



NOVARTIS PHARMACEUTICALS CORPORATION

UTA09-000553

**MASTER CLINICAL TRIAL AGREEMENT
FOR MEMBER INSTITUTIONS
OF**

THE UNIVERSITY OF TEXAS SYSTEM:

**The University of Texas Health Science Center at San Antonio
The University of Texas Health Science Center at Houston
The University of Texas Health Science Center at Tyler
The University of Texas at Austin
The University of Texas M. D. Anderson Cancer Center
The University of Texas Medical Branch at Galveston
The University of Texas Southwestern Medical Center at Dallas**

Effective Date: May 1, 2009 through April 30, 2014

UT System Institutions & Novartis Sponsor-Initiated Protocol
Master Clinical Trial Agreement
Effective Date: May 1, 2009 through April 30, 2014

MASTER CLINICAL TRIAL AGREEMENT

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Attachment A: Clinical Trial Request Form (Schedule A: Budget and Payment Schedule to be attached)

MASTER CLINICAL TRIAL AGREEMENT

This Master Clinical Trial Agreement ("Agreement") is entered into by and between The University of Texas Health Science 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, The University of Texas at Austin and The University of Texas Health Science Center at Tyler, each a member institution of The University of Texas System located at 201 West 7th Street, Austin, Texas 78701 (each an "Institution") and Novartis Pharmaceuticals Corporation, a corporation with its principal office and place of business at 59 Route 10, East Hanover, NJ 07936 ("Novartis"). The place of business for the participating Institution in a Clinical Trial shall be outlined in the respective Attachment A, Clinical Trial Request Form ("CTRF").

1. SCOPE OF WORK

- A. During the Agreement Period (defined below), Institution shall conduct mutually-agreed-upon research and clinical trials ("Clinical Trials") in accordance with the referenced clinical trial protocol ("Protocol"), as may be modified from time to time in writing, and as set forth in a CTRF. The terms and conditions of this Agreement shall apply to any CTRF entered into prior to the end of the Agreement Period. This Agreement pertains only to Clinical Trials initiated by Novartis and to be performed under Protocols that are developed by Novartis. This Agreement does not contemplate that Institution will hold, and Institution will not hold, the IND for any Clinical Trial under this Agreement.
- B. Each Clinical Trial shall investigate the safety, efficacy and/or related properties of one or more active ingredients (each a "Study Drug"), alone or in comparison to a placebo and/or one or more other active ingredients (each a "Comparator Drug"). It is understood that various formulations of the Study Drug and Comparator Drug may be used in a Clinical Trial and, except where the contrary is clear from the context, the terms "Study Drug" and "Comparator Drug" mean each formulation actually used in a Clinical Trial and each active ingredient thereof. For the avoidance of doubt, when a Study Drug or a Comparator Drug is a combination of two or more active ingredients, except where the contrary is clear from the context, each active ingredient and each combination shall also be deemed to be a Study Drug or Comparator Drug, as the case may be.

2. AGREEMENT TERM

The term of this Agreement shall be from May 1, 2009 until April 30, 2014 ("Agreement Period").

3. CLINICAL TRIAL REQUEST FORM

- A. The specific requirements for any Clinical Trial, including a determination of whether the Clinical Trial is an "Oncology-related Clinical Trial", shall be set forth in a CTRF. CTRFs shall be in substantially the form attached hereto as Attachment A, and shall include the information noted thereon, including the referenced attachments. Other terms and conditions shall be as set forth in this Agreement. The principal investigator for each Clinical Trial ("Principal Investigator") shall indicate assent by signature on the relevant CTRF.
- B. A copy of the budget (Schedule A) for each Clinical Trial, including the payment schedule, shall be attached to the CTRF. Checks will be made payable as outlined on Schedule A and shall be a part thereof. The total cost to Novartis for the completion of such Clinical Trial by Institution shall not exceed the amount set forth in the applicable Schedule A. Payment includes all applicable overheads as stated in such Schedule A. Any payment(s) for partially completed enrolled patients will be prorated and will reference the Agreement number and shall be dependent upon Novartis' verification and approval.

- C. Payment shall be made to Institution according to Schedule A appended to the CTRF and incorporated therein by reference. All costs outlined on such Schedule A shall remain firm for the duration of the Clinical Trial covered by such CTRF, unless otherwise agreed to in writing by Institution and Novartis.
- (1) Neither Institution nor the Principal Investigator shall directly or indirectly seek or receive compensation from patients or third-party payers for any treatment or services or materials ("Treatment") that are required by the Protocol and are paid for by Novartis. These Treatments, shall include, but are not limited to, Study Drug, Comparator Drug or other drug provided by Novartis, patient screening, treatment visits, infusion, physician or nurse fee, diagnostic tests or Study Drug administration.
- D. Checks will reference the Protocol and Principal Investigator number and will be mailed to the address shown in Schedule A attached to the CTRF.

