

## **RESTATED AND AMENDED MASTER CLINICAL STUDY AGREEMENT**

This RESTATED AND AMENDED MASTER CLINICAL STUDY AGREEMENT (this “Master Agreement”) is effective November 24, 2014 (the “Effective Date”) between GlaxoSmithKline LLC (“GSK”), and all of the following member institutions (each an “Institution”, and collectively the “Institutions”) of The University of Texas System (“System”) located at 201 West 7th Street, Austin, TX, 78701, that is governed by its Board of Regents (“Board”):

The University of Texas Health Science Center at Tyler  
The University of Texas Health Science Center at Houston  
The University of Texas Health Science Center at San Antonio  
The University of Texas Medical Branch at Galveston  
The University of Texas Southwestern Medical Center  
The University of Texas at Austin

### **BACKGROUND**

GSK and its Affiliates (as defined below) develop, manufacture, distribute, and sell pharmaceutical and healthcare products. Institution conducts clinical studies. GSK and Institution intend for this Master Agreement to establish terms and conditions for the performance of clinical studies. While this Master Agreement creates certain obligations between the parties, it does not obligate GSK or any GSK Affiliate to engage Institution to conduct any specific clinical study, or obligate Institution to conduct any specific clinical study.

On October 27, 2009, SmithKline Beecham Corporation re-domiciled from the Commonwealth for Pennsylvania to the State of Delaware, converted into a limited liability company and changed its name to GlaxoSmithKline LLC. The parties agree that “SmithKline Beecham Corporation, doing business as GlaxoSmithKline” as set forth in the Master Agreement and any Study Specific Agreement thereunder is hereby superseded by “GlaxoSmithKline LLC”.

This Master Agreement supersedes and replaces (i) the Master Clinical Study Agreement entered into between the parties effective November 10, 2003, (ii) Amendment #1 thereto effective April 6, 2005, and (iii) Amendment #2 thereto effective September 18, 2006.

### **DEFINITIONS**

“Affiliate” means any entity that controls, is controlled by, or is under common control with, GSK. In this context, “control” shall mean (1) ownership by one entity, directly or indirectly, of at least forty percent (40%) of the voting stock of another entity; (2) power of one entity to direct the management or policies of another entity, by contract or otherwise; or (3) any other relationship between GSK and an entity which GSK and Institution have agreed in writing may be considered an “Affiliate” of GSK or Institution.

“Biological Samples” include, without limitation, blood, serum, fluid and tissue biopsy samples collected from Study (as defined below) patients enrolled in a Study that are not directly related to patient care or safety monitoring, including pharmacokinetic, pharmacogenomic or biomarker testing. Biological Samples further include, without limitation, any tangible material directly or indirectly derived from such blood, fluid or tissue samples, such as: genes, gene fragments, gene sequences, proteins, protein fragments, protein sequences, probes, DNA, RNA, cDNA libraries, plasmids, vectors, expression systems, cells, cell lines, organisms, antibodies or other biological substances; and any constituents, progeny, mutants, variants, derivatives, replications, reagents or chemical compounds thereof or derived therefrom.

“GSK Confidential Information” means all information (including, without limitation, study protocols, case report forms, clinical data, other data, reports, specifications, computer programs or models and related documentation, know-how, trade secrets, or business or research plans) of GSK or GSK’s Affiliates that are: (1) provided to Institution in connection with this Master Agreement, a Study Specific Agreement (as defined below), or a Study, or in connection with a planned Study which potentially could be the subject of a Study Specific Agreement, even without an executed Study Specific Agreement; (2) and subject to Institution’s publication rights under Section 8 below, Study data, results, or reports created by Institution, Investigators (as defined below), or Study Staff (as defined below) in connection with the Study (except for a Study subject’s medical records); and (3) cumulative Study data, results, and reports from all sites conducting the Study.

“Invention” means any discovery, development, invention (whether patentable or not), improvement, work of authorship, formula, process, composition of matter, formulation, method of use or delivery, specification, computer program or model and related documentation, know-how or trade secret, that is made by Institution, Investigators (as defined below), or Study Staff (as defined below) as a direct result of the Study; or (2) which incorporate GSK Confidential Information.

“Investigator” means the individual(s) responsible for the conduct of the Study at Institution and for direct supervision of Study Staff.

“Protocol” means the written document that describes a Study and sets forth specific activities to be performed as part of Study conduct. The Protocol title and number are identified in a Study Specific Agreement.

“Study” means a clinical study sponsored by GSK or its Affiliates that utilizes a Protocol written by GSK or its Affiliate and /or GSK or its Affiliate’s Study Drug and conducted by Institution.

“Study Drug” means the GSK or its Affiliate’s investigational product(s) to be used in a Study, and other products which are required by the Protocol to be used in a Study as a comparator or in combination with the investigational product.

“Study Specific Agreement” means a written agreement between the parties or GSK Affiliates which incorporates by reference the terms of this Master Agreement and also contains terms and

conditions specifically applicable to the conduct of a specific Study in the form of Exhibit A attached hereto.

“Study Staff” means the individuals providing services on behalf of Institution with respect to the Study at Institution, including without limitation subinvestigators, Study coordinators, and other Institution employees, agents, or subcontractors.

## **1. MASTER AGREEMENT AND STUDY SPECIFIC AGREEMENTS**

(a) In the event that GSK and Institution agree that Institution will conduct a Study, the parties shall enter into a Study Specific Agreement under this Master Agreement prior to conducting the Study at Institution. An executed Study Specific Agreement, along with this Master Agreement, shall constitute the agreement of the parties with respect to that Study. Where affirmatively stated in this Master Agreement, the parties agree that certain terms of this Master Agreement shall apply without an executed Study Specific Agreement. A Study Specific Agreement form, which may be modified by mutual agreement of the parties for specific Studies, is included as Exhibit A.

(b) Each Study Specific Agreement will incorporate by reference the terms of this Master Agreement, but each Study Specific Agreement shall be a unique agreement and shall stand alone with respect to any other Study Specific Agreement. If any provisions of a Study Specific Agreement are in direct conflict with this Master Agreement so that the provisions of both cannot be given effect, the terms of the Master Agreement shall govern the specific issue.

(c) Institution shall make this Master Agreement available to Investigators and Study Staff and require Investigators and Study Staff to comply with the provisions of this Master Agreement and the applicable Study Specific Agreement.

(d) GSK and Institution intend that GSK Affiliates may also execute Study Specific Agreements. Unless the context requires otherwise, references to “GSK” in this Master Agreement (and the related rights and obligations) as incorporated into such Study Specific Agreement shall apply to the GSK Affiliate that is a party to the Study Specific Agreement.

(e) **Contract Research Organizations (CROs)**. When a CRO is authorized by GSK or its Affiliate to manage a GSK or GSK Affiliate sponsored Study, including the preparation, negotiation and finalization of the Study agreement, such CRO shall conform the terms of the GSK-approved CRO’s template agreement with the pre-approved language from this Master Agreement for all material provisions, including but not limited to, intellectual property (Section 9), confidentiality (Section 7), publication (Section 8), indemnification (Section 10), insurance (Section 11), biological samples (Section 12), subject injury (Section 10(e)), AAHRPP (Section 2(g)), state law (Section 22) and state agency limitations (Section 24).

## **2. STUDY CONDUCT**

(i) the Study Protocol, as approved by GSK, Investigator, Institution and its responsible Institutional Review Board (along with any subsequently approved (by all parties) written amendments to the Study Protocol);

(ii) all applicable local, state and federal laws, rules and regulations, including, but not limited to, the Federal Food, Drug and Cosmetic Act and the regulations of the United States Food and Drug Administration (“FDA”), the International Conference on Harmonisation (“ICH”) Good Clinical Practices, and the Form FDA 1572 Statement of Investigator;

(iii) all applicable medical privacy laws or regulations, including without limitation, obtaining any required subject consent or authorization to allow GSK access to Study subject’s medical information as may be necessary to monitor the Study and to receive and use Study data; and

(iv) the terms of this Master Agreement and the applicable Study Specific Agreement.

