AMENDED AND RESTATED MASTER CLINICAL STUDY AGREEMENT
ABBOTT INITIATED

This amended and restated master clinical study agreement ("Master Agreement"), effective as of the full execution hereof ("Effective Date"), sets forth the terms and conditions by and among 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 Health Science Center at Tyler, The University of Texas Medical Branch at Galveston, The University of Texas Southwestern Medical Center, 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) Definitions. 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** (Confidentiality for the Statement of Works).

"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** (Compensation) of the ICH Guidelines.

"FDA" means the United States Food and Drug Administration or any successor entity thereto.

"Financial Disclosure Certification Form" 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** (Indemnity).

"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.

"Personal Data" means information identifying or, in combination with other information, identifiable to a living individual, including Study Subjects and others, participating in or associated with the Study.

"Principal Investigator" 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** (Statement of Work Template) 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)** (Term and Termination).

(b) Scope of Master Agreement. This Master Agreement replaces and supersedes the original Master Clinical Study Agreement between ABBOTT and INSTITUTION, having an effective date of December 12, 2006, and as amended July 29, 2009. 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 in a Statement of Work. The Statement of Work shall be executed by an authorized representative of ABBOTT and INSTITUTION and applicable Principal Investigator. Each Statement of Work will include, as appropriate, the name of the Study Product; the title of the Protocol; the name of the Principal Investigator; the Budget; timeframes to enroll Study Subjects; timeframe to enter Subject data into CRFs; Principal Investigator and ABBOTT contacts; compensation; and Study Term. The Protocol shall be provided separately for each individual Study and referred to and incorporated by reference in the Statement of Work. 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.

(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.

(e) INSTITUTION shall use reasonable efforts to complete enrollment of all Subjects within the enrollment timelines and enter Subject data, as required in the Protocol, within the timeline as set forth in the applicable Statement of Work. ABBOTT may immediately terminate a Statement of Work consistent with the terms set forth herein, if after INSTITUTION's reasonable efforts, INSTITUTION does not meet enrollment criteria, IRB/IEC approval, or Essential Document submission within the timelines set forth in the applicable Statement of Work.

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 or if Principal Investigator leaves INSTITUTION's employment during the Study Term, then INSTITUTION will promptly notify ABBOTT in writing. If a mutually acceptable successor to Principal Investigator is not promptly identified, ABBOTT may immediately, in its sole discretion, terminate the applicable Statement of Work without any further financial obligation to INSTITUTION. INSTITUTION's contact(s) at ABBOTT and ABBOTT's contact(s) at INSTITUTION will be identified in the Statement of Work. INSTITUTION represents and certifies that each Principal Investigator identified in a Statement of Work is an employee of INSTITUTION.

3. Compliance with Law. INSTITUTION represents and certifies and shall require the Principal Investigator to represent and certify that for each Study during the Study Term 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 and/or ABBOTT's designees 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 Study Term 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. INSTITUTION will ensure Principal Investigator understands that Principal Investigator and all subinvestigators conducting the Study, and their immediate families, may not have a direct ownership interest (e.g., intellectual property rights) in the Study Product and may not be compensated with ABBOTT securities in exchange for being a Principal Investigator or subinvestigator in a Study.

5. Study Supplies. ABBOTT shall provide INSTITUTION with sufficient quantity of Study Product and CRFs to conduct each Study, as well as any other compounds, materials and information which the Protocol specifies or other materials as ABBOTT deems necessary to conduct the Study at no cost solely for use by INSTITUTION and Principal Investigator in the conduct of the applicable Study. Neither INSTITUTION nor Principal Investigator will use any of the Study Product, CRFs or any other compounds, materials and information provided by ABBOTT for any purpose other than to conduct the applicable Study pursuant to the Protocol under the applicable Statement of Work. All such Study Product, CRFs and other information provided by ABBOTT in connection with this Master Agreement are and will remain the sole property of ABBOTT. INSTITUTION represents and certifies that for each Study during the Study Term, it will and will require each Principal Investigator to ensure that: (a) the supply of Study Product is adequate and that the Study Product will be stored and handled in accordance with ABBOTT's written instructions and as set forth in the labeling of the applicable Study Product and in accordance with applicable regulatory requirement(s); (b) the Study Product will not be used past the labeled expiration date; and (c) upon conclusion of a Study or termination of a Statement of Work or at ABBOTT's request, any remaining or expired Study Product, CRFs, as well as any other Study compounds, Study materials and Study information provided by ABBOTT under the applicable Statement of Work will be returned to ABBOTT, at ABBOTT's expense, in accordance with the Protocol and in compliance with applicable requirements governing the shipment of such Study Product or will be disposed of pursuant to the Protocol, and any local, state and federal laws and regulations governing the disposal of such Study Product, CRFs or any other Study compounds,

Study materials and Study information. For Study Product, CRFs or other Study compounds, Study materials and Study information disposed by or on behalf of INSTITUTION, INSTITUTION represents and certifies that it has the necessary facilities, expertise and regulatory approvals required to dispose such Study Product, CRFs and other Study compounds, Study materials and Study information and that such disposal will be at INSTITUTION's expense. INSTITUTION will document such return or disposal of such Study Product, CRFs, any other Study compounds, Study materials and Study information pursuant to ABBOTT's written instructions. Additionally, Principal Investigator shall maintain adequate records of the disposition of Study Product, including dates, quantity, and use by Subjects.

6. Delivery of Essential Documents and Reports, Etc. 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. Any audits conducted by ABBOTT and/or ABBOTT's designees will be undertaken in compliance with INSTITUTION's premises rules for purposes of protecting the confidentiality, safety, and security of Study Subjects, that are generally applicable to all persons at INSTITUTION's facilities. Such rules shall be provided to ABBOTT and/or ABBOTT's designees prior to access of the Study site.

