

**MASTER CLINICAL TRIAL AGREEMENT  
FOR INSTITUTIONS  
AT THE UNIVERSITY OF TEXAS SYSTEM**

**Effective Date: January 1, 2004 through December 31, 2008**

# MASTER CLINICAL TRIAL AGREEMENT

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# 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 and The University of Texas Health Center at Tyler each with an office and place of business as set forth in Article 12 and each a component 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").

## 1. SCOPE OF WORK

During the Agreement Period (defined below), Institution shall conduct the research ("Research"), including 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 individual Clinical Trial Request Forms, as hereinafter described. The terms and conditions of this Agreement shall apply to any Clinical Trial Request Form(s) entered into prior to the end of the Agreement Period.

## 2. AGREEMENT TERM

The term of this Agreement shall be from January 1, 2004 until December 31, 2008 (5 years from the effective date) ("Agreement Period").

## 3. CLINICAL TRIAL REQUEST FORM

- A. The specific requirements for any Research, including a determination of whether the Research is an "Oncology-related research trial", shall be set forth in Clinical Trial Request Forms. Clinical Trial Request Forms 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 Clinical Trial Request Form.
- B. A copy of the budget (Schedule A) for each Clinical Trial, including the payment schedule, shall be attached to the Clinical Trial Request Form. Checks will be made payable to the applicable Clinical Trial Request Form Institution(s) 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 Clinical Trial Request Form and incorporated therein by reference. All costs outlined on such Schedule A shall remain firm for the duration of the Research covered by such Clinical Trial Request Form, 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, test compounds provided by Novartis, patient screening, treatment visits, infusion, physician or nurse fee, diagnostic tests or test compound administration.

- D. Checks will reference the Agreement number and/or account name referenced in the applicable Clinical Trial Request Form and the account name and will be mailed to the address shown in Schedule A attached to such Clinical Trial Request Form.

#### 4. PRINCIPAL INVESTIGATOR

Institution's Principal Investigator identified on a Clinical Trial Request Form will be responsible for the direction and performance of the Research described in such Clinical Trial Request Form and Protocol, in accordance with applicable Institution policies, which Institution represents are not inconsistent with the terms of this Agreement or the applicable Clinical Trial Request Form 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 Clinical Trial Request Form as provided in Article 15 (B).

#### 5. PERFORMANCE PERIOD

The Research program will be initiated and completed by Novartis and Institution within the dates, and shall include the number of Research Subjects (as defined below in Section 6B(2)) set forth in the applicable Clinical Trial Request Form. In the event that the Research is not completed within the specified period (also known as the "Performance Period"), Novartis may extend the period by written notification to the Institution.

#### 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 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 Research; and
- (2) inspect and copy all data and work products relating to the Research, provided that no portion of a Research Subject's medical record will be copied.

- 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 Research. 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 direct to the Novartis contact for "Research 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 Research 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 Research ("Research Subject").

## 7. CONFIDENTIAL INFORMATION

- A. Subject to its rights under Article 8, the Institution agrees not to disclose or to use for any purpose other than performance of the Research any and all trade secrets, privileged records, results of the Research, or other confidential or proprietary information (collectively "Information") disclosed to or developed by the Institution pursuant to this Agreement or any previous confidentiality agreement(s) relating to the Research 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) information at or after such time that it is or becomes publicly available through no fault of the Institution;
  - (2) information that is already independently known to the Institution as shown by its prior written records, provided that the Institution promptly advises Novartis that the 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) information at or after such time that is disclosed to the Institution on a non-confidential basis by a third party with the legal right to do so;
  - (4) information required by law or regulation to be disclosed, provided that the Institution notifies Novartis prior to making such disclosure;
  - (5) information independently developed by Institution as shown by its prior written records.
- B. All written records, reports and data of the Research (other than individual patient records) 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.
- C. 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 Research in any regulatory filing concerning the test compound(s). 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 Research therein.