(b) For a Study, GSK, Institution, and Investigator shall agree to a written Study enrollment plan. Institution agrees that this enrollment plan may set a target number for enrolled Study subjects at Institution, and that applying the enrollment plan may operate, from time to time, to modify that target number (for example, without limitation, the target number may be automatically reduced if Institution fails to meet interim enrollment goals set by the plan or if the overall Study enrollment goal across all participating sites is met). In no event shall Institution or Investigator enroll a number of subjects into the Study which exceeds the then-current target number set by the enrollment plan without the written agreement of GSK.

(c) Institution and Investigator shall use Study Drug only to conduct the Study in accordance with the Protocol; shall not chemically, physically or otherwise modify Study Drug, unless specifically required to do so by the Protocol; and shall handle, store, and ship or dispose of Study Drug in compliance with all applicable local, state and federal laws, rules and regulations including, but not limited to, those governing hazardous substances. Institution and Investigator shall not charge any Study subject or third-party payor for any Study Drug, or for Study procedures for which payment by GSK has or will be made under the applicable Study Specific Agreement.

(d) In accordance with mutually agreed time periods, Institution shall resolve all written data queries from GSK and shall deliver to GSK complete and accurate case report forms (electronic or paper, as applicable) throughout the Study, with final delivery of case report forms after Study conclusion, and any other Study-related deliverables identified in writing by GSK and agreed to by Investigator/Institution.

(e) Institution agrees that no individual or entity shall provide services on behalf of Institution in connection with a Study if that individual or entity has been debarred under the provisions of the Generic Drug Enforcement Act of 1992, 21 U.S.C. § 335a (a) and (b); disqualified as a testing facility under the provisions of 21 C.F.R. Part 58, Subpart K; or disqualified as a clinical investigator under the provisions of 21 C.F.R. § 312.70. Institution

shall notify GSK of any action with respect to debarment or disqualification against Institution or any individual or entity providing services on behalf of Institution in connection with the Study. Institution represents to GSK that, other than any such actions disclosed to GSK in writing, Investigator and other Study Staff who are licensed health care providers have not been subject to or are not in the process of being subjected to any action taken against them by the relevant state licensure or professional board (including actions taken that did not result in any significant curtailment of their license), and that during the term of this Master Agreement or any Study Specific Agreement, Institution will promptly notify GSK of any arising licensure or professional board action against Investigator or licensed Study Staff.

(f) **Non-Exclusive Relationships.** Nothing in this Master Agreement will limit or prohibit Institution or any Study Staff, or any Investigator, from conducting any research or for performing research for or with any entity or person, including any other outside sponsors. Sponsor acknowledges that this provision is intended to preserve the academic freedom and integrity of Institution and its faculty.

(g) **Study Subject Safety.** Institution and GSK shall promptly notify each other of any significant new findings developed during a Study and thereafter that may (i) adversely affect the safety, well-being, or medical care of Study Subjects, (ii) affect the willingness of a Study subject to continue participation in the Study, or (iii) alter the IRB's continuing approval of the Study. Institution shall promptly notify the IRB of any such events. When Study subject safety or medical care could be directly affected by Study results, Institution shall be free to provide the Study results to Study subject in accordance with IRB policy. GSK agrees to monitor Study data and will provide to Institution urgent safety information in accordance with International Conference on Harmonization ("ICH") E6 Guidelines (section 5.17) and FDA IND regulations (CFR § 312.32) and shall provide routine annual Study update reports.

### **3. COMPENSATION**

(a) In consideration for conducting the Study, GSK shall pay in accordance with the terms of the applicable Study Specific Agreement. Such terms shall be consistent with the principles of fair market value payments for the performance of Study-related activities and that no payments by GSK pursuant to a Study Specific Agreement shall be passed in whole or in part, directly or indirectly, to any third party as a rebate or discount for the purchase of GSK products. Notwithstanding the foregoing, commercially reasonable payments to a subcontractor who is performing services under the terms of this Master Agreement or any Study Specific Agreement that meet the criteria for bona fide services are not considered to be a pass-through rebate or discount payment (even if the subcontractor is a GSK customer). GSK shall have no obligation to make payments for activities or costs in the absence of an executed Study Specific Agreement or for which GSK has not specifically agreed to pay under the terms of the Study Specific Agreement.

(b) GSK's final payment obligation is conditioned upon Institution reporting to GSK all data required by the Protocol and other governing documents for the Study, including all adverse events, and upon Institution's compliance with standards identified in this Master

Agreement and the applicable Study Specific Agreement. GSK will not make payments or, if payment has been made by GSK, Institution will repay to GSK any payments for Study visits, procedures, or other work associated with a Study subject if GSK determines that the Study visits, procedures, or other work associated with the subject was not conducted by Investigator or Study Staff in compliance with the Protocol, applicable law or regulation, or ICH Good Clinical Practices.

#### **4. TERM; TERMINATION**

(a) This Agreement shall take effect on the Effective Date and shall continue for seven (7) years or until terminated as provided below. Each Study Specific Agreement shall take effect as of an effective date designated in the Study Specific Agreement. Termination of this Master Agreement or of any Study Specific Agreement shall not affect any other Study Specific Agreement; each Study Specific Agreement shall continue in full force and effect unless specifically terminated in accordance with the terms of this Master Agreement or the terms of that Study Specific Agreement.

(b) Either party may terminate this Master Agreement, without cause, upon sixty (60) days written notice; or immediately upon written notice to the other, if that party fails to remedy a material breach of this Master Agreement within thirty (30) days after written notice of the breach.

(c) Either party may terminate this Master Agreement or any Study Specific Agreement immediately upon written notice if the other party becomes insolvent, or if proceedings are instituted against the other party for reorganization or other relief under any bankruptcy law, or if any substantial part of the other party's assets come under the jurisdiction of a receiver or trustee in an insolvency proceeding authorized by law.

(d) GSK may terminate any Study Specific Agreement, in whole or in part, with or without cause, immediately upon written notice to Institution. Written notice by GSK that a Study is terminated shall also constitute effective notice of termination of the applicable Study Specific Agreement.

(e) Either party may terminate a Study Specific Agreement immediately upon written notice if necessary to protect the health, safety or welfare of a Protocol subject.

#### **5. EFFECT OF TERMINATION**

(a) Upon written notice of termination of a Study Specific Agreement by either Institution or GSK, Institution shall cease enrolling subjects into the Study, and shall discontinue conduct of the Study as soon as is medically practicable.

(b) Upon written notice of termination of a Study Specific Agreement by either Institution or GSK, Institution shall use reasonable efforts to revoke any financial obligations incurred and shall avoid incurring any additional costs in connection with the Study. Institution

shall be compensated only for Study-related work actually performed or reimbursed only for expenses actually and reasonably incurred through the effective date of termination which GSK has agreed to pay as part of the Study under the applicable Study Specific Agreement. If, upon the effective date of termination, GSK has advanced funds which are unearned by Institution, Institution shall repay such funds within sixty (60) days of the effective date of termination. In the event Institution fails to repay such funds in a timely manner, GSK may deduct an equivalent amount from any payment then or later due from GSK to Institution under this or any other arrangement between the parties.

(c) Upon termination of a Study Specific Agreement, all unused Study Drug and all GSK Confidential Information (except for such records that Institution is required by law or regulation to retain and one copy of Study Data, results and reports for internal, non-commercial, educational purposes) in Institution's possession shall be promptly delivered to GSK, at GSK's expense, or, at GSK's option, destroyed with the destruction certified in writing.

## **6. RECORDKEEPING; ACCESS**

(a) Institution shall make and retain records regarding a Study as required by the Protocol, applicable law or regulation, or ICH Good Clinical Practices, and in accordance with Institution's standard archiving procedures. Institution will retain such records a minimum of ten (10) years commencing upon the "Effective Date" of the applicable Study Specific Agreement. Thereafter, Institution will notify the then-GSK Study contact in writing, for which email is preferable, prior to destroying any such records and, will retain the records for such longer period only if GSK requests in written response to Institution within sixty (60) days from the date GSK receives Institution written notice. Any such extended record retention is strictly subject to a mutually agreeable arrangement between GSK and Institution which will include the reasonable cost of Institution's extended storage as approved by GSK taking into account any prior agreed-upon storage fee as set forth in the applicable Study Per Subject Budget (Exhibit 1) in which case such storage cost payment by GSK to Institution will apply to and include any such Institution's extended storage costs.

