MASTER CLINICAL STUDY AGREEMENT - ABBOTT INITIATED

This master clinical study agreement ("Master Agreement"), effective as of the full execution hereof ("Effective Date"), sets forth the terms and conditions by and between Abbott Laboratories, an Illinois corporation having its principal place of business at 100 Abbott Park Road, Abbott Park, Illinois, 60064-3500 ("ABBOTT") and each of The University of Texas Health Science Center at San Antonio, The University of Texas Health Science Center at Houston, The University of Texas Southwestern Medical Center at Dallas, and The University of Texas at Austin (collectively referred to as "INSTITUTION"), each with an office and place of business as set forth on the signature line hereto, and each a component institution of The University of Texas System, located at 201 West 7th Street, Austin TX 78701, as governed by its Board of Regents.

The parties agree as follows:

- 1. Definitions; Scope of Master Agreement; Statement of Work; Conduct of Study,
 - (a) <u>Definitions</u>. As used in this Master Agreement, each capitalized term listed below shall have the meaning that is given after it:
 - "Abbott Confidential Information" shall have the meaning ascribed to it in Section 9.
 - "Act" means the Federal Food, Drug and Cosmetic Act, as amended, and regulations promulgated thereunder.
 - "Budget" means a detailed budget established for each Study, as detailed in the applicable Statement of Work.
 - "CRF" or "Case Report Form" means a printed, optical, or electronic document designed to record all of the Protocol required information to be reported to ABBOTT on each Subject.
 - "CRO" or "contract research organization" shall mean a person or an organization contracted by ABBOTT to perform one or more of ABBOTT's study-related duties and functions. The CRO for a Study, if applicable, will be provided in each respective Statement of Work.
 - "Essential Documents" mean all of those documents defined by Section 8 of the ICH Guidelines.
 - "FDA" means the United States Food and Drug Administration or any successor entity thereto.
 - "<u>Financial Disclosure Certification Form</u>" means the financial disclosure certification, in compliance with 21 CFR 54.
 - "HIPAA" means the Health Insurance Portability and Accountability Act of 1996, as amended, and the rules and regulations promulgated thereunder.
 - "ICH Guidelines" means the International Conference on Harmonization, Harmonized Tripartite Guidelines for Good Clinical Practice E6, 1996, or such successor provisions in force at the time of performance of the services.
 - "IEC/IRB" means the Independent Ethics Committee ("IEC"), as the term is defined in ICH Guidelines and/or the Institutional Review Board ("IRB), as that term is defined under the Act, and shall include any other review board required by local law or ICH Guidelines.
 - "Indemnitees" shall have the meaning ascribed to it in Section 16.
 - "Informed Consent" means a consent signed by or on behalf of a Subject which consent shall comply with the regulations of the Department of Health and Human Services, its supporting agencies, the FDA and any other applicable regulatory agency governing informed consent,

including without limitation, Section 4.8 of the ICH Guidelines, 45 C.F.R. 46.116(a), 21 C.F.R. 50 and 21 C.F.R 812.

"<u>Principal Investigator</u>" means, with respect to any Study, a qualified clinical investigator as defined in ICH E6 4.1.1 to conduct a clinical investigation of a Study Product on the terms and conditions of a specified Protocol and Statement of Work.

"Protocol" means the document that specifies the clinical trial procedures, as developed by ABBOTT applicable for the performance of a Study and any amendments thereto. A Protocol shall be provided and referred to in the Statement of Work for each individual Study.

"Source Documents" means the original documents, data, and records whether in paper form or other media, which are used, referenced or created as part of performance of the Study.

"Statement of Work" means each individual written agreement between ABBOTT and INSTITUTION, a sample of which is attached hereto as Exhibit A, related to a specific Study.

"Study" means an ABBOTT sponsored clinical trial of a Study Product or the scientific evaluation of a Study Product, which conforms to the terms and conditions of a specified Protocol.

"Study Product" means a pharmaceutical form of an active ingredient or placebo, which may be an unapproved/uncleared product or may be an approved/cleared product to be used as a comparator or assembled (formulated or packaged) in a way different from the approved/cleared form or for an unapproved/uncleared indication, or used to gain further information about an approved/cleared use. The specific Study Product shall be referred to in the Statement of Work for each individual Study.

"Study Term" means the period of time specified in the applicable Statement of Work for the specific Study.

"Subject" means an individual who participates in a Study, either as a recipient of the Study Product or as a control.

"Term" shall have the meaning ascribed to it in Section 15(a).