- D. The obligations of the Institution under this Article shall survive and continue for five (5) years after termination of this Agreement.
- E. If Novartis comes into contact with Research 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.
- F. If the Institution finds it necessary to disclose Information to a proper authority to defend its Research 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 Information for this limited purpose.
- G. To the extent required by the privacy regulations issued pursuant to the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), 45 C.F.R. Parts 160 & 164, Novartis agrees that it will appropriately safeguard protected health information ("PHI"). As used in this Agreement, PHI shall have the meaning of that term as defined in the HIPAA privacy regulations.

## 8. PUBLICATIONS/PRESENTATIONS

- A. Novartis acknowledges that each Institution is dedicated to a free scholarly exchange and to public dissemination of the results of their scholarly activities. Except as set forth in this Article or in the CONFIDENTIAL INFORMATION and DATA, OTHER INFORMATION, INVENTIONS AND PATENTS Articles, nothing in this Agreement shall restrict the right of each Institution, its physicians, other employees and/or students to publish, disseminate, or otherwise disclose the results of the Research pursuant to this Agreement.
- 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 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 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, however, 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 Research be restricted from publishing independently after the expiration of twenty-four (24) months from the completion of the Research covered by the applicable Clinical Trial Request Form.

## 9. INVENTIONS AND PATENTS

- A. All inventions and patents resulting from the performance of the Research 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 Research, 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 Research 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 Article 9.

## 10. PUBLICITY

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). 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 Research sponsor and the amount of funding received from Novartis for the Research, but will not include in such report any information which identifies the name of the Research compound or the therapeutic areas of the Research.

## APPLICABLE LAW

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

## 12. NOTICE

Any notice required or permitted hereunder 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 Clinical Trial Request Form, including the Principal Investigator:

If to Novartis:

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

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

**For Contract Matters:**

***Insert Contract/Grant Manager's Name***  
 Novartis Pharmaceuticals Corporation  
 One Health Plaza  
 59 Route 10, Bldg. 419-2  
 East Hanover, NJ 07936-1080  
 Phone: 862-778-\_\_\_\_\_  
 Fax: 973-781-3035\_\_\_\_\_

**and Contact:**

Marie Ronca  
 Novartis Pharmaceuticals Corporation  
 One Health Plaza  
 59 Route 10, Bldg. 419, Rm. 2180  
 East Hanover, NJ 07936  
 862-778-8526

**For Medical / Research Related Matters:**

***{ Enter on the Clinical Trial Request Form the Clinical Trial Leader's Name, Address, & Phone }***

The above information must also be included on all invoices.

If to Institution:

**For Administrative or Contract Matters:**

<p>Melinda Mathis, MPA Director Sponsored Programs and Compliance Office of Research Administration UT M.D. Anderson Cancer Center 1515 Holcombe Boulevard, Unit 307 Room B8.4453 Houston, TX 77030</p> <p>phone: 713-745-3468 fax: 713-794-4535 email: <a href="mailto:mmathis@mdanderson.org">mmathis@mdanderson.org</a> Tax ID: 74-6001118</p>	<p>Shawn Hammes, MPA Clinical Trials Office The University of Texas Southwestern Medical Center at Dallas 5323 Harry Hines Blvd., B1.204 Dallas, TX 75390-9016</p> <p>phone: 214-648-6449 fax: 214-648-3362 email: <a href="mailto:shawn.hammes@utsouthwestern.edu">shawn.hammes@utsouthwestern.edu</a> Tax ID: 75-6002868</p>
<p>Kathryn A. Bradley Senior Grants/Contracts Specialist The University of Texas Health Science Center at Houston P.O. Box 20036 Houston, TX 77225</p> <p>phone: 713-500-3073 fax: 713-500-0355 email: <a href="mailto:Kathryn.A.Bradley@uth.tmc.edu">Kathryn.A.Bradley@uth.tmc.edu</a> Tax ID: 74-1761309</p> <p>Overnight address is:</p> <p>7000 Fannin Street, Suite 1006D Houston, TX 77030</p>	<p>Chris Rubio Director, Office of Pre-Award Services The University of Texas Health Center at Tyler 11937 U.S. Hwy. 271 Tyler, TX 75708-3154</p> <p>phone: 903-877-7069 fax: 903-877-7558 email: <a href="mailto:chris.rubio@uthot.edu">chris.rubio@uthot.edu</a> Tax ID: 75-600-1354</p>
<p>Susan E. Ramsey Manager of Research Operations The University of Texas Medical Branch at Galveston Basic and Clinical Research Management 301 University Boulevard 2.240 Gail Borden Galveston, TX 77555-0671</p> <p>phone: (409) 772-0574 fax: (409) 747-3793 email: <a href="mailto:seramsey@utmb.edu">seramsey@utmb.edu</a> Tax ID: 74-6000949</p>	<p>Jane A. Youngers Director, Grants Management The University of Texas Health Science Center at San Antonio 7703 Floyd Curl Drive, Mail Code 7828 San Antonio, TX 78229-3900</p> <p>phone: 210-567-2333 fax: 210-567-2344 email: <a href="mailto:youngers@uthscsa.edu">youngers@uthscsa.edu</a> Tax ID: 74-1586031</p>