(b) Authorized representatives of GSK, upon reasonable advance written notice and during regular business hours, shall have the right to inspect Institution's facilities used in the conduct of the Study and to inspect and copy (if authorized and legal) all records directly relating to the Study (including, without limitation, access to records as necessary for Study monitoring or to audit the conduct of the Study in accordance with GSK standards) provided that GSK's access is limited to those specific records addressed in the Study subjects' authorization. GSK will maintain the confidentiality of any subject-identifiable medical records.

(c) If any governmental or regulatory authority notifies Institution that it will inspect Institution's records, facilities, equipment, or procedures, or otherwise take action related to the Study, Institution shall promptly notify GSK, allow GSK to be present at the inspection/action or participate in any response to the inspection/action, and provide GSK with copies of any reports issued by the authority and Institution's proposed response.

(d) The parties agree that obligations under this Section may exist without an executed Study Specific Agreement. The obligations of this Section shall survive termination of this Master Agreement and any applicable Study Specific Agreement.

## **7. CONFIDENTIALITY**

(a) GSK Confidential Information and all tangible expressions, in any media, of GSK Confidential Information are the sole property of GSK (excluding works of authorship notwithstanding Section 8). Each party shall endeavor to identify tangible Confidential Information provided to the other party as “Confidential” given the understanding that failure to do so does not constitute a designation of non-confidentiality when the confidential nature is apparent from context and subject matter. Institution agrees to treat GSK’s Confidential Information as it would its own proprietary and confidential information. Institution will only accept information from GSK which is required for conduct of the Study and which must be maintained for Institution’s records. The Investigator reserves the right to refuse to accept any Confidential Information s/he does not consider to be essential to the performance of the Study.

(b) Institution agrees, for a period of five (5) years after the expiration or termination of the Study, not to use GSK Confidential Information for any purposes other than to conduct a Study. Institution agrees not to disclose GSK Confidential Information to third parties except as necessary to conduct a Study and under an agreement by the third party to be bound by the obligations of this Section. Institution shall safeguard GSK Confidential Information with the same standard of care that is used with Institution’s Confidential Information, but in no event less than reasonable care. The parties understand and agree that information which is communicated to Institution’s scientific and/or institutional review committees is confidential.

(c) The obligations of confidentiality and limited use under this Section shall not extend to any information:

- (i) which is or becomes publicly available, except through breach of this Master Agreement or the relevant Study Specific Agreement; or
- (ii) which Institution can demonstrate that it possessed prior to, or developed independently from, disclosure or development under this Master Agreement or the relevant Study Specific Agreement; or
- (iii) which Institution receives from a third party which is not legally prohibited from disclosing such information; or
- (iv) which Institution is required by law to disclose, provided that GSK is notified of any such requirement with sufficient time to seek a protective order or other modifications to the requirement; or
- (v) which is appropriate to include in a Multicenter Publication (as defined below) of which Investigator or other representatives of Institution participate as a named author and which is otherwise made in accordance with this Master Agreement; or
- (vi) which is appropriate to include in an Institution Publication (as defined below) made in accordance with this Master Agreement; or
- (vii) a Study subject’s specific medical information, as necessary for the appropriate medical care of the subject; or

(viii) is required to be disclosed in order to obtain informed consent from patients or subjects who may wish to enroll in the Study, provided however, that the information will be disclosed only to the extent necessary and Confidential Information will not be provided in answers to unsolicited inquiries by telephone or to individuals who are not eligible Study candidates.

(d) The parties agree that obligations under this Section may exist without an executed Study Specific Agreement. The obligations of this Section shall survive termination of this Master Agreement and any applicable Study Specific Agreement.

(e) Institution acknowledges and agrees that the Health Insurance Portability and Accountability Act of 1996, P.L. 104-191, Subtitle F, and regulations from time to time promulgated thereunder (“HIPAA” or the “Privacy Rule”), require that Institution and/or Investigator, as a “Covered Entity” under the Privacy Rule, obtain a signed authorization from a patient prior to using or disclosing such patient’s “Protected Health Information”, as defined in the Privacy Rule, obtained or created in connection with this Study. All parties agree to use and disclose Protected Health Information only in a manner consistent with the requirements of the Privacy Rule and an applicable patient authorization, including the terms and conditions of the informed consent and authorization executed by each patient, or as otherwise may be permitted or required by applicable law.

## **8. STUDY TRANSPARENCY AND PUBLICATION**

(a) GSK will post a Study Protocol summary on a publicly available protocol register prior to the enrollment of Study subjects.

(b) GSK will post a summary of the Study results on a publicly available results register no later than twelve (12) months following completion of the Study at all Study sites. Posting of summary Study results may occur prior to publication of Study results in the peer-reviewed literature.

(c) GSK will seek to publish the Study results in the searchable, peer reviewed scientific literature in the form of a publication or presentation of Study results from all Study sites (a “Multicenter Publication”). In the event a proposed manuscript is not accepted for publication or publication is otherwise not feasible (e.g., early-stage studies of a terminated product), GSK will include results conclusions and context on the GSK Clinical Study Register to supplement the Study results summary.

(d) Any participation of Investigator or other representatives of Institution as a named author of this Multicenter Publication will be determined in accordance with the International Committee of Medical Journal Editors (“ICMJE”) Uniform Requirements for Manuscripts, and Institution acknowledges and shall ensure that Investigator understands that the enrollment of Study subjects alone is not a qualification for authorship. If the Investigator or other representative of Institution is a named author of the Multicenter Publication, GSK and Institution (on behalf of such authors at Institution) agree that authors: (i) will have access to the

Study data from all Study sites as necessary to fully participate in the development of the Multicenter Publication; (ii) will adhere to ICMJE requirements regarding authorship; (iii) will disclose as part of the Multicenter Publication that GSK financially supported the Study and any personal financial relationship with GSK; (iv) has made substantial contributions to the Study and has given or will give final approval to the version of the Multicenter Publication ultimately published; and (v) upon completion of author activities will certify in writing to the foregoing and that the authored publication is fair, accurate, and balanced.

(e) Institution agrees and shall ensure that Investigator acknowledges that GSK may make public the names of the Investigator and the Institution as part of a list of Investigators and Institutions conducting the Study when making either protocol or results summary register postings. Institution agrees and shall ensure that Investigator acknowledges that GSK may make public the amount of funding provided to Institution by GSK for the conduct of the Study and may identify Institution and Investigator as part of this disclosure. Institution agrees and shall ensure that Investigator understands that, if Investigator, consistent with the terms of this Agreement, speaks publicly or publishes any article or letter about a matter related to the Study or Study Drug or that otherwise relates to GSK and this Master Agreement and a Study Specific Agreement, Investigator will disclose that he/she was an investigator for the Study. For sake of clarity, GSK agrees that an Investigator's acknowledgement as evidenced by his/her signature at the end of a Study Specific Agreement is sufficient to meet the requirements of this subsection (e).

(f) Institution and Investigator, consistent with scientific standards and in a scientific forum, may publish or present the Study results from Institution's Study data (an "Institution Publication"), provided that the Institution Publication does not also disclose any GSK Confidential Information other than the Study results from Institution's Study data. Institution and Investigator shall submit to GSK for review and comment any proposed Institution Publication at least thirty (30) days prior to submitting the Institution Publication to any third party. If GSK requests a delay in order to file patent applications relating to a GSK Invention, Institution and Investigator agree to delay submitting the Institution Publication to any third party for up to sixty (60) days after GSK's written request. Institution also agrees and shall ensure that Investigator understands that any Institutional Publication shall only be made after the Multicenter Publication, provided that the Multicenter Publication is submitted within twelve (12) months after conclusion of the Study at all Study sites. If Multicenter Publication is not submitted within twelve (12) months after conclusion of the Study at all Study sites, Institution and Investigator will be free to publish. Institution agrees and shall ensure that Investigator acknowledges that GSK's financial support of the Study will be disclosed in any Institution Publication and will require all authors of such Institution Publication to disclose any financial relationship with GSK. Institution shall ensure that Investigator complies with the obligations identified in this subsection.

