fully executed

Bristol-Myers Squibb
Pharmaceutical Research Institute

P.O. Box 4000 Princeton, NJ 08543-4000 609 252-4000

Ann Damsgaard
Director
Strategic Planning
(609) 252-4773
Fax (609) 252-7274

June 25, 1998

BethLynn Maxwell, Ph.D.
The University of Texas System
Office of General Counsel
201 West Seventh Street
Austin, Texas 78701-2981

Dear BethLynn:

I have enclosed a fully executed copy of the master agreement between Bristol-Myers Squibb and the various University of Texas System institutions.

Thank you for all your assistance in expediting this agreement.

Sincerely,

Ann

Ann Damsgaard

OFFICE OF GENERAL COUNSEL
The University of Texas System
201 West 7th Street
Austin, Texas 78701
Telephone (512) 499-4337 Fax (512) 499-4523

Michael Brooks
Legal Assistant

November 6, 2003

FACSIMILE

TO: Chris

FROM: Michael

SUBJECT: BMS

PAGES: 37 (Including Cover)

Chris:

Per your request, please find the BMS documents attached.

If you have any questions, give us a call.

Michael

MASTER CLINICAL TRIAL AGREEMENT

THIS AGREEMENT is made and entered into as of June 23, 1998 (hereinafter "Effective Date") by and between **BRISTOL-MYERS SQUIBB PHARMACEUTICAL RESEARCH INSTITUTE**, a division of E.R. Squibb & Sons, Inc., a Delaware corporation, having a place of business at Route 206 and Province Line Road, Princeton, NJ 08543-4000 (hereinafter *"BMS"*), and each of **The University of Texas Health Sciences Center at San Antonio, The University of Texas Health Science Center at Houston, The University of Texas - M.D. Anderson Cancer Center, The University of Texas Southwestern Medical Center at Dallas, The University of Texas Medical Branch at Galveston, and The University of Texas Health Center at Tyler** (each an "*Institution*"), each with an office and place of business as set forth on *Schedule 1.1(a)* hereto and each a component of The University of Texas System located at 201 West 7th Street, Austin, Texas 78701.

RECITALS

WHEREAS, BMS conducts business in the research, development, manufacture and sale of pharmaceutical, nutritional and healthcare products, and

WHEREAS, BMS desires to enter into a master agreement with each Institution to cover the conduct of one or more clinical studies at such Institution under specific protocols involving BMS investigational drugs, as each such Institution and BMS may mutually agree upon hereafter in writing, and each Institution desires to enter into same, said trials being ones that will advance each such Institution's educational and research purposes.

NOW, THEREFORE, subject to the terms, conditions and covenants hereinafter set forth, Institution and BMS agree as follows:

Article 1 - Master Contract; The Studies

1.1 General. (a) The purpose of this Agreement is to establish a master contract between BMS and each Institution for the conduct of clinical studies at such Institution. Such studies are ones that will be sponsored by BMS and will involve BMS's investigational study drugs (and which, in applicable cases, may involve comparators, such as placebo and drugs of third parties that have been approved for the indication being studied). Each such clinical study ("*Study*") shall be evidenced by a protocol for such Study (each such protocol, as it may be amended or supplemented from time to time thereafter, is referred to hereinafter as a "*Study Protocol*").

The parties acknowledge that they intend that only such clinical studies for which the conception for the Study Protocol originated completely with BMS or with third parties under contract with BMS (other than Institution or an Institution employee) shall be covered by this Master Agreement. In the event that Institution believes that any of its investigators should be considered as having conceived, in whole or in part, a clinical study that BMS desires to sponsor at Institution, Institution shall be free to raise that issue and to request that the parties enter into a separate clinical trial agreement for such study that is outside the scope of this Agreement and which may protect the parties intellectual property rights different than as contemplated in this Master Agreement (the terms of such separate agreement shall be as the same may be negotiated and mutually agreed to at such time). To avoid ambiguity and clarify any doubt the parties agree that BMS shall be considered the sole owner of all rights in and to the conception for a Study

(including as to any novel indication, use, form of administration, or dosage for a Study drug as the same may be reflected in the Study Protocol) and the related Study Protocol for those Studies conducted under a Study Letter Agreement entered into pursuant to this Master Agreement.

(b) In order for the parties hereto to be bound to sponsor and conduct a Study, Institution and BMS must have jointly prepared, agreed upon, and duly executed a study letter agreement consistent with the terms of this Agreement and in the format attached as *Schedule 1.1(b)* hereto (each such study letter agreement, as it may be amended or supplemented from time to time by mutual written agreement of the parties, is hereinafter referred to as a "*Study Letter Agreement*"). This Agreement shall be deemed to apply to each such Study Letter Agreement so executed as fully and with like effect as though this Agreement were re-executed at the time each such Study Letter Agreement is executed.

(c) Each Study Letter Agreement shall contain (1) the name of the protocol, (2) the name of the investigator ("*Investigator*") for the Study at each participating Institution where an Investigator will be supervising the conduct of the Study, as well as any subinvestigators participating in the Study under the direction of the Investigator (to the extent known at such time), (3) the anticipated duration of the Study and the number of completed subjects that each such Institution expects for the Study with such Investigator; (4) the maximum grant (including the individual procedures costs and other assumptions on which such maximum grant is determined), schedule of payments, and other related terms and conditions of the Study budget (including any amounts to be paid or refunded upon early termination of a Study), and (5) any other terms and conditions pertinent to the individual Study. If any provisions of any such Study Letter Agreement should conflict with any provisions set forth in this Agreement, the provisions of this Agreement shall take precedence, unless such Study Letter Agreement expressly refers to the provision(s) of this Agreement that it is intended to replace or modify (and which change shall be limited in force and effect to such Study Letter Agreement only). A separate Study Letter Agreement shall be executed for each Investigator participating in the Study at each Institution.

(d) Each Study shall be conducted in accordance with the applicable Study Letter Agreement, generally accepted standards of good clinical practice, and the applicable Study Protocol approved by Institution's human subject Institutional Review Board ("IRB"). Changes to a Study Protocol may be made (i) in accordance with procedures outlined in such Study Protocol, or (ii) by agreement of Institution, BMS and the applicable Investigator. Changes to a Study Protocol shall be accompanied by such notification, review and/or approval of the IRB as may be required by applicable law and/or the Study Protocol.

(e) The Investigator named in a Study Letter will supervise the conduct of such Study at the sites indicated in the Study Letter, and shall be responsible for leading any subinvestigators at such sites. If the named Investigator under a Study Letter Agreement should become unable to complete a Study at the applicable Institution, such Institution shall consult with BMS regarding the appointment of a new Investigator and if both parties cannot agree on a substitute, all further enrollment of subjects into that Study pursuant to that Study Letter Agreement at such Institution shall immediately cease.

(f) The Investigator(s) and any such subinvestigators participating in a Study are referred to hereinafter, collectively, as the "*Participating Investigators*".

1.2 Determination of Interest. BMS will endeavor to inform each Institution about its upcoming multi-center, Phase II or III clinical studies that are being planned for the United States as BMS begins

considering site selection; however, BMS shall be under no express or implied obligation to do so. Subject to Section 1.1, after it is determined by BMS and Institution that Institution and its investigators have therapeutic experience pertinent to a given clinical study, BMS will forward a copy of the proposed Study Protocol outline, including the anticipated study initiation date, to the Office of Clinical Trials at the selected Institution(s). Institution's Office of Clinical Trials will perform the following within two (2) weeks of receipt of a proposed Study Protocol outline:

(i) Forward the proposed Study Protocol outline to appropriate investigators to determine each such investigator's capability and interest in conducting the proposed trial. Any further information pertaining to a proposed Study, including a copy of the proposed Study Protocol, will be provided only if the investigator shall first have agreed in writing with BMS to hold such information in confidence in accordance with Article 5 hereof.

(ii) Forward to BMS (A) the list of names and addresses of Institution's investigators that it proposes to use in the proposed Study, and (B) a current and up-to-date curriculum vitae for each such physician and their current institutional affiliations.

BMS will endeavor to notify Institution within two (2) weeks of receipt of such list (a) whether some, all or none of the prospective physicians included on such list are acceptable for consideration and (b) whether BMS will accept such nominated individual(s) for consideration as the Investigator (s) at such Institution (as well as any other individuals nominated to serve as Participating Investigator's under the Investigator's supervision at such Institution), and if BMS is so interested, the parties will use reasonable efforts thereafter to finalize one or more Study Letter Agreements, as applicable, as promptly as practicable thereafter.