**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 of activities to be carried out pursuant to the Protocol (non-standard of care) including but not



limited to Novartis' use of the results obtained from the performance of the Research, or in connection with the administration or use of the test compounds as set forth in the Protocol during the course of the Research, provided however:

- (1) that the Research 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 Research test compounds 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;
  - (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; 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 component 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 Malpractice Self-Insurance Plan, under the authority of Section 59.01, Texas Education Code. Institution has and will maintain in force during the term of this Agreement adequate insurance to cover its indemnification obligations hereunder.

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. RESEARCH SUBJECT INJURY

- A. Both parties agree that the extent and availability of Research Subject injury compensation shall be described in the informed consent approved by the Institution, Novartis and the IRB relating to each individual trial detailed in an attached Clinical Trial Request Form.
- B. To the extent that such compensation is provided for in the applicable informed consent document, Novartis agrees to provide reimbursement to Institution for reasonable and necessary medical expenses incurred by the Institution as a result of the administration or use of the test compounds during the course of the Research.
- C. Notwithstanding the foregoing, Novartis will provide reimbursement directly to Research Subject for treatment provided at a medical facility other than the Institution.

#### 15. TERMINATION

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

- B. This Agreement or Research under any individual Clinical Trial Request Form may be terminated by Novartis for any other reason, other than those listed in section 15A above, upon thirty (30) days written notice.
- C. Novartis will pay Institution within sixty (60) days any funds due regarding the terminated Research based on the pro-rata per Research Subject amount based on Research Subjects completed and/or accrued under the Clinical Trial Request Form budget terms.
- D. The Institution will return within sixty (60) days to Novartis any funds received regarding such terminated Research exceeding the pro rate per Research Subject amount based on Research Subjects completed and/or accrued under the Clinical Trial Request Form budget terms.
- E. Immediately upon receipt of a notice of termination, the Principal Investigator shall stop entering Research Subjects into the relevant Clinical Trial and as directed by Novartis and to the extent medically permissible shall cease conducting procedures on Research Subjects already entered in the Clinical Trial.
- F. Termination of this Agreement 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. However, Novartis, without the consent of Institution but with written notice to Institution, may assign all of its rights and obligations thereunder to an affiliate or to a successor or assign of the business to which this Agreement relates.

**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**

Novartis may at any time modify a Protocol after written approval by Institution, the Principal Investigator and, if required, by the Institutional Review Board by written notice to Institution. No financial adjustments shall be made because of such modification unless the parties hereto amend the applicable Clinical Trial Request Form accordingly.

**20. DELIVERY TO NOVARTIS OF UNUSED MATERIALS**

Within thirty (30) days following termination or completion of the Research, all unused test compounds and 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 Research in conformance with generally accepted standards of good clinical practice, with the Protocol, 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 those of comparable foreign agencies and regulations of the FDA and comparable foreign agencies, and the privacy rule issued under HIPAA.