(g) The obligations of this Section shall survive termination of this Master Agreement and any applicable Study Specific Agreement.

## **9. INTELLECTUAL PROPERTY**

(a) Institution will notify GSK, promptly and in writing, of any Invention.

(b) Institution hereby assigns, and will cause Investigators and Study Staff to assign, to GSK any and all rights, title, and interest in any Invention comprised of a novel process, formulations, or method of use or delivery, of any Study Drug, each without additional consideration from GSK.

(c) For any Invention not covered by Section 9(b) of this Agreement, Institution will cause Investigators and Study Staff to assign all rights, title and interests in the Invention to Institution, and Institution hereby grants to GSK an option to an exclusive period to negotiate a royalty-bearing license to all rights, title and interest which Institution may have or obtain in the Invention, each without additional consideration from GSK. If not exercised by GSK in writing, this option will expire sixty (60) days following Institution's written notice of the Invention. If GSK exercises its option, GSK and Institution agree to negotiate in good faith, for up to one hundred eighty (180) days or such mutually agreeable longer period, commercially reasonable terms for an exclusive, worldwide, royalty-bearing license, to include the right to sublicense, for GSK to make, have made, use, or sell the Invention or products incorporating the Invention. If GSK exercises its option and the parties enter into a license agreement, all costs associated with filing, prosecution, issuance and maintenance of patents related to the licensed Invention shall be GSK's sole responsibility; provided that the license agreement grants GSK the right to control the timing and nature of filing, prosecution, and maintenance of such patents.

(d) Upon GSK's written request, Institution will execute and will cause Investigators and Study Staff to execute any instruments or testify as GSK deems necessary to obtain patents or otherwise to protect GSK's interest in an Invention. GSK will reasonably compensate Institution for the time devoted to such activities and will reimburse Institution for reasonable and necessary expenses incurred.

(e) The obligations of this Section shall survive termination of this Master Agreement and any applicable Study Specific Agreement.

## **10. INDEMNIFICATION**

(a) GSK agrees to indemnify, defend and hold harmless Institution and its Affiliates, System, its Board, Investigators, Study Staff, and other Institution employees, officers, agents and subcontractors ("Institution Indemnitees") from and against any loss, expense, cost (including reasonable attorneys fees), liability, damage, or claim by third parties including but not limited to personal injury, including death, that arises out of the conduct of the Study by Institution, or that arises out of the negligence or willful malfeasance of GSK, or that arises out of GSK's use of the Study results ("Institution Claim"), provided that GSK shall not indemnify any Institution Indemnitee for any Institution Claim to the extent the Institution Claim arose out of:

- (i) failure by Institution Indemnitees to conduct the Study in accordance with the Protocol, GCPs, GSK's written instructions, or applicable laws or regulations;
- (ii) the negligence or willful misconduct of Institution Indemnitees; or
- (iii) a material breach by Institution Indemnitees of this Master Agreement or the applicable Study Specific Agreement.

(b) GSK's obligations under this Section with respect to an Institution Claim are conditioned on:

- (i) Prompt written notification to GSK of the Institution Claim so that GSK's ability to defend or settle the Institution Claim is not adversely affected; and
- (ii) Subject to the statutory duties of the Texas Attorney General, GSK has sole control over the defense or settlement of the Institution Claim and, subject to the statutory duties of the Texas Attorney General, Institution will fully cooperate with GSK in the defense or settlement of the Institution Claim; provided, that, no Institution Indemnitee shall be required to admit fault or responsibility in connection with any settlement.

(c) To the extent authorized under the Constitution and laws of the State of Texas, Institution agrees to indemnify, defend and hold harmless GSK and its Affiliates, employees, agents, and subcontractors ("GSK Indemnitees") from and against any loss, expense, cost (including reasonable attorney fees), liability, damage, or claim by third parties for personal injury, including death, resulting from the negligent acts or omissions of Institution, its agents or employees, including but not limited to, Investigators, or Study Staff, pertaining to the activities to be carried out pursuant to the obligations of this Master Agreement ("GSK Claim"); provided that Institution shall not indemnify any GSK Indemnitee for any GSK Claim to the extent the GSK Claim arose out of:

- (i) the negligence or willful misconduct of GSK Indemnitees; or
- (ii) a breach by GSK Indemnitees of this Master Agreement or the applicable Study Specific Agreement.

(d) Institution's obligations under this Section with respect to a GSK Claim are conditioned on:

- (i) Prompt written notification to Institution of the GSK Claim so that Institution's ability to defend or settle the GSK Claim is not adversely affected; and
- (ii) GSK Indemnitees' agreement that, subject to the statutory duties of the Texas Attorney General, Institution has sole control over the defense or settlement of the GSK Claim and, subject to the statutory duties of the Texas Attorney General, to fully cooperate with Institution in the defense or settlement of the GSK Claim; provided, that, no GSK Indemnitee shall be required to admit fault or responsibility in connection with any settlement.

(e) **Subject Injury.** GSK agrees to reimburse Institution for the cost of reasonable and necessary medical treatment of any injury sustained by a Study subject as a direct result of a Study Drug or the performance of any procedure required under the Protocol, provided that:  
(1) the Study Drug or required procedure was administered or performed in accordance with the

Protocol (except where deviations from the terms of the Protocol arise out of the necessity to protect the safety, rights or welfare of patients enrolled in the Study and such deviations have been authorized by GSK, except in the case of an emergency) and all then-current written instructions from GSK regarding the administration of the Study Drug or performance of such procedure; and (2) the injury is not attributable to the negligence or willful misconduct of the Institution, its Affiliate(s) or Investigator in attending to such Study subject.

(f) The obligations of this Section shall survive termination of this Master Agreement and any applicable Study Specific Agreement.

## **11. INSURANCE**

(a) Institution, as a member institution of System, is an agency of the State of Texas and provides professional liability insurance 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 Investigator has and will maintain in force, during the term of this Master Agreement, 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 101 of the Texas Civil Practice and Remedies Code, and 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 Institution are provided Worker's Compensation coverage under a self-insuring, self-managed program as authorized by Chapter 503, Section 503.022, Texas Labor Code.

(b) GSK shall maintain appropriate insurance coverage in respect of its potential product liability in amounts not less than \$8,000,000.00 (Eight Million dollars) per incident and \$8,000,000.00 (Eight Million dollars) annual aggregate. Upon written request, GSK shall provide Institution with written evidence of its insurance program.

## **12. BIOLOGICAL SAMPLES**

(a) If and to the extent so specified in a particular Protocol, Investigator may collect and provide to GSK or its designee, Biological Samples (as defined above) obtained from Study patients for testing that is not directly related to patient care or safety monitoring. Such testing includes, but is not limited to, pharmacokinetic, pharmacogenomics or biomarker testing.

(b) **Institution's Collection, Retention and Use of Biological Samples.** Institution will collect, retain and use Biological Samples in accordance with the applicable Protocol. Institution may collect and/or reserve additional quantities of Biological Samples ("Secondary Biological Samples") for use in research not described in such Protocol ("Non-Protocol Research"), provided that (i) such collection complies with all applicable laws, regulations and acceptable clinical trial practices, including, but not limited to, applicable patient privacy and informed consent laws, and (ii) no GSK Confidential Information or any other information which links the Secondary Biological Samples to any GSK Confidential Information is available to Investigator or Study Staff for such Non-Protocol Research (for example, without limitation,

Institution may annotate such Secondary Biological Samples with a Study patient's demographic information [e.g., age, gender and clinical diagnosis], but not with information related to administration of, or response to, or adverse events associated with, a Study Drug).

(c) **GSK's Receipt and Use of Biological Samples**

(i) GSK or its designee may receive pre-determined quantities of Biological Samples from Institution, as set forth in the applicable Protocol, for use in research as described in such Protocol, provided that such research complies with all applicable laws and regulations, including, but not limited to, applicable patient privacy and informed consent laws. GSK will ensure that if it uses a designee that its designee agrees to follow the terms, conditions and obligations of this Master Agreement.

