

OGC# 65432



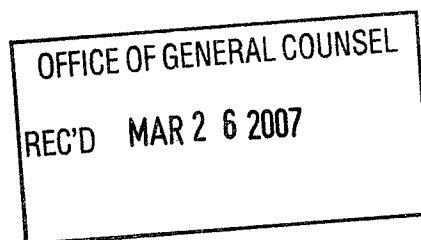
Yutaline Peña  
Tel: 862-778-5013  
Fax: 973 781-3035  
Email: yutaline.pena@novartis.com

Novartis Pharmaceuticals Corporation  
One Health Plaza  
East Hanover, NJ 07936-1080

Tel 862 778 8300

March 22, 2007

BethLynn Maxwell, J.D.  
The University of Texas System  
201 West Seventh Street  
Austin, TX 78701



**Re: Amendment#2 to Master Clinical Trial Agreement**

Dear BethLynn:

Enclosed herein please find one fully executed original Amendment #2 to the Master Clinical Trial Agreement, between THE UNIVERSITY OF TEXAS AND NOVARTIS PHARMACEUTICAL CORPORATION. Thank you for your assistance in completing this amendment.

The purpose of Amendment#2 is to amend the terms of the Master Clinical Trial Agreement Article 7G. Confidential Information.

Should you have any questions, please do not hesitate to contact me.

Respectfully,

*Yutaline Peña*

Yutaline Peña  
Administrative Assistant  
Clinical Study Start-Up  
Medical Operations - US CD&MA

Enclosure

cc. Ann Koch



**NOVARTIS PHARMACEUTICALS CORPORATION**  
 East Hanover, NJ 07936

**MASTER CLINICAL TRIAL AGREEMENT (CTA) - AMENDMENT 2**

The following is Amendment # 2 ("Amendment #2") to the Master Clinical Trial Agreement dated January 1, 2004 and amended on April 14, 2004 between Novartis Pharmaceuticals Corporation ("Novartis") and 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 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 (each an Institution hereinafter collectively "Institution"), the "Master Clinical Trial Agreement". The effective date of Amendment #2 is November 27, 2006.

Novartis and Institution now wish to amend the terms of the Master Clinical Trial Agreement as set forth below. NOW, THEREFORE, it is hereby agreed as follows:

**Article 7G. Confidential Information** of the Master Clinical Trial Agreement is hereby **deleted in its entirety and replaced with the following:**

"7G. The Institution hereby represents, certifies and agrees that, as of the date of enrollment of each individual participating as a Research 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 Research.

FURTHER, it is hereby agreed that Attachment A (Clinical Trial Request Form) will be revised as attached herein.

**In witness whereof**, the parties hereto have executed this Amendment #2 in duplicate (if necessary) by proper persons thereunto duly authorized.

**NOVARTIS PHARMACEUTICALS CORPORATION**


By: 

Name: George Betts, MBA

Title: Executive Director,  
 Medical Operations - US CD&MA

Date: 3/20/2007

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

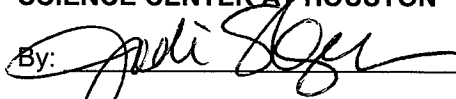
By: 

Name: Vernon Moore

Title: Chief Business and Finance Officer

Date: 2/27/07

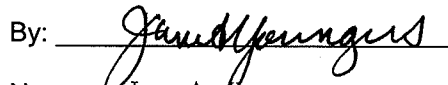
**THE UNIVERSITY OF TEXAS HEALTH  
SCIENCE CENTER AT HOUSTON**

By:   
Name: Jodi S. Ogden

Title: Contracts Director  
Office of Sponsored Projects

Date: 12/12/06


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

By:   
Name: Jane A. Youngers

Title: Assistant Vice President for Research  
and Sponsored Programs

Date: 12/18/04

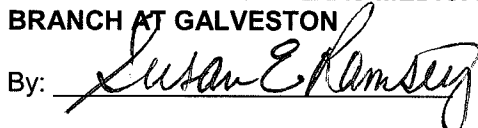
**THE UNIVERSITY OF TEXAS M.D.  
ANDERSON CANCER CENTER**

By:   
Name: Leonard A. Zwelling, MD, MBA

Title: VP, Research Administration

Date: 1.12.2009

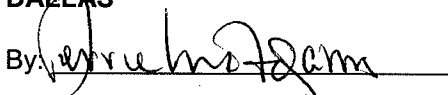
**THE UNIVERSITY OF TEXAS MEDICAL  
BRANCH AT GALVESTON**

By:   
Name: Susan E. Ramsey

Title: Manager, Contracts

Date: 2/23/07

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

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

Title: Associate Dean for Research

Date: 2/28/07



## 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, as amended on April 14, 2004 and November 27, 2006 and attached hereto.*

#### 1. CLINICAL TRIAL-RELATED INFORMATION

Effective Date:

Principal Investigator:

(For Institution Use)  
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:

(For Institution Use)  
Agreement No. :

(For Institution Use)  
Are Biological Samples as defined  
in Article 25 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 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 Contract Manager's Information*  
Novartis Pharmaceuticals Corporation  
One Health Plaza, 59 Route 10  
East Hanover, NJ 07936-1080  
Phone: 862-778-XXXX  
Fax: 973-781-XXXX

**The above information must also be included on all invoices.**

### **For Payment and Research Related Matters:**

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

### **IF TO INSTITUTION:**

#### **For Administrative/ Contract Matters:**

*(Insert Correct Contact Info for the Location)*

Insert Contact Name  
Office of Research Administration  
UT M.D. Anderson Cancer Center  
1515 Holcombe Boulevard  
Houston, TX 77030  
phone: 713-XXX-XXXX  
fax: 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  
fax: 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  
fax: 713-XXX-XXXX  
Tax ID: 74-1761309  
Overnight address is:  
7000 Fannin Street, Suite 1006  
Houston, TX 77030

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

Insert Contact Name  
The University of Texas  
Medical Branch at Galveston  
Basic and Clinical Research Management

Insert Contact Name  
The University of Texas Health Science  
Center at San Antonio  
7703 Floyd Curl Drive, Mail Code 7828

301 University Boulevard  
2.240 Gail Borden  
Galveston, TX 77555-0671  
phone: (409) XXX-XXXX  
fax: (409) XXX-XXXX  
Tax ID: 74-6000949

San Antonio, TX 78229-3900  
phone: 210-XXX-XXXX  
fax: 210-XXX-XXXX  
Tax ID: 74-1586031

**For Technical Research Matters:**

*(Insert Investigator's Information)*

Name  
Address  
Phone  
Fax

**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.

**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 \_\_\_\_\_