**22. DEBARMENT CERTIFICATION**

Neither the Institution nor any person employed thereby directly in the performance of the Research 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. ADVERTISEMENTS**

Principal Investigator must inform the Institutional Review Board ("IRB") should (s)he propose to utilize advertisements to recruit Research Subjects. Principal Investigator will supply the proposed advertisement to Novartis and the IRB for approval. Any promotional representation or suggestion that an investigational test compound 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).

**24. 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.

**25. BIOLOGICAL SAMPLES**

For this Agreement, Biological Samples include, without limitation, blood, serum, fluid and tissue biopsy samples collected from Research Subjects enrolled in a Clinical Trial as set forth in the Protocol. Biological Samples further include, without limitation, any tangible material directly or indirectly derived from such blood, serum, fluid and tissue biopsy 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.

**A. Institution's Collection, Retention and Use of Biological Samples.**

For this Agreement, Institution will collect, retain and use Biological Samples in accordance with the applicable Protocol. Institution may collect and/or reserve additional quantities of Biological Samples ("Secondary Biological Samples") for use in research not described in such Protocol ("Non-Protocol Research"), provided that (a) such collection complies with all applicable laws, regulations and acceptable clinical trial practices, including, but not limited to, applicable patient privacy and informed consent laws, and (b) no information or any other information which links the Secondary Biological Samples to any confidential information is available to Principal Investigator for such Non-Protocol Research (for example, without limitation, Institution may annotate such Secondary Biological Samples with a Research Subject's

demographic information (e.g., age, gender and clinical diagnosis), but not with information related to administration of, or response to, or adverse events associated with, a test compound.

**B. Novartis' Receipt and Use of Biological Samples.**

- (1)** If and to the extent so specified in the particular Protocol, Novartis, or its designee, may receive pre-determined quantities of Biological Samples from Institution, as set forth in the applicable Protocol, for use in Research as described in such Protocol, provided that such Research complies with all applicable laws and regulations, including, but not limited to, applicable patient privacy and informed consent laws. Novartis will ensure that if it uses a designee that its designee agrees to follow the terms, conditions and obligations of this Agreement.
- (2)** Using the same unique identifier utilized to identify the original Biological Sample, Novartis will disclose to Principal Investigator all raw data generated from its research using such Biological Samples ("Biological Samples Raw Data"). Novartis reserves the right to withhold any such Biological Samples Raw Data on any such genes which are pre-obligated and/or encumbered in any manner. Such Biological Samples Raw Data (i) shall be treated by Institution as confidential information under this Agreement, and (ii) 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, and (iii) Principal Investigator may use such Biological Samples Raw Data for non-commercial research and academic purposes, either within Institution or, with prior written notice to Novartis, may disclose such Biological Samples Raw Data to academic investigators outside Institution; provided that Institution provides written notice to the recipient of such Biological Samples Raw Data (with a copy to Novartis) that such Biological Samples Raw Data is Novartis' confidential information.
- (3)** 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.

**REST OF PAGE LEFT INTENTIONALLY BLANK**

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

<b>NOVARTIS PHARMACEUTICALS CORPORATION</b> By: <u><i>Sheila Straub</i></u> Sheila Straub Vice President US International Clinical Research Operations Date: <u>1/22/04</u>	<b>THE UNIVERSITY OF TEXAS M. D. ANDERSON CANCER CENTER</b> By: <u><i>Leonard A. Zwelling</i></u> Leonard A. Zwelling, M.D., M.B.A. Vice President for Research Administration Date: <u>JAN -7 2004</u>
<b>THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON</b> By: <u><i>Catherine Moore</i></u> Catherine Moore Director, Office of Sponsored Projects Date: <u>1-8-04</u>	<b>THE UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER AT DALLAS</b> By: <u><i>Perrie M. Adams</i></u> Perrie M. Adams, Ph.D. Associate Dean for Research Date: <u>1/12/04</u>
<b>THE UNIVERSITY OF TEXAS MEDICAL BRANCH AT GALVESTON</b> By: <u><i>Barbara DeHaven</i></u> Barbara DeHaven, M.P.A. Director of Sponsored Research Date: <u>1.5.04</u> <i>Approved as to Form Shammy 1/5/04 UTMB Contract Mgr.</i>	<b>THE UNIVERSITY OF TEXAS HEALTH CENTER AT TYLER</b> By: <u><i>Kirk A. Calhoun</i></u> Kirk A. Calhoun, M.D. President Date: <u>1/16/04</u>
<b>THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT SAN ANTONIO</b> By: <u><i>Jane Youngers</i></u> Jane Youngers Director, Grants Management Date: <u>1-9-04</u>	