- (b) Scope of Master Agreement. This Master Agreement allows the parties to specify distinct clinical study activities to be performed by INSTITUTION through the issuance of multiple Statements of Work. This Master Agreement covers the provision of certain Studies in relation to certain Study Products, as set forth in the relevant Statement of Work. ABBOTT shall, in its sole discretion, determine when and whether to offer Studies under this Master Agreement to INSTITUTION, including the decision whether or not to enter into a specific Statement of Work.
- (c) Statement of Work. The specific details and tasks of each Study shall be separately negotiated and specified in writing on a Statement of Work. The Statement of Work shall be executed by an authorized representative of ABBOTT and INSTITUTION. Each Statement of Work will include, as appropriate, the name of the Study Product, reference to the Protocol, the name of the Principal Investigator, the Budget, timeframes to enroll Subjects, ABBOTT contacts, procedure for returning or destroying Study Product and other supplies, delivery of Essential Documents, compensation, whether the Study is a single site or multi-site study to determine how publications will be addressed, and Study Term. Each Statement of Work shall be subject to all of the terms and conditions of this Master Agreement, in addition to the specific details set forth in the Statement of Work. To the extent any terms or provisions of a Statement of Work conflict with the terms and provisions of this Master Agreement, the terms and provisions of this Master Agreement, the terms and provisions of this Master Agreement shall control, unless the Statement of Work expressly and specifically states an intent to supersede the Master Agreement on a specific matter (but then only with respect to the particular Statement of Work and with respect only to the matter so specified). A change in a

Statement of Work shall be evidenced by a written amendment to the relevant Statement of Work duly executed by authorized representatives of ABBOTT and the INSTITUTION and the Principal Investigator in a form acceptable to all parties.

- (d) Conduct of Study. INSTITUTION shall conduct a Study pursuant to the terms of this Master Agreement, the Statement of Work and in strict adherence to the Protocol, as the same may be amended from time to time in writing by ABBOTT, and any other written instructions that may be provided from time to time to INSTITUTION by ABBOTT. Prior to conducting each Study, the applicable Principal Investigator shall review and understand the Protocol, as evidenced by the Principal Investigator's signature on the "Investigator Agreement(s)" contained within the applicable Protocol, as may be amended from time to time, all of which are incorporated herein by reference.
- 2. Principal Investigator; ABBOTT Contacts. ABBOTT is entering into this Master Agreement with INSTITUTION with the understanding that the Principal Investigator identified in the Statement of Work shall be personally responsible on INSTITUTION's behalf for the conduct of the Study set forth in said Statement of Work. If such personal services are not available for any reason, ABBOTT may terminate the applicable Statement of Work immediately without any further financial obligation to INSTITUTION. INSTITUTION agrees to return to ABBOTT any unearned or unaccounted for amounts paid by ABBOTT that exceeds the amount to which INSTITUTION is entitled hereunder. INSTITUTION's contact(s) at ABBOTT will be identified on the Statement of Work, or whomever ABBOTT may designate in writing.
- 3. Compliance with Law. INSTITUTION represents and shall require the Principal Investigator to represent that each shall comply with all applicable laws in performing its obligations under this Master Agreement. In particular, but not to limit the generality of the foregoing, INSTITUTION shall conduct and shall require the Principal Investigator to conduct each Study in accordance with all applicable federal, state and local laws, regulations and guidelines and rules governing federal and state healthcare programs, including, but not limited to, the Medicare/Medicaid anti-kickback statute, 42 U.S.C. § 1320a-7b, and similar state laws, the Act, and the FDA regulations. For Study Product that is a drug, FDA regulations include, without limitation, FDA regulations governing the protection of human subjects and regulations governing clinical investigators at 21 C.F.R. § 50 and 21 C.F.R. § 312.50 et seq. In furtherance of the foregoing obligations, INSTITUTION shall ensure that an IEC/IRB as applicable, established and constituted in accordance with applicable laws and regulations, oversees the conduct of each Study and is fully compliant with 21 C.F.R. § 56. INSTITUTION shall comply with the directives of the IEC/IRB respecting the conduct of each Study. and shall notify ABBOTT to the extent any such directives vary from the Protocol. INSTITUTION shall obtain from each Subject, prior to the Subject's participation in a Study, a signed Informed Consent and necessary authorization to disclose health information to ABBOTT in a form approved in writing by the IEC/IRB and in conformity with ABBOTT's guidelines therefore set forth in the Protocol.

INSTITUTION agrees and shall require the Principal Investigator to agree that, if Study Product and/or other services are paid for or provided without charge by ABBOTT, none of INSTITUTION, its agents or Principal Investigator shall separately bill or seek reimbursement for such Study Product and/or services from any third party including, without limitation, the Subject, any private provider of insurance, or any federal or state program (e.g., Medicare, Medicaid, Tricare, Department of Veterans Affairs programs, state Children's Health Insurance Program (CHIP) programs, and block grant programs under titles V and XX of the Social Security Act). If a Study involves Subjects whose Study Product and/or services are covered under global payment systems, such as Diagnosis-Related Groups (DRGs), any Study Product and/or services paid for or provided without charge by ABBOTT as part of a Study must be treated appropriately by the INSTITUTION under the billing procedures applicable to the payment system. INSTITUTION further agrees that it shall accurately report receipt of such Study Product to any federal, state or private insurance program, as may be required by law.

INSTITUTION agrees and shall require the Principal Investigator to understand and to adhere to the requirement that neither Principal Investigator nor any subinvestigator shall receive any additional funds from ABBOTT other than the funds paid to INSTITUTION set forth in the Budget attached to the applicable Statement of Work, for any of their work relating to this Study.