(ii) GSK will disclose to Investigator all raw data generated by GSK from its research using such Biological Samples ("Biological Samples Raw Data"). GSK reserves the right to withhold any such Biological Samples Raw Data on any such genes which are pre-obligated and/or encumbered in any manner. Such Biological Samples Raw Data (1) shall be treated by Institution as GSK Confidential Information under this Master Agreement, and (2) Investigator may use such Biological Samples Raw Data for the purpose of generating for non-commercial purposes, a manuscript to be published in a scientific peer-reviewed journal, and (3) Investigator may use such Biological Samples Raw Data for non-commercial research and academic purposes, either within Institution or, with prior written notice to GSK, may disclose such Biological Samples Raw Data to academic investigators outside Institution; provided that Institution provides written notice to the recipient of such Biological Samples Raw Data (with a copy to GSK) that such Biological Samples Raw Data is GSK's Confidential Information.

(iii) In the event that Investigator desires to conduct further research in collaboration with GSK with respect to such Biological Samples Raw Data, GSK agrees to consider any such request. Any such further research agreed upon by GSK shall be subject to the terms of a separate research agreement.

**13. INDEPENDENT CONTRACTOR**

The relationship of the parties is that of independent contractors. Neither party is the partner, joint venturer, or agent of the other and neither party has authority to make any statement, representation, commitment, or action of any kind which purports to bind the other without the other's prior written authorization.

**14. USE OF PARTIES' NAMES**

To the extent required by law or regulation and except as set forth in Section 8 – STUDY TRANSPARENCY AND PUBLICATION above, neither party shall make (or have made on its behalf) any oral or written release of any statement, information, advertisement or publicity in

connection with this Master Agreement, any Study Specific Agreement, or a Study, which uses the other party's name, symbols, or trademarks without the other party's prior written approval.

## **15. NOTICES**

All notices under this Master Agreement or a Study Specific Agreement shall be sent by registered or certified mail, postage prepaid, or by overnight courier service. Notices pertaining to a Study will be sent to the Notices contact(s) as identified in the applicable Study Specific Agreement. Notices pertaining to this Master Agreement only shall be sent to:

***If to Institution:***

Institution contacts set forth in Exhibit B – TABLE OF INSTITUTION CONTACTS attached hereto

and

Head, Intellectual Property Section, Office of General Counsel  
The University of Texas System  
201 West 7<sup>th</sup> Street  
Austin, TX 78701  
Email: bmaxwell@utsystem.edu

***If to GSK:***

Judith A. Welsh, Contract Manager  
Study Start Up and Delivery US  
RD Projects Clinical Platforms & Sciences  
GlaxoSmithKline  
2301 Renaissance Boulevard  
Mailstop RN0310  
King of Prussia, PA 19406  
eMail: judith.a.welsh@gsk.com”

## **16. ASSIGNMENT AND SUBCONTRACTING**

GSK may assign (with written notice to Institution) its rights and duties under this Master Agreement or any Specific Study Agreement without Institution's consent. Any assignment or subcontracting of the performance of any obligations under this Master Agreement by Institution is valid only upon the prior written consent of GSK. In the event that GSK consents to such subcontracting by the Institution, the Institution (1) shall ensure that such subcontractor indemnifies GSK Indemnitees to the same extent as set forth in Section 10 (c) above and that such subcontracting does not limit or restrict GSK's indemnification of Institution Indemnitees as set forth in Sections 10 (a) above, and (2) will be responsible for the acts and omissions of its subcontractors. To the extent permitted above, this Master Agreement and each Study Specific Agreement shall be binding upon and inure to the benefit of the parties and their permitted successors and assigns.

**17. SEVERABILITY**

If any provision(s) of this Master Agreement or a Study Specific Agreement should be illegal or unenforceable in any respect, the legality and enforceability of the remaining provisions of this Master Agreement or the Study Specific Agreement shall not be affected.

**18. WAIVER; MODIFICATION OF AGREEMENT**

No waiver, amendment, or modification of any of the terms of this Master Agreement or a Study Specific Agreement shall be valid unless in writing and signed by authorized representatives of both parties. Failure by either party to enforce any rights under this Master Agreement or a Study Specific Agreement shall not be construed as a waiver of such rights nor shall a waiver by either party in one or more instances be construed as constituting a continuing waiver or as a waiver in other instances.

**19. GOVERNING LAW**

This Master Agreement and any Study Specific Agreement shall be governed by and interpreted in accordance with the laws of State of Texas.

**20. HUMAN RIGHTS**

Institution represents that, with respect to employment and conducting the Study under this Master Agreement and any Study Specific Agreement, Institution will:

- (a) not use child labor in circumstances that could cause physical or emotional impairment to the child;
- (b) not use forced labor (prison, indentured, bonded or otherwise);
- (c) provide a safe and healthy workplace; safe housing (if housing is provided by Institution to its employees); and access to clean water, food, and emergency healthcare in the event of accidents in the workplace;
- (d) not discriminate against employees on any grounds (including race, religion, disability or gender);
- (e) not use corporal punishment or cruel or abusive disciplinary practices;
- (f) pay at least the minimum wage and provide any legally mandated benefits;
- (g) comply with laws on working hours and employment rights;
- (h) respect employees' right to join and form independent trade unions;

(i) encourage subcontractors under this Agreement to comply with these standards;  
and,

(j) maintain a complaints process to address any breach of these standards.

## **21. EQUIPMENT**

(a) GSK may provide equipment to Institution under a Study Specific Agreement, including but not limited to, computer hardware and software if provided for the Investigator and Study Staff to use, collect, enter, and report Study data to GSK (respectively referred to herein as “Loaned Equipment” and “Transferred Equipment”).

(b) With respect to any equipment provided on loan to Institution by GSK and/or vendor designated by GSK for use in the Study, Institution agrees that no title to nor any proprietary rights related to the Loaned Equipment is transferred to Institution, that the Loaned Equipment will be used only for the Study and only as described in the Protocol and any other written directions provided by GSK, that the Loaned Equipment will not be transferred by Institution to the possession of any third party without the written consent of GSK and vendor, if applicable, and that, at the completion of the Study or at GSK’s request, Institution will return the Loaned Equipment and all related training materials and documentation to GSK or to vendor, at either GSK’s or vendor’s expense, as applicable.

(c) Investigator and Study Staff will attend scheduled training to use the loaned equipment following reasonable advance notice of scheduling. The Loaned Equipment will be kept in a safe and secure location and Institution will be responsible for any theft, damage, or loss to the loaned equipment due to Institution’s negligence, wrongful acts or acts of omissions, other than normal wear and tear. Institution will be responsible for arranging and paying for any required internet connection, telephone line, and/or facsimile line as necessary to use the Loaned Equipment. At the completion of the Study or at GSK’s request, Institution will return, at GSK’s or vendor’s expense, to GSK and/or vendor the Loaned Equipment and all Loaned Equipment related training materials and documentation. If the Institution fails to return the Loaned Equipment due to the Institution’s negligence, wrongful acts, or acts of omissions, within the timeframe specified by GSK, Institution will be responsible for reimbursing GSK for any penalties, late fees, and/or replacement costs (“Costs”). It is the responsibility of the Institution to promptly inform GSK if the Institution is unable to return all Loaned Equipment to GSK due to the above-stated reasons and to reimburse GSK for the Costs.

(d) Institution acknowledges that the Loaned Equipment may involve valuable patent, trademark, trade name, trade secret, and other proprietary rights of the Loaned Equipment manufacturer. Institution will not violate and will take appropriate steps and precautions to ensure that those with access to the Loaned Equipment do not violate these proprietary rights, including, without limitation:

(i) not removing any label or notice of Loaned Equipment ownership or other rights,

(ii) not making any copy, reproduction, changes, modification, or alteration of any software or firmware included with the Loaned Equipment or

(iii) not disassembling or decompiling any such software or firmware or otherwise attempting to discover any source code or trade secret related to such software or firmware.

(e) With respect to any Transferred Equipment necessary for use in the Study provided to Institution by GSK, GSK and Institution hereby agree that title to and ownership of the Transferred Equipment is transferred to Institution as of the execution of the Study Specific Agreement, Institution agrees that the value of the Transferred Equipment is part of Institution's compensation for the Study, and that the compensation otherwise described in the Study Specific Agreement has been adjusted accordingly. The description of the Transferred Equipment and its value shall be described in the Study Specific Agreement. Investigator and Study Staff will attend scheduled training to use the Transferred Equipment following reasonable advance notice of scheduling. The Transferred Equipment will be kept in a safe and secure location and, as owner of the Transferred Equipment, Institution will be responsible for maintenance of the Transferred Equipment and for any theft, damage, or loss to the Transferred Equipment. Institution will be responsible for arranging and paying for any required internet connection, telephone line, and/or facsimile line as necessary to use the Transferred Equipment.

