliate of SPONSOR, or any agent or representative of SPONSOR, that relates to the Study, Study Drug (and/or any analog thereof owned by or licensed to SPONSOR or an affiliate of SPONSOR) and/or other proprietary information of SPONSOR, 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.

(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 Personnel and members of the IRB who have a need to know such Confidential Information to further this Agreement and/or the Study. Institute and its Personnel 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 SPONSOR, 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 SPONSOR, and reasonably cooperates with SPONSOR, so that if possible, SPONSOR 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 8(A)(i) shall no longer be deemed to be confidential when published in accordance with Section 10 herein.

(C) Institute shall advise its Personnel 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 SPONSOR, 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 8 or Section 10 (Publication) 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 publication provisions of Section 10 herein.

(F) Unless specifically agreed to in writing by the Parties in a Work Order, the obligations described in this Section 8 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.

9. **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) SPONSOR, 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 SPONSOR, Institute or its Personnel, individually or jointly ("**Inventions**") and (ii) subject to Institute's publication rights as set forth in Section10 herein, all records, reports and other data required to be delivered to SPONSOR 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 SPONSOR 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 SPONSOR, including all patents, Institution's rights in copyrights 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 SPONSOR to execute and shall cause all Personnel to execute all documents reasonably necessary for SPONSOR to secure, perfect, effectuate and preserve SPONSOR's ownership rights in the Research Results.

(D) Institute shall cause its Personnel and IRB members to comply with the terms and conditions of this Section 9. The obligations described in this Section 9 shall survive the expiration or earlier termination of this Agreement and/or an Order.

(E) SPONSOR grants Institute the right to use Trial Data for Institute's internal, non-commercial research, and educational purposes, and for purposes of publication in accordance with Section 10 herein, provided, that, Institute's use of the Trial 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 8 herein. SPONSOR 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 the use of the Trial Data by Institute

10. **Publication.**

(A) Institute and/or Principal Investigator may publish or present Trial Data generated from a Study at their specific Study site; provided: (i) no Confidential Information of the type described in Section 8 is revealed and (ii) no Trial Data is presented and/or published prior to publication of the multi-center data from a Study, or until eighteen (18) months have elapsed following completion of the multi-center Study, whichever comes first. Any manuscript or communication of clinical research findings may represent an official summary for purposes of regulatory submissions. Institute shall provide SPONSOR 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, SPONSOR 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 8(A) or which may impair SPONSOR's ability to obtain patent protection. SPONSOR 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 8(A) and/or to delay publication an additional sixty (60) days so that SPONSOR 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 SPONSOR, which will not be unreasonably withheld. This provision does not prohibit publication or presentation of specific Study site Trial Data in compliance with Section 10(A).

(C) SPONSOR shall post the Study on clinicaltrials.gov and/or clinicaltrialresults.org in accordance with its internal policy and any applicable laws, rules and regulations.

(D) The obligations described in this Section 10 shall survive the expiration or earlier termination of this Agreement and/or an Order.

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

(A) SPONSOR shall defend, indemnify and hold harmless Institute, System, Board and their respective officers and Personnel (**"Institute Indemnitees"**) 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 Indemnitees arising from, resulting from or relating to: (i) the Study Drug; (ii) a procedure properly performed in accordance with the applicable Protocol; or (iii) SPONSOR's use of Institute's results from a Study, provided that such results are not derived from falsified Study data. SPONSOR's indemnification obligations under this Section 11(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 Indemnitees; (ii) the negligence or willful misconduct of any of Institute Indemnitees; or (iii) any unauthorized deviation by any of Institute Indemnitees 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 SPONSOR, its subsidiaries, affiliates, business collaborators, directors, officers, shareholders, employees, predecessors, successors and/or assigns (**"SPONSOR Indemnitees"**) from any and all Losses related to (i) a violation of applicable law, rule, or regulation by any of Institute Indemnitees; (ii) the negligence or willful misconduct of any of Institute Indemnitees pertaining to the activities to be carried out pursuant to the obligations of this Agreement; or (iii) any unauthorized deviation by any of Institute Indemnitees from the Protocol (except for any such deviation required as medical necessity). Institute's indemnification obligations

under this Section 11(B) shall not apply to the extent any Losses arise from, result from or relate to: (a) a violation of applicable law, rule or regulation by any SPONSOR Indemnitees; (b) the negligence or willful malfeasance by any SPONSOR Indemnitees; or (c) any unauthorized deviation by any SPONSOR Indemnitees 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 11(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 SPONSOR 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, PREDECESSORS, NOR ANY OF THEIR RESPECTIVE REGENTS, DIRECTORS, OFFICERS, EMPLOYEES, PERSONNEL, 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 member institution 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) SPONSOR 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 11 shall survive the expiration or earlier termination of this Agreement or a Work Order for a period of ten (10) years.