   INSTITUTION shall retain Study documents for each Study under a Statement of Work in accordance with the applicable laws and regulations. At ABBOTT's request and expense, INSTITUTION shall retain the Study documents for an even longer period than the retention period described above. For these purposes, INSTITUTION shall provide ABBOTT at least forty-five (45) days' written notice before deleting any Study documents from its files. ABBOTT's right to audit shall survive the expiration of this Master Agreement and applicable Statement of Work until the period of Study document retention ends in accordance with this paragraph. If, as a result of Study monitoring, ABBOTT requests corrective and/or preventive action, INSTITUTION shall comply with the timely creation and implementation of a corrective action and/or preventive action plan.

   INSTITUTION will, to the extent permitted by law, notify ABBOTT promptly upon receiving any requests by an properly authorized officer or employee of any regulatory authority to inspect and/or have access to documents related to the Study and will, to the extent permitted by law, promptly provide ABBOTT with a copy of any documents received from or provided to regulatory authorities. In the event a regulatory citation or notice (e.g. Form FDA 483) is issued which relates to the services under the applicable Statement of Work and this Master Agreement, INSTITUTION agrees, to the extent permitted by law, to promptly furnish to ABBOTT, such regulatory citation or notice, a summary of such regulatory citation or notice that includes an explanation of the issues identified by the regulatory authority, an explanation of any response to the significant issues identified by the regulatory authority, and an explanation of the applicability of such regulatory citation or notice to the service(s) provided under the applicable Statement of Work and this Master Agreement.

8. Compensation.

(a) In exchange for the full performance of services under the relevant Statement of Work, ABBOTT shall pay INSTITUTION as per the Budget. In addition, INSTITUTION's employees, including Principal Investigator, may be reimbursed for reasonable and necessary expenses related to travel, consistent with ABBOTT's travel policy (including economy coach air travel, reasonable and customary lodging and meal rates based on the geographic region of travel), and may be provided meals at investigator meetings or other ABBOTT required meetings. The parties agree that the amount for payments set forth in the Budget represents the fair market value for the services to be rendered and has not been determined in any manner that takes into account the volume or value of any referrals or business otherwise generated between or among INSTITUTION and ABBOTT. All payments shall be payable in U.S. dollars and in accordance with the terms of this Master Agreement and relevant Statement of Work, and only after all parties have signed the relevant Statement of Work.

Reimbursement of IRB/IEC fees requires evidence of the IRB/IEC's review and final decision regarding all submitted Study documents including, but not limited to, the Protocol and/or Protocol revisions. ABBOTT will not be obligated to reimburse INSTITUTION for pass through expenses that are invoiced to ABBOTT more than one hundred eighty (180) days after the termination date of the relevant Statement of Work.

In the event of premature termination of a Statement of Work by ABBOTT for any reason other than for INSTITUTION's material breach, ABBOTT shall pay INSTITUTION according to the extent of services performed and expenses incurred in accordance with the budgeted amounts set forth in the Budget. Nothing herein shall alleviate ABBOTT's responsibility to render payment for all properly completed procedures in accordance with the Study Protocol.

The Budget is based on the full performance of services contemplated by the applicable Statement of Work and full compliance with the terms of this Master Agreement and applicable Statement of Work (including the Protocol). ABBOTT will not be responsible for paying for Subject visits or treatments for a Subject that is enrolled or treated in violation of the Protocol or for the data contained in a CRF which is not complete and accurate.

(b) INSTITUTION agrees and shall require Principal Investigator to agree that in the event of a dispute regarding ABBOTT's approval of documentation supporting costs incurred under a Statement of Work, INSTITUTION and Principal Investigator shall not withhold Study data or information pending resolution of the dispute. ABBOTT and INSTITUTION agree, and INSTITUTION shall require Principal Investigator to use 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 under the applicable Statement of Work, 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 **Section 6** (Delivery of Essential Documents and Reports, Etc) 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.

9. 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. Notwithstanding the foregoing, Abbott Confidential Information identified as an ABBOTT trade secret will not be disclosed to INSTITUTION unless INSTITUTION has specifically agreed in writing in advance to receive such ABBOTT trade secret. In such event, INSTITUTION's obligations of confidentiality and non-use with respect to such disclosed trade secret shall survive for as long as the ABBOTT trade secret retains its status as a trade secret under applicable law.

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

(i) 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 nonconfidential 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.

(c) INSTITUTION or the Principal Investigator shall also be permitted to disclose Abbott Confidential Information for the purposes of emergency or immediate treatment of a Subject, provided that any such disclosure is limited to the extent reasonably necessary and provided further that INSTITUTION gives notice to ABBOTT prior to making such release of Abbott Confidential Information (if reasonably possible, and if not, promptly after making such disclosure).

10. Subject Confidentiality; Data Protection. The parties agree to abide by all laws and regulations regarding Subject confidentiality and data protection. 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 IRB/IEC 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 an authorization for ABBOTT and its representatives and other third parties involved with or evaluating a Study to access and obtain copies of Study data, which is compliant with HIPAA, ABBOTT's guidelines and all applicable state laws. Participation in a Study shall be contingent upon execution of the aforementioned authorization.