4. PRINCIPAL INVESTIGATOR

Institution's Principal Investigator identified on a CTRF will be responsible for the direction and performance of the Clinical Trial described in such CTRF and Protocol, in accordance with applicable Institution policies, which Institution represents are not inconsistent with the terms of this Agreement or the applicable CTRF and the Protocol. If for any reason, he/she is unwilling or unable to continue to serve as Principal Investigator and a successor, acceptable to both the Institution and Novartis, is not available, this Agreement shall be terminated as to the work contemplated in the applicable CTRF as provided in Article 15 (B).

5. PERFORMANCE PERIOD

The Clinical Trial will be initiated and completed by Novartis and Institution within the dates, and shall include the number of subjects set forth in the applicable CTRF.

6. RECORDKEEPING, REPORTING AND ACCESS

- A. It is agreed that Novartis' authorized representative(s) and regulatory authorities, to the extent required by law, may, during regular administrative business hours, arrange with advance written notice to the Principal Investigator and Institution:

- (1) examine and inspect the Institution's facilities required for performance of the Clinical Trial; and
- (2) inspect and copy all data and work products relating to the Clinical Trial, subject to any applicable privacy laws, regulations or requirements.

- B. The Institution and the Principal Investigator shall perform the following recordkeeping and reporting obligations in a timely fashion:

- (1) Prepare and maintain complete, accurately written records, accounts, notes, reports and data of the Clinical Trial. Federal regulations require that copies of case report forms (Case Reports) and all source documentation be retained by the Principal Investigator for a period of no less than two years following either the approval of the New Drug Application or the withdrawal of the Investigational New Drug Application. Foreign laws and regulations may require longer retention periods. For example, current International Conference on Harmonization ("ICH") guidelines currently provide:

"Essential documents should be retained until at least 2 years after the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applications in an ICH region or at least 2 years have elapsed since the formal discontinuation of clinical development of the investigational product. These documents should be retained for a longer period however if required by the applicable regulatory requirements or by an agreement with Novartis. It is the responsibility of Novartis to inform the Principal Investigator/Institution as to when these documents no longer need to be retained."

Institution shall retain the above records unless and until Novartis provides written permission to dispose of the same, consistent with applicable laws, regulations and guidelines. Novartis will respond promptly to Institution's requests directed to the Novartis contact for "Clinical Trial Related Matters" (identified below), to dispose of records.

Novartis will advise the Principal Investigator when the applicable retention period begins. Principal Investigator may be subject to a field audit by inspectors of the U.S. Food and Drug Administration ("FDA") and/or by Novartis representatives to verify that Clinical Trial is conducted according to the applicable Protocol, and is in compliance with the federal regulations relating to Investigational New Drugs; and

- (2) Prepare and submit to Novartis all original Case Reports and electronic files (if applicable) for each patient participating in the Clinical Trial ("Clinical Trial Subject").
- C. Novartis shall provide notice to Institution of any findings that could (i) affect the safety and welfare of Clinical Trial Subjects, (ii) affect the willingness of Clinical Trial Subjects to continue their participation in the Clinical Trial, (iii) influence the conduct of the Clinical Trial, or (iv) alter the IRB's approval to continue the Clinical Trial. Institution shall promptly notify the IRB of any such events. When Clinical Trial Subject safety or medical care could be directly affected by Clinical Trial results, then notwithstanding any other provision of this Agreement, Institution may send Clinical Trial Subjects a written communication about the results.

7. CONFIDENTIAL INFORMATION

- A. Subject to its rights under Article 8, the Institution and Principal Investigator agree not to disclose or to use for any purpose other than performance of the Clinical Trial any and all trade secrets, privileged records, results of the Clinical Trial, or other confidential or proprietary information (collectively "Confidential Information") disclosed to or developed by the Institution pursuant to this Agreement or CTRF relating to the Clinical Trial between Novartis and Institution. Information provided by each party to the other shall be provided on a "need-to-know" basis only. The obligation of non-disclosure and non-use shall not apply to the following:
- (1) Confidential Information at or after such time that it is or becomes publicly available through no fault of the Institution or Principal Investigator;
 - (2) Confidential Information that is already independently known to the Institution or the Principal Investigator as shown by prior written records, provided that the Institution or Principal Investigator promptly advises Novartis that the Confidential Information is already independently known to the Institution; provided further, that Novartis provides Institution with written notice of breach and Institution shall have 30 days to offer evidence of prior independent knowledge;
 - (3) Confidential Information at or after such time that is disclosed to the Institution or the Principal Investigator on a non-confidential basis by a third party with the legal right to do so;
 - (4) Confidential Information required by law or regulation to be disclosed, provided that the Institution or Principal Investigator notifies Novartis prior to making such disclosure;
 - (5) Confidential Information independently developed by Institution or Principal Investigator as shown by its prior written records.
 - (6) Confidential Information disclosed to Institution's IRB Committee and its members, provided that such IRB and its members are under a non-disclosure agreement substantially similar to that imposed on the Institution.
 - (7) Confidential Information disclosed in order to obtain informed consent from patients or subjects who may wish to enroll in the Clinical Trial, provided, however, that the Confidential Information will

be disclosed only to the extent necessary and will not be provided in answer to unsolicited inquiries by telephone or to individuals who are not eligible Clinical Trial candidates.