1.3 Study Initiation Activities and Execution of Study Letter Agreement. Within two (2) months after BMS has (i) notified an Institution of its interest in a given Study (as provided in section 1.2 above), (ii) provided such Institution with the Study Protocol for such Study, and (iii) provided preliminary approval for specific investigators, such Institution will use its best efforts to complete the Study Initiation Activities, and to finalize and forward the clinical trial package documents to BMS, as provided on and in accordance with *Schedule 1.3* attached hereto.

Notwithstanding the activities contemplated by this Section 1.3, no party shall be under any obligation, express or implied, to conduct a Study unless and until the corresponding Study Letter Agreement has been executed by all parties thereto, and no party hereto shall be under any obligation, express or implied, to execute any particular Study Letter Agreement.

1.4 General Duties of the Parties in Conducting a Study. Each participating Institution, BMS, and each Participating Investigator shall comply with their respective obligations under a Study Protocol, the Study Letter Agreement, and with all applicable laws, rules, regulations and other governmental requirements in the performance and documentation of a Study. Each participating Institution represents that its Participating Investigators and all other Study personnel that may perform services hereunder shall be its employees and shall abide by the terms and conditions of this Agreement as if each were a party hereto. Without in any way limiting the foregoing, these obligations shall include the following:

(a) The Participating Investigators shall, in compliance with applicable governmental requirements and a Study Protocol, prepare, document and maintain records and case histories on case report forms supplied by BMS, retain such data and records after completion of the Study, and obtain advance

informed consent from each of the subjects (or their duly authorized representatives) participating in a Study.

(b) A Participating Investigator shall notify BMS of any adverse reaction in the course of each Study of which he/she becomes aware in accordance with the Study Protocol and applicable governmental requirements.

(c) Upon reasonable notice and at reasonable times during the term of this Agreement, each Institution will, and will cause its Participating Investigators to, permit representatives of BMS and applicable regulatory agencies to examine their respective facilities during appropriate business hours, to validate case reports against original data in their files (where duly approved in the informed consent or otherwise permitted under applicable law), to make copies of relevant records (exclusive of patient identifying information) and monitor the work performed hereunder, and to determine the adequacy of the facilities and whether a Study is being conducted in compliance with this Agreement, the Study Letter Agreement, and relevant legal requirements.

(d) Each Participating Investigator shall keep appropriate records of Study drug (whether it be BMS's investigational drug, placebo, or a comparator drug) received, dispensed, used, and returned in accordance with applicable law and the Study Protocol.

1.5 Study Drug Supplies. BMS shall provide, without cost to Institution, sufficient amounts of the Study drug (and any comparators contemplated by the Study Protocol, such as placebos or other investigational or approved drugs) to conduct each Study. Institution and any Participating Investigator may not use or dispose of the Study drug and any such comparators in any way other than as specified in such Study's Protocol, and upon completion of a Study, shall return to BMS or destroy any remaining supplies in accordance with the Study Protocol (other than such bioavailablity and bioequivalence test samples as Institution may be required to retain under applicable law).

1.6 Coordinators. BMS and Institution will identify a single contact from each organization to call for questions concerning the implementation of this Agreement. These contacts are as follows:

Traci G. Dalton, Associate Director
Worldwide Clinical Operations
Bristol-Myers Squibb
Pharmaceutical Research Institute
5 Research Parkway
Wallingford, CT 06492
(203) 284-6217 phone
(203) 284-6090 fax

See *Schedule 1.6* for the individual contacts for each Institution

Each party may change its contact upon written notice to the other. If applicable, each Institution will also identify a separate contact person to be responsible for all administrative support at such Institution participating in a given Study to handle administrative details (such as IRB support and approvals, the provision of laboratory normals and certifications, Participating Investigator curriculum vitae, etc.).

Article 2 - Study Budgets

2.1 Study Budget - General.

(a) All funds to be paid by BMS for the conduct of any Study shall be paid by BMS to Institution in accordance with each Study's budget ("*Study Budget*") as attached to its respective Study Letter Agreement, as such Study Budget is determined in accordance with this Article 2 for the conduct of the Study. Institution shall be solely responsible for the determination and payment of all fees, compensation, cost reimbursements, and other payments due to any Participating Investigators and other Study personnel and contractors used by Institution to perform any services connected with the conduct of a Study.

Institution will accomplish and complete a Study within the maximum budget set forth on the related Study Letter Agreement, and will not commit to any expenses in excess of such maximum amount without BMS's prior written consent. If, prior to completion of the Study, this Agreement is terminated in accordance with the Article 7 hereof, BMS shall pay such amount as shall be determined pursuant to section 2.5 hereof. Each party agrees to discuss budgetary matters with the other party as either party may request from time to time.

(b) Except for the funds to be provided by BMS as set forth in the Study Letter Agreement for a Study or as may be otherwise mutually agreed in writing, Institution shall arrange and pay for all necessary laboratory and other facilities, equipment, supplies (other than the Study drug), and physicians and clinical support staff required to discharge its obligations under a Study.

(c) All matters of compensation, benefits and other terms of engagement of any nature for the Participating Investigators and any other personnel, as well as each contractor, used by Institution in the conduct of in a Study shall be solely a matter between Institution and such individuals or entities, regardless of whether such individuals or entities are considered employees, agents, partners, joint venturers, or independent contractors of Institution.

2.2 Determination of Study Budget for a Study. The parties will negotiate a detailed Study Budget (including the procedures and their respective costs used in determining the budget) for each Study as the parties may mutually agree. Once agreed upon in the Study Letter Agreement, such Study Budget costs shall remain firm for the duration of the research conducted pursuant to that Study Letter Agreement, unless otherwise expressly for provided to the contrary therein.

2.3 Payee. All funds under a Study Letter Agreement shall be paid by BMS to the Institution named in a Study Letter Agreement and shall be sent by corporate check to the attention of the applicable named individual at the addresses listed on *Schedule 1.6* attached hereto. Checks will reference the number of the applicable Study Letter Agreement and the Investigator's name. Payments may also be made by means of a mutually acceptable wire transfer procedure.

2.4 Payment Schedule. The parties recognize that the payment schedule of the Study Budget may vary depending on the Study Protocol, the number of subjects, and the frequency and cost of the procedures being performed, and the payment schedule to be followed for a given Study shall be as set forth in the Study Letter Agreement. However, the parties agree to incorporate the following payment schedule into the Study Letter Agreement for a given Study in the absence of legitimate reasons to vary same:

i) An initial payment of ten percent (10%) of the total anticipated Study Budget will be made within 30 days after the Study Letter Agreement has been executed and the first patient enrolled, and Institution has completed its obligations under Section 1.3 hereof to BMS' satisfaction;

ii) A mutually acceptable payment structure shall be determined for the payments to be made other than those in (i) above and (iii) below, and which shall reflect the type of Study and procedures being performed, the number of patients, the frequency of the case report forms to be completed and submitted, and other pertinent factors;

iii) Ten percent (10%) of the total Study Budget (based on total anticipated number of completed subjects) will be withheld and paid out following the conclusion of the Study, provided that (a) Institution shall have provided a reconciliation of all drug supplies received, dispensed, used by, and returned to it by subjects, and BMS has received all returned and unused drug supplies (or received written certification, if destruction of unused supplies was requested by BMS, of such destruction), and (b) duly completed case report forms have been received by BMS for all subjects participating in the Study.

2.5. Early Termination. In the event that a Study terminates prematurely in accordance with this Agreement, the total amount due Institution for such Study, unless otherwise specifically provided in the Study Letter Agreement, shall be determined based on the procedures and/or tasks performed as the cost of same is reflected in the Study Budget. If that amount exceeds the payments made by BMS through such early termination date, BMS shall promptly pay the difference, provided that it has received duly completed case report forms for all applicable subjects; if it is less than the payments made by BMS through such date, Institution shall promptly refund the difference to BMS. Notwithstanding the foregoing, BMS shall have no obligation to make any final payment on account of early termination, unless and until (a) Institution shall have provided a reconciliation of all drug supplies received, dispensed, used by, and returned to it, and BMS has received all returned and unused drug supplies, and (b) duly completed case report forms have been received by BMS for all subjects participating in the Study. No other payments shall be made or due as a result of any such early termination.

Article 3 - Reports; Use of Study Data

3.1 Periodic Reports. Where provided for in the Study Protocol, Investigator shall keep BMS advised of the status of each Study via periodic reports. If required by BMS, there shall also be a final report of each Study presented to BMS.