    Where INSTITUTION and/or the Principal Investigator collects, retains, processes or discloses Personal Data in performing its obligations under the Master Agreement or any Statement of Work, it shall only do so in accordance with the Master Agreement or ABBOTT's written instructions. INSTITUTION and the Principal Investigator shall adopt technical and organizational measures appropriate to prevent any unauthorized or accidental use, access or processing of Personal Data, and promptly inform ABBOTT of any unauthorized access to or disclosure of Personal Data ("Security Breach") and provide ABBOTT with all reasonable assistance to remedy the Security Breach. Where applicable data protection laws require that the parties enter into additional agreements or undertakings, including international data transfer agreements, INSTITUTION will undertake to ensure that all necessary agreements are implemented and in place.

11. Publicity. 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. Notwithstanding the foregoing, INSTITUTION and ABBOTT understand and agree that the terms and conditions of this Master Agreement and any Statement of Work, including the amount of any payment made thereunder, may be disclosed and made public by either party as required by law or regulation or where ABBOTT deems appropriate.

12. Inventions. 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) Publication Requirements. To foster the highest standards of conduct related to scientific publications, including manuscripts, abstracts, and poster/oral presentations (collectively, "Publication(s)"), ABBOTT is committed to transparency and ethical publication practices. If INSTITUTION and/or Principal Investigator serve(s) as an author on any publication emanating from the Study, INSTITUTION and Principal Investigator must comply with the Requirements for Scientific Publications attached hereto as **Exhibit C** (Requirements for Scientific Publications).

(b) Procedures. As the Study sponsor, ABBOTT retains the first right to disclose the results of each Study through a Publication or any other public disclosure (collectively, a "Study Results Disclosure"). Following the earliest of: (i) ABBOTT's Study Results Disclosure; or (ii) twelve (12) months after completion, termination, or abandonment of a Study at all Study sites, INSTITUTION and Principal Investigator shall have the right to prepare and submit for Publication a Study Results Disclosure in appropriate scientific journals or other professional publications. If INSTITUTION or Principal Investigator prepares a Study Results Disclosure, INSTITUTION shall provide or shall require Principal Investigator to provide ABBOTT, at least thirty (30) days prior to any submission of a Study Results Disclosure, with a draft of the same for ABBOTT's review and comment 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 Study Results Disclosure ("Review Period"). In addition, INSTITUTION or Principal Investigator shall delay any proposed Study Results Disclosure an additional sixty (60) days in addition to the Review Period in the event ABBOTT so requests (in writing) to enable ABBOTT to secure patent or other proprietary protection ("Delay Period"). INSTITUTION agrees and shall require each Principal Investigator to keep the proposed Study Results Disclosure confidential until the Review Period and, if elected by ABBOTT, the Delay Period has expired. INSTITUTION agrees and shall require Principal Investigator to agree that due consideration will be given to ABBOTT comments; and further, Abbott Confidential Information (other than the results of the Studies generated hereunder or any other information that is necessary to allow for the complete and accurate presentation and interpretation of the results of the Study in accordance with scientific and academic custom) shall be deleted from any Study Results Disclosure. In the event that INSTITUTION, Principal Investigator and ABBOTT differ in their opinion or interpretation of data in a Study Results Disclosure, the parties shall resolve such differences in good faith through appropriate scientific debate.

14. Representations and Certifications. INSTITUTION represents and certifies that during the Term of the Master Agreement and Study Term of each Statement of Work that:

(a) to the best of INSTITUTION's knowledge after due inquiry, the terms of this Master Agreement and each Statement of Work are valid and binding obligations of INSTITUTION, and are not inconsistent with any other contractual or legal obligation it or Principal Investigator may have or with INSTITUTION's policies and procedures;

(b) INSTITUTION's performance of the services and acceptance of compensation, including the acceptance of any meals and/or reimbursement of reasonable expenses for Principal Investigator meetings or other ABBOTT required meetings, which may be provided to Principal Investigator or INSTITUTION (including its employees and agents) under a Statement of Work, is in compliance with all policies and procedures of INSTITUTION;

(c) each applicable Principal Investigator has received any required authorization, written or otherwise, from INSTITUTION for Principal Investigator's performance of the services and acceptance of any meals and/or reimbursement of reasonable expenses for investigator meetings or other ABBOTT required meetings, which may be provided to Principal Investigator under a Statement of Work;

(d) INSTITUTION and each applicable Principal Investigator have the experience, capabilities and resources, including but not limited to, experience with the relevant subject population in general so that Principal Investigator has the potential for recruiting the required number of suitable Subjects, sufficient personnel and equipment, to efficiently and expeditiously perform the Study under the applicable Statement of Work in a professional and competent manner and will utilize due diligence and devote the necessary personnel and equipment at all times to perform the Study thereunder in such a manner;

(e) any subinvestigators used by INSTITUTION for a Study will be selected based upon a consideration of the following: (i) training and expertise in relevant fields; (ii) appropriate research facilities; (iii) experience with the relevant subject population so that the subinvestigator has a reasonable likelihood of recruiting the appropriate research participants and following through to the completion of the Study; (iv) prior scientific research or clinical experience; and (v) ability to conduct the Study in accordance with applicable legal and regulatory requirements; and

(f) each Principal Investigator conducting the Study under a specific Statement of Work has a current and valid medical license in the jurisdiction in which the Study is being performed, and to the best of INSTITUTION's knowledge after due inquiry, (i) no Principal Investigator participating in a specific Statement of Work hereunder has ever had his/her license revoked, restricted, or suspended by a medical board or other licensing agency, (ii) his/her privileges or ability to practice have never been revoked, restricted, or suspended by a health care institution or other provider of health care services, and (iii) Principal Investigator is not under an investigation that could lead to a revocation, restriction, or suspension of his/her medical license or privileges or ability to practice at a health care institution or other provider of health care services. In the event that any of the foregoing changes during the Term or Study Term, INSTITUTION shall promptly notify ABBOTT, and ABBOTT shall have the right to immediately terminate this Master Agreement and/or the applicable Statement of Work.