- 4. Financial Disclosure Certification. INSTITUTION shall ensure that the Principal Investigator and any subinvestigators connected with a Study, complete and return to ABBOTT with all other Essential Documents the Financial Disclosure Certification Form, prior to the initiation of the applicable Study in order to ensure compliance with 21 C.F.R. § 54. INSTITUTION shall require the Principal Investigator and any subinvestigators to promptly notify ABBOTT of any change in the accuracy of the Financial Disclosure Certification Form during the term of Study and for one (1) year following completion of the applicable Study. In addition, INSTITUTION shall comply with all applicable requirements of the National Institutes of Health and the Public Health Service regarding reporting and management of conflicts of interest.
- 5. <u>Study Supplies</u>. ABBOTT shall provide INSTITUTION with a sufficient quantity of Study Product and CRFs to conduct each Study, as well as any other compounds, materials and information which the Protocol specifies ABBOTT shall deliver or which ABBOTT deems necessary to conduct a Study. All such Study Product, CRFs (whether paper or electronic), compounds, materials and other information are and shall remain the sole property of ABBOTT. The INSTITUTION shall require that the Principal Investigator ensures that the Study Product supplies are adequate and that the Study Product is stored and handled properly. The INSTITUTION shall require that the Principal Investigator ensures that the Study Product is not used past the labeled expiration date. In addition, upon completion or premature termination of the Study, Study Product shall be returned or destroyed pursuant to the procedure set forth in the applicable Statement of Work.
- 6. <u>Delivery of Essential Documents and Reports. Etc.</u> INSTITUTION shall provide to ABBOTT all Essential Documents within the time frame set forth in the applicable Statement of Work. Upon the request of ABBOTT, INSTITUTION shall submit oral and/or written reports on the progress of a Study. Within forty-five (45) days following the completion or premature termination of a Study, INSTITUTION shall furnish ABBOTT with the final IEC/IRB report on the applicable Study prepared by the Principal Investigator, as well as all completed, used and unused CRFs not already delivered to ABBOTT, and all data, reports and other information generated in relation to the applicable Study, as well as all other materials and information provided by ABBOTT, unless ABBOTT directs otherwise in writing.
- 7. Monitoring of Study. INSTITUTION shall permit ABBOTT and/or ABBOTT designee(s) access to Study site(s), during regular business hours with reasonable prior notice, to monitor the conduct of a Study as well as to audit records, CRFs, Source Documents, and other data relating to the applicable Study, in order to verify INSTITUTION's and Principal Investigator's compliance with their obligations herein and in the Statement of Work.

8. Compensation.

- (a) ABBOTT shall pay INSTITUTION the amounts set forth in and in accordance with the Statement of Work. All payments shall be payable in United States dollars and made within thirty (30) days of ABBOTT's receipt and approval of an invoice for INSTITUTION's services under the applicable Statement of Work.
- (b) INSTITUTION agrees and shall require the Principal Investigator to acknowledge and adhere to on each applicable Statement of Work that in the event of a dispute regarding ABBOTT's approval of documentation of supporting costs incurred under this Master Agreement or the applicable Statement of Work, data and information resulting from INSTITUTION's research support of the applicable Study cannot be withheld by INSTITUTION or Principal Investigator prior to the resolution of the dispute because such withholding of data may cause irreparable harm to the applicable Study. ABBOTT and INSTITUTION agree, and INSTITUTION shall

require the Principal Investigator to use commercially reasonable efforts to resolve any disputes of this type in a timely manner.

- (c) If, at the date of Study termination, the total amount that ABBOTT has paid exceeds the amount to which INSTITUTION is entitled pursuant to the applicable Statement of Work, INSTITUTION shall return the overpayment to ABBOTT within forty-five (45) days from the termination date. If, at the date of termination, the total amount ABBOTT has paid is less than the amount to which INSTITUTION is entitled, ABBOTT shall pay the amount due INSTITUTION within forty-five (45) days following termination of the applicable Study, delivery to ABBOTT of the remaining acceptable CRFs, final reconciliation of any remaining amounts due, and the return to ABBOTT of all items described in paragraph 6 above. Any overpayment due ABBOTT pursuant to this Master Agreement shall be made payable to Abbott Laboratories and sent to the Controller, Global Pharmaceutical Research & Development, Dept. R404, Bldg AP9, 100 Abbott Park Road, Abbott Park, IL 60064, along with accompanying support documentation for the remittance with written notification of such overpayment sent to the ABBOTT contact as set forth in the applicable Statement of Work for the Study.
- (d) Pass through costs relating to a Study, if any and as described in the Budget, shall be paid by ABBOTT within thirty (30) days of receipt and approval of an invoice submitted by INSTITUTION.
- (e) Upon written notice to INSTITUTION, payment obligations under this Master Agreement and/or the Statement of Work may be delegated to ABBOTT's CRO. All payments made by the CRO shall be payable in United States dollars. INSTITUTION understands and shall require the Principal Investigator to understand that as to any payments delegated by ABBOTT and made hereunder by the CRO, INSTITUTION's and Principal Investigator's recourse shall be to seek redress from the CRO for compensation.
- (f) INSTITUTION and ABBOTT shall negotiate in good faith the overhead charge, if any, on a per Study basis.

Confidentiality for the Statement of Works.

(a) On a Statement of Work by Statement of Work basis, during the Study Term and for five (5) years thereafter, INSTITUTION, its employees, agents, and subcontractors (if any) shall not disclose (other than to ABBOTT or ABBOTT-designated parties) or use Abbott Confidential Information for any purpose other than that indicated in this Master Agreement or the applicable Statement of Work without ABBOTT's prior written consent.