3.2 Data. All case report forms and other reports submitted to BMS with respect to a particular Study shall become the property of BMS, and all data generated by a Study may be used by BMS (together with the Study results) for any purpose without further obligation or compensation to Institution. BMS shall have the exclusive right to use any data generated by a Study for any commercial purpose, including without limitation in filings with regulatory authorities. A Participating Investigator shall have the right to retain and use the data and results in order to publish the Study results as provided in Article 4 below, for continuing internal academic research (subject to Article 4) and for the treatment and medical care of any Study subject. A subject's individual medical records shall remain the property of Institution. Institution will, to the extent duly authorized or within the bounds of legal requirements, provide or make such medical records available to BMS and such governmental agencies designated by BMS. Medical records and data relating to a Study

shall be retained by Institution for such period of time required by law and/or by the Study Protocol. Institution shall be entitled to retain in its archives a copy of the case report forms submitted by it, and may use same solely to verify compliance with its obligations hereunder.

Article 4 - Publication

4.1 Publication. Investigator may freely publish and disseminate the results of its investigative findings under a particular Study. The authorship and contents (including scientific conclusions and professional judgments) of any such paper, abstract, or other similar publication shall be determined by Investigator. Where a Study is part of a multi-center study, Investigator will allow a reasonable time for the initial major publication based on the results and data obtained from all sites participating in such Study (including the results and data obtained by Institution) to be made first prior to publishing the results of Investigator's investigative findings hereunder (but not to delay publication of its findings more than one year following completion or termination of such multi-center study). Investigator shall provide BMS with a copy of the papers prepared for publication by it, or by any Participating Investigators at the earliest practicable time, but in any event not less than thirty (30) days prior to their submission to a scientific journal or presentation at scientific meetings and a reasonably detailed summary or abstract of any other oral presentation or written publication not less than thirty (30) days prior to their submission or presentation. BMS may comment upon, but may not make any editorial changes to, the results and conclusions set forth in the papers; however, Investigator will delete any of BMS's Confidential Information (as defined below) identified by BMS that may be contained therein. BMS' contribution to the Study shall be acknowledged in accordance with customary scientific practice. Where requested by BMS, Investigator agrees to delay submission or publication of the Study results up to sixty (60) days in order for appropriate patent protection to be filed on any patentable invention that may be disclosed by such publication. The Study database may not be provided to, or used on behalf of, third parties without BMS' prior written consent.

4.2 No Sub-Studies. Institution and the Participating Investigators may not use the data obtained from a Study or any Study drug to conduct or publish any sub-studies or other studies beyond the scope of the Study Protocol without the prior written consent of BMS.

Article 5 - Confidential Information

5.1 Confidentiality. In furtherance of the conduct of a Study, it may be necessary or desirable for BMS to disclose confidential information and data relating to the study drug or research procedures (hereinafter "*Confidential Information*") to Institution and its Participating Investigators. All such confidential information disclosed by BMS must be in writing and marked "confidential". BMS may request potential investigators to whom such Confidential Information may be disclosed to first sign a confidentiality agreement in the form attached as *Schedule 5.1* hereto. In the event that a proposed Investigator is interested in reviewing further information (such as the proposed Study Protocol) for a Study after review of the proposed Study outline, Institution will forward said form to such Investigator to sign and return to BMS prior to forwarding any further information to such proposed investigator.

All such Confidential Information shall remain the property of BMS. Each party hereto agrees that any such Confidential Information shall be used only in connection with the legitimate purposes of this Agreement, shall be disclosed only to those persons or entities who have a need to know it and are obligated to keep same in confidence, and shall be safeguarded with reasonable care; provided, however, that the disclosing party marks the Confidential Information as such at the time of disclosure (or, if disclosed

verbally, is reduced to writing and so marked within a reasonable period of time thereafter).

The foregoing confidentiality obligation shall not apply when, after and to the extent the Confidential Information disclosed in connection with a given Study

(i) is now, or hereafter becomes, generally available to the public through no fault of the receiving party or its employees, agents or contractors,

(ii) was already in the possession of the receiving party without restriction as to confidentiality at the time of disclosure as evidenced by competent written records;

(iii) is subsequently received by the receiving party from a third party without restriction and without breaching any confidential obligation between the third party and the disclosing party hereunder;

(iv) is independently developed by the recipient party; or

(v) is disclosed after a date that is five (5) years following the conclusion of a Study.

Confidential Information may also be disclosed to the extent required by law (including without limitation the filing and prosecution of patent applications), provided that the party making such disclosure of the other party's Confidential Information shall give reasonable advance notice of same and request such confidential treatment of such disclosure from the recipient thereof as may be afforded by law. Notwithstanding the foregoing, the text of this Agreement shall not be considered Confidential Information of either party.

Article 6 - Independent Contractor

6.1 Independent Contractors. The relationship of BMS to Institution under this Agreement and each Study conducted hereunder is, and is intended to be, that of independent contractors, and not that of partners, joint venturers, representatives, or agents of one another. No party to this Agreement shall have the power to bind or obligate any other party. All Participating Investigators hereunder shall be either employees of, or independent contractors with, Institution.

Article 7 - Term and Termination

7.1 Term and Termination of Agreement. This Agreement shall commence on the Effective Date of this Agreement and shall continue indefinitely thereafter, unless and until terminated by a party, with or without cause, upon ninety (90) days prior written notice to the other. Notwithstanding any such termination, the terms and conditions of this Agreement and each applicable Study Letter Agreement shall continue to apply, and the parties shall continue to perform in accordance with this Agreement and the applicable Study Letter Agreement, with respect to each Study to which the parties shall have signed a Study Letter Agreement prior to the effective date of termination of this Agreement. Termination shall be limited, in the case of BMS, only as to those Institution(s) to which it sends such notice. An Institution sending such notice to BMS shall not affect the continuing nature of this Agreement as to those Institution(s) not sending such notice and BMS.

7.2 Termination of a Study. Each Study conducted hereunder shall continue until completion of such Study or until such Study is sooner terminated or suspended as provided for in the Study Protocol, in section 1.1(e) hereof, or as follows:

(a) By BMS, with or without cause, effective as of such date as BMS may specify in a written notice (which shall be not less than thirty (30) days prior written notice if without cause) given by BMS to Institution;

(b) By Institution, either (i) if it believes such termination is necessary to protect the best interests of the Study subjects, or (ii) for a breach by BMS of any of its material obligations under such Study hereof by BMS, which breach is not cured by BMS within thirty (30) days following receipt of written notice thereof from Institution; or

(c) by written mutual agreement.

Upon receipt of notice of any termination or suspension of any Study, all further enrollment in such Study shall cease and the parties will meet and confer promptly to determine an appropriate phase-out for subjects already enrolled in such Study.

7.3 Effect of Termination. Any termination of this Agreement, or any termination or suspension of a Study hereunder, that is made in accordance with the terms of this Agreement shall be without penalty or liability therefor, and without the payment of any monies other than such amounts as may be provided for under Section 2.5 hereof. Articles 1.4, 1.5, 1.6, 2.1, 2.3, 2.4, 2.5, 3, 4, 5, 6, and 8 shall survive any termination or expiration of this Agreement, as well as any other rights and obligations which by their intent or meaning are intended to so survive. No termination hereunder shall constitute a waiver of any rights or causes of action that either party may have based upon events occurring prior to the termination date.

Article 8 - Indemnity, Miscellaneous Provisions

8.1 Indemnification by BMS. Distinct from any medical expenses covered by Article 8.2 below, BMS will indemnify and hold harmless The University of Texas System, each Institution, and its respective Regents, officers, employees and agents and any Participating Investigator (all of the foregoing persons and entities referred to individually as an "*Indemnitee*" and, collectively, as the "*Indemnitees*"), from and against any amounts paid or payable by an Indemnitee to a Study subject resulting from (i) claims, legal proceedings or causes of actions asserted or initiated by such subject, but not attorney's fees, resulting from personal injury (including death) to such Study subject or from damage to a subject's property sustained as a result of the administration of a Study drug in accordance with a Study Protocol or the performance of medical procedures specifically required by a Study Protocol (except where such claims, legal proceedings or causes of action are attributable to comparators or a third party's drug or device used in a Study), and/or (ii) claims, causes of action, suits, liability, damages and costs (other than attorneys' fees) incurred by an Indemnified Party based upon personal injury (including death) to any third party (other than an Indemnified Party) arising out of the design, manufacture, sale, or use of BMS' investigational Study drug after such Study drug has been approved for marketing, regardless of the form of the cause of action (such as in tort, product liability or otherwise) (all of the foregoing claims under (i) and (ii) referred to hereinafter, collectively, as "*Claims*") , except to the extent such Claims are attributable to:

(i) the failure by an Institution, any Participating Investigator, or any Study personnel,

contractor or other Indemnitee: (A) to comply with the terms of the pertinent Study Protocol, applicable terms of the Study Letter Agreement, or any written instructions (including, without limitation, package inserts, where appropriate) relative to the use of any drugs or devices used in the performance of a Study, or (B) to comply with applicable FDA or other governmental requirements, or

(ii) any negligent or wrongful act or omission, or willful malfeasance, on the part of any Institution, any Participating Investigator, or any Study personnel, contractor or other Indemnitee involved in the performance of a Study.