During the Term of this Master Agreement and Study Term of each Statement of Work, if any significant changes occur with regard to the circumstances surrounding this Master Agreement (e.g., there is a change in a policy or procedure that could reasonably be interpreted to affect the propriety of INSTITUTION or Principal Investigator's involvement in this Master Agreement and applicable Statement of Work), INSTITUTION agrees to promptly notify ABBOTT in writing of any such changes.

15. Term and Termination.

(a) Unless otherwise terminated by the provisions set forth herein, this Master Agreement shall be effective for seven (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: (i) the personal services of Principal Investigator are not available, pursuant to **Section 2** (Principal Investigator; ABBOTT Contacts) of this Master Agreement; (ii) in ABBOTT's sole judgment, an adverse safety concern with respect to Study Product makes continued testing unadvisable; (iii) if after INSTITUTION's reasonable efforts, INSTITUTION does not meet enrollment criteria, IRB/IEC approval, or Essential Documents submission within the timelines set forth in **Section 1(b)** (Protocol; Conduct of Study) of the applicable Statement of Work and pursuant to **Section 1(d)** (Conduct of Study) of this Master Agreement; (iv) Principal Investigator's medical license becomes restricted or suspended or Principal Investigator becomes a subject to any investigation or disciplinary action by any state medical board pursuant to **Section 14(f)** (Representations and Certifications) of this Master Agreement; or (v) INSTITUTION or INSTITUTION employees, including Principal Investigator, agents or subcontractors performing under a Statement of Work, including any subinvestigators becomes a Debarred, Excluded, or Convicted Entity or Individual or becomes the subject of a proceeding which could lead to that party becoming a Debarred, Excluded, or Convicted Entity or Individual or becomes added to FDA's Disqualified/Restricted List for clinical investigators pursuant to **Section 17** (Debarment and Exclusion) of this Master Agreement.

(f) ABBOTT may also terminate a Statement of Work without cause upon delivering at least thirty (30) days prior written notice to INSTITUTION.

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.

(d) 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: (i) the Subject follows the directions of the Principal Investigator; and (ii) 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. INSTITUTION may arrange for care for any research related injury.

(e) In accordance with FDA requirements, ABBOTT shall notify Principal Investigator in writing of any Subject safety issues that may arise during the course of the Study and thereafter. In addition, if ABBOTT becomes aware of any findings of noncompliance or scientific misconduct during its monitoring process at the INSTITUTION that may affect the safety or welfare of the Subjects or their willingness to continue participation, influence the conduct of the Study, or alter the IRB's approval to continue the Study, ABBOTT will notify the INSTITUTION.

17. Debarment and Exclusion. INSTITUTION represents and certifies that, none of INSTITUTION, any INSTITUTION employees, including Principal Investigator, agents and subcontractors performing the Study under an applicable Statement of Work, including any subinvestigators, have ever been, are currently, or are the subject of a proceeding that could lead to INSTITUTION or such employees, agents or subcontractors becoming, as applicable, a Debarred Entity or Debarred Individual, an Excluded Entity or Excluded Individual or a Convicted Entity or Convicted Individual, nor are they listed on the FDA's Disqualified/Restricted List for clinical investigators. INSTITUTION further represents and certifies that if, during the Term, INSTITUTION, or any of INSTITUTION's employees, including Principal Investigator, agents or subcontractors, including any subinvestigators, performing hereunder, becomes or is the subject of a proceeding that could lead to that party becoming, as applicable, a Debarred Entity or Debarred Individual, an Excluded Entity or Excluded Individual or a Convicted Entity or Convicted Individual, or added to FDA's Disqualified/Restricted List for clinical investigators, INSTITUTION will promptly notify ABBOTT, and ABBOTT will have the right to immediately terminate this Master Agreement. The provision of this paragraph regarding notice of acts occurring during the Term of this Master Agreement will survive for a period of three (3) years from the termination or expiration of this Master Agreement. For purposes of this provision, the following definitions will apply:

(a) A "Debarred Individual" is an individual who has been debarred by the FDA pursuant to Title 21 of the United States Code ("USC") Section 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 Title 21 of USC Section 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) is 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 Title 21 of USC Section 335a(a) or Title 42 of USC Section 1320a – 7(a), but has not yet been excluded, debarred, suspended or otherwise declared ineligible.

(e) "FDA's Disqualified/Restricted List" is the list of clinical investigators restricted from receiving investigational drugs, biologics, or devices if FDA has determined that the investigators have repeatedly or deliberately failed to comply with regulatory requirements for studies or have submitted false information to the study sponsor or the FDA.

18. Independent Contractor. 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. Assignment. 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.

    ABBOTT announced on October 19, 2011 that it intends to separate into two publicly traded companies: (a) a diversified medical products company that will retain the name of Abbott Laboratories, and (b) a research-based pharmaceutical company that will be named later ("Pharmaco"). INSTITUTION hereby consents to the transfer or assignment of ABBOTT's rights and obligations under this Master Agreement to Pharmaco or a subsidiary of ABBOTT or Pharmaco in connection with or in anticipation of the separation, and notwithstanding anything to the contrary that may be contained in this Master Agreement, such transfer or assignment shall not violate, constitute a breach of, result in any additional obligations or loss of rights under, or give rise to any right to terminate or cancel this Master Agreement. Following such transfer or assignment, the new entity shall assume all rights and obligations under this Master Agreement and any applicable Study, and ABBOTT shall have no further obligations under this Master Agreement. Notwithstanding anything to the contrary that may be contained in this Master Agreement, no consent from INSTITUTION or advance notice to INSTITUTION shall be required for the direct or indirect transfer of any equity of ABBOTT to Pharmaco or a subsidiary of ABBOTT or Pharmaco in connection with or anticipation of the separation, and such transfer shall not violate, constitute a breach of, result in any additional obligations or loss of rights under, or give rise to any right to terminate or cancel this Master Agreement. ABBOTT or Pharmaco will provide written notice to INSTUTION of such transfer or assignment.