## **22. ANTI-BRIBERY AND ANTI-CORRUPTION**

Institution agrees to the terms of Exhibit C attached hereto.

## **23. STATE AGENCY LIMITATIONS**

Institution is an agency of the State of Texas and under the Constitution and laws of the State of Texas possesses certain rights and privileges, is subject to certain limitations and restrictions, and only has such authority as is granted to it under the Constitution and laws of the State of Texas. Notwithstanding any provision hereof, nothing in this Master Agreement is intended to be, nor will it be construed to be, a waiver of the sovereign immunity of the State of Texas or a prospective waiver or restriction of any of the rights, remedies, claims, and privileges of the State of Texas. Moreover, notwithstanding the generality or specificity of any provision hereof, the provisions of this Master Agreement as they pertain to Institution are enforceable only to the extent authorized by the Constitution and laws of the State of Texas; accordingly, to the extent any provision hereof conflicts with the Constitution or laws of the State of Texas or exceeds the right, power or authority of Institution to agree to such provision, then that provision will not be enforceable against Institution or the State of Texas.

**24. ENTIRE AGREEMENT**

This Master Agreement, in conjunction with separate Study Start-up Agreements (or Master Study Start-up Agreements with certain member Institutions) and the individual Study Specific Agreements entered into under this Master Agreement, represents the entire and integrated agreement between the parties and supersedes all prior negotiations, representations or agreements, either written or oral, regarding its subject matter, including the Master Clinical Study Agreement entered into between the parties effective November 10, 2003, Amendment #1 thereto effective April 6, 2005, and Amendment #2 thereto effective September 18, 2006. This Master Agreement and any Study Specific Agreement may be executed in one or more counterparts, each of which shall be deemed an original and all of which shall constitute the same instrument.

**IN WITNESS WHEREOF**, the parties have acknowledged their consent and agreement to this Master Agreement with November 24, 2014 as an Effective Date (as stated in the Preamble) by executing below.

**GLAXOSMITHKLINE LLC**

Judith Welsh

**SAFE**

Reason: I am signing this document as author and attest to its accuracy, completeness and integrity  
Date: 2014-12-18 08:36:45 -0500

<sup>1</sup> Facsimile of Original Digital Signature

Judith A. Welsh  
Contract Manager  
ICG-Investigator Contracts Group  
SSO-Study Start Optimization

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

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

Name:

Title:

Date: \_\_\_\_\_

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

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

Name:

Title:

Date: \_\_\_\_\_

***(SIGNATURES CONTINUE ON NEXT PAGE)***

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Judith A. Welsh  
Contract Manager  
ICG-Investigator Contracts Group  
SSO-Study Start Optimization

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

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

Name: David Anderson  
Title: Director, Pre-Award Services

Date: 12/19/14 \_\_\_\_\_

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

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

Name:  
Title:

Date: \_\_\_\_\_

***(SIGNATURES CONTINUE ON NEXT PAGE)***

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**GLAXOSMITHKLINE LLC**

Judith Welsh

**SAFE**  
Reason: I am signing this document as author and attest to its accuracy, completeness and integrity  
Date: 2014-12-18 08:36:45 -0500

<sup>1</sup> Facsimile of Original Digital Signature

Judith A. Welsh  
Contract Manager  
ICG-Investigator Contracts Group  
SSO-Study Start Optimization

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

By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_  
Date: \_\_\_\_\_

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

By: \_\_\_\_\_ Digitally signed by  
Name: Karen Niemeier karen.niemeier@uth.tmc.edu  
Title: Karen S. Niemeier DN:  
Date: Director, Contracts cn=karen.niemeier@uth.tmc.edu  
Sponsored Projects Administration Date: 2014.12.19 15:09:16  
-06'00'

**(SIGNATURES CONTINUE ON NEXT PAGE)**

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

By: Chris G. Green

Name: Chris G. Green, CPA

Title: Director, Office of Sponsored Programs

Date: 05 January 2015

**THE UNIVERSITY OF TEXAS MEDICAL  
BRANCH AT GALVESTON**

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

Name:

Title:

Date: \_\_\_\_\_

**THE UNIVERSITY OF TEXAS  
SOUTHWESTERN MEDICAL CENTER**

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

Name:

Title:

Date: \_\_\_\_\_

**THE UNIVERSITY OF TEXAS AT  
AUSTIN**

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

Name:

Title:

Date: \_\_\_\_\_

***(END OF SIGNATURES)***

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

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

Name:

Title:

Date: \_\_\_\_\_

**THE UNIVERSITY OF TEXAS MEDICAL  
BRANCH AT GALVESTON**

By: Angela Cook

Name: ANGELA Cook

Title: DIRECTOR, OFFICE OF CLINICAL RESEARCH

Date: 12/19/2014

**THE UNIVERSITY OF TEXAS  
SOUTHWESTERN MEDICAL CENTER**

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

Name:

Title:

Date: \_\_\_\_\_

**THE UNIVERSITY OF TEXAS AT  
AUSTIN**

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

Name:

Title:

Date: \_\_\_\_\_

***(END OF SIGNATURES)***

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

By: \_\_\_\_\_  
Name:  
Title:

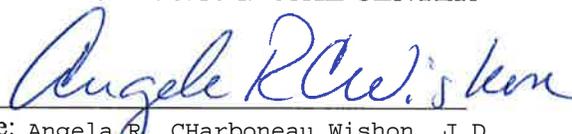
Date: \_\_\_\_\_

**THE UNIVERSITY OF TEXAS MEDICAL  
BRANCH AT GALVESTON**

By: \_\_\_\_\_  
Name:  
Title:

Date: \_\_\_\_\_

**THE UNIVERSITY OF TEXAS  
SOUTHWESTERN MEDICAL CENTER**

By:   
Name: Angela R. Charboneau Wishon, J.D.  
Title: Vice President for Research Administration

Date: 12-19-2014

**THE UNIVERSITY OF TEXAS AT  
AUSTIN**

By: \_\_\_\_\_  
Name:  
Title:

Date: \_\_\_\_\_

***(END OF SIGNATURES)***

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

By: \_\_\_\_\_  
Name:  
Title:  
  
Date: \_\_\_\_\_

**THE UNIVERSITY OF TEXAS MEDICAL  
BRANCH AT GALVESTON**

By: \_\_\_\_\_  
Name:  
Title:  
  
Date: \_\_\_\_\_

**THE UNIVERSITY OF TEXAS  
SOUTHWESTERN MEDICAL CENTER**

By: \_\_\_\_\_  
Name:  
Title:  
  
Date: \_\_\_\_\_

**THE UNIVERSITY OF TEXAS AT  
AUSTIN**

By:  \_\_\_\_\_  
Name: Mr David Hawkins, Associate Director  
Title: Office of Sponsored Projects  
The University of Texas at Austin  
Date: 12.19.2014

***(END OF SIGNATURES)***

## EXHIBIT A - STUDY SPECIFIC AGREEMENT

This STUDY SPECIFIC AGREEMENT (“Study Specific Agreement”) is effective on the last date of signature below, between [Insert only the applicable UT Institution of the following: **The University of Texas Health Science Center at Tyler, The University of Texas Health Science Center at Houston, The University of Texas Health Science Center at San Antonio, The University of Texas Medical Branch at Galveston, The University of Texas at Austin, OR The University of Texas Southwestern Medical Center**] (“Institution”) and GlaxoSmithKline LLC (“GSK”).

**BACKGROUND.** GSK and Institution are parties (or are Affiliates of the parties) to a Restated and Amended Master Clinical Study Agreement effective November 24, 2014 (the “Master Agreement”) which supersedes and fully replaces the Master Clinical Study Agreement effective November 10, 2003 and as amended by Amendment #1 to Master Clinical Study Agreement effective April 6, 2005, and Amendment #2 to Master Clinical Study Agreement effective September 18, 2006. Under the Master Agreement, GSK and Institution are executing this Study Specific Agreement to contract for the following Study.