- B. Institution or the Principal Investigator shall also be permitted to disclose Confidential Information for the purposes of emergency or immediate treatment of a Clinical Trial Subject, provided that any such disclosure is limited to the extent reasonably necessary and provided further that Institution gives notice to Novartis prior to making such release of Confidential Information (if reasonably possible, and, if not, promptly after making such disclosure).
- C. All written records, reports and data of the Clinical Trial (other than individual patient records and the physical laboratory notebooks of Institution's research personnel) shall be the sole and exclusive property of Novartis. However, nothing shall prevent the Institution and the Principal Investigator from:
 - (1) maintaining copies of such materials;
 - (2) using such materials for their own internal educational, research and patient care purposes;
 - (3) using such materials to comply with any federal, state or local government laws or regulations; or
 - (4) publishing articles based on these materials under the provisions of this Agreement.
- D. Novartis and its affiliates, assigns, licensees and its licensors and its licensors' affiliates, assigns and other licensees shall be free to incorporate the results of the Clinical Trial in any regulatory filing concerning the Study Drug as defined in Section 1. The Institution understands and agrees that they shall have no ownership, license or access rights in, or to, such regulatory filings solely based upon the inclusion of the results of the Clinical Trial therein.
- E. The obligations of the Institution under Section 7 shall survive and continue for five (5) years after termination of the CTRF. Notwithstanding any other provision of this Agreement, if and when Confidential Information is subject to one of the exclusions mentioned in Section 7(A)1, 2, 3 and/or 5 above or is no longer confidential as a result of an authorized disclosure of such information under the terms of this Agreement or is subject to disclosure under Texas' Open Records Act, including any publication in accordance with Section 8 below, then Institution will not have any restriction upon its use or disclosure of such information.
- F. If Novartis comes into contact with a Clinical Trial Subject's medical records, Novartis shall hold in confidence the patient's identity and shall comply with all applicable laws regarding the confidentiality of such records.
- G. If the Institution finds it necessary to disclose Confidential Information to a proper authority to defend its Clinical Trial against an allegation of fraud, the Institution shall first notify Novartis and the Institution and Novartis shall agree upon a mutually satisfactory way to disclose such Confidential Information for this limited purpose.
- H. Should Novartis come into contact with any proprietary information, trade secrets, internal business records, or records of another sponsor or project unrelated to a Novartis Clinical Trial, Novartis shall treat those records as confidential, in a manner consistent with how it treats its own trade secrets.
- I. The Institution hereby represents, certifies and agrees that, as of the date of enrollment of each individual participating as a Clinical Trial Subject, it will obtain from each such individual an authorization that meets the requirements of the privacy rule issued under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA Privacy Rule") set forth at 45 CFR 164.508(b) and (c). Such authorization shall permit (i) all necessary uses of the individual's "protected health information", as that term is defined in the HIPAA Privacy Rule, 45 CFR 164.501, by the Institution and the Principal Investigator as part of the Clinical Trial and (ii) all disclosures of such protected health information by the Institution and the Principal Investigator to Novartis and its authorized agents and the Clinical Trial team and other professionals involved in the Clinical Trial for purposes relating to the Clinical Trial or other purposes permitted by law or regulation. The authorization is subject to the

approval of the Institution's IRB and Novartis, and until the Institution's IRB approves an authorization that meets the above obligations, the Institution cannot conduct the Clinical Trial.

8. PUBLICATIONS/PRESENTATIONS

- A. The presentation and publication of the results of the Clinical Trial in accordance with the provisions of this Section is permissible. Novartis acknowledges that each Institution is dedicated to a free scholarly exchange and to public dissemination of the results of their scholarly activities.
- B. For any publication or presentation, a manuscript of the paper, abstract or other materials must be reviewed by Novartis prior to any outside submission. A period of fifteen (15) working days for presentational materials and abstracts and forty-five (45) working days for manuscripts will be required for Novartis review. These requirements acknowledge Novartis' responsibility to evaluate such publications for their accuracy, to ascertain whether proprietary or Confidential Information (including trade secrets and patent protected materials) is being utilized and inappropriately released, to provide the investigator with information which may not yet have been available to him/her, and to provide input from co-authors regarding content and conclusions of the publication or presentation.
- C. If an invention is described in a proposed publication which in the opinion of Novartis, and at its sole expense, should be made the subject of a patent application, Novartis shall have three (3) months after full disclosure to Novartis to file such patent application. Institution shall withhold publication with respect to such invention until such application is so filed by Novartis provided, however, that such delay shall not exceed this three (3) month period.
- D. For multicenter studies it is mandatory that the data be pooled and analyzed as stipulated in the Protocol. Authorship will include representatives from each active Clinical Trial site and from Novartis. It is agreed that no presentations or publications will be authorized individually or by subgroups participating in the Clinical Trial without the consent of all the relevant parties prior to publication of the pooled data, but in no event shall any Institution involved in the Clinical Trial be restricted from publishing independently after the expiration of eighteen (18) months from the completion, termination or abandonment of the Clinical Trial at all sites, provided, however, that all other provisions of this Section have been satisfied and provided that the presentation or publication adequately describes the results as obtained from a dataset other than the final pooled dataset, if that is the case.