Subject to INSTITUTION's publication rights as set forth in Section 13, "Abbott Confidential Information" shall include the Protocol, CRFs, Study Product, and all materials and information concerning ABBOTT and a Study disclosed to INSTITUTION by ABBOTT or developed as a result of conducting a Study, except any portion thereof which:

- is known to INSTITUTION, its employees, agents, or subcontractors before receipt thereof under this Master Agreement or the applicable Statement of Work, as evidenced by its written records;
- (ii) is disclosed to INSTITUTION, its employees, agents, or subcontractors after acceptance of this Master Agreement or the applicable Statement of Work by a third party who has a right to make such disclosure in a non-confidential manner:
- (iii) is or becomes part of the public domain through no fault of INSTITUTION, its employees, agents, or subcontractors; or

(iv) is independently developed by INSTITUTION, its employees, agents, or subcontractors, without reference to, use of, or disclosure of Abbot's Confidential Information, as evidenced by written records.

Nothing in this Master Agreement shall be construed to restrict INSTITUTION from disclosing Abbott Confidential Information as required by law or court order or other governmental order or request, provided in each case INSTITUTION shall timely inform ABBOTT and use all reasonable efforts to limit the disclosure and maintain the confidentiality of such Abbott Confidential Information to the extent possible. In addition, INSTITUTION shall permit ABBOTT to attempt to limit such disclosure by appropriate legal means.

- (b) INSTITUTION, its employees, agents, and subcontractors shall not disclose to ABBOTT any information which is confidential or proprietary to a third party unless INSTITUTION has first obtained the prior written approval of both such third party and ABBOTT.
- 10. <u>Subject Confidentiality</u>. The parties agree to abide by all laws and regulations regarding Subject confidentiality. INSTITUTION shall require the Principal Investigator to be responsible, on behalf of the INSTITUTION, for obtaining from each Subject, prior to the Subject's participation in a Study, a signed Informed Consent in a form approved in writing by the IEC/IRB and in conformity with ABBOTT's guidelines set forth in the Protocol. If the Informed Consent does not include such language, INSTITUTION shall require the Principal Investigator to also obtain a signed authorization which is approved by the IEC/IRB and is compliant with HIPAA, ABBOTT's guidelines and all applicable state laws and regulations, for ABBOTT, its representatives, and other third parties involved with and/or evaluating a Study to access and use Study data as set forth in such authorization. Participation in a Study shall be contingent upon execution of the aforementioned authorization.
- 11. <u>Publicity</u>. To the extent permitted by law or regulation, neither party shall disclose the existence or terms of this Master Agreement and/or any Statement of Work nor use the name of the other party, nor the names of other party's employees, in any publicity, advertising or announcement without the consenting party's prior written approval.
- 12. <u>Inventions</u>. Any information, inventions, data or discoveries (whether patentable or copyrightable or not), innovations, communications and reports, conceived, reduced to practice, made or developed by INSTITUTION, its agents, employees, subcontractors and/or Principal Investigator, during the performance of a Study and which relates to the Study, Protocol, or the Study Product or its use shall be promptly disclosed to ABBOTT and shall be the sole property of ABBOTT; provided however, that INSTITUTION and Principal Investigator will have a fully-paid-up, royalty-free, perpetual, non-exclusive right without the right to sublicense, to make, have made, and use any invention created hereunder for its own internal, noncommercial research, noncommercial patient care, and academic purposes. INSTITUTION agrees, upon ABBOTT's written request and at ABBOTT's expense, to execute such documents and to take such other reasonable actions as ABBOTT deems necessary or appropriate to obtain patent or other proprietary protection in ABBOTT's name covering any of the foregoing.

13. Publications and Presentations.

(a) General procedures. If INSTITUTION or Principal Investigator prepares any presentation or publication, INSTITUTION shall provide or shall require the Principal Investigator to provide ABBOTT at least sixty (60) days prior to publication or presentation, with a draft of the same for ABBOTT's review and comment for ABBOTT to ascertain whether any patentable subject matter or Abbott Confidential Information (other than the results of the Study generated hereunder) are disclosed therein. ABBOTT shall return comments to INSTITUTION or Principal Investigator within thirty (30) days after receipt of the draft presentation or publication ("Review Period"). In addition, INSTITUTION or PRINCIPAL INVESTIGATOR shall delay any proposed publication/presentation an additional sixty (60) days in addition to the Review Period in the

event ABBOTT so requests to enable ABBOTT to secure patent or other proprietary protection ("Delay Period"). The INSTITUTION agrees and shall require the Principal Investigator to keep the proposed publication confidential until the Review Period and, if elected by ABBOTT, the Delay Period has expired. The INSTITUTION agrees and shall ensure that the Principal Investigator understands that, with respect to any proposed publication or presentation, good faith consideration will be given to ABBOTT'S comments with due regard for ABBOTT'S commercial and proprietary interests and at ABBOTT'S request, any ABBOTT Confidential Information will be deleted from such article or presentation. For this provision, "any Abbott Confidential Information" excludes the results of the Study. In the event that INSTITUTION or Principal Investigator and ABBOTT differ in their opinion or interpretation of data in the publication, the parties shall resolve such differences in good faith through appropriate scientific debate.