Where a Claim falls within BMS indemnification obligation hereunder, BMS agrees to assume control of the defense and disposition (including all decisions relative to litigation, appeal or settlement) of such Claim using attorneys selected by it and paid for by BMS. It is a condition precedent to BMS's indemnification obligations under this article 8.1 that each such Indemnitee seeking indemnity hereunder must (i) promptly notify BMS of the assertion of any such Claims against it/him/her, (ii) subject to the statutory duties of the Attorney General of the State of Texas, authorize and permit BMS to conduct and exercise sole control of the defense and disposition (including all decisions relative to litigation, appeal or settlement) of such Claims and (iii) subject to the statutory duties of the Attorney General of the State of Texas, fully cooperate with BMS regarding any such Claims (including access to pertinent records and documents and provision of relevant testimony) and in determining the scope of BMS's obligations hereunder. Each Indemnified Party further agrees not to negotiate, settle or compromise any such claim, lawsuit or proceeding hereunder for which indemnification may be sought from BMS without BMS'S prior written approval, or this indemnification as to same shall be null and void. Subject to the foregoing, each Indemnitee may participate in any such Claims at its/his/her own cost and expense.

Institution shall, to the extent authorized under the Texas Constitution and the Texas Tort Claims Act, (1) indemnify and hold BMS harmless from liability resulting from the negligent acts or omissions of Institution, its agents or employees pertaining to the activities to be carried out pursuant to the obligations of this Agreement, provided, however, that Institution shall not indemnify and hold BMS harmless from claims to the extent arising out of the negligence of BMS, its officers, agents, or any person or entity not subject to Institution supervision or control, and (2) provided that BMS has paid to Institution all amounts due Institution in connection with the conduct of a Study, will indemnify and hold BMS harmless from and against any claims, liabilities, damages, costs and expenses for any fees, compensation, benefits, costs reimbursements, and other payment due to any such individuals or entities so used by Institution to perform any services connected with the conduct of a Study; provided, that the foregoing shall not relieve BMS of any obligation it may have under Sections 8.1 or 8.2 hereof.

8.2 Reimbursement of Medical Costs. BMS agrees to pay for the reasonable cost of reasonable and customary medical treatment of any illness or injury sustained by a Study subject as a result of the administration of a BMS investigational Study drug (but not any comparators) in accordance with the Study Protocol (except to the extent such costs are covered by the subject's insurance or other third party coverage); provided, however, that BMS's obligations under this Article 8.2 shall not apply to the extent that any such costs or such illness or injury is attributable to:

(i) the failure by an Institution, any Participating Investigator, or any Study personnel, contractor or other Indemnitee: (A) to comply with the terms of the pertinent Study Protocol, applicable terms of the Study Letter Agreement, or any written instructions (including, without

limitation, package inserts, where appropriate) relative to the use of any drugs or devices used in the performance of a Study, or (B) to comply with applicable FDA or other governmental requirements, or

(ii) any negligent or wrongful act or omission, or willful malfeasance, on the part of any Institution, any Participating Investigator, or any Study personnel, contractor or other Indemnitee involved in the performance of a Study.

(iii) a Study subject's primary disease or any concurrent disease not caused by the administration of the BMS investigational Study drug in accordance with the Study Protocol; and/or

(iv) a Study subject's failure to comply with instructions contained in the Informed Consent executed by such subject or communicated to the subject by Study personnel.

8.3 No Implied Rights. No right or license is granted under this Agreement by either party to the other either expressly or by implication, except those specifically set forth herein. No party shall have any obligation of exclusivity of any nature to another, express or implied, or any obligation to sponsor or conduct, or to offer to sponsor or conduct, any particular study or any number of studies, and regardless of whether the parties may previously have agreed to sponsor and conduct a particular study. Each party shall be free to enter into and participate in other activities (either alone or with a third party), including without limitation to conduct or sponsor clinical studies, sponsored projects, and other research projects involving other parties, so long as a party's agreement with any such third party does not conflict with its obligations hereunder or with respect to an ongoing Study.

8.4 Miscellaneous.

(a) All matters affecting the interpretation, validity and performance of this Agreement shall be governed by the laws of the State of Texas, without regard or giving effect to its conflict of laws principles.

(b) This Agreement, including the Schedules attached hereto and including the Study Protocol(s) and Study Letter Agreement(s) for each Study conducted under the terms hereof, set forth the entire understanding between the parties herein, and there are no other understandings or promises, written or verbal, not set forth herein, that relate to the subject matter hereof.

(c) This Agreement may not be assigned by either party without the prior written consent of the other party (not to be unreasonably withheld); provided, however, without such consent BMS may assign this Agreement (and all Study Letter Agreements executed hereunder) and all related rights and obligations hereunder in connection with the transfer or sale of all or substantially all of its assets or business or its merger or consolidation with another company. This Agreement shall be binding upon and inure to the benefit of each party, and its successors and permitted assigns.

(d) This Agreement may not be changed or supplemented, except by a writing executed by Institution and BMS.

(e) No failure or delay in exercising any right hereunder will be considered a waiver thereof unless expressly waived in writing by the party to be charged therewith. No waiver on one occasion

will be considered a continuing waiver or subsequent waiver on any other occasion.

(f) The invalidity or unenforceability of any term or provision (or part thereof) of this Agreement shall not affect the validity or enforceability of any other term or provision (or remaining part of such provision).

(g) Institution and BMS shall not unlawfully discriminate against any employee or applicant for employment because of race, color, gender, sexual preference, marital status, age, religion, national or ethnic origin, disability or status as a veteran.

(h) The headings and captions used in this Agreement are for convenience of reference only and shall not affect its construction or interpretation. This Agreement shall not be strictly construed against either party hereto.

8.5 Notices. All legal notices to be given by either party to the other shall be made in writing by hand delivery or by registered or certified mail, return receipt requested or by other method reasonably capable of proof of receipt thereof and addressed to the parties at their respective addresses first set forth above to the attention of:

If to Institution, to: See Schedule 1.1(a)

If to BMS, to: Bristol-Myers Squibb Pharmaceutical Research Institute
Route 206 at Province Line Road
Princeton, New Jersey 08543-4000
ATTN: Senior Vice President for Clinical Research

or to such other address as either may designate from time to time to the other. Any notice shall be effective as of its date of receipt.

8.6 Use of a Party's Name. BMS will not use the name of Institution or any variants thereof in any advertising or promotional material or make any representation relative to an investigational Study drug which would constitute an express or implied endorsement by Institution of any commercial product or service (and will not authorize others to do so), except as may be required by law or with Institution's written permission. Institution will not use BMS's name, or a variant thereof, for any advertising or promotional purpose without BMS's prior written consent.

8.7 Patents and Inventions. (a) All rights, title and interests in and to any invention conceived and/or reduced to practice by Institution, any Participating Investigator and any Institution personnel as a direct result of the performance of the work conducted under this Agreement using the Study drug in accordance with the Protocol shall belong to BMS and shall be promptly disclosed to BMS. Institution agrees to assign to BMS, at the request of BMS, the sole and exclusive ownership thereto, upon payment of all costs by BMS, if any, incurred by Institution in the filing, prosecution, issuance and/or maintenance of any patent application or patent issuing thereon prior to the date of assignment to BMS. Further prosecution, defense, maintenance and enforcement of any such application(s) and patent(s), as well as the costs thereof, shall thereafter be the sole responsibility of BMS. Determinations of inventorship shall be made in accordance with U.S. patent law. Institution and its personnel will reasonably assist BMS, at BMS's expense, in executing any documents or other instruments reasonably appropriate for vesting or confirming ownership of said rights and title in BMS where applicable hereunder and will provide reasonable cooperation to BMS, at BMS's expense, in prosecuting such patent applications and enforcing such patents

against third parties.

(b) No Conflict. Institution agrees not to enter into agreements with third parties which is in conflict with its obligations, and the rights granted by it to BMS, under this Agreement or any applicable Study Letter Agreement. Institution represents that the Participating Investigators and other personnel that may perform research hereunder are its employees and shall abide by the terms and conditions of this Agreement as if each were a party hereto in the same manner as Institution hereunder.

(c) BMS Property. Nothing in this Agreement shall be interpreted as giving Institution any rights under any intellectual property rights now, or hereafter, owned by BMS.