9. INVENTIONS AND PATENTS

- A. All inventions and patents resulting from the performance of the Clinical Trial shall be owned by Novartis and may be used and/or transferred by Novartis for any lawful purpose with no further payment to the Institution and/or Principal Investigator. The Institution and Principal Investigator shall be free to use such inventions and patents for their own internal educational, research and patient care purposes, as well as to comply with any federal, state or local government laws or regulations.
- B. In the event that Novartis decides to file one or more United States and/or foreign patent applications covering one or more inventions resulting from the performance of the Clinical Trial, the Institution and each Principal Investigator shall, at the request and expense of Novartis, assist Novartis in the preparation and prosecution of such patent application(s) and shall execute all documents deemed necessary by Novartis for the filing thereof and/or for the vesting in Novartis of title thereto.
- C. The Institution agrees that no part of the Clinical Trial shall be conducted under a "funding agreement" (such as defined in 35 USC 201) with the United States Government or any agency thereof that may jeopardize or adversely impact on the rights granted to Novartis in this Article 9.

10. PUBLICITY

- A. Neither party shall use the other party's name, nor issue any public statement about this Agreement, including its existence, without the prior written permission of the other party, except as required by law

(and, in such case, only with prior notice to the other party if reasonably possible, and if not, as many days as reasonably possible). The preceding sentence shall not apply to presentations and publications in accordance with the provisions of Section 8. To the extent permission is required, such prior permission shall not be unreasonably withheld. The parties agree that in order for Institution to satisfy its reporting obligations, it may identify Novartis as the Clinical Trial sponsor and the amount of funding received from Novartis for the Clinical Trial, but will not include in such report any information which identifies the name of the Study Drug.

- B. All advertising of a Clinical Trial must be reviewed and approved by Novartis prior to use. Principal Investigator must inform the Institutional Review Board ("IRB") should (s)he propose to utilize advertisements to recruit Clinical Trial Subjects. Principal Investigator will supply the proposed advertisement to Novartis and the IRB for approval. Any promotional representation or suggestion that an investigational Study Drug is safe or effective for the purposes for which it is offered under investigation, is a violation of federal regulations 21 CFR 312.7 (a).
- C. As part of the registration of a Clinical Trial on www.ClinicalTrials.gov and/or other applicable clinical trial registries, Novartis may disclose the Institution's name and contact information (including, but not limited to, the Institution's address and telephone number) and the name of the Principal Investigator.

11. APPLICABLE LAW

This Agreement shall be governed by the laws of the State of Texas.

12. NOTICE

- A. Any notice required or permitted hereunder for this Agreement shall be in writing and shall be deemed given as of the date it is (A) delivered by hand or (B) sent by registered or certified mail, postage prepaid, return receipt request, and addressed to the party to receive such notice at the address set forth below, or such other address as is subsequently specified in writing, as well as any persons so designated under an applicable CTRF, including the Principal Investigator. For the avoidance of doubt, a writing provided by E-mail shall **not** be deemed to comply with the notice requirements of this Agreement.

IF TO NOVARTIS:

Ann Koch
Novartis Pharmaceuticals Corporation
One Health Plaza
East Hanover, NJ 07936-1080
862-778-6873 (Tel)

IF TO UT SYSTEM:

BethLynn Maxwell, Ph.D., J.D.
Senior Attorney
The University of Texas System
Office of General Counsel
201 West 7th Street
Austin, Texas 78701
phone 512-499-4518

- B. Any notice relating to a Clinical Trial or a CTRF shall be given as set forth in Section 2 of the CTRF.
- C. Upon conclusion of a Clinical Trial, if the Institution is unable to communicate with and/or contact one of the Novartis personnel referenced above or in the CTRF, the Institution shall telephone 1-888-669-6682 to obtain the appropriate contact information.