12. **Agency Access.**

Institute shall allow SPONSOR, its affiliates, business collaborators, representatives and/or designees and any Agency and their designees reasonable access to Institute's or any of its Personnel's facilities and/or medical records to permit monitoring a Study and reviewing, inspection and copying of Trial Data, source documents, and signed Authorization Documents (as defined in 2(E)) to the extent not prohibited by applicable law. Institute shall notify SPONSOR promptly by telephone and facsimile (with a follow-up by mail) upon, but not later than twenty-four (24) hours after, learning that an Agency inspection is scheduled to take place, or, if there is no prior notice by an Agency, that an inspection has commenced. Upon request, Institute shall make all reasonable efforts to coordinate any scheduling of Agency inspections to permit SPONSOR and its representatives to attend such inspections. Institute shall provide SPONSOR with copies of all Trial Data, source documents and any other materials, correspondence and documents which Institute receives, obtains, provides or generates pursuant to any such inspection or in connection with any inquiries, communications or correspondence from any Agency. Institute agrees to give SPONSOR the opportunity to review and comment on any written response by Institute to any Agency.

13. **Subject Injury Compensation.**

SPONSOR agrees to reimburse Institute for the reasonable costs of medical treatment provided by Institute's facilities/physicians or any licensed health care provider's facility in the event an Evaluable Subject (as defined in the applicable Work Order) is injured as a direct result of the use of the Study Drug, and/or any Study procedure required and conducted in accordance with the Protocol, as determined jointly by SPONSOR and the Principal Investigator. Such reimbursement will be

provided only if the Study Drug and/or procedure has been used or performed in accordance with the Protocol and any other written instructions provided to Institute by SPONSOR. The obligations described in this Section 13 shall survive the expiration or earlier termination of this Agreement and or a Study.

14. **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 SPONSOR may assign this Agreement and/or its rights and obligations hereunder without the consent of Institute (but with written notification of such assignment by SPONSOR to System 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 SPONSOR's business. Institute acknowledges that Institute and Principal Investigator are conducting each Study as independent contractors and not as agents or employees of SPONSOR. 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 SPONSOR under this Agreement may be exercised or performed by one or more affiliates of SPONSOR.

15. **Non-Exclusive Relationships.**

Nothing in this Agreement will limit or prohibit Institutes or any of its Personnel 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. SPONSOR acknowledges that this provision is intended to ensure that Institutes and their faculty are not regarded as captive researchers for SPONSOR.

16. **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.

17. **Term and Termination.**

(A) This Agreement shall begin on the Effective Date and shall continue for the longer of (a) seven (7) years from the Effective Date (April 18, 2021) 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) SPONSOR 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 SPONSOR 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 SPONSOR any and all of the remaining Study Drug and other SPONSOR property, including without limitation, Equipment (if applicable) and 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 8 (Confidentiality).

18. **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 SPONSOR: Astellas Pharma Global Development, Inc.
Attention: Global Contracts & Outsourcing Management (GCOM)
1 Astellas Way
Northbrook, IL 60062
cc: General Counsel
Facsimile: 224-205-5915

To Institute: See Exhibit B.

With a copy to System:

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.

19. **Entire Agreement; Amendment; Severability.**

This Agreement, an Order, 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, including the Master Agreement entered into by SPONSOR and Institutes on April 18, 2007 and twice amended. Notwithstanding the foregoing, however, any confidentiality agreement previously entered into between SPONSOR, its affiliates, and/or its predecessors and/or designee 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, unless a deviation is specifically agreed to in writing by SPONSOR and Institute(s) in a Work Order and approved by System's Office of General Counsel. This Agreement may not be amended except by a writing signed by SPONSOR and Institutes and approved by System's Office of General Counsel. Notwithstanding the foregoing two sentences, it is understood and agreed by the Parties that such Office of General Counsel approval will be obtained by Institute(s) prior to signing any revised or amended Work Order or amendment. 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.