(d) Copyright Ownership and Licenses. Title to and the right to determine the disposition of any copyrights or copyrightable material first authored by Institution in its performance of a Study shall remain with Institution (or be jointly owned by Institution and BMS, if jointly authored by BMS and Institution, in which event each may dispose of its rights therein without accounting or compensation to the other), subject to an irrevocable, royalty-free, non-transferable, non-exclusive right and license granted by Institution or Investigator, as the case may be, to BMS to use, reproduce, display, distribute, make derivative works of, and perform all such copyrightable materials; provided, however, that such license shall be exclusive as to any Study report authored by Institution, and that BMS shall be the sole owner of all title and rights in any completed case report forms.

8.8 Institution will not, and will advise each Participating Investigator and Study personnel not to, enter into agreements with third parties which would impair their ability to perform this Agreement.

8.9 This Agreement anticipates educational training and may involve health science postgraduates and other students of the Institution.

8.10 Institution represents that it has never been and that it will not use any individuals to conduct a Study that have been (1) debarred or (2) convicted of a crime for which a person can be debarred, under Section 306(a) or 306(b) of the Generic Drug Enforcement Act of 1992 ("Section 306(a) or (b)"). Institution represents that it has never been and that it will not use any individuals to conduct a Study that have been (1) threatened to be debarred or (2) indicted for a crime or otherwise engaged in conduct for which a person can be debarred under Section 306(a) or (b). Institution agrees that it will promptly notify BMS in the event it becomes aware of any such debarment, conviction, threat, or indictment. This certification applies in respect of officers, agents and employees of Institution, as well as third parties with whom Institution may subcontract. Institution agrees to notify BMS promptly in the event any person so used ever becomes debarred under the GDEA. Upon request by BMS, Institution agrees to provide a list of persons used to perform the services performed pursuant to this Agreement who, within the five years preceding such request, or subsequent to such request, were or are convicted of one of the criminal offenses required by the GDEA to be listed in any application for approval of an abbreviated application for drug approval.

IN WITNESS WHEREOF, Institution and BMS have caused this Agreement to be executed in multiple counterparts by their duly authorized representatives.

BRISTOL-MYERS SQUIBB PHARMACEUTICAL RESEARCH INSTITUTE

By: _____

Title: Sr. Vice President, Worldwide Clinical R & D

Date: 6/23/98

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT SAN ANTONIO

By: _____
Jane A. Youngers

Title: Director, Grants Management

Date: 6-10-98

Tax I.D. No. 74-1586031

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON

By: _____
David E. Kusnerik

Title: Contract Administrator

Date: 6/3/98

Tax I.D. No. 74-1761309

THE UNIVERSITY OF TEXAS M.D. ANDERSON CANCER CENTER

By: _____

Title: Manager, Sponsored Programs

Date: 5/28/98

Tax I.D. No. 74 6001118 A1

THE UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER AT DALLAS

By: _____
Perrie M. Adams, Ph.D.

Title: Associate Dean for Research

Date: 5/12/98

Tax I.D. No. 75-6002868W

THE UNIVERSITY OF TEXAS MEDICAL BRANCH AT GALVESTON

By: _____
Wayne Patterson, Ph.D.

Title: Director, Internal Review Coordination

Date: 6/9/98

Tax I.D. No. 74-6000949

THE UNIVERSITY OF TEXAS HEALTH CENTER AT TYLER

By: _____

Title: _____

Date: 5/25/98

Tax I.D. No. #756001354

SCHEDULES

SCHEDULE 1.1(a)	-	LIST OF INSTITUTION NAMES AND ADDRESSES
SCHEDULE 1.1(b)	-	FORM OF STUDY LETTER AGREEMENT
SCHEDULE 1.3	-	STUDY INITIATION ACTIVITIES
SCHEDULE 1.3B-1	-	STATEMENT FOR INCLUSION IN INFORMED CONSENT RE PATIENT COMPENSATION
SCHEDULE 1.3B-2	-	STATEMENT FOR INCLUSION IN INFORMED CONSENT RE WOMEN OF CHILD-BEARING POTENTIAL
SCHEDULE 1.3B-3	-	ADDITIONAL TOPICS TO BE INCLUDED IN INFORMED CONSENT FOR WOMEN OF CHILD-BEARING POTENTIAL
SCHEDULE 1.3B-4	-	STATEMENTS TO BE INCLUDED IN INFORMED CONSENT FOR WOMEN OF CHILD-BEARING POTENTIAL REGARDING AVAILABILITY OF ANIMAL REPRODUCTIVE STUDIES
SCHEDULE 1.6	-	LIST OF INSTITUTION CONTACTS
SCHEDULE 5.1	-	FORM OF CONFIDENTIALITY AGREEMENT

SCHEDULE 1.1(a)
LIST OF INSTITUTION ADDRESSES
LIST OF INSTITUTION CONTACTS

The University of Texas Southwestern
Medical Center at Dallas
5323 Harry Hines Blvd.
Dallas, Texas 75235-~~9105~~ 9007
Attn: ~~Ms. Janice Hinds, Director, Grants Management~~ Perrie M. Adams, Ph.D.
Fax: 214-648-3362 Associate Dean for Research

The University of Texas Health
Science Center at Houston
P.O. Box 20036
Houston, Texas 77225
Attn: Mr. David Kusnerik, Contract Administrator
Fax: 713-500-3275

The University of Texas M.D. Anderson Cancer Center
1515 Holcombe Blvd., Box 202
Houston, Texas 77030
Attn: Ms. Donna Gilberg - Manager, Sponsored Programs
Fax: 713-796-0381

The University of Texas Medical
Branch at Galveston
Galveston, Texas 77550-2774
Attn: Ms. Marcie Padia, Research Administrative Services
Fax: 409-747-0044

The University of Texas Health
Science Center at San Antonio
7703 Floyd Curl Drive
San Antonio, Texas 78284-7862
Attn: Ms. Jane A. Youngers - Director, Grants Management
Fax: 210-567-2344

The University of Texas Health
Center at Tyler
11937 U.S. Highway 271
Tyler, Texas 75708
Attn: Ms. Michelle Hargis - Administrator, Sponsored Programs
Fax: 903-877-7755

SCHEDULE 1.1(b)
FORM OF STUDY LETTER AGREEMENT

{BMSPRI Letterhead}

{Date}

{Institution Name and Address}
ATTN: _____

Re: BMS Study No. _____; Investigator (_____).

Dear _____:

This Study Letter Agreement confirms the terms and conditions under which {Name of Institution} ("*Institution*") has agreed to conduct a specific clinical study under our Study Protocol entitled *{Name of Study}* (the "Study"). It is estimated that it will take *{___}* months to complete such Study and that Institution expects to be able to provide *{___}* completed subjects for such Study.

The Study will be conducted under the direction of: *{Name of Investigator}*
{Address}
{Telephone}

This Study Letter Agreement is a schedule to the Master Clinical Trial Agreement ("Agreement") between Bristol-Myers Squibb and the Institution effective *{Insert date}*. We confirm with you that the Agreement remains in full force and effect, and that this Study Letter Agreement is governed by and is subject to the terms and conditions of that Agreement.

All funds under this Study Letter Agreement shall be paid by BMS to the "{Name of Institution}" (Tax Identification Number _____) and shall be sent by corporate check to the attention of _____ at the following address:

{Address}

All payments will reference the number of the applicable Study Letter Agreement and the Investigator's name. Wire transfers may also be used pursuant to a mutually acceptable procedure.

For purposes of this Study, all communications (other than legal notices under section 9.5 of the Agreement) should be sent to the following persons:

If to Institution, to: *{Name and Address}*

If to the BMS, to: Bristol-Myers Squibb Pharmaceutical Research Institute
{Address}
ATTN: *{Name of BMS Medical Director for the Study}*

The maximum Study grant and the payment schedule for same, the number of patients to be enrolled, randomized, and completed, and the financial terms and conditions pertaining to this Study are as set forth

in the Exhibit attached to this letter.

****

If the foregoing is acceptable to you, please arrange to have both copies of this Study Letter Agreement executed by a duly authorized official at the Institution and return one duly executed original to me. Thank you.

Sincerely,

{*Signature and title of BMSPRI employee*}

ACCEPTED AND AGREED:

{Name of Institution}

By:_____

Title:_____

Date:_____

I HAVE READ AND UNDERSTAND THE ABOVE STUDY LETTER AGREEMENT AND RELATED AGREEMENT:

_____
Signature of the Investigator

_____
Print Name of the Investigator

_____
Date

SCHEDULE 1.3

Study Initiation Activities.