1. **THE STUDY.** Institution agrees to perform the Study described below.

STUDY TITLE AND PROTOCOL NUMBER: «Study\_Title»

INVESTIGATOR’S NAME: «PI\_First\_Name» «PI\_Last\_Name», M.D.

INSTITUTION’S ENROLLMENT MAXIMUM: «Site\_specific\_max\_enrollment» subjects

INSTITUTION’S TAX ID NUMBER: [Insert Tax ID for specific UT Institution from Exhibit B below]

TARGET ENROLLMENT END DATE: «Enroll\_End\_Date»

TARGET VISITS COMPLETED DATE: «Visits\_by»

CRF TARGET DATE: «CRF\_Data\_by»

2. **ENROLLMENT.** The following Enrollment plan will apply to the Study:

(a) Institution will use its best reasonable endeavors to enroll «Insert\_Number\_of\_Subjects» Study subjects to participate in the Study in accordance with the Study timelines as set forth in Section 1 above. [Adjust or remove only the following sentence for the applicable Study] With the express, written pre-approval of GSK, Institution may enroll beyond these «Insert\_Number\_of\_Subjects» randomized subjects up to **Institution’s Enrollment Maximum**. Subject enrollment shall be completed on or before the **Target Enrollment End Date**. Upon written notice to Institution, GSK may at any time reduce this **Enrollment Maximum** or end enrollment at Institution at any time at GSK’s discretion, including, but not limited to, upon the completion of the overall Study enrollment goal across all Study centers. The parties agree that such written notice hereunder may be provided to Institution and Investigator in email. Institution will not enroll more Study subjects than **Institution’s Enrollment Maximum** and GSK will not be obligated to make any payment with respect to any subject enrolled in excess of **Institution’s Enrollment Maximum**. Without any

obligation to do so, the parties may agree to increase **Institution's Enrollment Maximum** by amendment to this Agreement executed by the authorized representative of each party.

(b) All subject visits will be completed no later than **Target Visits Completed Date**. All case report form ("CRF") information associated with a Study subject's visit must be satisfactorily completed **within «days\_CRF\_completed» business days** after the Study subject's visit, after receipt of data queries or, if applicable, receipt of the Study subject's test results. Notwithstanding the foregoing, GSK may require shortened timings during interim analysis or Study closeout periods. All final CRF data will be entered into the CRF and submitted to GSK no later than the **CRF Target Date**.

(c) The target dates as set forth in Section 1 above and as referenced in this Section 2, are projected Study milestones subject to change by GSK. GSK shall promptly communicate any target date update(s) to Institution and Investigator without the necessity of modifying this Study Specific Agreement.

### **3. COMPENSATION**

(a) In consideration for conducting the Study, GSK shall pay Institution the Per Patient Budget covering Study visits, procedures, or other work associated with a Study subject in accordance with Exhibit 1 attached and incorporated by reference as part of this Study Specific Agreement.

#### **EXCEPT AS SET FORTH HEREUNDER, COMPENSATION SUBSECTIONS WILL VARY ACCORDING TO STUDY**

(e) All checks shall be made payable to Institution, as identified on the Federal Tax Form W-9 provided by Institution. Institution represents and certifies that such entity is the appropriate entity to receive payments under this Agreement.

Mailing address for checks (if different from mailing address on Federal Tax form W-9):

U.S. Mail:

[UT Institution: Insert applicable Institution address and contact, if any]

FedEx or Other Courier:

[UT Institution: Insert applicable Institution address and contact, if any]

(f) For all items requiring an invoice, payments will be made following receipt of Institution's invoice. Invoices must be originals or copies of original invoices (e.g., scanned to .pdf), must be submitted to GSK in accordance with GSK invoice instructions provided to Institution contemporaneously with this Agreement, and for pass through costs, must be accompanied by the invoice from the third party providing the service(s) for the Study.

(g) In the event that Investigator or Study Staff are required to travel in connection with a Study (e.g., to an Investigator meeting), GSK will reimburse Institution for all necessary and reasonable out-of-pocket expenses (including, but not limited to, meals, travel, and lodging) that are pre-approved by GSK in writing or, in GSK's discretion, arrange and provide such items directly. GSK shall reimburse appropriate expenses after receipt of an invoice and supporting documentation.

4. **TERM; TERMINATION.** This Study Specific Agreement shall continue until the Study is completed or until terminated as provided in the Master Agreement.

5. **INCORPORATION BY REFERENCE.** The terms and conditions of the Master Agreement and the Protocol, as approved by GSK, Investigator, and the responsible Institutional Review Board (along with any subsequently approved amendments to the Protocol), are hereby incorporated by reference into and made a part of this Study Specific Agreement. All defined terms in the Master Agreement shall have the same meaning when used in this Study Specific Agreement.

6. **NOTICES.** Notices applicable to this Study Specific Agreement shall be sent to:

If to GSK:

The GSK Study Manager as referenced in the Study Reference Manual

If to Institution for administrative matters:

[UT Institution: Insert applicable Institution contact, address, phone/fax/email]

If to Institution for clinical matters:

«PI\_First\_Name» «PI\_Last\_Name», M.D.

[Insert PI address, phone/fax/email]

7. **TRANSFERRED EQUIPMENT.** [If no Transferred Equipment is provided, please insert N/A in place of the fields below] In accordance with the terms of the Master Agreement, the following Transferred Equipment shall be provided to Institution by GSK for use in the conduct of the Study: «List\_Transferred\_Equipment». The Transferred Equipment is valued at \$«Insert\_Transferred\_Equipment\_value».

8. **ENTIRE AGREEMENT.** This Study Specific Agreement represents the entire and integrated agreement between Institution and GSK and supersedes all prior negotiations, representations or agreements, either written or oral, regarding the Study.

GLAXOSMITHKLINE LLC

[INSERT THE APPLICABLE INSTITUTION  
NAME]

Master CSA for GSK-Initiated Protocols - Phases I, II, III, IV

Effective Date November 24, 2014; effective until November 24, 2021 (7 years, see Section 4a)

«GSK\_Signatory»  
«GSK\_Signatory\_Title»

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

Name:

Title:

Date: \_\_\_\_\_

**INVESTIGATOR**

By my signature I indicate that Institution has made the Master Agreement available to me and that I am aware of its terms and also indicate my agreement to fulfill the role and obligations of Investigator under this Study Specific Agreement and Master Agreement and consent to the disclosure by GSK of my name and of Study payments to the institution(s) with which I am affiliated in publicly accessible Study registers.

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

«PI\_First\_Name» «PI\_Last\_Name», M.D.

Date: \_\_\_\_\_

**EXHIBIT B - TABLE OF INSTITUTION CONTACTS**

<p>David Anderson Director, Office of Pre-Award Services</p> <p><b>The University of Texas Health Science Center at Tyler</b> 11937 U.S. Hwy. 271 Tyler, TX 75708-3154</p> <p>Phone: 903-877-7486 Fax: 903-877-7558</p> <p><b>Tax ID: 75-6001354</b></p>	<p>Chris Green Director, Office of Sponsored Programs</p> <p><b>The University of Texas Health Science Center at San Antonio</b> 7703 Floyd Curl Dr, Mail Code 7828 San Antonio, TX 78229-3900</p> <p>Phone: 210-567-2340 Fax: 210-567-8107</p> <p><b>Tax ID: 74-1586031</b></p>
<p>Karen Niemeier Director, Contracts</p> <p><b>The University of Texas Health Science Center at Houston</b> P.O. Box 20036 Houston, TX 77225</p> <p>Overnight address: 7000 Fannin Street, Suite 1006 Houston, TX 77030</p> <p>Phone: 713-500-3999 Fax: 713-383-3746</p> <p><b>Tax ID: 74-1761309</b></p>	<p>Angela R. Charboneau Wishon, J.D. Vice President for Research Administration</p> <p><b>The University of Texas Southwestern Medical Center</b> 5323 Harry Hines Blvd. Dallas, Texas 75390-9016</p> <p>Phone: 214-648-6449 Fax: 214-648-4474</p> <p><b>Tax ID: 75-6002868</b></p>
<p>Angela Cook Director Office of Clinical Research</p> <p><b>The University of Texas Medical Branch at Galveston</b> Office of Sponsored Projects 301 University Boulevard 4.400 Rebecca Sealy Hospital Galveston, TX 77555-0156</p> <p>Phone: 409-772-1978 Fax: 409-772-1968</p> <p><b>Tax ID: 74-6000949</b></p>	<p>David Hawkins Associate Director Office of Sponsored Projects</p> <p><b>The University of Texas at Austin</b> North Office Bldg., Suite 5.300 Austin, TX 78712</p> <p>Phone: 512-471-6424 Fax: 512-471-6564</p> <p><b>Tax ID: 74-6000203</b></p>