- (b) Multi-Center Studies. It is agreed and understood by INSTITUTION that a Study may be part of a multi-center study, as indicated on the applicable Statement of Work. If a Study is part of a multi-center study INSTITUTION hereby acknowledges that an independent, joint publication is anticipated to be authored by investigators in the multi-center study, including Principal Investigator. Therefore, INSTITUTION agrees and shall require the Principal Investigator not to publish or present the results of the applicable Study before the publication of the multi-center investigator paper, but in no event shall INSTITUTION or Principal Investigator be so restricted after the expiration of twelve (12) months from completion of the applicable Study at all sites. For the avoidance of doubt, the first paragraph of this Section 13 (Section 13(a)) applies to Studies at both a single site and a multi-center study.
- 14. <u>Binding Obligations</u>. INSTITUTION represents and certifies that the terms of this Master Agreement are valid and binding obligations of INSTITUTION, and are not inconsistent with any other contractual and/or legal obligations it may have, or with INSTITUTION's policies or the policies of any institution or company with which it is associated.

15. Term and Termination.

- (a) Unless otherwise terminated by the provisions set forth herein, this Master Agreement shall be effective for 7 years following the Effective Date and may be extended upon written agreement signed by the parties ("Term"). Termination or expiration of this Master Agreement shall not affect any rights or obligations which have accrued prior thereto. In the event of premature termination of this Master Agreement, INSTITUTION shall complete the Study(ies) for then-enrolled Subjects where required by accepted medical practice.
- (b) ABBOTT may terminate this Master Agreement without cause at any time during the Term on thirty (30) days prior written notice to INSTITUTION; provided however, notwithstanding such termination, the terms of this Master Agreement shall remain in full force and effect with regard to any existing Statement of Work until the expiration of such Statement of Work according to its terms.
- (c) Either ABBOTT or INSTITUTION may terminate a Statement of Work immediately: (i) upon the breach by the other of a material provision of the Statement of Work or this Master Agreement as it applies to the Statement of Work, and/or (ii) in the event of termination of the applicable Study by the FDA or any other governmental or regulatory authority.
- (d) In the event INSTITUTION and/or Principal Investigator have concerns about the health, safety and/or welfare of the Study Subject(s), INSTITUTION shall give prompt notice to ABBOTT of such concerns, and may suspend enrollment of Study Subjects for a period not to exceed thirty (30) days or such other time period agreed to by the parties ("Suspension Period"). During this Suspension Period, ABBOTT shall evaluate the concerns raised by INSTITUTION and/or Principal Investigator to determine whether the Study should be terminated pursuant to this Section 15. In any event, INSTITUTION and Principal Investigator shall continue to monitor and

follow-up in strict adherence to the Protocol for currently enrolled Study Subjects during the Suspension Period.

- (e) ABBOTT may immediately terminate a Statement of Work upon delivering written notice to INSTITUTION if, at any time during the term of the Statement of Work:
 - the personal services of Principal Investigator are not available, as provided in Section 2 above; or
 - (ii) in ABBOTT's judgment, an adverse safety concern with respect to Study Product makes continued testing unadvisable.
- (f) ABBOTT may also terminate a Statement of Work without cause upon delivering at least thirty (30) days prior written notice to INSTITUTION.
- (g) ABBOTT may immediately terminate this Master Agreement and/or a Statement of Work pursuant to paragraph 17.

16. Indemnity.

- (a) ABBOTT shall indemnify INSTITUTION, The University of Texas System, their Regents, officers, agents and employees, Principal Investigator, and all other qualified personnel working under their direct supervision in the conduct of a Study ("Indemnitees") for any damages and liabilities, including the cost of defense and for compensatory damages awarded, if any, as a result of any claim or lawsuit against them arising out of the performance of the Study pursuant to the obligations of the applicable Statement of Work. This indemnification is limited to those incidents where Study Product or Protocol procedures are used during the Study in accordance with the Protocol and any other written instructions furnished by ABBOTT. It shall not extend to any damages and liabilities, including bodily injury, to the extent such injury results from the negligence or willful misconduct by INSTITUTION, The University of Texas System, their regents, officers, Principal Investigator, or their employees, agents or subcontractors.
- (b) ABBOTT shall indemnify, defend and hold harmless INSTITUTION, The University of Texas System, their Regents, its employees, officers and agents and Principal Investigator for any damages and liabilities, including the cost of defense and for compensatory damages awarded, if any, as a result of any third party claim or lawsuit being made as a result of ABBOTT's use of the Study data and/or results, provided that ABBOTT shall have no such liability or obligation in the event the Study data and/or results communicated to ABBOTT by INSTITUTION or Principal Investigator is inaccurate or incomplete.
- (c) The foregoing agreement to indemnify is conditioned upon the obligation of Indemnitee to:
 - (i) advise ABBOTT (Abbott Laboratories, 100 Abbott Park Road, Abbott Park, Illinois 60064-3500, Attention: Risk Management, D-317) of any claim or lawsuit, in writing, within fifteen (15) days after Indemnitee has received notice of said claim or lawsuit, or within such other time frame so that ABBOTT's ability and rights to defend or settle such claim or lawsuit, as determined in ABBOTT's sole discretion, are not prejudiced;
 - (ii) subject to the statutory duties of the Texas Attorney General, assist ABBOTT and its representatives in the investigation and defense of any lawsuit and/or claim for which indemnification is provided; and
 - (iii) not compromise or otherwise settle any such claim or lawsuit on behalf of ABBOTT without ABBOTT's prior written consent.