13. INDEMNIFICATION AND INSURANCE

- A. Novartis shall defend, indemnify and hold harmless the Institution, the Principal Investigator, The University of Texas System, their Regents, officers, agents and employees (collectively the "Indemnitees") from any and all liabilities, claims, actions or suits for personal injury or death arising out from (i) any non-standard of care properly performed procedures required by the Protocol (non-standard of care procedures being defined as those which the Principal Investigator would not have performed as a matter of routine care of the Clinical Trial Subject's disease, and which are solely being

performed to satisfy the Protocol), (ii) Novartis' use of the results obtained from the performance of the Clinical Trial, or (iii) in connection with the administration or use of the Study Drug as set forth in the Protocol during the course of the Clinical Trial, provided however:

- (1) that the Clinical Trial is conducted in accordance with the respective Protocol, compliance with the applicable requirements of the FDA, all written instructions delivered by Novartis concerning administration of the Study Drug, Comparator Drug or devices and Good Clinical Practice regulations;
 - (2) that such loss does not arise out of the negligence or willful malfeasance of any Indemnitee, exclusive of Novartis employees, or any other person on the Institution's property, exclusive of Novartis employees or agents.
 - (3) that Novartis is promptly notified in writing no later than ten (10) business days of any complaint, claim or injury relating to any loss subject to this indemnification, provided, however, that if such notice or notification is given more than ten (10) days after receipt of such notice or notification, this indemnification provision shall nonetheless apply unless Novartis has been materially prejudiced in its defense by such late notice or notification; and
 - (4) that Novartis shall have the right to select defense counsel for whose fees it may be liable and to direct, subject to the statutory duties of the Texas Attorney General, the defense or other disposition (including settlement) of any such claim or suit.
- B. Deviations from the terms of the Protocol that may arise out of necessity do not constitute negligence or willful malfeasance provided that Institution promptly notifies Novartis in writing of any such deviations.
- C. Novartis warrants that it maintains a policy or program of insurance or self-insurance at levels sufficient to support the indemnification obligations assumed herein. Upon request Novartis will provide evidence of its insurance.
- D. Institution, as a member institution of The University of Texas System, is an agency of the State of Texas and is self-insured pursuant to The University of Texas System Professional Medical Liability Benefit 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. The Institution is responsible for the conduct of its employees to the extent provided for in Texas Tort Claims Act Chapter 101, Texas Civil Practice and Remedies Code.

14. CLINICAL TRIAL SUBJECT INJURY

- A. Institution may arrange for care for any research related injury. Novartis will provide payment to the Institution for reasonable, unreimbursed medical expenses, including hospitalization, which the Institution may incur as a direct result of the treatment of a Clinical Trial Subject's injuries which directly result from the Study Drug taken during the Clinical Trial or directly as a result of non-standard of care properly performed procedures required by the Protocol as defined in Section 13A. Institution need not submit to federally funded programs for reimbursement first if submission to such programs is prohibited by law. Novartis will not provide payment for expenses that are in any way attributable to the negligence or misconduct of any person employed by or acting on behalf of the Institution, or the Clinical Trial Subject's failure to follow instructions. Novartis will not pay for medical expenses for injuries unrelated to the Study Drug or the non-standard of care properly performed procedures outlined above, or which are in any way attributable to the natural course of any underlying disease or treatment process. No other type of compensation will be provided by Novartis. Institution acknowledges that the Clinical Trial Subject is not obligated to seek such treatment from the Institution.

15. TERMINATION OF THIS AGREEMENT OR OF A CLINICAL TRIAL

- A. A Clinical Trial hereunder may be terminated by either party for any regulatory, safety and/or efficacy concerns, upon ten (10) days prior written notice.

- B. A Clinical Trial under any individual CTRF may be terminated by Novartis for any reason, upon thirty (30) days written notice.
- C. In the event that Novartis shall materially breach a Clinical Trial under this Agreement and a corresponding CTRF, the Institution shall give Novartis written notice specifying such breach with reasonable detail. Should Novartis fail to cure such breach within thirty (30) calendar days of its receipt of such notice, then Institution may terminate a Clinical Trial.
- D. Novartis will pay Institution within sixty (60) days any funds due regarding the terminated Clinical Trial based on the pro-rata per Clinical Trial Subject amount based on Clinical Trial Subjects completed and/or accrued under the CTRF budget terms.
- E. The Institution will return within sixty (60) days to Novartis any funds received regarding such terminated Clinical Trial exceeding the pro rate per Clinical Trial Subject amount based on Clinical Trial Subjects completed and/or accrued under the CTRF budget terms.
- F. Immediately upon receipt of a notice of termination, the Principal Investigator shall stop entering Clinical Trial Subjects into the relevant Clinical Trial and as directed by Novartis and to the extent medically permissible shall cease conducting procedures on Clinical Trial Subjects already entered in the Clinical Trial.
- G. Termination of this Agreement or a CTRF by either party shall not affect the rights and obligations of the parties accrued prior to the effective date of the termination. The rights and duties under Articles 6, 7, 8, 9, 10, 11, 13, 14, 15, 20, 21 and 22 survive the termination or expiration of this Agreement.

16. ENTIRE AGREEMENT

This Agreement represents the entire understanding of the parties with respect to the subject matter hereof. In the event of any inconsistency between this Agreement and the Protocol, the terms of this Agreement shall govern. The invalidity or unenforceability of any term or provision of this Agreement shall not affect the validity or enforceability of any other term or provision hereof.

17. ASSIGNMENTS BY INSTITUTION

Institution may not assign this Agreement, and all rights and obligations hereunder, without the express written consent of Novartis.