20. **Regulatory Requirements.**

(A) Institute certifies to SPONSOR 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 SPONSOR should the accuracy of the foregoing certification be compromised.

(B) SPONSOR and Institutes 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 and/or Order.

(C) Institute covenants, represents and certifies, with respect to any committee of which any of its Personnel are members and which (1) sets drug formularies, and/or (2) develops clinical practice guidelines ("**Committee**"), shall be informed promptly, upon Agreement execution, of the existence of this Agreement and the nature of the Study services provided by Institute and its Personnel hereunder. Such disclosures shall be made on a confidential basis. Furthermore, Institute shall require that each of its Personnel follow the procedures set forth by the Committee to avoid any appearance of impropriety that may result from Personnel's performance of the applicable Study, which procedures may include Institute and/or the Personnel recusing it/him/herself from decisions relating to the subject matter of this Agreement. The obligations of this section shall remain in effect for the term of this Agreement and for two (2) years thereafter.

(D) Institute covenants, represents and certifies that neither it nor any of its Personnel has made, offered or solicited and will not make, offer or solicit any remuneration, kickbacks, or anything else of value to any person or entity in violation of the federal Anti-Kickback Statute (42 U.S.C. § 1320-a7b(b)) or any applicable state anti-kickback statutes (together **"Statutes"**), which Statutes are incorporated hereby by this specific reference.

(E) Institute covenants, represents and certifies that Institute and its Personnel: (i) is not or has not been the subject of a proceeding by any Board of Medical Examiners or similar agency (including an Agency) and has not been and is not currently a party to any litigation, arbitration or mediation involving the practice of medicine; (ii) is not subject to an ongoing investigation and/or has not been found by any Agency to have violated any statutes, rules, or regulations concerning the conduct of clinical investigations; (iii) is not the subject of a disqualification proceeding or has not been disqualified as a clinical investigator pursuant to 21 C.F.R. § 312.70; or (iv) has not been terminated from any investigation or research project by the sponsor for clinical or medical misconduct.

(F) If any of Institute's Personnel are licensed by, and practicing in, a state that requires SPONSOR to report payments or other value (e.g., value of meals or textbooks) transferred to Institute and/or its Personnel, or if reporting is otherwise required, it is understood by Institute that SPONSOR will report all payments and may be required to report other value transferred to Institute and/or its Personnel under this Agreement to that state. Institute understands that information about

payments or other value transferred to Institute, and/or its Personnel by SPONSOR may be made publicly available.

(G) Institute covenants, represents and certifies that the IRB used for any Study has not been disqualified by the FDA.

(H) The foregoing may be relied on by SPONSOR in any application to any Agency for marketing approvals. A Party shall notify the other Party should the accuracy of the foregoing certifications, covenants, and/or representations become compromised.

21. **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.

22. **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.

23. **Survival.**

Obligations of the Parties that have accrued shall survive expiration or termination of this Agreement, and under Sections 2(G) (Study subject safety) , 8 (Confidential Information), 9 (Intellectual Property), 10 (Publication), 11 (Indemnification, Limitation of Liability, Insurance),12 (Agency Access), 13 (Subject Injury Compensation), and 18 (Notice) shall survive expiration or termination of this Agreement according to the periods of survival stated in such sections and, if no specific period is stated, then indefinitely.

24. **Different Provisions for Specific Compounds.**

Institute accepts that certain terms herein, including, but not limited to, those respecting confidentiality, publications and intellectual property, may need to be modified for a specific Order, based upon SPONSOR's obligations to the licensor of the particular Study Drug relating to that Order or other considerations. Any such modified terms shall be set forth in the affected Order and those terms shall control over any terms herein for that Order notwithstanding anything to the contrary herein. This Agreement shall also be amended to reflect such changes for that Order.

25. **Transfer of Work Orders**. The Parties agree that as of the Effective Date all Transferred Work Orders shall be attached hereto as a Work Order and as of the Effective Date such Transferred Work Orders shall be governed by the terms of this Agreement.

26. **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 GLOBAL DEVELOPMENT, INC.

By: Lorri J. Erhardt

Name: Lorri Erhardt

Title: Executive Director
Clinical Site & Document Management

12 Jun 2014

THE UNIVERSITY OF TEXAS AT AUSTIN

By: D Hawkins

Name: DAVID HAWKINS

Title: ASSOCIATE DIRECTOR, OSP

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON HOUSTON

By: _____

Name: _____

Title: _____

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT SAN ANTONIO

By: _____

Name: _____

Title: _____

THE UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER TYLER

By: _____

Name: _____

Title: _____

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT

By: _____

Name: _____

Title: _____

THE UNIVERSITY OF TEXAS MEDICAL BRANCH AT GALVESTON

By: _____

Name: _____

Title: _____

26. **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 GLOBAL DEVELOPMENT, INC.