20. Subinvestigators. 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.

21. Notices. 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** (Administrative Contact Person and Address for Each Institution)

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. Entire Agreement. This Master Agreement, including all exhibits hereto, contains the entire understanding of the parties with respect to the subject matter herein and replaces and supersedes all previous agreements and undertakings with respect thereto including, but not limited to, that certain original Master Clinical Study Agreement effective December 12, 2006, as amended July 29, 2009 between ABBOTT and INSTITUTION. In the event of a conflict between provisions of a Protocol and the terms and provisions of this Master Agreement or any exhibits hereto, the Protocol shall control with respect to matters of science, medical practice, and Study Subject safety. In all other matters, the terms and provisions of this Master Agreement shall control. In the event of any conflict between the terms and provisions of this Master Agreement and those in the exhibits hereto or any Statement of Work, the provisions of this Master Agreement shall control, unless a particular Statement of Work specifically acknowledges the conflict and expressly states that the conflicting term or provision found in the Statement of Work controls for that Statement of Work only and such Statement of Work is approved by the Office of General Counsel of The University of Texas System as set forth in Section 6 (Entire Agreement) of **Exhibit A** (Statement of Work Template). None of this Master Agreement or any of its terms including any attachment or exhibit hereto, may be amended, restated or otherwise altered except by written agreement signed by the parties.

23. Survival. 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. Severability. 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 affected thereby.

25. Insurance. INSTITUTION, as a member institution of the University of Texas System, is an agency of the State of Texas and provides professional liability for its faculty physicians pursuant to The University of Texas System Professional Medical Liability Benefit Plan, under the authority of Section 59, Texas Education Code. INSTITUTION shall ensure the Principal Investigator has and will maintain in force, during the Term of this Master Agreement and Study Term of each Statement of Work, adequate professional liability insurance to cover his/her obligations hereunder. INSTITUTION, an agency of the State of Texas, is subject to the provisions of Title 5, Chapter 5, Chapter 101 of the Texas Civil Practice and Remedies Code, and the INSTITUTION 's personnel or employees are subject to Title 5, Chapter 104 of the Texas Civil Practice and Remedies Code, also known as the Texas Tort Claims Act. Employees of the INSTITUTION are provided Worker's Compensation coverage under the self-insuring, self-managed program as authorized by Chapter 503, Section 503.022, Texas Labor Code.

    ABBOTT agrees to maintain a policy or program of insurance or self-insurance at levels sufficient to support its obligation under this Master Agreement.

26. Counterparts. This Master Agreement may be executed in any number of counterparts, each of which shall be deemed to be an original, and all of which together shall constitute one and the same agreement. Each party acknowledges that an original signature or a copy thereof transmitted by facsimile or by PDF shall constitute an original signature for purposed of this Master Agreement.

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

ABBOTT LABORATORIES

By: Dionne M. Serio

Name: Dionne M. Serio

Title: Manager, GPRD Outsourcing

Address: 100 Abbott Park Rd, Abbott Park, IL 60030

Date: 20 March 2012

THE UNIVERSITY OF TEXAS AT AUSTIN

By: Bill Catlett

Name: Bill Catlett

Title: Director, Office of Industry Engagement

Address: PO Box 7227, Austin, TX 78713-7727

Phone: (214) 648-4474

Date: MAR 21 2012

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON

By: _____

Name: _____

Title: _____

Address: _____

Phone: _____

Date: _____

THE UNIVERSITY OF TEXAS HEALTH CENTER AT TYLER

By: _____

Name: _____

Title: _____

Address: _____

Phone: _____

Date: _____

THE UNIVERSITY OF TEXAS MEDICAL BRANCH AT GALVESTON

By: _____

Name: _____

Title: _____

Address: _____

Phone: _____

Date: _____

THE UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER AT DALLAS

By: _____

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

Title: Vice President for Research Administration

Address: 5323 Harry Hines Blvd.
Dallas, TX 75390-9105

Phone: (214) 648-4474

Date: _____

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Title: Director, Office of Industry Engagement

Address: PO Box 7227, Austin, TX 78713-7727

Phone: (214) 648-4474

Date: _____

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON

By: Kathy Bradley

Name: Kathryn Bradley

Title: Assistant Director, Contracts
Office of Sponsored Projects

Address: 7000 Fannin, UCT 1006
Houston, Texas 77030

Phone: 713-500-3999

Date: 3/26/2012

THE UNIVERSITY OF TEXAS HEALTH CENTER AT TYLER

By: _____

Name: _____

Title: _____

Address: _____

Phone: _____

Date: _____

THE UNIVERSITY OF TEXAS MEDICAL BRANCH AT GALVESTON

By: _____

Name: _____

Title: _____

Address: _____

Phone: _____

Date: _____

THE UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER AT DALLAS

By: _____

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Date: _____

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON

By: _____

Name: _____

Title: _____

Address: _____

Phone: _____

Date: _____

THE UNIVERSITY OF TEXAS HEALTH CENTER AT TYLER

By: _____

Name: Conna Sutton

Title: Director, Pre-Award Services

Address: The University of Texas Health Science Center at Tyler
Tyler, TX 75708-3154
conna.sutton@uthct.edu
903-877-7585 FAX: 903-877-7558