18. NO TRANSFER OF PROPRIETARY RIGHTS NOT SPECIFIED

It is agreed that neither party transfers to the other any patent right, copyright right, or other proprietary right of either party, except as specifically set forth herein.

19. CHANGES TO THE PROTOCOL

Upon written notice to Institution and subject to written approval by Institution, the Principal Investigator and, if required, by the Institutional Review Board, Novartis may at any time modify a Protocol. No financial adjustments shall be made because of such modification unless the parties hereto amend the applicable CTRF accordingly, provided, however, that if the changes to a Protocol materially increase the cost of performance of the Clinical Trial by Institution, then as a prerequisite to the implementation of the changes, the parties shall renegotiate the budget for the Clinical Trial in good faith.

20. DELIVERY TO NOVARTIS OF UNUSED MATERIALS

Within thirty (30) days following termination or completion of the Clinical Trial, all unused Study Drug, Comparator Drug, devices, Case Reports, whether or not completed, and other related materials that were furnished to the Institution by or on behalf of Novartis shall be returned to Novartis at Novartis' expense.

21. CONFORMANCE WITH LAW AND ACCEPTED PRACTICE

The Institution shall perform the Clinical Trial in conformance with generally accepted standards of good clinical practice, with the Protocol, the Institution's human subject research protection program and policies provided they are not in contradiction with regulations and Good Clinical Practices, and with all applicable local, state, federal and foreign laws and regulations governing the performance of clinical investigations including but not limited to the Federal Food, Drug and Cosmetic Act, regulations of the FDA including 21 CFR Part 54 relating to Financial Disclosure by Clinical Investigators [if applicable], and the privacy rule issued under HIPAA.

22. DEBARMENT CERTIFICATION

Neither the Institution nor any person employed thereby directly in the performance of the Clinical Trial has been debarred under section 306(a) or (b) of the Federal Food, Drug and Cosmetic Act and no debarred person will in the future be employed by the Institution in connection with any work to be performed for or on behalf of Novartis. In addition, the Institution has verified that no person employed by the Institution in connection with any work performed for or on behalf of Novartis is on any of the following FDA Restricted Lists: Disqualified/Totally Restricted List for Clinical Investigators, Restricted List for Clinical Investigators, Adequate Assurances List for Clinical Investigators. If at any time after execution of this Agreement, the Institution becomes aware that the Institution or any person employed thereby is, or is in the process of being debarred or is on any of the 3 FDA Restricted Lists noted above, the Institution hereby certifies that the Institution will promptly notify Novartis in writing.

23. USE OF MASTER AGREEMENT BY THIRD-PARTY AGENT/CRO

Novartis shall require each of its third-party Clinical Research Organizations ("CROs"), whenever employed, to utilize this Agreement.

24. BIOLOGICAL SAMPLES

- A. "Biological Samples" include, without limitation, blood, serum, fluid and tissue biopsy samples collected from Clinical Trial Subjects (as defined in Section 6B(2)) enrolled in the Clinical Trial. 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.
- B. (1) Institution's Collection, Retention and Use of Biological Samples.
Institution will collect, retain and use Biological Samples in accordance with the Protocol. Institution may collect and/or reserve additional quantities of Biological Samples ("secondary Biological Samples") for use in research not described in the Protocol ("non-Protocol research"), provided that (a) such collection complies with all applicable laws, regulations and acceptable clinical trial practices, including, but not limited to, patient privacy and informed consent laws in the country in which the Clinical Trial is being conducted, and (b) no Confidential Information or any other information which links the secondary Biological Samples to any Confidential Information is available to investigator(s) for such non-Protocol research (for example, without limitation, Institution may annotate such secondary Biological Samples with Clinical Trial Subject 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).
- (2) Novartis' Receipt and Use of Biological Samples.

Novartis shall receive pre-determined quantities of Biological Samples from Institution, as set forth in the Protocol, for use in research as generally described in the Protocol, provided that such research complies with all applicable laws and regulations, including, but not limited to, patient privacy and informed consent laws in the country in which Biological Samples were collected. Using the same unique identifier ("Study Subject Number") utilized to identify the original Biological Sample, Novartis will disclose and provide to the Principal Investigator in a timely manner upon written request all raw data generated by Novartis in support of the primary objectives of the Clinical Trial, as specified in and required by the Protocol, and which is derived from Biological Samples ("Biological Samples Raw Data"). Novartis agrees to make reasonable efforts to disclose and provide such Biological Samples Raw Data to Institution, upon written request to Novartis, within one year after completion of the Protocol, or for multicenter studies, within one year after completion of the Protocol at all sites. For sake of clarity, Institution agrees not to perform experiments with or analyze Biological Samples Raw Data which are pre-obligated and/or encumbered in some manner. Such Biological Samples Raw Data (i) shall be treated by Institution as Confidential Information under this Agreement; (ii) Institution agrees to maintain the patient's confidential information as set forth in the informed consent document that corresponds to the Protocol; (iii) the Principal 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; (iv) Institution may use such Biological Samples Raw Data for its own internal non-commercial research and academic purposes, (v) Institution may disclose such Biological Samples Raw Data to other academic investigators outside Institution for non-commercial collaborative research and academic purposes, provided that investigators outside Institution and any institution to whom such investigators may have an obligation to assign inventions or other intellectual property rights enter into a Proprietary Data Transfer Agreement with Novartis, and Institution will identify in writing to Novartis any such Biological Samples Raw Data provided to other academic investigators at the time it is provided, and (vi) all publications relating to the Biological Samples Raw Data and all data, information and inventions resulting from the use of Biological Samples Raw Data shall be in performance of the Clinical Trial and subject to all provisions of this Agreement.