- (iv) If any injury occurs to the Subject as a direct result of the applicable Study Product or procedures in the Protocol, ABBOTT agrees to pay all reasonable medical expenses necessary to treat such injury, provided: (1) the Subject follows the directions of the Principal Investigator; and (2) to the extent such injury was not caused by the negligence of INSTITUTION, its officers, agents, or employees, or Principal Investigator or the failure of INSTITUTION or Principal Investigator to follow the Study Protocol or comply with applicable law. Injury to Subject does not include the natural progression of any pre-existing disease or any underlying illness, whether previously diagnosed or not.
- 17. <u>Debarment and Exclusion</u>. INSTITUTION represents and certifies that neither it, nor any of its employees or agents performing hereunder or a Statement of Work, have ever been, are currently, or are the subject of a proceeding that could lead to it or such employees or agents becoming, as applicable, a Debarred Entity or Individual, an Excluded Entity or Individual or a Convicted Entity or Individual. INSTITUTION further represents and certifies that if, during the Term, or Study Term if longer, it, or any of its employees or agents performing hereunder, become or are the subject of a proceeding that could lead to that party becoming, as applicable, a Debarred Entity or Individual, an Excluded Entity or Individual or a Convicted Entity or Individual, INSTITUTION shall promptly notify ABBOTT, and ABBOTT shall have the right to immediately or as soon as practicable, terminate this Master Agreement and/or any or all Statements of Work. For purposes of this provision, the following definitions shall apply:
 - (a) A "Debarred Individual" is an individual who has been debarred by the FDA pursuant to 21 U.S.C. §335a (a) or (b) from providing services in any capacity to a person that has an approved or pending drug product application.
 - (b) A "Debarred Entity" is a corporation, partnership or association that has been debarred by the FDA pursuant to 21 U.S.C. §335a (a) or (b) from submitting or assisting in the submission of any abbreviated drug application, or a subsidiary or affiliate of a Debarred Entity.
 - (c) An "Excluded Individual" or "Excluded Entity" is (i) an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise ineligible to participate in federal health care programs such as Medicare or Medicaid by the Office of the Inspector General (OIG/HHS) of the U.S. Department of Health and Human Services, or (ii) an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise ineligible to participate in federal procurement and non-procurement programs, including those produced by the U.S. General Services Administration (GSA).
 - (d) A "Convicted Individual" or "Convicted Entity" is an individual or entity, as applicable, who has been convicted of a criminal offense that falls within the ambit of 21 U.S.C. §335a (a) or 42 U.S.C. §1320a 7(a), but has not yet been excluded, debarred, suspended or otherwise declared ineligible.
- 18. <u>Independent Contractor</u>. INSTITUTION's relationship to ABBOTT under this Master Agreement and each Statement of Work is that of an independent contractor, and INSTITUTION has no authority to bind or act on behalf of ABBOTT.
- 19. <u>Assignment</u>. INSTITUTION may not assign this Master Agreement or any Statement of Work to any other party, nor may it subcontract any of its services hereunder, without ABBOTT's prior written consent. Any attempted assignment without ABBOTT's prior written consent shall be null and void and shall, for the avoidance of doubt, constitute a material breach of this Master Agreement.
- 20. <u>Subinvestigators</u>. INSTITUTION hereby agrees that as to any individuals identified on the applicable FDA Form 1572 or Investigator Information and Agreement Form as subinvestigators for a Study, INSTITUTION shall ensure such individuals' compliance with the terms and conditions hereof and the applicable Statement of Work.

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21. <u>Notices</u>. All notices hereunder shall be in writing and shall be effective upon deposit in the United States mail, certified mail, return receipt requested with postage paid, or personally delivered by express courier, or faxed as follows:

If to INSTITUTION:

(See Exhibit B)

If to ABBOTT:

Associate Director GPRD Outsourcing Dept. R479, Bldg. AP6B-1 Abbott Laboratories 100 Abbott Park Road Abbott Park, IL 60064-3500 Fax: 847-938-8878 with a copy to:

Divisional Vice President and Associate General Counsel PPG Legal Operations D323, Bldg. AP6A Abbott Laboratories 100 Abbott Park Road Abbott Park, IL 60064-6011

Fax: 847-938-1342

22. <u>Entire Agreement</u>. This Master Agreement contains the entire understanding of the parties with respect to the subject matter herein and supersedes all previous agreements and undertakings with respect thereto. This Master Agreement may be modified only by written agreement signed by the parties.

- 23. <u>Survival</u>. Notwithstanding termination of this Master Agreement or a Statement of Work for any reason, rights and obligations which by the terms of this Master Agreement or the Statement of Work survive termination thereof, shall remain in full force and effect.
- 24. <u>Severability</u>. If any of the provisions, or a portion of any provision, of this Master Agreement or a Statement of Work is held to be unenforceable or invalid by a court of competent jurisdiction, the validity and enforceability of the other portion of any such provision and/or the remaining provisions shall not be effected thereby.

IN WITNESS WHEREOF, the parties have executed this Master Agreement as of the last date written below.