Phone: _____

Date: 3/21/2012

THE UNIVERSITY OF TEXAS MEDICAL BRANCH AT GALVESTON

By: _____

Name: _____

Title: _____

Address: _____

Phone: _____

Date: _____

THE UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER AT DALLAS

By: _____

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

Title: Vice President for Research Administration

Address: 5323 Harry Hines Blvd.
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Title: **Manager, GPRD Outsourcing**

Address: 100 Abbott Park Rd, Abbott Park, IL 60030

Date: 20 March 2012

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By: _____

Name: Bill Catlett

Title: Director, Office of Industry Engagement

Address: PO Box 7227, Austin, TX 78713-7727

Phone: (214) 648-4474

Date: _____

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON

By: _____

Name: _____

Title: _____

Address: _____

Phone: _____

Date: _____

THE UNIVERSITY OF TEXAS HEALTH CENTER AT TYLER

By: _____

Name: _____

Title: _____

Address: _____

Phone: _____

Date: _____

THE UNIVERSITY OF TEXAS MEDICAL BRANCH AT GALVESTON

By: Susan E. Ramsey

Name: Susan E. Ramsey, CRA

Title: Manager of Research Operations

Address: 301 University Blvd.
Galveston, TX 7755-0156

Phone: 409-266-9413

Date: March 21, 2012

THE UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER AT DALLAS

By: _____

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

Title: Vice President for Research Administration

Address: 5323 Harry Hines Blvd.
Dallas, TX 75390-9105

Phone: (214) 648-4474

Date: _____

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Name: **Dionne M. Serio**

Title: **Manager, GPRD Outsourcing**

Address: 100 Abbott Park Rd, Abbott Park, IL 60030

Date: 20 March 2012

THE UNIVERSITY OF TEXAS AT AUSTIN

By: _____

Name: Bill Catlett

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Address: PO Box 7227, Austin, TX 78713-7727

Phone: (214) 648-4474

Date: _____

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By: _____

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Phone: _____

Date: _____

THE UNIVERSITY OF TEXAS HEALTH CENTER AT TYLER

By: _____

Name: _____

Title: _____

Address: _____

Phone: _____

Date: _____

THE UNIVERSITY OF TEXAS MEDICAL BRANCH AT GALVESTON

By: _____

Name: _____

Title: _____

Address: _____

Phone: _____

Date: _____

THE UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER ~~AT DALLAS~~

By: Angela R. Charboneau Wishon

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

Title: Vice President for Research Administration

Address: 5323 Harry Hines Blvd.
Dallas, TX 75390-9105

Phone: (214) 648-4474

Date: 3-21-2011

INITIAL

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT SAN ANTONIO

By: Jane A Youngers

Name: Jane A. Youngers

Title: Assistant Vice President for Research Administration

Address: 7703 Floyd Curl Drive, MC 7828
San Antonio, TX 78229-3900

Phone: 210.567.2340

Date: 21 March 2012

EXHIBIT A

STATEMENT OF WORK TEMPLATE

This Statement of Work is issued under the Amended and Restated Master Agreement ("Master Agreement"), contract number 48194, effective March __, 2012, which replaced and superseded the original Master Agreement, contract number 14561, effective December 12, 2006 and as amended July 29, 2009, (the "Master Agreement") by and between Abbott Laboratories ("ABBOTT") and Insert Institution name ("INSTITUTION"), having its principal place of business at Insert address. This Statement of Work includes the terms and conditions of the Master Agreement, which are hereby incorporated herein by this reference.

1. Protocol; Conduct of Study.

   (a) INSTITUTION and Principal Investigator (defined below) will conduct the Study in relation to ABBOTT's Insert compound investigational compound ("Study Product") pursuant to the terms of this Statement of Work and the Master Agreement and in strict adherence to Protocol No. Insert # entitled "Insert Protocol Title" (the "Protocol"), as the same may be amended from time to time in writing by ABBOTT, and any other written instruction that may be provided from time to 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.

   (b) INSTITUTION shall use reasonable efforts to complete enrollment of all subjects within Insert Number (#) months of Study initiation. ABBOTT may terminate this Statement of Work immediately consistent with the terms set forth in the Master Agreement, if after INSTITUTION's reasonable efforts (i) INSTITUTION does not enroll at least Insert Number (#) subject(s) within Insert Number (#) month(s) of Study Product shipment; or (ii) all Essential Documents have not been executed and received by ABBOTT within Insert Number (#) weeks of INSTITUTION's receipt of IRB or IEC's written approval.

   (c) INSTITUTION will use reasonable effort to ensure that Subject data, as required in the Protocol, is entered into the CRFs (whether electronic or paper) within Insert Number (#) business days of Subject visit.

2. Principal Investigator; Contacts. Insert Investigator's Name ("Principal Investigator") will be responsible on INSTITUTION's behalf for the conduct of the Study. INSTITUTION's contact(s) at ABBOTT will be Insert Abbott Contact Name, Insert Address, Phone: Insert Phone #, Fax: Insert Fax # of ABBOTT's Global Pharmaceutical Research and Development Division, or whomever ABBOTT may designate in writing. ABBOTT's contact(s) at INSTITUTION will be Insert Institution Contact Name, Insert Address, Phone: Insert Phone #, Fax: Insert Fax #.

3. Compensation.

   (a) In consideration for INSTITUTION's services hereunder, ABBOTT shall pay INSTITUTION as per the Budget attached hereto as **Appendix I** (Budget Summary and Payment Schedule) and in accordance with the terms of the Master Agreement.