After BMS has (1) notified Institution of its interest in a given Study (as provided in section 1.3 of this Agreement), (2) provided Institution with the Study Protocol for such Study, and (3) given preliminary approval of the Investigator, Institution will use its best efforts to complete the Study Initiation Activities, and to finalize and forward the clinical trial package documents described below to BMS, within two (2) months thereafter:

(i) Institution and BMS will use all reasonable efforts to complete the Study Letter Agreement form to be used for such Study as quickly as practicable after BMS has notified Institution of its interest in a Study as provided above. When so completed, Institution will forward the Study Letter Agreement to each Investigator to whom BMS has given preliminary approval for use in the Study and will seek to obtain such Investigator's signature on such Study Letter Agreement as promptly as possible. Each Participating Investigator proposed for participation in the Study must receive final approval by BMS prior to participation. In the case of each Investigator, final approval shall be deemed given only by BMS' signature on the Study Letter Agreement for such Investigator. BMS shall be the final party to sign off on a Study Letter Agreement.

(ii) Assist each Participating Investigator to develop the informed consent form that will be submitted to the IRB for the Study. In the event that an informed consent template has been prepared by BMS for a given Study, Institution will submit the template to such Investigator for his/her consideration. Any such template provided by BMS shall be provided solely to assist an Investigator in preparing the informed consent actually to be submitted by him/her for IRB approval, it being understood that final authority and responsibility for preparation and content of the informed consent and for assurance that the informed consent complies with applicable law (including all elements required by 21 CFR, Part 50, Protection of Human Subjects) rests with such Investigator. Notwithstanding the foregoing, unless otherwise agreed to in writing by BMS, each informed consent used in a clinical study must (A) include the Compensation Statement verbatim attached as *Schedule 1.3B-1* hereto, and (B) if the study includes Women of Child Bearing Potential, include verbatim the required statements and cover the additional topics specified in *Schedules 1.3B-2, B-3 and B-4*. BMS shall have the right to change or supplement any such schedules within Schedule 1.3B at any time, subject to the approval of Institution (not to be unreasonably withheld or delayed).

(iii) On behalf of each proposed Investigator approved by BMS to participate in a Study, submit the final informed consent form and the Study Protocol to the IRB for approval, as well as for approval by the IRB of any medical facilities (e.g., office, hospital) to be used by a Participating Investigator in conducting the Study. Institution will be responsible for assuring that the IRB meets with applicable FDA regulations (21 C.F.R. 56, et seq. *Investigational Review Boards*). If any Participating Investigator(s) are members of the IRB, the chair of the IRB must inform BMS in writing that any such Participating Investigator has not participated in the approval of the Study Protocol for such Study or such individual shall not be permitted to participate in such Study.

(iv) Obtain and forward to BMS the IRB approval letter for the Study Protocol and for the informed consent, as well as a copy of the then current annual Assurance Letter provided

by the IRB to Institution certifying that the IRB meets with membership/meetings requirements imposed by applicable law. Institution will also notify BMS of any material information known to it that may adversely affect reliance by BMS upon such letter.

(v) Obtain and forward to BMS the original signed FDA 1572 from each Investigator.

(vi) Assure that each Participating Investigator is appropriately qualified to conduct clinical trials under all applicable laws, as well as with all rules and procedures maintained by Institution.

(vii) Obtain from each Investigator and provide to BMS a signed and dated acknowledgment page for the approved Study Protocol.

(viii) Obtain and provide the most recent Institution laboratory certifications and most recent annual normal ranges for each Participating Investigator's medical /hospital facility where the Study is to be conducted (as applicable), together with any material changes (e.g., changes to normal values) thereto since such date.

(ix) For Study Protocols that will include a controlled substance, obtain from each Participating Investigator and from the Institution pharmacies that will be participating in the Study and who or which will have access to the controlled substance a copy of such individual's or institution's Drug Enforcement Administration (DEA) registration and a copy of the DEA Form 222 (as applicable), and provide same to BMS.

(x) For radio-labeled drug studies, obtain and provide BMS with either documentation of Institution Radiation Safety Committee approval or documentation reasonably acceptable to BMS that such approval is not required by applicable law.

Institution will promptly forward the documents indicated in this Schedule to BMS as and when they are received by Institution.

During such two-month period, BMS shall further be entitled to conduct a site evaluation of each proposed Participating Investigator's facility by BMS representatives (as well as from time to time thereafter during the term of the Study at such time(s) as are mutually convenient to BMS and the proposed Participating Investigator).

SCHEDULE 1.3B.1

COMPENSATION STATEMENT

In the event that you experience an adverse reaction during the course of the study, you should immediately contact <INVESTIGATOR> at <TELEPHONE NUMBER>. If you suffer a physical injury as a result of the administration of BMS's investigational study drug, you will be reimbursed for reasonable medical expenses actually incurred to treat such injury (to the extent not paid by your insurance or other third party coverage); provided, that medical expenses will not be reimbursed if your injury is attributable to your failure to follow instructions contained in this informed consent or otherwise communicated to you by Study personnel. Such medical care may be obtained by you in the same manner as you would ordinarily obtain any other medical treatment. No provision has been made for financial payments or other forms of compensation (such as for lost wages, lost time, or discomfort) with respect to such injuries; however, you do not waive any legal rights by signing this consent form.

SCHEDULE 1.3B-2

STANDARD STATEMENTS TO BE INCLUDED IN INFORMED CONSENT
FOR WOMEN OF CHILD BEARING POTENTIAL

The following text must be included in Informed Consent for Women of Child Bearing Potential:

_____has reviewed information on pregnancy prevention for
Investigator or Designee

women of childbearing potential in clinical trials with me. I understand that I may be receiving an investigational new drug and should not become pregnant while I am participating in this study. I understand that I should immediately call Dr. _____or the study coordinator
Print name

_____at _____if:
Print name Telephone number

- I am pregnant or think I might be pregnant.
- I have missed my period or it is late, or I have a change in my usual menstrual cycle (for example, heavier bleeding during my period or bleeding between periods).

I should also call if I have changed or plan to change my birth control method or if I need to take any prescription drug or other medication not given to me by

Dr(s)_____

_____ _____
Investigator or Designee's Signature Study Participant's Signature

Date_____ Date_____

SCHEDULE 1.3B-3

ADDITIONAL TOPICS TO BE INCLUDED IN INFORMED CONSENT FOR WOMEN OF CHILDBEARING POTENTIAL

Laboratory & Animal Reproductive Toxicology

A statement addressing what is known about the study drug from laboratory and animal reproductive toxicity studies concerning possible mutagenic and/or teratogenic effects should be included in the consent. The consent should indicate that this information has limited predictive value for humans.

Unforeseeable Risks

The consent must indicate that exposure to the study drug may involve currently unforeseeable risks to the subject (or embryo or fetus, if the subject is or may become pregnant).

Occurrence of Pregnancy or Suspected Pregnancy

The informed consent must include study contact name(s) and telephone number(s) for the subject to call if she becomes pregnant or suspects pregnancy, has missed her period or it is late, or she has a change in her usual menstrual cycle (e.g., heavier bleeding during her period or bleeding between periods).

Discontinuation from the Study

Any subject who becomes pregnant during the course of the study will be immediately withdrawn (unless allowed or stated differently in the protocol) and referred for obstetrical care. All financial aspects of obstetrical, child or related care are the responsibility of the subject.

Pregnancy Follow-up

If a subject becomes pregnant, BMS will require access to the subject's and/or infant's clinic/hospital records through the pregnancy, and for a minimum of 8 weeks following delivery.

SCHEDULE 1.3B-4

STATEMENTS TO BE INCLUDED IN INFORMED CONSENT
FOR WOMEN OF CHILD BEARING POTENTIAL
REGARDING AVAILABILITY OF ANIMAL REPRODUCTIVE STUDIES

Animal Teratology Studies Done Show Abnormal Findings

Studies in animals with drug Y at doses of X times the doses being used in this study have shown abnormalities in the offspring of the animals (e.g., heart defects, cleft palate). While it is not known if these effects or other problems might occur in humans, women should avoid becoming pregnant while participating in this study.

Animal Studies Conducted to Date are "Clean"

Limited studies have been conducted in animals to assess reproductive problems or birth defects. At this time, no abnormalities have been identified. However, care should be taken to avoid pregnancy, since the study drug effects in pregnant women or their babies are not known.

No Animal Teratology Studies Done or Completed

No studies have been completed to assess reproductive problems or birth defects in animals. If information becomes known about any problems in animals related to the study drug, you will be notified by investigator X. However, care should be taken to avoid pregnancy, since the study drug effects in pregnant women or their babies are not known.