ABBOTT CABORATORIES By:	THE UNIVERSITY OF TEXAS AT AUSTIN By: Www.uvatt Diduuh
Name: Cory Gutterman	Name: Susan W. Sedwick
Date: O2 November 2006	Title: Associate VP for Research 101 E. 27th St., Suite 4.308 Address: Austin, TX
	Phone: <u>512-471-6424</u> Date: <u>DEC 1 2 2003</u>
THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON	THE UNIVERSITY OF TEXAS HEALTH CENTER AT TYLER
By John St	By: Vellion Shoon
Name Jodi S. Ogden	Name: - Vernon Moore Chief Business and Finance Officer
Title: Contracts Director	nue
Address: 7000 Fannin Houston, TX Suite 10.06 Phone: 713-500-3968	Address: 11937 US Highway 271 Tyler TX 75708-3154 Phone: 903-877-2831
Date: November 21, 2006	Date:

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THE UNIVERSITY OF TEXAS MEDICAL BRANCH	THE UNIVERSITY OF TEXAS
AT GALVESTON	SOUTHWESTERN MEDICAL CENTER AT
	DALLAS
By: Susan & Kamsey	By: Congruent of Com
Name: Susan Ramsey	Name: Perrie M. Adams, Ph.D.
Title: Manager Research Operations	Title: Associate Dean for Research
Address: 4.400 Rebecca Sealy Hospital	5323 Harry Hines Blvd., H1.108 Address: <u>Dallas</u> , TX 75390-9016
301 University BLVD. Galvestion. Phone: 409-266-9413 77555	Phone: 214-648-6449
Date:	Date: 12/7/0 6
THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT SAN ANTONIO	
By: Janelloungus	
Name: Jane A. Youngers	
Asst. Vice President for Title: Research and Sponsored Programs	
7703 Floyd Curl Dr. Address: San Antonio, Texas 78229	
Phone: (210) 567-2340	
Date:	

EXHIBIT A STATEMENT OF WORK TEMPLATE

This Statement of Work, effective upon full execution by the parties is issued under the Master Agreement effective insertion Mesa Execution Date (the "Master Agreement") by and between Abbott Laboratories, an Illinois Corporation having its principal place of business at 100 Abbott Park Road, Abbott Park, Illinois, 60064-6400 ("ABBOTT") and insertion Name, having its principal place of business at insertion (INSTITUTION").

This Statement of Work includes the terms and conditions of the Master Agreement, which are hereby incorporated by this reference.

1. <u>Definitions</u>. The following definitions shall have the meaning ascribed to them in the Master Agreement as well as the following specifc meanings for this Statement of Work:

"Budget" means the Study budget set forth in Appendix I, attached hereto and incorporated herein.

"Principal Investigator" means insert Principal Investigator's Name.

"Protocol" means Protocol No. insert Protocol # entitled "insert Protocol Title", incorporated by reference herein, as the same may be amended from time to time in writing by ABBOTT.

"Study Product" means insert Product Name.

 Protocol; Conduct of Study. INSTITUTION is undertaking this collaborative research project with ABBOTT as an independent contractor for the sole purpose of carrying out the Study with the Study Product in strict adherence to the Protocol, the terms and conditions of this Statement of Work and the Master Agreement, and any other written instructions that may be provided from time to INSTITUTION by ABBOTT.

Principal Investigator hereby acknowledges reviewing and understanding the Protocol, as evidenced by the Principal Investigator's signature on the "Investigator Agreement(s)" contained within the Protocol, as may be amended from time to time, all of which are incorporated herein by reference.

INSTITUTION shall use it commercially reasonable efforts to complete enrollment of all Subjects within insert Number (##) months of Study initiation. ABBOTT may terminate this Statement of Work upon written notice, if INSTITUTION does not enroll at least insert Number (##) Subject(s) within insert Number (##) month(s) of Study Product shipment. Additionally, if IEC/IRB approval is not obtained within insert Number (##) weeks of receipt of all necessary materials for IEC/IRB submission, ABBOTT may terminate this Statement of Work upon written notice.

- 3. ABBOTT Contacts. INSTITUTION's contact(s) at ABBOTT will be insert Contact Name, insert Address Phone & Fax #15, and insert Contact Name, insert Address Phone & Fax #15 of ABBOTT's Global Pharmaceutical Research and Development Division, or whomever ABBOTT may designate in writing.
- 4. Return or Destruction of Study Supplies. Upon completion or premature termination of the Study, Study Product shall be returned or destroyed pursuant to the Protocol.
- 5. <u>Delivery of Essential Documents</u>. INSTITUTION shall provide to ABBOTT all Essential Documents within <u>insert Number (#)</u> weeks of INSTITUTION's receipt of IEC/IRB's written approval. If all Essential Documents have not been executed and received by ABBOTT within weeks of INSTITUTION's receipt of IEC/IRB's written approval, ABBOTT may terminate this Statement of Work upon written notice.

 Compensation. The amount for payments discussed hereunder represents the fair market value for the services that INSTITUTION has agreed to render and has not been determined in any manner that takes into account the volume or value of any referrals or business otherwise generated between INSTITUTION and ABBOTT.