   (b) The Budget is based on the full performance of services contemplated by this Statement of Work and full compliance with the terms of the Budget and Master Agreement (including the Protocol). ABBOTT will not be responsible for paying for subject visits or treatments for a subject that is enrolled or treated in violation of the Protocol or for the data contained in a CRF which is not complete and accurate. If at the date of Study termination, any overpayment made by ABBOTT

shall be made payable to ABBOTT as described in **Section 8(c)** (Compensation) of the Master Agreement.

4. Study Term. This Statement of Work shall be effective upon full execution by the parties (the "Effective Date"), and shall terminate on the later of: (a) one (1) year from the Effective Date; (b) the date of Study database lock if there is subject enrollment under this Statement of Work in the Study; or (c) the date of completion of all of the obligations of the parties hereunder (the "Term"), unless terminated earlier pursuant to the terms of the Master Agreement or this Statement of Work.

5. Notices. Any notice required or otherwise made pursuant to this Statement of Work shall be in writing, personally delivered or sent by certified mail, return receipt requested, or recognized courier service, properly addressed, or by facsimile with confirmed answer-back, to the other party at the address set forth below. Notices shall be deemed effective (a) on the date received if personally delivered or sent by certified mail or recognized courier, or (b) upon the date of confirmed answer-back if sent by facsimile.

If to INSTITUTION:
Insert Name
Insert Address
Phone: Insert #
Fax: Insert #

If to Principal Investigator:
Insert Name
Insert Address
Phone: Insert #
Fax: Insert #

If to ABBOTT:
Insert Name
Insert Title
Dept. Insert #, Bldg. Insert #
Abbott Laboratories
Insert 100 or 200 Abbott Park Road
Abbott Park, IL 60064
Phone: Insert #
Fax: Insert #

with a copy to:
Divisional Vice President and
Associate General Counsel
Pharmaceutical Products Legal Operations
Dept. 323, Bldg. AP6A
Abbott Laboratories
100 Abbott Park Road
Abbott Park, IL 60064-6011
Fax: 847-938-1342

6. 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 provisions of the Protocol and the terms and provisions of this Statement of Work or any exhibits hereto, the Protocol shall control with respect to matters of science, medical practice and Study subject safety. In all other matters, the terms and provisions of this Statement of Work shall control. In the event of any conflict between the terms and provisions of the Master Agreement and those in this Statement of Work, the terms and provisions of the Master Agreement shall control, unless this Statement of Work specifically acknowledges the conflict and expressly states that the conflicting term or provision found in this Statement of Work controls for this Statement of Work only and such Statement of Work is approved by the Office of General Counsel of The University of Texas System. This Statement of Work may be modified only by written agreement signed by the parties to this Statement of Work and approved by the Office of General Counsel of The University of Texas System.

IN WITNESS WHEREOF, the parties have caused this Statement of Work to be executed by their duly authorized representatives.

ABBOTT LABORATORIES

By: _____

Name: _____

Insert name of Institution in ALL CAPS

By: DRAFT – NOT FOR SIGNATURE

Name: _____

Title: _____

Date: _____

Title: _____

Date: _____

I acknowledge that I have read this Statement of Work and the Master Agreement and agree to be bound by the provisions of this Statement of Work and Master Agreement as though I were a party hereto.

By: DRAFT – NOT FOR SIGNATURE

Name: _____

Title: Investigator

Date: _____

APPENDIX I TO STATEMENT OF WORK

BUDGET SUMMARY AND PAYMENT SCHEDULE

PRINCIPAL INVESTIGATOR	Insert Name	
ADDRESS	Insert Address	
PHONE NUMBER	Insert Phone Number	
DRUG: Insert Name	PROTOCOL: Insert Number	Visits: Screening through week Insert Number
Total estimated visits per Subject (including follow-up visit, if required)		Insert Number
Number of Subjects at INSTITUTION required per Protocol/Study		Insert Minimum Number up to Insert Maximum Number
[OPTIONAL:] INSTITUTION may enroll additional Subjects, more than the Maximum number of Subjects set forth above, provided that: (a) prior to commencement of any additional enrollment activity INSTITUTION has obtained ABBOTT's prior written approval; and (b) the total number of additional Subjects does not exceed Insert Number. Payments will correspond to the procedure amounts listed in **Attachment I** (Per Subject Breakdown).		Not to Exceed $Insert Amount
Total per subject cost (see **Attachment I to Appendix I** (Per Subject Breakdown); payments to be made per the Subject Visit Payments schedule, described below)		$Insert Amount
Total cost for all Subjects		**$Insert Amount**
ADDITIONAL STUDY FEES: Payments will be made as follows, in accordance with Section 8 (Compensation) of the Master Agreement. [INSERT ADDITIONAL FEES AS APPLICABLE]		
Study Start-up: A Study Start-up fee will be paid to INSTITUTION for study start-up related activities, including but not limited to, completion of regulatory documents, review of Protocol and Investigator's Brochure, and training of internal staff on Study related activities. Payment will be made within thirty (30) days after receipt and approval of an itemized invoice by ABBOTT.		Not to Exceed $Insert Amount
Local IRB/IEC Fees: Local IRB/IEC fees will be paid to INSTITUTION for initial IRB/IEC review. Payment will be made within thirty (30) days after receipt and approval of an itemized invoice by ABBOTT.		Not to Exceed $Insert Amount
Screen Failures: Reimbursement of Screen Failures will be limited to Insert Number for every Insert Number Subject(s) enrolled or randomized into the Study. ABBOTT will pay Insert Amount Dollars (US$Insert Amount) per each Screen Failure within the number above. "Screen Failure" means a Subject has, at a minimum, signed the informed consent and authorization document for the Study, but does not enroll or randomize into the Study. Screen Failure payments will be made along with Subject Visit Payments, as described below.		Not to Exceed $Insert Amount
TOTAL COMPENSATION (Not to Exceed)		**$Insert Amount**
SUBJECT VISIT PAYMENT SCHEDULE: Payments will be made as follows, in accordance with Section 8 (Compensation) of the Master Agreement:		
Subject Visit Payments: Payments for subject visits will be made US: monthly, Non-US: quarterly following enrollment of the first Subject. Payments will be made after data is entered by INSTITUTION into the CRFs and reviewed by ABBOTT, and will correspond to amounts listed in **Attachment I to Appendix I**. INSTITUTION understands that such payments are subject to subsequent verification by ABBOTT and will be adjusted per **Section 8** (Compensation) of the Master Agreement if necessary.		