SCHEDULE 1.6
LIST OF INSTITUTION CONTACTS

~~Ms. Janice Hinds~~ Perrie M. Adams, Ph.D.
~~Director, Grants Management~~ Associate Dean for Research
The University of Texas Southwestern
Medical Center at Dallas
5323 Harry Hines Blvd.
Dallas, Texas 75235-~~9105~~ 9007
Fax: 214-648-3362
Tax ID#: 75-6002868W

Mr. David Kusnerik
Contract Administrator
The University of Texas Health
Science Center at Houston
P.O. Box 20036
Houston, Texas 77225
Fax: 713-500-3275
Tax ID#: 74-1761309

Ms. Donna Gilberg
Manager, Sponsored Programs
The University of Texas M.D. Anderson Cancer Center
1515 Holcombe Blvd., Box 202
Houston, Texas 77030
Fax: 713-796-0381
Tax ID#: 74-6001118-A1

Ms. Marcie Padia
Research Administrative Services
The University of Texas Medical
Branch at Galveston
Galveston, Texas 77550-2774
Fax: 409-747-0044
Tax ID#: 1-74-6000949-A1

Ms. Jane A. Youngers
Director, Grants Management
The University of Texas Health
Science Center at San Antonio
7703 Floyd Curl Drive
San Antonio, Texas 78284-7862
Fax: 210-567-2344
Tax ID#: 1-74-1586031-A3

Ms. Michelle Hargis
Administrator, Sponsored Programs
The University of Texas Health
Center at Tyler
11937 U.S. Highway 271
Tyler, Texas 75708
Fax: 903-877-7755
Tax ID#: 175-600-1354

Exhibit 5.1

{BMSPRI Letterhead}

{insert date}

{physician name & address}

Re: Confidential Disclosures re *{insert name of BMS compound}*

Dear Dr. _____:

Bristol-Myers Squibb Pharmaceutical Research Institute ("BMS") is pleased to be able to provide you with certain confidential information and data pertaining to our proprietary compound, *{insert name}*, so that both of us may mutually determine whether, and upon what terms, you might participate in one or more clinical trials or other studies at the {Name of Institution} ("Institution") with BMS involving this compound. The purpose of this letter is to confirm the terms that will apply to your receipt of this confidential information and data from BMS, as follows:

1. All information, documentation and data ("BMS Confidential Information") that you may learn through BMS, or which BMS may disclose to you, from time to time hereafter relating to this compound (including without limitation, investigators brochures, Study Protocols, newsletters, clinical and preclinical data, and business plans) is considered proprietary and confidential to Bristol-Myers Squibb Company and its affiliates. You will hold all such BMS Confidential Information in confidence, will not use the BMS Confidential Information for any purpose other than the aforesaid evaluation purpose without first entering into an agreement with BMS covering the use thereof, and will not disclose the BMS Confidential Information to any other person or entity, including other employees or personnel of Institution, without BMS' prior written consent. The foregoing restrictions on confidentiality shall not apply to BMS Confidential Information which:

   (a) at the time of disclosure by BMS to you is in the public domain;

   (b) becomes part of the public domain by publication or otherwise, other than by breach of this Agreement by you or your employees or agents, after the date hereof;

   (c) you can establish by competent proof was in your possession without restriction as to confidentiality at the time of disclosure by us to you and which had not been previously acquired directly from BMS or indirectly from BMS through a third party; or

   (d) you receive without restriction as to confidentiality or use from a third party not under an obligation of confidentiality, direct or indirect, to BMS with respect to same.

   You may disclose BMS Confidential Information where required to do so by law. You will give BMS maximum practical advance notice of any such disclosure and provide reasonable cooperation at BMS' request to obtain and maintain available confidential treatment for same.

2. You will use all reasonable efforts to safeguard such BMS Confidential Information.

3. Nothing herein contained shall be construed as granting or implying any rights or license to you in the BMS Confidential Information disclosed to you pursuant to this Agreement or in any patent rights, copyrights, trademarks, or other intellectual property rights owned or controlled by BMS, other than the non-exclusive, personal right to use the BMS Confidential Information solely to evaluate your interest in conducting clinical trial(s) with us. Nothing in this Agreement creates, or is intended to create, any obligation, express or implied, on either you or BMS to negotiate or enter into any subsequent agreement under which you would conduct a clinical trial or other study with BMS.

4. You will not make copies or notes in any form of such BMS Confidential Information except as needed in furtherance of the above evaluation purpose. All BMS Confidential Information (and copies and notes thereof) shall remain the property of BMS, and shall be returned to BMS immediately following notice by either you or BMS that no interest exists in pursuing the above purpose for which such BMS Confidential Information was provided.

5 Where identified by BMS, you will delete BMS Confidential Information from any publication proposed to be made by you.

6 This Agreement shall continue unless and until terminated by a writing signed by both parties.

7. This Agreement sets forth the entire understanding of the parties with respect to the subject matter hereof, and there are no other understandings or agreements, written or verbal, relating to any such subject matter. The Agreement may not be changed or supplemented in any way, or the benefit of any provision hereof be waived, except by a written agreement duly executed by both you and BMS. This Agreement shall be governed by, enforced and interpreted in accordance with the laws of the State of Texas, without regard or giving effect to its principles of conflict of laws.

If you agree to the foregoing, kindly indicate your acceptance thereto by signing and dating the duplicate copy of this letter at the space provided for below, and returning such signed copy to us.

Very truly yours,

BRISTOL-MYERS SQUIBB
PHARMACEUTICAL RESEARCH
INSTITUTE

By:_____

Title:_____

AGREED TO AND ACCEPTED:

_____

Signature of Addressee

Date:_____

07953

AMENDMENT NO. 1
TO MASTER CLINICAL TRIAL AGREEMENT

This Amendment is entered into by and between **BRISTOL-MYERS SQUIBB PHARMACEUTICAL RESEARCH INSTITUTE** a division of E.R. Squibb & Sons, Inc., a Delaware corporation, having a place of business at Route 206 and Province Line Road, Princeton, NJ 08543-4000 (hereinafter "*BMS*"), and each of **The University of Texas Health Sciences Center at San Antonio, The University of Texas Health Science Center at Houston, The University of Texas - M.D. Anderson Cancer Center, The University of Texas Southwestern Medical Center at Dallas, The University of Texas Medical Branch at Galveston, and The University of Texas Health Center at Tyler** (each an "*Institution*"), each with an office and place of business as set forth on *Schedule 1.1(a)* of the Master Clinical Trial Agreement and each a component of The University of Texas System located at 201 West 7th Street, Austin, Texas 78701.

RECITALS

WHEREAS, SPONSOR and each Institution entered into a master agreement effective as of June 23, 1998, to cover the conduct of one or more clinical studies at each Institution under specific protocols involving BMS investigational drugs, and

WHEREAS, the parties now wish to amend the Master Clinical Trial Agreement.

NOW, THEREFORE, the parties agree to the following:

1. Section 1.1 is amended to add subparagraphs (g) as follows:

"(g) Each PARTICIPATING INVESTIGATOR shall provide such financial disclosures as required by applicable law to BMS as BMS may reasonably request, on such forms as BMS may supply or as BMS may approve, so that BMS may fulfill its certification and other financial disclosure obligations to applicable regulatory authorities in accordance with applicable law. During the term of an applicable Study and for one (1) year thereafter, each PARTICIPATING INVESTIGATOR shall update such forms promptly and provide same to BMS whenever any material change occurs in the information disclosed by a previous form or as may be requested by BMS."

2. This Amendment shall be effective upon signing by the last party to sign below. It shall apply to any studies that commence after, or are ongoing as of, February 1, 1999.

3. Except as amended by this Amendment, both parties hereby confirm that the Master Clinical Trial Agreement remains in full force and effect.

IN WITNESS WHEREOF, the parties have executed this Amendment in multiple counterparts by proper persons thereunto duly authorized.

