

## **MASTER CLINICAL STUDY AGREEMENT**

This MASTER CLINICAL STUDY AGREEMENT (this "Master Agreement") is effective November 10, 2003 (the "Effective Date") between SmithKline Beecham Corporation, doing business as GlaxoSmithKline ("GSK") and one of the following component institutions ("Institution" and collectively "Institutions") of The University of Texas System ("System") located at 201 West 7th Street, Austin, Texas 78701, that is governed by its Board of Regents ("Board") as named in Exhibit B: The University of Texas Health 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 M.D. Anderson Cancer Center, The University of Texas Medical Branch at Galveston, and The University of Texas Southwestern Medical Center at Dallas.

### **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 contracts 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.

### **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.

"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 a 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, or Study Staff: (1) as a direct result of a 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.

"Materials" means Study drug(s) and related devices, equipment, or other materials provided by GSK for the conduct of the Study.

"Protocol" means the written document that describes a Study and sets forth specific activities to be performed as part of Study conduct as set forth in Exhibit A, Study Specific Agreement Form (as defined below).

"Study" means a clinical study sponsored by GSK that utilizes a protocol written by GSK and/or GSK drugs and/or devices and conducted by Institution.

"Study Specific Agreement" means a written agreement between the parties or 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 (see Exhibit A

"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 a Study Specific Agreement shall apply to the GSK Affiliate that is a party to the Study Specific Agreement.

## **2. STUDY CONDUCT**

(a) Institution agrees to conduct any Study in strict compliance with:

(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"), FDA and 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 Materials only to conduct the Study in accordance with the Protocol; shall not chemically, physically or otherwise modify Materials, unless specifically required to do so by the Protocol; and shall handle, store, and ship or dispose

of Materials 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 Materials, 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 a Study.

(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. GSK acknowledges that this provision is intended to preserve the academic freedom and integrity of Institution and its faculty.

### **3. COMPENSATION**

(a) In consideration for conducting a Study, GSK shall pay Institution 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. 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 payment obligation is conditioned upon Institution's compliance with standards identified in this Master Agreement and the applicable Study Specific Agreement. GSK will not make payments for work associated with a Study subject if that subject's data is not evaluable because of a violation of the Protocol by Investigator or Study Staff.

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

(a) This Master Agreement shall take effect on the Effective Date and shall continue 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 Materials 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 in accordance with 21 CFR § 312.62 and applicable law or guidelines. Study record storage by Institution for up to five (5) years past the time required by applicable FDA regulations will be subject to reasonable storage fees. Notwithstanding the foregoing, Institution will not destroy such records without giving GSK prior written notice and the opportunity to further store such records at GSK.

(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 a 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 Principal 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 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 and Investigator acknowledge and agree 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 Institute 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. PUBLICATION**

(a) In the event GSK coordinates a publication or presentation of Study results from all Study sites (a "Multicenter Publication"), the participation of Investigator or other representatives of Institution as a named author shall be determined in accordance with generally accepted standards for authorship. If the Investigator or other representative of Institution is a named author of the Multicenter Publication, such person shall have access to the Study data from all Study sites as necessary to fully participate in the development of the Multicenter Publication.

(b) 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 an Invention, Institution agrees to and Investigator shall delay submitting the Institution Publication to any third party for up to sixty (60) days after GSK's written request. Institution and Investigator also agree 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 Institution. If Multicenter Publication is not submitted within twelve (12) months after conclusion of the Study at Institution, Institution will be free to publish.

(c) 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, formulation, or method of use or delivery, of any Materials, each without additional consideration from GSK.

(c) For any Invention not covered by Section 9(b) of this Master 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, 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 a 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 by the Constitution and the 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 attorneys fees), liability, damage, or claim by third parties for personal injury, including death, resulting from the negligent acts or omissions of Institution, its agents and 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) The obligations of this Section shall survive termination of this Master Agreement and any applicable Study Specific Agreement.

## **11. INSURANCE**

(a) Institution, as a component of System, is an agency of the State of Texas and is self-insured pursuant to The University of Texas System Professional Medical Malpractice Self-Insurance Plan, under the authority of Section 59.01, Texas Education Code. Institution has and will maintain in force during the term of this Agreement adequate insurance to cover its indemnification obligations hereunder

(b) GSK shall, through its self-insurance program, provide comprehensive general liability insurance in amounts not less than \$2,000,000.00 per incident. Such insurance shall provide (1) product liability coverage and (2) broad form contractual liability coverage. Upon written request, GSK shall provide Institution with written evidence of its self-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 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 (a) shall be treated by Institution as GSK Confidential Information under this Agreement, and (b) 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 (c) 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**

Except to the extent required by law, regulation or academic policy, 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 which shall not be unreasonably withheld.

**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 this Master Agreement shall be sent to:

If to Institution: See Name of Person in Exhibit B

If to GSK:  
Judith A. Welsh  
Global Resourcing, Grants and Contracts  
GlaxoSmithKline  
2301 Renaissance Blvd.  
King of Prussia, PA 19406

**16. ASSIGNMENT**

GSK may assign (with written notice to Institution) its rights and duties under this Master Agreement or any Study Specific Agreement without Institution's consent. Any assignment by Institution is valid only upon the prior written consent of GSK. 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 the State of Texas.

19. **ENTIRE AGREEMENT**

This Master Agreement, in conjunction with 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. 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.

SMITHKLINE BEECHAM CORPORATION  
d/b/a GLAXOSMITHKLINE

By: R. Cheetham  
Rosalind F. Cheetham  
Vice President, CDMA-NA  
Clinical Operations

Date: Nov 10 2003

THE UNIVERSITY OF TEXAS HEALTH  
CENTER AT TYLER

By: Rick Hefner  
Rick Hefner  
Vice President for Finance and  
Administration

Date: 12/4/03

THE UNIVERSITY OF TEXAS HEALTH  
SCIENCE CENTER AT HOUSTON

By: Catherine Moore  
~~Kathryn A. Bradley~~ Catherine Moore, Director  
~~Senior Grants/Contracts Specialist~~  
Office of Sponsored Projects

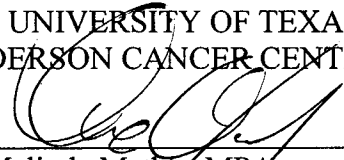
Date: 11-21-03

THE UNIVERSITY OF TEXAS HEALTH  
SCIENCE CENTER AT SAN ANTONIO

By: Jane A. Younger  
Jane A. Younger  
Director, Grants Management

Date: 11-24-03

THE UNIVERSITY OF TEXAS M.D.  
ANDERSON CANCER CENTER

By:   
~~Melinda Mathis, MPA~~ Leonard A. Zwelling, M.D.  
Director, Sponsored Programs and Compliance M.B.A.  
Vice President for Research Administration

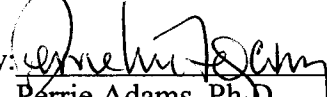
Date: NOV 19 2003

THE UNIVERSITY OF TEXAS  
MEDICAL BRANCH AT GALVESTON

By:   
~~Lively Williams~~ Barbara DeHaven, M.P.A.  
Clinical Trial Specialist  
Director of Sponsored Research

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

THE UNIVERSITY OF TEXAS  
SOUTHWESTERN MEDICAL CENTER  
AT DALLAS

By:   
Perrie Adams, Ph.D.  
Associate Dean for Research

Date: 12/1/03

Approved as to Form  
  
UTMB Contract Mgr.