CHECK PAYMENT INFORMATION:

Checks shall be made payable to (Must be exact name as it appears on the IRS tax form):	Insert Payee	Federal Employer ID Number:	Insert Number
Individual and Address to receive Payment at INSTITUTION:	Insert Name Insert Address		
Name and e-mail address of Individual at INSTITUTION to receive detailed payment information:	Insert Name Insert e-mail address		
Individual and Address to receive Invoices at ABBOTT:	Payment Specialist Abbott Laboratories Dept. R477, Bldg AP30-3 200 Abbott Park Road Abbott Park, IL 60064-6145 Abbott_Invoices@abbott.com If sending electronically, please be sure to **include the Study number** on the subject line of the e-mail. If the invoice is not study-specific, please **include the 5-digit contract number** located in the lower left-hand corner of the Statement of Work		
(Information must be accurate for IRS and FDA purposes)			

ATTACHMENT I to APPENDIX I

PER SUBJECT BREAKDOWN

EXHIBIT B

ADMINISTRATIVE CONTACT PERSON AND ADDRESS FOR EACH INSTITUTION

Bill Catlett Director Office of Industry Engagement **The University of Texas at Austin** P.O. Box 7727 Austin, Texas 78713-7727 Overnight address: 101 E. 27th Street North Office Bldg. A (NOA), Suite 5.200 Austin, TX 78712 Phone: 512-471-3866 Fax: 512-471-7839 Tax ID: 74-600023	Angela R. Charboneau Wishon, J.D. Vice President for Research Administration **The University of Texas Southwestern Medical Center** 5323 Harry Hines Blvd. Dallas, Texas 75390-9105 Phone: 214-648-4494 Fax: 214-648-4474 Tax ID: 75-6002868
Jane A. Youngers Assistant Vice President for Research and 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: 210-567-2340 Fax: 210-567-2344 Tax ID: 74-1586031	Kathryn Bradley Assistant Director, Contracts, Office of Sponsored Projects **The University of Texas Health Science Center at Houston** 7000 Fannin Street, Suite 1006 Houston, TX 77030 Phone: 713-500-3073 Fax: 713-383-3746 Tax ID: 74-1761309
Conna Sutton 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: 903-877-7585 Fax: 903-877-7558 Tax ID: 75-6001354	Susan Ramsey Manager of Research Operations **The University of Texas Medical Branch at Galveston** Office of Sponsored Projects 301 University Boulevard 4.40 Rebecca Sealy Hospital Galveston, TX 77555-0156 Phone: 409-266-9413 Fax: 409-266-9469 Tax ID: 74-6000949

EXHIBIT C

REQUIREMENTS FOR SCIENTIFIC PUBLICATIONS

1. Criteria for Authorship. Based on the October 2007 guidelines of the International Committee of Medical Journal Editors (ICMJE), authorship credit must be based on:

   (a) Substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; and

   (b) Drafting or revising the article for important intellectual content; and

   (c) Final approval of the version to be published.

   A person must meet all three of the above criteria to warrant authorship.

2. Acknowledgement of Medical Writers and Other Contributors. Those individuals who have made a significant contribution to the Study or Publication, but do not meet the criteria for authorship noted above, must be listed in an acknowledgments section, including disclosure of the source of any financial support given to such contributors. All persons must give written permission to be acknowledged.

3. Conflict of Interest. In the interest of transparency and maintaining the highest possible standards of conduct, authors will comply with each journal's or congress's requirements for conflict of interest disclosure in the Publication. Such conflict of interest disclosure requirements may include, but are not limited to, disclosure of an author's receipt of research grants, author's receipt of payments for consultant or speaker services, and/or author's ownership of stock.

4. Sponsorship. Authors must acknowledge ABBOTT as the funding source of a Study, and must also comply with additional sponsorship-related disclosures required by the journal or congress.

5. Access to Data. ABBOTT will provide all authors with the final protocol, statistical analysis plan, relevant statistical tables generated from the plan, figures, and reports needed to prepare the planned Publication. ABBOTT will provide a copy of the clinical trial protocol and plan for statistical analysis when requested by a medical journal considering a submitted manuscript for publication, with the understanding that the documents are confidential, the property of ABBOTT, and should not be disclosed to any third party without ABBOTT's prior written permission.

6. Redundant Publication. Duplicate or redundant publication of the Study results in peer-reviewed journals is not permitted. Secondary Publications that present significant and scientifically sound additional analyses or groupings of data are permitted. Publication of foreign language translations of the original manuscript, in accordance with the policies of the journals involved is permitted. Encore presentation of data, when permitted by scientific congress policy, is permitted.