NOVARTIS PHARMACEUTICALS CORPORATION  
 East Hanover, NJ 07936

## ATTACHMENT A: Clinical Trial Request Form

UNIVERSITY OF TEXAS

*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 first written above. It is subject to the terms of the Master Clinical Trial Agreement dated January 1, 2004 and attached hereto. .*

### 1. CLINICAL TRIAL-RELATED INFORMATION

Effective Date:

Principal Investigator:

Account No.:

Test Compound:

Brief Description of Clinical Trial  
 [Protocol Title]:

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

Clinical Trial Dates (Performance Period):

Initiation:

Completion:

Is this an Oncology-Related Research  
 Trial?

[Yes or No]:

Number of Patients To Be Enrolled:

Agreement 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 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)

**For Contract Matters:**

***Insert Grant Manager's Name***  
 Novartis Pharmaceuticals Corporation  
 One Health Plaza 59 Route 10, Bldg. 419-2  
 East Hanover, NJ 07936-1080  
 Phone: 862-778-\_\_\_\_\_  
 Fax: 973-781-3035\_\_\_\_\_

**and Contact:**

Marie Ronca  
 Novartis Pharmaceuticals Corporation  
 One Health Plaza 59 Route 10,  
 Bldg. 419, Rm. 2180  
 East Hanover, NJ 07936  
 862-778-8526

**For Medical / Research Related Matters:**

***{ Enter on the Clinical Trial Request Form the Clinical Trial Leader's Name, Address, & Phone }***

The above information must also be included on all invoices.

**If to Institution:**

**For Administrative / Contract Matters:**

<p>Melinda Mathis, MPA                  Director                  Sponsored Programs and Compliance                  Office of Research Administration                  UT M.D. Anderson Cancer Center                  1515 Holcombe Boulevard, Unit 307                  Room B8.4453                  Houston, TX 77030</p> <p>phone: 713-745-3468                  fax: 713-794-4535                  email: <a href="mailto:mmathis@mdanderson.org">mmathis@mdanderson.org</a>                  Tax ID: 74-6001118</p>	<p>Shawn Hammes, MPA                  Clinical Trials Office                  The University of Texas Southwestern                  Medical Center at Dallas                  5323 Harry Hines Blvd., B1.204                  Dallas, TX 75390-9016</p> <p>phone: 214-648-6449                  fax: 214-648-3362                  email: <a href="mailto:shawn.hammes@utsouthwestern.edu">shawn.hammes@utsouthwestern.edu</a>                  Tax ID: 75-6002868</p>
<p>Kathryn A. Bradley                  Senior Grants/Contracts Specialist                  The University of Texas Health                  Science Center at Houston                  P.O. Box 20036                  Houston, TX 77225</p>	<p>Chris Rubio                  Director, Office of Pre-Award Services                  The University of Texas Health Center at Tyler                  11937 U.S. Hwy. 271                  Tyler, TX 75708-3154</p>