By: Lorri J. Erhardt

Name: Lorri Erhardt

Title: Executive Director
Clinical Site & Document Management
12 Jun 2014

THE UNIVERSITY OF TEXAS AT AUSTIN

By: _____

Name: _____

Title: _____

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON HOUSTON

By: Karen S. Niemeier

Name: Karen S. Niemeier
Director, Contracts
Office of Sponsored Projects

Title: _____

Digitally signed by karen.niemeier@uth.tmc.edu
DN: cn=karen.niemeier@uth.tmc.edu
Date: 2014.06.09 10:37:52 -05'00'

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT SAN ANTONIO

By: _____

Name: _____

Title: _____

THE UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER TYLER

By: _____

Name: _____

Title: _____

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT

By: _____

Name: _____

Title: _____

THE UNIVERSITY OF TEXAS MEDICAL BRANCH AT GALVESTON

By: _____

Name: _____

Title: _____

26. **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 GLOBAL DEVELOPMENT, INC.

By: Lorri J. Erhardt

Name: Lorri Erhardt

Title: Executive Director
Clinical Site & Document Management

12 Jun 2014

THE UNIVERSITY OF TEXAS AT AUSTIN

By: _____

Name: _____

Title: _____

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON HOUSTON

By: _____

Name: _____

Title: _____

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT SAN ANTONIO

By: Chris G. Green

Name: Chris G. Green, CPA

Title: Director, Office of Sponsored Programs

THE UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER TYLER

By: _____

Name: _____

Title: _____

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT

By: _____

Name: _____

Title: _____

THE UNIVERSITY OF TEXAS MEDICAL BRANCH AT GALVESTON

By: _____

Name: _____

Title: _____

26. **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 GLOBAL DEVELOPMENT, INC.

By: Lorri J. Erhardt

Name: Lorri Erhardt

Title: Executive Director
Clinical Site & Document Management
12 Jun 2014

THE UNIVERSITY OF TEXAS AT AUSTIN

By: _____

Name: _____

Title: _____

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON HOUSTON

By: _____

Name: _____

Title: _____

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT SAN ANTONIO

By: _____

Name: _____

Title: _____

THE UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER

aw ~~TYLER~~

By: Angela R Wish

Name: Angela R. Charboneau Wishon, J.D.

Title: Vice President for Research Administration

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT

By: _____

Name: _____

Title: _____

THE UNIVERSITY OF TEXAS MEDICAL BRANCH AT GALVESTON

By: _____

Name: _____

Title: _____

26. **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 GLOBAL DEVELOPMENT, INC.

By: Lorri J. Erhardt

Name: Lorri Erhardt

Title: Executive Director
Clinical Site & Document Management
12 Jun 2014

THE UNIVERSITY OF TEXAS AT AUSTIN

By: _____

Name: _____

Title: _____

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON HOUSTON

By: _____

Name: _____

Title: _____

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT SAN ANTONIO

By: _____

Name: _____

Title: _____

THE UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER

By: _____

Name: _____

Title: _____

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT TYLER

By: _____

Name: David Anderson

Title: Director of Pre-Award Services

THE UNIVERSITY OF TEXAS MEDICAL BRANCH AT GALVESTON

By: _____

Name: _____

Title: _____

26. **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 GLOBAL DEVELOPMENT, INC.

By: Lorri J. Erhardt

Name: Lorri Erhardt

Title: Executive Director
Clinical Site & Document Management
12 Jun 2014

THE UNIVERSITY OF TEXAS AT AUSTIN

By: _____

Name: _____

Title: _____

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON HOUSTON

By: _____

Name: _____

Title: _____

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT SAN ANTONIO

By: _____

Name: _____

Title: _____

THE UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER TYLER

By: _____

Name: _____

Title: _____

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT

By: _____

Name: _____

Title: _____

THE UNIVERSITY OF TEXAS MEDICAL BRANCH AT GALVESTON

By: Connie J Barton

Name: Connie J. Barton

Title: Director, Office of Sponsored Programs

EXHIBIT A
WORK ORDER #_____

This Work Order is issued pursuant to the Master Clinical Study Agreement (Restated and Amended) ("**Agreement**") between [Insert Sponsor] ("**SPONSOR**") and [Insert Institute] ("**Institute**") dated _____, and is subject to all terms and conditions of this Agreement.