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

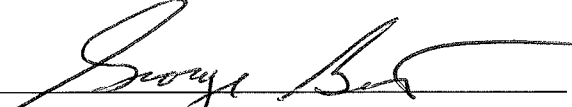
25. STATE AGENCY LIMITATIONS

Institution is an agency of the State of Texas and, under the Constitution and the laws of the State of Texas, possesses certain rights and privileges, is subject to certain limitations and restrictions, and only has such authority as is granted to it under the Constitution and laws of the State of Texas. Notwithstanding any provision hereof, nothing in this Agreement is intended to be, nor will it be construed to be, a waiver of the sovereign immunity of the State of Texas or a prospective waiver or restriction of any of the rights, remedies, claims, and privileges of the State of Texas. Moreover, notwithstanding the generality or specificity of any provision hereof, the provisions of this Agreement as they pertain to Institution are enforceable only to the extent authorized by the Constitution and laws of the State of Texas.


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IN WITNESS WHEREOF, the parties hereto have executed this Agreement in duplicate by proper persons thereunto duly authorized.

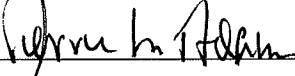
NOVARTIS PHARMACEUTICALS CORPORATION

By: 
George Betts
Executive Director, US Medical Operations (USCD)
Date: 6/24/2009

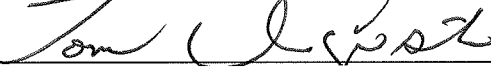
**THE UNIVERSITY OF TEXAS
M. D. ANDERSON CANCER CENTER**

By: 
Printed Name: Melinda Cotten, CRA
Executive Director, Sponsored Programs
Title: _____
Date: 6/4/09


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

By: 
Printed Name: Perrie M. Adams, Ph.D.
Title: Associate Dean for Research
Date: 6/12/09

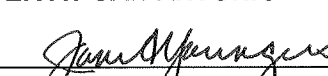
**THE UNIVERSITY OF TEXAS MEDICAL BRANCH AT
GALVESTON**

By: 
Printed Name: Toni D'Agostino
Director, Sponsored Programs
Title: _____
Date: 6/10/09


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

By: 
Printed Name: Conna Sutton
Director, Pre-Award Services
Title: _____
Date: 5/27/09


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

By: 
Printed Name: Jane A. Youngers
Title: Assistant Vice President for Research
Date: 6-15-09

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

By: 
Printed Name: Jodi S. Ogden
Contracts Director
Office of Sponsored Projects
Title: _____
Date: 6/8/09

THE UNIVERSITY OF TEXAS AT AUSTIN

By: 
Printed Name: Susan W. Sedwick
Associate VP for Research
Director, Office of Sponsored Projects
Title: _____
Date: JUN 17 2009



ATTACHMENT A: Clinical Trial Request Form

THE UNIVERSITY OF TEXAS
(Insert Location)

This Clinical Trial Request Form shall be binding upon the undersigned upon its execution by the duly authorized representatives of the Parties as of the day and year of the Effective Date below. It is subject to the terms of the Master Clinical Trial Agreement dated May 1, 2009 and attached hereto.

1. CLINICAL TRIAL-RELATED INFORMATION

Effective Date:

Principal Investigator:

(For Institution Use)
Account No. / Agreement No.:

Study Drug:
Brief Description of Clinical Trial:
[Protocol Title]:

Is This a Multi-Center Trial? [Yes or No]:

Will this Clinical Trial be registered on www.clinicaltrials.gov? **Note to Novartis CM:** If answer is Yes, add the following into Section 3 (Modifications) of this CTRF. If "No", answer accordingly and delete the following.

Section 10D (Publicity) is hereby incorporated into the Agreement for this Clinical Trial as follows:
"10D. Novartis agrees to register the Clinical Trial on www.clinicaltrials.gov, populating all required fields."