**EXHIBIT C**  
**GSK ANTI-BRIBERY AND ANTI-CORRUPTION TERMS**

1. Institution acknowledges receipt of the GSK ‘Prevention of Corruption – Third Party Guidelines’ included in this Exhibit C and agrees to perform its obligations under this Master Agreement and any Study Specific Agreement in accordance with the principles set out therein.
2. Institution shall comply fully at all time with all applicable laws and regulations, including but not limited to applicable anti-corruption laws, of the territory in which the Institution conducts business with GSK.
3. Institution agrees that it has not, and it will not, in connection with the performance of this Master Agreement or any Study Specific Agreement, directly or indirectly promise, authorize, ratify or offer to make, or take any act in furtherance of any payment or transfer of anything of value for the improper purpose of influencing, inducing, or as a reward for, any act, omission or decision to secure an improper advantage or to improperly assist Institution or GSK in obtaining or retaining business. It is the intent of the parties that no payments or transfers of value shall be made, promised, authorized, ratified or offered with the purpose or effect of public or commercial bribery, acceptance of or acquiescence in extortion, kickbacks or other unlawful or improper means of securing an improper advantage or obtaining or retaining business.
4. Institution shall not knowingly contact or meet with any Government Official whose role is related to the funding or provision of healthcare or the regulation of GSK products for the purpose of discussing activities under this Master Agreement or any Study Specific Agreement, without prior notice to GSK.

For the purpose of this clause “Government Official” means: (a) any officer or employee of a government or any department, agency or instrument of a government; (b) any person acting in an official capacity for or on behalf of a government or any department, agency, or instrument of a government; (c) any officer or employee of a company or business owned in whole or part by a government; (d) any officer or employee of a public international organization such as the World Bank or United Nations; (e) any officer or employee of a political party or any person acting in an official capacity on behalf of a political party; and/or (f) any candidate for political office.

5. Institution represents that it has not been convicted of or pleaded guilty to a criminal offense, including one involving fraud or corruption, except as has been disclosed to GSK in writing, and that it is not now, to the best of its knowledge, the subject of any government investigation for such offenses except as has been disclosed to GSK in writing, and that it is not now listed by any government agency as debarred, suspended, proposed for suspension or debarment, or otherwise ineligible for government programs.
6. Institution represents and certifies that except as disclosed to GSK in writing: (1) it does not have any interest which directly or indirectly conflicts with its proper and ethical performance of this Master Agreement or any Study Specific Agreement; and (2) it shall maintain arms length

relations with all third parties with which it deals for or on behalf of GSK in performance of this Master Agreement or any Study Specific Agreement.

7. GSK shall have the right during the terms of this Master Agreement or any Study Specific Agreement to conduct an investigation and audit of Institution to monitor compliance with the terms of this Exhibit C. Institution shall cooperate fully with such investigation or audit, the scope, method, nature and duration of which shall be at the sole reasonable discretion of GSK.

8. Institution shall ensure that all transactions under any Study Specific Agreement are properly and accurately recorded in all material respects on its books and records and each document upon which entries such books and records are based is complete and accurate in all material respects. Institution must maintain a system of internal accounting controls reasonably designed to ensure that it maintains no off-the-books accounts.

9. Institution agrees that in the event that GSK believes that there has been a possible violation of the terms of this Exhibit C GSK may make full disclosure of such belief and related information at any time and for any reason to any competent government bodies and its agencies, and to whomsoever GSK determines in good faith has a legitimate need to know.

10. GSK shall be entitled to terminate this Master Agreement and any Study Specific Agreement immediately on written notice to the Institution, if Institution fails to perform its obligations in accordance with this Exhibit C. Institution shall have no claim against GSK for special damages by virtue of the termination of this Master Agreement or any Study Specific Agreement in accordance with this Exhibit C. To the extent (and only to the extent) that the laws of the territory provide for any such compensation to be paid to Institution for special damages upon the termination of this Master Agreement or any Study Specific Agreement, Institution hereby expressly agrees to waive (to the extent possible under the laws of the territory) or to repay to GSK any such compensation for special damages or indemnity.

### **PREVENTION OF CORRUPTION – THIRD PARTY GUIDELINES**

The GSK Anti-Bribery and Corruption (“ABAC”) Policy (POL-GSK-007) requires compliance with the highest ethical standards and all anti-corruption laws applicable in the countries in which GSK (whether through a third party or otherwise) conducts business. POL-GSK-007 requires all GSK employees and any third party acting for or on behalf of GSK to ensure that all dealings with third parties, both in the private and government sectors, are carried out in compliance with all relevant laws and regulations and with the standards of integrity required for all GSK business. GSK values integrity and transparency and has zero tolerance for corrupt activities of any kind, whether committed by GSK employees, officers, or third-parties acting for or on behalf of GSK.

**Corrupt Payments** – GSK employees and any third party acting for or on behalf of GSK, shall not, directly or indirectly, promise, authorize, ratify or offer to make or make any “payments” of “anything of value” (as defined in the glossary section) to any individual (or at the request of any individual) including a “government official” (as defined in the glossary section) for the

improper purpose of influencing or inducing or as a reward for any act, omission or decision to secure an improper advantage or to improperly assist the company in obtaining or retaining business.

**Government Officials** – Although GSK’s policy prohibits payments by GSK or third parties acting for or on its behalf to any individual, private or public, as a “quid pro quo” for business, due to the existence of specific anticorruption laws in the countries where we operate, this policy is particularly applicable to “payments” of “anything of value” (as defined in the glossary section), or at the request of, “government officials” (as defined in the glossary section).

**Facilitating Payments** – For the avoidance of doubt, facilitating payments (otherwise known as “greasing payments” and defined as payments to an individual to secure or expedite the performance of a routine government action by government officials) are no exception to the general rule and therefore prohibited.

## GLOSSARY

The terms defined herein should be construed broadly to give effect to the letter and spirit of the ABAC Policy. GSK is committed to the highest ethical standards of business dealings and any acts that create the appearance of promising, offering, giving or authorizing payments prohibited by this policy will not be tolerated.

**Anything of Value:** this term includes cash or cash equivalents, gifts, services, employment offers, loans, travel expenses, entertainment, political contributions, charitable donations, subsidies, per diem payments, sponsorships, honoraria or provision of any other asset, even if nominal in value.

**Payments:** this term refers to and includes any direct or indirect offers to pay, promises to pay, authorisations of or payments of anything of value.

**Government Official** shall mean:

- Any officer or employee of a government or any department, agency or instrument of a government;
- Any person acting in an official capacity for or on behalf of a government or any department, agency, or instrument of a government;
- Any officer or employee of a company or business owned in whole or part by a government;
- Any officer or employee of a public international organization such as the World Bank or United Nations;
- Any officer or employee of a political party or any person acting in an official capacity on behalf of a political party; and/or
- Any candidate for political office.

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Subject CN Judith Welsh  
Subject DN CN=Judith Welsh,OU=0976d8e5-ce1d-410c-a9b6-afbee9512fad,O=GlaxoSmithKline,C=US  
Email judi.a.welsh@gsk.com  
Serial # 65494179762387071272609286310644447865659057766  
Issuer DN CN=Trans Sped SAFE CA III,OU=Individual Subscriber CA,O=Trans Sped SRL,C=RO  
Signing Time 2014-12-18 08:36:45 -0500  
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 The Certificate chain was successfully built to a Trusted Root Certificate.

 The Signer's identity is valid.

 The Document has not been modified since the signature was applied.

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