[PAYMENTS AND PAYMENT SCHEDULE TO BE NEGOTIATED - See Appendix I "Budget"]

- 7. Reimbursement of IEC/IRB Fees. ABBOTT shall reimburse INSTITUTION for IEC/IRB fees within the later of thirty (30) days of delivery to ABBOTT of an invoice for such IEC/IRB fees or thirty (30) days after full execution of this Statement of Work, provided INSITUTION submits to ABBOTT evidence of the IEC/IRB's review and final decision regarding all submitted Study documents including, but not limited to, the Protocol and/or Protocol revision.
- 8. Remittance of Payment. Payments in accordance with this Statement of Work will be made by check, made payable to insert Payer, tax ID number insert ax ID and will be sent to:

insert Address

- Publication. It is understood and agreed by INSTITUTION and Principal Investigator that the Study is [not] part of a multi-center study and therefore Section 13(b) of the Master Agreement does [not] apply to the Study under this Statement of Work.
- 10. Study Term. This Statement of Work shall be effective for insert Number (##) Insert Statement of Work and may be extended upon written agreement signed by the parties. Termination or expiration of this Statement of Work shall not affect any rights or obligations which accrued prior thereto. In the event of premature termination of this Statement of Work, INSTITUTION shall complete the Study for then-enrolled Subjects where required by accepted medical practice.
- 11. <u>Notices</u>. All notices hereunder shall be in writing and shall be effective upon deposit in the United States mail, certified mail, return receipt requested with postage paid, or personally delivered by express courier, or faxed as follows:

If to INSTITUTION:

insent Name insent Address Phone: Insent# Fax: Insent#

If to ABBOTT:



Abbott Laboratories 100 Abbott Park Road Abbott Park, IL 60064-3500

Phone: Insen# Fax: Insen# if to INVESTIGATOR:



with a copy to:

Divisional Vice President and Associate General Counsel PPG Legal Operations D323, Bldg. AP6A Abbott Laboratories 100 Abbott Park Road Abbott Park, IL 60064-6011

Fax: 847-938-1342

- 12. <u>Binding Obligations</u>. INSTITUTION represents and certifies that the terms of this Statement of Work are valid and binding obligations of INSTITUTION, and are not inconsistent with any other contractual and/or legal obligations it or Principal Investigator may have, or with INSTITUTION's policies or the policies of any institution or company with which it or Principal Investigator is associated.
- 13. <u>Institution and Principal Investigator Relationship</u>. INSTITUTION represents that Principal Investigator's relationship to INSTITUTION is that of an employee, and INSTITUTION further agrees

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- to be responsible that Principal Investigator shall be compensated for his/her services by INSTITUTION.
- 14. Entire Agreement. This Statement of Work and the Master Agreement contain the entire understanding of the parties with respect to the subject matter herein and supersedes all previous agreements and undertakings with respect thereto. In the event of a conflict between the terms and conditions of this Statement of Work and those of the Protocol, the terms and conditions of this Statement of Work shall control. This Statement of Work may be modified only by written agreement signed by the parties.

IN WITNESS WHEREOF, the parties have executed this Statement of Work as of the last date written below.

ABBOTT LABORATORIES	TRISEIR AVERNIE VOI TRISTITUITION TO AND COAPES
Ву:	Ву:
Name:	Name:
Title:	Title:
Date:	Date:
bound by the provisions of paragraphs 2 and 9 t	of Work and the Master Agreement and agree that I am under this Statement of Work and 1(d), 3, 4, 5, 6, 7, 8(b), nt as fully as if my name was inserted in such paragraphs
Ву:	
Name:	
Title: Principal Investigator	
Date:	

APPENDIX I TO STATEMENT OF WORK BUDGET

EXHIBIT B

ADMINISTRATIVE CONTACT AND ADDRESS INFORMATION FOR EACH INSTITUTION

Susie Sedwick Director Office of Sponsored Projects The University of Texas at Austin P.O. Box 7726 Austin, Texas 78713-7726

phone: 512-471-6424 fax: 512-471-6564

email: sedwick@austin.utexas.edu

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Perrie Adams
Assoc. Dean for Research
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phone: 713-500-3968 fax: 713-500-0355

email: jodi.ogden@uth.tmc.edu

Tax ID: 74-1761309

Overnight address is:

7000 Fannin Street, Suite 1006 Houston, TX 77030

Susan E. Ramsey
Manager of Research Operations
The University of Texas
Medical Branch at Galveston
Basic and Clinical Research Management
301 University Boulevard
2.240 Gail Borden Bldg.
Galveston, TX 77555-0657

phone: (409) 772-0574 fax: (409) 747-3793 email: <u>seramsey@utmb.edu</u>

Tax ID: 74-6000949

Conna Sutton
Director, Office of Pre-Award Services
The University of Texas Health Center at
Tyler
11937 U.S. Hwy. 271
Tyler, TX 75708-3154

phone: 903-877-7585 fax: 903-877-7558

email: conna.sutton@uthct.edu

Tax ID: 75-600-1354

Mark Gallyoun Agreements Specialist The University of Texas Health Science Center at San Antonio 7703 Floyd Curl Drive, Mail Code 7828 San Antonio, TX 78229-3900

phone: 210-567-3008 fax: 210-567-2344

email: gallyoun@uthscsa.edu

Tax ID: 74-1586031