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.

1.4 "**Study Drug**" means _____.

2. **Protocol Title and Number.**

3. **Principal Investigator's Name, Address, and Institute ("Institute").**

4. **SPONSOR'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 Evaluable Subject (**"Per**

Subject Fee"). The Per Subject Fee is payable in installments depending upon each Evaluable 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 SPONSOR 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 SPONSOR does not receive an Acceptably Completed CRF for that visit.

6.2. **Site-Related Costs.** SPONSOR 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. SPONSOR 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 SPONSOR (**"IRB Fees"**). Institute shall provide SPONSOR with all necessary documentation in support of the IRB Fees.

Advertising Fee. SPONSOR 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 SPONSOR (**"Advertising Fees"**). Institute shall invoice SPONSOR and provide SPONSOR with all necessary documentation in support of the Advertising Fees.

Start-Up Fee. SPONSOR 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.** SPONSOR 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. SPONSOR 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. SPONSOR 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. SPONSOR 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 SPONSOR 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 thisWork Order's Section 6.1 and shall be made upon SPONSOR's verification of such services. Payments due for Site-Related Costs shall be based on services completed in accordance with the terms of this Work Order's Section 6.2 and shall be paid [state period] upon SPONSOR'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 Work Order's Section 6.3 and shall be paid [state period] upon SPONSOR's receipt and acceptance of all supporting documentation required for payment. Institute shall timely provide any additional documentation as SPONSOR requests in order to verify any payments owed hereunder.

7.3 SPONSOR 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 #].

8. Upon the early termination of this Work Order or the completion of the Study, any funds owed Institute shall either be promptly paid by SPONSOR (provided that the Study has been performed in accordance with this Agreement, the Protocol and any written instructions provided by SPONSOR); however, any unearned funds shall be reimbursed by Institute as appropriate under the payment terms herein, no later than thirty (30) days after the effective date of termination. Reimbursement to SPONSOR shall be made to the following: [INSERT CORRECT SPONSOR NAME AND ADDRESS]

9. Equipment. SPONSOR shall provide the following Equipment, for Institute's use in

performing the Study:

[list equipment]

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:

[INSERT SPONSOR NAME]
By: _____
Name: _____
Title: _____
Date: _____

INSTITUTE

By: _____
Name: _____
Title: _____
Date: _____

Read and understood:

PRINCIPAL INVESTIGATOR

By: _____
Date: _____

EXHIBIT B
AUTHORIZED REPRESENTATIVES OR HIS/HER DESIGNEE

David Hawkins Associate Director Office of Sponsored Projects **The University of Texas at Austin** 101 E. 27th Street North Office Bldg., Suite 5.300 Austin, TX 78712 Phone: 512-471-6424 Fax: 512-471-6564 Tax ID: 74-6000203	Angela R. Charboneau Wishon Vice President for Research Administration **The University of Texas Southwestern Medical Center at Dallas** 5323 Harry Hines Blvd. Dallas, Texas 75390-9016 Phone: 214-648-0455 Fax: 214-648-2119 Tax ID: 75-6002868
Chris Green Director, Office of Sponsored Programs **The University of Texas Health Science Center at San Antonio** 7703 Floyd Curl Dr, Mail Code 7828 San Antonio, TX 78229-3900 Phone: 210-567-4938 Fax: 210-567-2344 Tax ID: 74-1586031	Karen Niemeier Director, Contracts **The University of Texas Health Science Center at Houston** 7000 Fannin Street, Suite 1006 Houston, TX 77030 Phone: 713-500-3999 Fax: 713-383-3746 Tax ID: 74-1761309
David Anderson Director, Office of Pre-Award Services **The University of Texas Health Science Center at Tyler** 11937 U.S. Hwy. 271 Tyler, TX 75708-3154 Phone: 903-877-7486 Fax: 903-877-7558 Tax ID: 75-6001354	Rohan Hebbar Associate Legal Officer **The University of Texas Medical Branch at Galveston** Office of Sponsored Projects 301 University Boulevard Galveston, TX 77555-0156 Phone: 409-747-8743 Fax: 409-266-9470 Tax ID: 74-6000949