Clinical Trial Dates (Performance Period):

Initiation:
Completion:
Is this an Oncology-Related Clinical Trial?
[Yes or No]:

Number of Patients To Be Enrolled:

(For Institution Use)
Are Biological Samples as defined in Article 24 contemplated in this Protocol?
[Yes or No]:

2. NOTICE

Any notice required or permitted hereunder shall be in writing and shall be deemed given as of the date if it is (A) delivered by hand or (B) sent by registered or certified mail, postage prepaid, return receipt request, and addressed to the party to receive such notice at the address set forth below, or such other address as is subsequently specified in writing, as well as any persons so designated under the Master Clinical Trial Agreement itself:

IF TO NOVARTIS:

For Payment and Clinical Related Matters:

{ Enter the Clinical Trial Leader's Name,
Address, & Phone }

For Contract Matters:

Insert Contract Manager's Name
Novartis Pharmaceuticals Corporation
One Health Plaza 59 Route 10, Bldg. 419-2
East Hanover, NJ 07936-1080
Phone: 862-778-_____

For all payment queries, the following information must be provided (please refer to Schedule A):

- 1. Project (compound)
- 2. Study #
- 3. Center #
- 4. PI name
- 5. PO # (if available)

The above information must also be included on all invoices.

If to INSTITUTION:

For Administrative/ Contract Matters: (Delete any locations not used for this CTRF)

Insert Contact Name
UT M.D. Anderson Cancer Center
Office of Sponsored Programs
1515 Holcombe Boulevard
Houston, TX 77030
phone: 713-XXX-XXXX
Tax ID: 74-6001118

Insert Contact Name
Clinical Trials Office
The University of Texas Southwestern
Medical Center at Dallas
5323 Harry Hines Blvd.
Dallas, TX 75390-9016
phone: 214-XXX-XXXX
Tax ID: 75-6002868

Insert Contact Name
The University of Texas Health Science
Center at Houston
P.O. Box 20036
Houston, TX 77225
phone: 713-XXX-XXXX
Tax ID: 74-1761309

Insert Contact Name
The University of Texas Health Science Center at
Tyler
11937 U.S. Hwy. 271
Tyler, TX 75708-3154
phone: 903-XXX-XXXX
Tax ID: 75-600-1354

Overnight address is:
7000 Fannin Street, Suite 1006
Houston, TX 77030

Insert Contact Name
The University of Texas
Medical Branch at Galveston
Office of Sponsored Programs
4.400 Rebecca Sealy Hospital
Galveston, TX 77555
phone: (409) XXX-XXXX
Tax ID: 74-6000949

Insert Contact Name
The University of Texas Health Science
Center at San Antonio
7703 Floyd Curl Drive, Mail Code 7828
San Antonio, TX 78229-3900
phone: 210-XXX-XXXX
Tax ID: 74-1586031

Insert Contact Name

The University of Texas at Austin
PO Box 7726
Austin, TX 78713-7726
Phone XXX-XXX-XXXX
Tax I.D. 74-600023

3. MODIFICATIONS AND ADDITIONAL TERMS FOR THIS CLINICAL TRIAL:

NOTE: This Section 3 supersedes any conflicting provisions of the Master Clinical Trial Agreement and must be approved in writing by Institution and the Office of General Counsel of The University of Texas System. The parties agree and acknowledge that this Section 3 will only be used for Clinical Trial-specific revisions on a case-by-case basis. The parties further agree and acknowledge that this Section 3 is not intended to be used to revise terms or conditions that are applicable to all Clinical Trials and that the Master Clinical Trial Agreement will be duly revised for such revisions.

If this Clinical Trial Request Form requires services to be performed beyond the expiration or termination date of the Master Clinical Trial Agreement, then the terms of the Master Clinical Trial Agreement shall remain in effect until the expiration or termination of this CTRF.

4. LIST OF ATTACHMENTS AND PROTOCOL:

Protocol: [Code Number and Title]:
Schedule A
Copy of Master Clinical Trial Agreement

5. COST AND PAYMENT

- A. Payment shall be made to the Institution according to Schedule A appended hereto and incorporated herein by reference. All costs outlined on Schedule A shall remain firm for the duration of the Clinical Trial, unless otherwise agreed to in writing by the Institution and Novartis.
- B. Checks will be made payable to “ **Insert name from Contacts above** ”. Checks will reference the Protocol number and the Principal Investigator and will be mailed to the address shown in Schedule A.
Institution Tax Identification Number: **Insert TAX ID # from above**
- C. The costs of the Clinical Trial set forth on the Schedule A attached hereto represent all costs of performing the Clinical Trial, including overhead.

REST OF PAGE LEFT INTENTIONALLY BLANK

In Witness Whereof, the parties hereto have executed this Clinical Trial Request Form in duplicate by proper persons thereunto duly authorized.

NOVARTIS PHARMACEUTICALS CORPORATION

ENTER INSTITUTION NAME}

By _____
(signature)

By _____
(signature)

(print or type name)

(print or type name)

Title: _____

Title: _____

Date _____

Date _____

PRINCIPAL INVESTIGATOR

I have read this Clinical Trial Request Form, including the copy of the Master Clinical Trial Agreement, and understand and accept my obligations hereunder.

By _____
(signature)

(print or type name)

Title _____

Date _____