BRISTOL-MYERS SQUIBB PHARMACEUTICAL RESEARCH INSTITUTE

By: _____
Sol I. Rajfer, M.D.
Title: Sr. V.P. WW Clinical R & D

Date: 5/21/99

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT SAN ANTONIO

By: _____
Jane A. Youngers, Director
Title: Office of Grants Management

Date: 5-14-99

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON

By: _____
David E. Kusnerik
Title: Contract Administrator

Date: 5/3/99

THE UNIVERSITY OF TEXAS M.D. ANDERSON CANCER CENTER

By: _____
Leonard A. Zwelling, MD, CBA
Title: Associate Vice President for
Date: 4/27/99 Research Administration

THE UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER AT DALLAS

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

Date: 4-13-99

THE UNIVERSITY OF TEXAS MEDICAL BRANCH AT GALVESTON

By: _____
Title: Director Clinical Trials

Date: 5/6/99

THE UNIVERSITY OF TEXAS HEALTH CENTER AT TYLER

By: _____
Title: Director, Sponsored Programs

Date: 4-16-99

[redacted]

AMENDMENT NO. 2
TO MASTER CLINICAL TRIAL AGREEMENT

This Amendment is entered into by and between **BRISTOL-MYERS SQUIBB PHARMACEUTICAL RESEARCH INSTITUTE** a division of E.R. Squibb & Sons, Inc., a Delaware corporation, having a place of business at Route 206 and Province Line Road, Princeton, NJ 08543-4000 (hereinafter "*BMS*"), and each of **The University of Texas Health Sciences Center at San Antonio, The University of Texas Health Science Center at Houston, The University of Texas - M.D. Anderson Cancer Center, The University of Texas Southwestern Medical Center at Dallas, The University of Texas Medical Branch at Galveston, and The University of Texas Health Center at Tyler** (each an "*Institution*"), each with an office and place of business as set forth on *Schedule 1.1(a)* of the Master Clinical Trial Agreement and each a component of The University of Texas System located at 201 West 7th Street, Austin, Texas 78701.

RECITALS

WHEREAS, BMS and each Institution entered into a master agreement effective as of *June 23, 1998 and amended May 21, 1999,* to cover the conduct of one or more clinical studies at each Institution under specific protocols involving BMS investigational drugs, and

WHEREAS, the parties now wish to amend the Master Clinical Trial Agreement.

NOW, THEREFORE, the parties agree to the following:

1. Article 4 is amended to add Section 4.3 as follows:

"4.3 (a) Institution agrees not to provide the Study Data (as defined below) to any third party or to use the Study Data in any commercially-sponsored research (that is, research sponsored by a commercial entity or in which a commercial entity has rights or an option to obtain rights), without BMS' prior written consent, which will not be unreasonably withheld. For purposes of this subsection (a) and subsections (c) and (d) below, "Study Data" means the data recorded on the clinical case report forms for each Study.

(b) Subject to Subsections (c) and (d) below, Institution agrees not to disclose the identity of any subjects participating in a Study.

(c) Institution agrees that it will not:

(i) assist a third party to identify Study subjects; or
(ii) conduct research sponsored by, or for the benefit of (or in which an option or license is granted to), any third party that involves the identification or use of, study Subjects.

This subsection (c) is not intended to and shall not preclude or limit further clinical or other research by Institution that is sponsored by or conducted for the benefit of third parties (x) involving any specific Study subjects or (y) that uses tissue, blood or other samples obtained from such Study subjects.

However, the process used to select any such Study subjects (or to obtain their samples) for such research must not: (1) be based in whole or in part on any such Study subject having participated in the BMS Study, or (2) use criteria pertinent to the BMS Study Protocol (including Study entry or

exclusion criteria and/or the Study Data) in order to identify all or substantially all of the Study subjects who were enrolled in such BMS Study.

(d) Nothing in subsections (a), (b) and (c) above shall affect Institution's right:

(i) to publish the Study Results or Study Data as set forth in this Master Agreement;
(ii) to use the Study Data for internal academic research as set forth in this Master Agreement;
(iii) to disclose information required by law; or
(iv) to disclose or use Study Data for the medical care of any specific Study subject.

For purposes of this subsection (d), "Study Results" means the findings or conclusions reached as a result of an analysis of the Study Data."

2. This Amendment shall be effective upon signing by the last party to sign below, and it shall apply thereafter to any previously completed studies, ongoing studies and future studies conducted by BMS at INSTITUTION.

3. Except as amended by this Amendment, both parties hereby confirm that the Master Clinical Trial Agreement remains in full force and effect.

IN WITNESS WHEREOF, the parties have executed this Amendment in multiple counterparts by proper persons thereunto duly authorized.

BRISTOL-MYERS SQUIBB PHARMACEUTICAL RESEARCH INSTITUTE

By: _____
Beth Seidenberg, M.D.
Sr. Vice President, Clinical Development & Life Cycle Management

Date: 6/2/00

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT SAN ANTONIO

By: Jane A Youngers
Jane A Youngers

Title: Director, Grants Management

Date: 11 July 00

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON

By: _____
David E. Kusnerik

Title: Contract Administrator

Date: 6/8/00

THE UNIVERSITY OF TEXAS M.D. ANDERSON CANCER CENTER

By: _____

Title: Vice President of Research Administration

Date: 6/6/00

THE UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER AT DALLAS

By: _____

Title: ASSOCIATE DEAN FOR RESEARCH

Date: 6/26/00

THE UNIVERSITY OF TEXAS MEDICAL BRANCH AT GALVESTON

By: _____
Cheryl M. Chanaud, Ph.D.

Title: Director, Office of Clinical Trials

Date: 6/21/00

THE UNIVERSITY OF TEXAS HEALTH CENTER AT TYLER

By: _____
Director of Sponsored Programs

Title: Research Mgm & Special Operations

Date: 7-10-00

THIRD AMENDMENT TO MASTER CLINICAL TRIAL AGREEMENT

This Amendment No. 3 to Master Clinical Trial Agreement is made and entered into on **May 18, 2001**, between Bristol-Myers Squibb Pharmaceutical Research Institute, a division of E.R. Squibb & Sons, Inc., a Delaware corporation, having a place of business at Route 206 and Province Line Road, Princeton, NJ 08543-4000 (hereinafter "BMS") and each of The University of Texas M.D. Anderson Cancer Center ("Institution"); The University of Texas Health Science Center at Houston ("Institution"); The University of Texas Medical Branch at Galveston ("Institution"); The University of Texas Health Science Center at San Antonio ("Institution"); The University of Texas Southwestern Medical Center at Dallas; and The University of Texas Health Center at Tyler ("Institution") (collectively, "Institutions"); each with an office and place of business as set forth on *Schedule 1.1(a)* of the Master Clinical Trial Agreement and each a component of The University of Texas System located at 201 West 7th Street, Austin, Texas 78701 to revise the following:

RECITALS

A. Sponsor and Institution entered into a Master Clinical Trial Agreement dated June 23, 1998. This Master Clinical Trial Agreement has subsequently been amended in May, 1999 and in July, 2000.

B. Sponsor and Institution again wish to amend the terms of the Master Clinical Trial Agreement as set forth below to clarify the parties' understanding regarding compensation statements.

NOW THEREFORE, it is hereby agreed as follows:

1. Revise Section 8.2 by deleting the following parenthetical in line 4:

   delete: "(except to the extent such costs are covered by the subject's insurance or other third party coverage)"

   Also, add at the end of Section 8.2 the following new paragraph:

   "Institution agrees that it and the Investigator will not seek or collect, and will not assist the Study subject in seeking or collecting, reimbursement from any health insurance plan, PPO, or governmental medical plan or other government-provided health coverage available to the subject for any medical expenses paid by BMS pursuant to this Section 8.2."

2. Revise Schedule 1.3 (ii) to delete reference to Schedule 1.3B-1 by deleting the following from lines 11 and 12:

   delete: "include the Compensation Statement verbatim attached as *Schedule 1.3B-1* hereto, and (B)"

3. Delete Schedule 1.3 B.1 in its entirety.

4. For the parties convenience, the revisions/deletions are hand noted on the attached pages excerpted from the Master Clinical Trial Agreement.

5. This Amendment shall be effective upon signing by the last party to sign below, and it shall apply thereafter to any previously completed studies, ongoing studies and future studies conducted by BMS at Institution.

6. Except as amended by this Amendment No. 3, all parties hereby confirm that the Master Clinical Trial Agreement remains in full force and effect.

ACCEPTED AND AGREED TO:

Bristol-Myers Squibb
Pharmaceutical Research Institute

Beth Seidenberg, M.D.
Sr. Vice President, Clinical Development &
Life Cycle Management

6/19/07
Date

The University of Texas M.D. Anderson Cancer Center

Leonard Zwelling, M.D., MBA, Associate Vice President
for Research Administration

5/29/07
Date

The University of Texas Health Science Center at Houston

David Kusnerik, Contract Administrator

5/21/07
Date

The University of Texas Health Science Center at San Antonio

Jane A. Youngers, Director, Office of Grants Management

6-11-01
Date

The University of Texas Southwestern Medical Center at Dallas

Perrie M. Adams, Ph.D., Associate Dean for Research

8/22/01
Date

The University of Texas Medical Branch at Galveston

Cheryl M. Chanaud, Ph.D., Director, Clinical Trials

5/31/01
Date

The University of Texas Health Center at Tyler

Michelle Hargis, Director, Sponsored Programs

6/05/01
Date