<p>phone: 713-500-3073  fax: 713-500-0355  email: <a href="mailto:Kathryn.A.Bradley@uth.tmc.edu">Kathryn.A.Bradley@uth.tmc.edu</a>  Tax ID: 74-1761309</p> <p>Overnight address is:</p> <p>7000 Fannin Street, Suite 1006D  Houston, TX 77030</p>	<p>phone: 903-877-7069  fax: 903-877-7558  email: <a href="mailto:chris.rubio@uthct.edu">chris.rubio@uthct.edu</a>  Tax ID: 75-600-1354</p>
<p>Susan E. Ramsey  Manager of Research Operations  The University of Texas  Medical Branch at Galveston  Basic and Clinical Research Management  301 University Boulevard  2.240 Gail Borden  Galveston, TX 77555-0671</p> <p>phone: (409) 772-0574  fax: (409) 747-3793  email: <a href="mailto:seramsey@utmb.edu">seramsey@utmb.edu</a>  Tax ID: 74-6000949</p>	<p>Jane A. Youngers  Director, Grants Management  The University of Texas Health Science  Center at San Antonio  7703 Floyd Curl Drive, Mail Code 7828  San Antonio, TX 78229-3900</p> <p>phone: 210-567-2333  fax: 210-567-2344  email: <a href="mailto:youngers@uthscsa.edu">youngers@uthscsa.edu</a>  Tax ID: 74-1586031</p>

**For Research Related Matters:**

Name  
Phone  
Fax  
Email

**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 Study 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 Study(s) 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 Agreement, then the terms of the Master Agreement shall remain in effect until the expiration or termination of this Clinical Trial Request Form.



**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 Research, unless otherwise agreed to in writing by the Institution and Novartis.

B. Checks will be made payable to " \_\_\_\_\_ ". Checks will reference the Protocol number and account name and will be mailed to the address shown in Schedule A.

Institution Tax Identification Number: \_\_\_\_\_

C. The costs of the Research set forth on the Schedule A attached hereto represent all costs of performing the Research, 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

INSTITUTION {ENTER INSTITUTION NAME}

By \_\_\_\_\_  
(signature)

By \_\_\_\_\_  
(signature)

Sheila Straub

\_\_\_\_\_  
(print or type name)

Title: Vice President,  
US International Clinical Research Operations

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 \_\_\_\_\_

NOVARTIS PHARMACEUTICALS CORPORATION  
 59 Route 10, East Hanover, NJ 07936

**SCHEDULE A**

TA# TA Name

**PART I: VENDOR INFORMATION**

Project (compound): \_\_\_\_\_  
 Effective Period: From \_\_\_\_\_ to: \_\_\_\_\_  
 Vendor: \_\_\_\_\_  
 Principal: \_\_\_\_\_  
 Investigator: \_\_\_\_\_  
 Payee: \_\_\_\_\_  
 Payee Mailing Address: \_\_\_\_\_  
 Attention: \_\_\_\_\_  
 (Insert name and address)

Study #: \_\_\_\_\_  
 Center #: \_\_\_\_\_  
 Grant Mgr initials: \_\_\_\_\_  
 Phone: \_\_\_\_\_  
 Tax ID#: \_\_\_\_\_  
 Vendor Admin \_\_\_\_\_  
 Contact Name: \_\_\_\_\_  
 Admin. Phone: \_\_\_\_\_

Novartis Billing & Payments Contact: Marie Ronca  
 Novartis TA/Medical Contact: \_\_\_\_\_

Phone: 973-781-8526  
 Phone: \_\_\_\_\_

**PART I: PAYMENT SCHEDULE**

Add/ Delete/ Change (A, D, C)	P.O. Line Item	%	Amount (\$)	Expected Date	Condition of Payment	SAP Project Order No.	Order Items (Center #)	G/L Account Number
	1		\$0.00					607001
	2		\$0.00					
	3		\$0.00					
	4		\$0.00					
	5		\$0.00					
	6		\$0.00		Final Review and Acceptance of ALL Clinical Data for all Enrolled Patients by Novartis and Completion of all Required Administrative Matters by the Investigator			
		0%			<b>TOTALS</b>			

R & D PURCHASING			
Purchase Order #:	Vendor #:	Date Handled:	Keyed by:

