FIFTH AMENDMENT TO MASTER CLINICAL TRIAL AGREEMENT BETWEEN ELI LILLY AND COMPANY AND THE UNIVERSITY OF TEXAS SYSTEM COMPONENT INSTITUTIONS

This **Fifth Amendment** to Master Clinical Trial Agreement between Eli Lilly and Company and the University of Texas System Component Institutions ("Fifth Amendment"), effective as of the 18th day of November, 2004, is entered into by and between Eli Lilly and Company ("Lilly") and the component institutions of The University of Texas System (hereinafter, "University").

RECITALS

WHEREAS, University and Lilly have entered into a Master Clinical Trial Agreement ("Master"), signed on behalf of Lilly and each of the six component institutions of University;

WHEREAS, the aforementioned Master was amended on July 21, 1998; December 14, 1999; March 25, 2002; and December 12, 2003. A copy of the Master and the amendments are attached hereto as Attachment 1 and incorporated herein;

WHEREAS, the parties now desire to amend the Master for the fifth time as set forth below.

AMENDMENT

NOW, THEREFORE, in consideration of the mutual covenants contained herein, and for other good and valuable consideration, the parties hereby agree as follows:

1. New Article XVI, **Contract Research Organization**, is added as follows:

ARTICLE XVI
Contract Research Organization

Section 16.01. Contract Research Organization Involvement. Lilly shall be entitled to authorize a contract research organization ("CRO") to perform certain sponsor obligations for this Study. University and Principal Investigator (as defined in Section 3.01 of the Master Agreement) agree to cooperate with any Lilly-authorized CRO in performing this Study.

In the event a Principal Investigator at University is identified by CRO to conduct a Lilly-sponsored clinical trial at University, CRO, University and Principal Investigator shall execute a clinical research agreement for the CRO ("CRO CRA"), which CRO CRA shall append to this Agreement and incorporate the terms herein. With the exception of provisions in this Agreement regarding Data, Publications, Inventions and Publicity, all references to "Lilly" throughout this Agreement shall then refer to the "CRO". The template to be used for the CRO CRA is attached hereto as **Exhibit D**.

Section 16.02. Lilly Study Support. For each Study, Lilly will provide University and Principal Investigator with Study Drug(s) (as defined in Section 3.04 of the Master

Agreement). In addition, Lilly will provide financial support for the Study. For each Study, Lilly will pay University a total fee as set forth in the Schedule of Financial Support, a sample of which is attached hereto as **Exhibit B**, and a budget ("Budget") that will be mutually agreed upon for each Study. A sample Schedule of Financial Support for use with a CRO CRA is attached hereto as **Exhibit E**. Upon such agreement, the Schedule of Financial Support and Budget shall be attached as exhibits to each Study-specific CRA or CRO CRA.

Section 16.03. Payment. Payment in connection with each Study will be made to the name and address listed in a W-9 form provided by University to Lilly.

END OF NEW ARTICLE XVI

2. New Exhibit D, called "A Clinical Research Agreement for Use with a Clinical Research Organization", is added as follows:

Exhibit D

A Clinical Research Agreement
for use with a Clinical Research Organization ("CRO CRA")

Whereas, Lilly Research Laboratories, a division of Eli Lilly and Company ("Lilly") with its principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285 and **[name of University]** ("University"), with its principal place of business at _____ _____, entered into a Master Clinical Trial Agreement ("Master Agreement") effective on the day of _____, 20___;

Whereas, Lilly has entered into an agreement dated _____, with _____ ("CRO") to perform certain sponsor obligations;

Whereas, _____, M.D. ("Principal Investigator"), an employee of University, has agreed to conduct the study entitled, "**[insert Study title]**" (protocol **[insert protocol #]** ["Protocol"], which Protocol is incorporated herein by reference) ("Study");

Now, therefore, CRO and University agree to abide by the terms of the Master Agreement for conducting the Study. This Agreement shall serve as the Clinical Research Agreement referenced in the Master Agreement.

Notwithstanding the foregoing, Lilly shall remain responsible to University for the obligations of Indemnification of the Master Agreement.

CRO and University acknowledge that all references, except references to Article III, Section 3.05, Data, Article III, Section 3.06, Publications, Article III, Section 3.07, Inventions, Article III, Section 3.08, Publicity and Article VI, Indemnification, throughout the Master Agreement shall be understood as referring to "Lilly and/or CRO."

Notwithstanding the foregoing, Lilly and CRO reserve all rights to terminate this Agreement at any time in accordance with Article V, Termination, of the Master Agreement.

CRO shall pay University in accordance with the Payment Schedule, attached hereto as Exhibit 1 and a budget ("Budget") attached hereto as Exhibit 2. Exhibit 1 and Exhibit 2 are incorporated herein by reference and made part hereof for all purposes.

[insert name of CRO]	AGREED AND ACCEPTED: **[Name of University]**
_____	_____
(Signature of Authorized Official)	(Signature of Authorized Official)
_____	_____
(Typed or Printed Name and Title)	(Typed or Printed Name and Title)
_____	_____
(Date)	(Date)
	AGREED AND ACCEPTED:
	_____
	[Name of Investigator]
	_____
	(Date)

END OF NEW EXHIBIT D

3. New Exhibit E, called "A Sample Schedule of Financial Support for use with a CRO CRA, is added as follows:

Exhibit E

A Sample Schedule of Financial Support for use with a CRO CRA

In connection with the Study, University will be paid in accordance with the terms set forth in the Budget. For those amounts designated for patient services, University will receive payment only for data received based on the actual number of visits and procedures performed in accordance with agreed upon procedure fees outlined in the

Budget. Such compensation is limited to payment for the number of patients designated in the Budget who are enrolled in the Study within a maximum of ____ **months** of start, unless the CRO has given University written approval to enroll additional patients or extend the enrollment period. In the event that such approval is granted, University will be paid in accordance with the fees set forth in the Budget for the additional patients.

To be eligible for payment, the procedures must be performed in full compliance with the Protocol and the Master Agreement, and the data submitted must be complete and correct. For data to be complete and correct, each patient must have signed an IRB-approved informed consent document, and all procedures designated in the Protocol must be carried out on a "best efforts" basis; omissions must be satisfactorily explained. It is expected that for all items required under the Protocol for which CRO has agreed to provide compensation, CRO will be the sole source of compensation. University will not seek payment from any third party payor, whether public or private, for any costs covered by payments made by CRO under this Agreement.

An initial advance ("Advance") of ten percent (10%) of the entire Budget amount or Twenty Thousand Dollars ($20,000.00), whichever is less, will be made within thirty (30) days of receipt by CRO of a fully executed copy of this Agreement; provided, however, CRO must have a completed W-9 form before any payments may be made. If due, subsequent payments will be made at _____ **intervals** based upon the Budget and the data received; provided, however, that (1) the Advance shall be recovered in fifty percent (50%) increments in the form of a credit against subsequent payments until the entire Advance is recovered; (2) other than the final payment, payment shall not be issued for a total amount less than Five Hundred Dollars ($500.00); (3) the final payment will be made when all patients at University's site have completed the Study and all available data and case report forms have been received and accepted by CRO; and (4) matters in dispute shall be payable upon mutual resolution of such dispute. In the event that the Advance credit in any given period exceeds the amount of a payment due, the excess credit shall carry-over and be applied against the subsequent payment, in addition to any otherwise applicable credit. In the event the amount due in any given period is less than Five Hundred Dollars ($500.00), such amount shall carry over without payment to the next payment period.

When University's data are reviewed by an on-site scheduled visit of CRO, University will have all reasonably available data obtained through the preceding day complete and ready for evaluation. CRO reserves the right to refuse payment for data not received by CRO within ten (10) days after the representative's review.

In addition, if CRO requests the attendance of Investigator or Investigator's staff at a Study startup meeting or other meeting necessary to provide information regarding the Study or Study drug, CRO shall reimburse University for reasonable and necessary travel and lodging expenses incurred to attend such meeting(s) that have been specifically approved in advance. Such reimbursement shall be made within thirty (30) days of receiving acceptable detailed documentation of such expenses, provided that CRO

receives such documentation within sixty (60) days of the date that the expenses were incurred.

END OF NEW EXHIBIT E

4. This Fifth Amendment may be executed in one or more counterparts, each of which shall constitute an original of this Amendment, and, taken together, shall represent the binding agreement of the parties.

AS HEREBY AMENDED, the Master shall remain in full force and effect.

IN WITNESS THEREOF, the parties have executed this Amendment as of the date first written above.

LILLY RESEARCH LABORATORIES,
A DIVISION OF ELI LILLY AND
COMPANY
PROCUREMENT

(Signature of Authorized Official)

J. W. Vandeventer, Ph.D., C.P.M.
Sourcing Consultant
(Typed or Printed Name and Title)

Date : Nov 23, 2004

AGREED AND ACCEPTED:
THE UNIVERSITY OF TEXAS HEALTH
SCIENCE CENTER AT TYLER

Rick Hefner
Vice President for Finance and Administration

Date 1/14/05

THE UNIVERSITY OF TEXAS HEALTH
SCIENCE CENTER AT HOUSTON

Catherine Moore
Catherine Moore
Director, Office of Sponsored Projects

Date 12-9-04

THE UNIVERSITY OF TEXAS HEALTH
SCIENCE CENTER AT SAN ANTONIO

Jane Youngers
Director, Grants Management

Date 1-7-05

THE UNIVERSITY OF TEXAS MD ANDERSON CANCER CENTER

Leonard A. Zwelling, M.D., M.B.A.
Vice President for Research Administration

Date _____

THE UNIVERSITY OF TEXAS MEDICAL BRANCH AT GALVESTON

Susan E. Ramsey
Manager of Research Operations

Date 01/06/05

THE UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER AT DALLAS

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

Date 1/11/05

FOURTH AMENDMENT TO MASTER CLINICAL TRIAL AGREEMENT BETWEEN ELI LILLY AND COMPANY AND THE UNIVERSITY OF TEXAS SYSTEM COMPONENT INSTITUTIONS

This Fourth Amendment to Master Clinical Trial Agreement between Eli Lilly and Company and the University of Texas System Component Institutions ("Fourth Amendment"), effective as of the 12th day of December, 2003, is entered into by and between Eli Lilly and Company ("Lilly") and the component institutions of The University of Texas System (hereinafter, "University").

RECITALS

WHEREAS, University and Lilly have entered into a Master Clinical Trial Agreement ("Master"), signed on behalf of Lilly and each of the six component institutions of University;

WHEREAS, the aforementioned Master was amended on July 21, 1998, December 14, 1999, and March 25, 2002. A copy of the Master and the amendments are attached hereto as Attachment 1 and incorporated herein;

WHEREAS, the parties now desire to amend the Master for the fourth time as set forth below.

AMENDMENT

NOW, THEREFORE, in consideration of the mutual covenants contained herein, and for other good and valuable consideration, the parties hereby agree as follows:

Article III, Services of University, Section 3.01, Principal Investigator is deleted in its entirety and replaced with the following paragraph:

> University and its Principal Investigator in conducting the Study agree to comply with: all conditions specified in the Protocol, including the statements required by Lilly in University's informed consent document; applicable requirements of the US IND regulations (Title 21, Part 312.1 et seq.); the conditions specified in the Statement of Investigator Form (FD-1572); the approval of University's Institutional Review Board ("IRB"); the Code of Federal Regulations governing informed consent and IRBs (Title 21, Parts 50 and 56) and privacy of patient health information (Title 45, Parts 160 and 164) governing informed consents and IRBs; provisions of the Generic Drug Enforcement Act of o1992 (Public Law 102-282, 102nd Second Congress); and all other applicable federal, state and local laws or standards.

The following sentence shall be added as the first sentence of Article I, Protocol and Payment, Section 1.01.1, Additional Requirements, of the Master Clinical Trial Agreement "University and Principal Investigator agree to only use an informed consent document which has been reviewed and approved by Lilly, unless Lilly provides University and/or Principal Investigator written instructions detailing a different process that should be followed." The paragraph shall now read as follows:

> University and Principal Investigator agree to only use an informed consent document which has been reviewed and approved by Lilly, unless Lilly provides University and/or Principal Investigator written instructions detailing a different process that should be followed. In the event the Protocol does not specify the required language from Lilly for University's informed consent document, or it does not contain the adverse experiences which must be reported to Lilly, University agrees to the following:

This Amendment may be executed in one or more counterparts, each of which shall constitute an original of this Amendment, and, taken together, shall represent the binding agreement of the parties.

AS HEREBY AMENDED, the Master shall remain in full force and effect.

IN WITNESS THEREOF, the parties have executed this Amendment as of the date first written above.

LILLY RESEARCH LABORATORIES
A DIVISION OF ELI LILLY AND COMPANY

Karen L. Berger, Contracts Associate
Clinical Contracts and Grants Office

Date: December 12, 2003

AGREED AND ACCEPTED:
THE UNIVERSITY OF TEXAS HEALTH
SCIENCE CENTER AT TYLER

Kirk A. Calhoun, M.D.
President

Date: 1/14/04

THE UNIVERSITY OF TEXAS HEALTH
SCIENCE CENTER AT HOUSTON

Catherine Moore
Director, Office of Sponsored Projects

Date: 1-8-04

THE UNIVERSITY OF TEXAS HEALTH
SCIENCE CENTER AT SAN ANTONIO

Jane Youngers
Director, Grants Management

Date: 1-9-04

AGREED AND ACCEPTED:
THE UNIVERSITY OF TEXAS M.D.
ANDERSON CANCER CENTER

for Leonard A. Zwelling, M.D., M.B.A.
Vice President for Research Administration

Date: 12/22/2003

THE UNIVERSITY OF TEXAS MEDICAL
BRANCH AT GALVESTON

for Barbara DeHaven, M.P.A.
Director of Sponsored Research

Date: 12/18/03

THE UNIVERSITY OF TEXAS
SOUTHWESTERN MEDICAL CENTER AT
DALLAS

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

Date: 1/12/04

THIRD AMENDMENT TO MASTER CLINICAL TRIAL AGREEMENT BETWEEN ELI LILLY AND COMPANY AND THE UNIVERSITY OF TEXAS SYSTEM COMPONENT INSTITUTIONS

This Third Amendment to Master Clinical Trial Agreement between Eli Lilly and Company and the University of Texas System Component Institutions ("Third Amendment"), effective as of the 25th day of March, 2002, is entered into by and between Eli Lilly and Company ("Lilly") and the component institutions of The University of Texas System (hereinafter, "University").

RECITALS

WHEREAS, University and Lilly have entered into a Master Clinical Trial Agreement ("Master"), signed on behalf of Lilly and each of the five component institutions of University;

WHEREAS, the aforementioned Master was amended on July 21, 1998 and December 14, 1999. A copy of the Master and its amendments is attached hereto as Attachment 1 and incorporated herein;

WHEREAS, the parties now desire to amend the Master for the third time as set forth below.

AMENDMENT

NOW, THEREFORE, in consideration of the mutual covenants contained herein, and for other good and valuable consideration, the parties hereby agree as follows:

Section 1.01.1(c) of the Master, entitled "Additional Requirements," is hereby amended to delete the following sentence:

> **If I follow the directions of the doctors in charge of this study, and I am physically injured because of any substance or procedure properly given me under the plan for this study, Eli Lilly and Company will pay the medical expenses for the treatment of that injury which are not covered by my own insurance. No other compensation is available from Eli Lilly and Company if any injury occurs.**

and replace it with the following sentence:

> **If I follow the directions of the doctors in charge of this study, and I am physically injured because of any substance or procedure properly given me under the plan for this study, Eli Lilly and Company will pay the medical expenses for the treatment of that injury. No other compensation is available from Eli Lilly and Company if any injury occurs.**

Section 1.03 of the Master, entitled "Additional Cost to Lilly," is hereby amended to delete the following sentence:

> **Provided, however, Lilly will not reimburse costs that are covered by the patients' medical or hospital insurance or other governmental program providing such coverage.**

Section 3.05 of the Master, entitled "Data and Confidentiality," is hereby amended to delete the following sentence:

> **All information which**
>
> **(i) is disclosed in writing by Lilly to the University and marked "Confidential,"**
>
> **(ii) is disclosed visually or orally and is directly related to written information which has already been disclosed to University and marked "Confidential," or**
>
> **(iii) is disclosed visually or orally and subsequently confirmed in writing within thirty (30) days after first disclosure**

will be maintained in confidence by the University and will not be disclosed to any third party except to employees of the University under similar obligations of confidentiality, without the written consent of Lilly for the longer of either a period of five (5) years from the effective date of the Master Clinical Trial Agreement or as stated in Exhibit C of the CRA.

and replace it with the following sentence:

All information which

- **(i) is disclosed in writing by Lilly to the University and marked "Confidential,"**
- **(ii) is disclosed visually or orally and is directly related to written information which has already been disclosed to University and marked "Confidential," or**
- **(iii) is disclosed visually or orally and subsequently confirmed in writing within thirty (30) days after first disclosure**

will be maintained in confidence by the University and will not be disclosed to any third party except to employees of the University under similar obligations of confidentiality, without the written consent of Lilly for the longer of either a period of five (5) years from the effective date of the relevant Study Agreement or as stated in Exhibit C of the CRA.

Section 6.01 of the Master entitled "Indemnification," is hereby amended to delete the following sentence:

Lilly will not reimburse for those costs covered by the subject's or patient's medical or hospital insurance or by governmental programs providing such coverage.

Additionally, the University of Texas Health Center at Tyler has expressed an interest in becoming a party to the Master Agreement, as amended. By execution of this Third Amendment, the University of Texas Health Center at Tyler is hereby included as a party to the Master Agreement and agrees to abide by the terms set forth in the Master Agreement, as amended.

This Amendment may be executed in one or more counterparts, each of which shall constitute an original of this Amendment, and, taken together, shall represent the binding agreement of the parties.

AS HEREBY AMENDED, the Master shall remain in full force and effect.

IN WITNESS THEREOF, the parties have executed this Amendment as of the date first written above.

LILLY RESEARCH LABORATORIES
A DIVISION OF ELI LILLY AND COMPANY

(Signature of Authorized Official)
Laura A. Fludzinski, Executive Director
Global Clinical Research Operations
(Printed Name and Title)

(Date)

AGREED AND ACCEPTED:
THE UNIVERSITY OF TEXAS HEALTH
SCIENCE CENTER AT SAN ANTONIO

(Signature of Authorized Official)
Jane A. Youngers
Director of Grants Management
(Printed Name and Title)

22 April 2002
(Date)

AGREED AND ACCEPTED:
THE UNIVERSITY OF TEXAS HEALTH
SCIENCE CENTER AT HOUSTON

(Signature of Authorized Official)
4/1/02
(Printed Name and Title)
Daviid E. Kusnerik
Contract Administrator
(Date)

AGREED AND ACCEPTED:
THE UNIVERSITY OF TEXAS M.D.
ANDERSON CANCER CENTER

(Signature of Authorized Official)
Leonard A. Zwelling,M.D.,MBA
Vice President,Research Administration
(Printed Name and Title)
4/17/02
(Date)

AGREED AND ACCEPTED:
THE UNIVERSITY OF TEXAS SOUTHWESTERN
MEDICAL CENTER AT DALLAS

(Signature of Authorized Official)
Petrie M. Adams, Ph.D.
Associate Dean for Research
(Printed Name and Title)
4/23/02
(Date)

AGREED AND ACCEPTED:
THE UNIVERSITY OF TEXAS MEDICAL
BRANCH AT GALVESTON

(Signature of Authorized Official)
Cheryl M. Chanaud, Ph.D.
Assitant Vice President for Research
(Printed Name and Title)
4/19/02
(Date)

AGREED AND ACCEPTED:
THE UNIVERSITY OF TEXAS HEALTH
CENTER AT TYLER

Michelle Hargis
~~Manager, Sponsored Programs~~ Director Grants Admin
4-26-02
(Date)

SECOND AMENDMENT TO MASTER CLINICAL TRIAL AGREEMENT BETWEEN ELI LILLY AND COMPANY AND THE UNIVERSITY OF TEXAS SYSTEM COMPONENT INSTITUTIONS

This Second Amendment to Master Clinical Trial Agreement between Eli Lilly and Company and the University of Texas System Component Institutions ("Second Amendment"), effective as of the 14th day of December, 1999, is entered into by and between Eli Lilly and Company ("Lilly") and the component institutions of The University of Texas System (hereinafter, "University").

RECTIALS

WHEREAS, University and Lilly have entered into a Master Clinical Trial Agreement ("Master"), signed on behalf of Lilly and each of the five component institutions of University;

WHEREAS, the aforementioned Master was amended on July 21st, 1999;

WHEREAS, the parties now desire to amend the Master for the second time as set forth below.

AMENDMENT

NOW, THEREFORE, in consideration of the mutual covenants contained herein, and for other good and valuable consideration, the parties hereby agree as follows:

Section 3.05 of the Master, entitled "Data and Confidentiality," is hereby amended to delete the following sentence:

All information which

(i) is disclosed in writing by Lilly to the University and marked "Confidential,"

(ii) is disclosed visually or orally and is directly related to written information which has already been disclosed to University and marked "Confidential," or

(iii) is disclosed visually or orally and subsequently confirmed in writing within thirty (30) days after first disclosure

will be maintained in confidence by the University and will not be disclosed to any third party except to employees of the University under similar obligations of confidentiality, without the written consent of Lilly for a period of five (5) years from the effective date of this Agreement.

and replace it with the following sentence:

All information which

(i) is disclosed in writing by Lilly to the University and marked "Confidential,"

(ii) is disclosed visually or orally and is directly related to written information which has already been disclosed to University and marked "Confidential," or

(iii) is disclosed visually or orally and subsequently confirmed in writing within thirty (30) days after first disclosure

will be maintained in confidence by the University and will not be disclosed to any third party except to employees of the University under similar obligations of confidentiality, without the written consent of Lilly for the longer of either a period of five (5) years from the effective date of the Master Clinical Trial Agreement or as stated in Exhibit C of the CRA.

This Amendment may be executed in one or more counterparts, each of which shall constitute an original of this Amendment, and, taken together, shall represent the binding agreement of the parties.

AS HEREBY AMENDED, the Master shall remain in full force and effect.

IN WITNESS THEREOF, the parties have executed this Amendment as of the date first written above.

LILLY RESEARCH LABORATORIES
A DIVISION OF ELI LILLY AND COMPANY

Margaret C. Curl

Margaret C. Curl
Medical Associate, Business Office
Lilly USA Medical Division

January 5, 2000
(Date)

AGREED AND ACCEPTED:
THE UNIVERSITY OF TEXAS HEALTH
SCIENCE CENTER AT SAN ANTONIO

(Signature of Authorized Official)
JANE A. YOUNGERS
Director of Grants Management
(Printed Name and Title)

2-1-00
(Date)

AGREED AND ACCEPTED:
THE UNIVERSITY OF TEXAS HEALTH
SCIENCE CENTER AT HOUSTON

(Signature of Authorized Official)
David E. Kusnerik
Contract Administrator
(Printed Name and Title)

1/13/00
(Date)

AGREED AND ACCEPTED:
THE UNIVERSITY OF TEXAS M.D.
ANDERSON CANCER CENTER

(Signature of Authorized Official)
Melinda Mathis, MPA; Manager, Res. Admin.
(Printed Name and Title)

1/10/00
(Date)

AGREED AND ACCEPTED:
THE UNIVERSITY OF TEXAS SOUTHWESTERN
MEDICAL CENTER AT DALLAS

(Signature of Authorized Official)
PERRIE M. ADAMS ASSOC DEAN
(Printed Name and Title)

1/21/00
(Date)

AGREED AND ACCEPTED:
THE UNIVERSITY OF TEXAS MEDICAL
BRANCE AT GALVESTON

(Signature of Authorized Official)
Cheryl M. Chenard, Ph.D.
Director Office of Clinical Trials
(Printed Name and Title)

1/14/00
(Date)

FIRST

AMENDMENT TO MASTER CLINICAL TRIAL AGREEMENT BETWEEN ELI LILLY AND COMPANY AND THE UNIVERSITY OF TEXAS SYSTEM COMPONENT INSTITUTIONS

This Amendment to Master Clinical Trial Agreement Between Eli Lilly and Company and the University of Texas System Component Institutions ("Amendment"), effective as of the 21st day of July, 1998, is entered into by and between Eli Lilly and Company ("Lilly") and the component institutions of The University of Texas System (hereinafter, "University").

RECITALS

WHEREAS, University and Lilly have entered into a Master Clinical Trial Agreement ("Master"), signed on behalf of Lilly and each of the five component institutions of University.

WHEREAS, the parties now desire to amend the Master as set forth below.

AMENDMENT

NOW THEREFORE, in consideration of the mutual covenants contained herein, and for other good and valuable consideration, the parties hereby agree as follows:

1. Section 3.05 of the Master, entitled "Data and Confidentiality," is hereby amended to delete the following sentence:

> **All information which is disclosed in writing by Lilly to the University and marked "Confidential," or disclosed visually or orally and subsequently confirmed in writing within thirty (30) days after first disclosure, will be maintained in confidence by the University and will not be disclosed to any third party except to employees of the University under similar obligations of confidentiality, without the written consent of Lilly for a period of five (5) years from the effective date of this Agreement.**

and replace it with the following sentence:

> **All information which**
> - **(i) is disclosed in writing by Lilly to the University and marked "Confidential,"**
> - **(ii) is disclosed visually or orally and is directly related to written information which has already been disclosed to University and marked "Confidential," or**
> - **(iii) is disclosed visually or orally and subsequently confirmed in writing within thirty (30) days after first disclosure**

> **will be maintained in confidence by the University and will not be disclosed to any third party except to employees of the University under similar obligations of confidentiality, without the written consent of Lilly for a period of five (5) years from the effective date of this Agreement.**

2. Section 3.07 of the Master, entitled "Inventions" is hereby deleted in its entirety and replaced with the following:

> **All rights to any invention conceived or reduced to practice as a direct result of the performance of the work conducted under this Agreement using the Study drug in accordance with the protocol provided by Lilly to University shall belong to Lilly. University hereby assigns to Lilly the sole and exclusive ownership thereto, contingent upon payment of costs by Lilly, if any, incurred by University in the filing, prosecution, issuance and/or maintenance of any patent application or patent issuing thereon. Further prosecution and costs, if any, shall thereafter be borne by Lilly.**

3. Section 3.02 of the Master refers to a "Principal Investigator's Assurance" which is attached to the Master as Exhibit C. The Principal Investigator's Assurance is hereby amended as set forth in the attached Amended Exhibit C.

4. This Amendment may be executed in one or more counterparts, each of which shall constitute an original of this Amendment and, taken together, shall represent the binding agreement of the parties.

AS HEREBY AMENDED, the Master shall remain in full force and effect.

IN WITNESS WHEREOF, the parties have executed this Amendment as of the date first written above.

LILLY RESEARCH LABORATORIES
A DIVISION OF
ELI LILLY AND COMPANY

Wilbur B. Pittinger
Operations Officer
Global Clinical Research

AGREED AND ACCEPTED:
THE UNIVERSITY OF TEXAS HEALTH
SCIENCE CENTER AT SAN ANTONIO

(Signature of Authorized Official)

(Printed Name and Title)

(Date)

AGREED AND ACCEPTED:
THE UNIVERSITY OF TEXAS HEALTH
SCIENCE CENTER AT HOUSTON

(Signature of Authorized Official)

David E. Kusnerik, Contract Administator
(Printed Name and Title)

(Date) July 27, 1998

AGREED AND ACCEPTED:
THE UNIVERSITY OF TEXAS M.D.
ANDERSON CANCER CENTER

(Signature of Authorized Official)

(Printed Name and Title)

(Date)

AGREED AND ACCEPTED:
THE UNIVERSITY OF TEXAS SOUTHWESTERN
MEDICAL CENTER AT DALLAS

(Signature of Authorized Official)

(Printed Name and Title)

(Date)

AGREED AND ACCEPTED:
THE UNIVERSITY OF TEXAS MEDICAL
BRANCE AT GALVESTON

(Signature of Authorized Official)

(Printed Name and Title)

(Date)

MASTER CLINICAL TRIAL AGREEMENT

BETWEEN

ELI LILLY AND COMPANY

AND

THE UNIVERSITY OF TEXAS SYSTEM

COMPONENT INSTITUTIONS

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(Page numbers differ from Lilly Contract due to font differences)

MASTER CLINICAL TRIAL AGREEMENT

This Master Clinical Trial Agreement (hereinafter "Agreement") made effective this 5th day of December, 1994, by and between Lilly Research Laboratories, a division of Eli Lilly and Company, with its principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285 (hereinafter "Lilly") and the component institutions of The University of Texas System, (hereinafter "University").

Scope of Agreement

This Agreement sets forth the terms and conditions pursuant to which Lilly will fund and sponsor the conduct and performance of clinical trial studies with a Lilly drug as specified in the Protocol document. This Agreement is not intended to be an exclusive contract. Lilly retains the right to employ other institutions to perform any or all of the types of services contemplated by this Agreement.

The parties, intending to be legally bound, agree as follows:

Article I

Protocol and Payment

Section 1.01. Protocol. University will perform a clinical trial study or studies ("Study") for Lilly in accordance with a detailed Lilly approved protocol document ("Protocol") which will be provided by Lilly. The Protocol will specify: (1) the principal investigator, (i.e., the physician who will actually conduct the clinical investigation and under whose immediate direction the drug is to be administered to a subject and as defined in Section 3.01); (2) the Study design; (3) information desired; (4) estimated duration of the Study; (5) estimated charges; (6) University to perform Study and all other relevant matters. The Protocol will be attached to this Agreement as Exhibit A and is incorporated herein by reference. Lilly reserves the right to amend the Protocol at any time; however, any changes to the Protocol shall require a written amendment to this Agreement, including, an indication of the impact the amendment will have on the Study budget.

Section 1.01.1. Additional Requirements. In the event the Protocol does not specify the required language from Lilly for University's informed consent document, or it does not contain the adverse experiences which must be reported to Lilly, University agrees to the following:

(1) The IRB approved informed consent shall contain the following information:

(a) "I understand that the doctors in charge of this study or Eli Lilly and Company may stop the study or stop my participation in the study at any time, for any reason, without my consent."

(b) "I hereby give permission for the doctors in charge of this study to release the information regarding or obtained as a result of my participation in this study to Eli Lilly and Company, including its agents and contractors; the U.S. Food and Drug Administration; and other governmental agencies, and to allow them to inspect all my medical records. I understand that medical records which reveal my identity will remain confidential, except that they will be provided as noted above, or as may be required by law."

(c) "If I follow the directions of the doctors in charge of this study, and I am physically injured because of any substance or procedure properly given me under the plan for this study, Eli Lilly and Company will pay the medical expenses for the treatment of that injury which are not covered by my own insurance. No other compensation is available from Eli Lilly and Company if any injury occurs."

The above language may be altered to match the style of the informed consent document which University drafts, providing the substance of the statements is unchanged.

(2) The adverse experiences which shall be reported to Lilly immediately by telephone include any event that: (a) is associated with the patient's death, (b) is associated with inpatient hospitalization or prolonged hospitalization of the patient, (c) is alarming, (d) is life-threatening to the patient, (e) is associated with permanent disability, cancer, or birth

defect, (f) is a drug overdose, or (g) is associated with University's unblinding the patient's therapy assignment.

All adverse experiences, including those for which telephone reports have been made, shall be promptly reported to Lilly on the clinical report form.

Section 1.02. Payments. Lilly will pay to University a total fee as is agreed upon for each Study and as set forth in the Schedule of Financial Support which will be attached to this Agreement as Exhibit B and is incorporated herein by reference. It is expected that for all items required under the Protocol for which Lilly has agreed to provide compensation, Lilly will be the sole source of compensation.

Section 1.03. Additional Cost to Lilly. Lilly agrees to reimburse University for the following additional costs:

(1) all reasonable and customary costs incurred by University and associated with the diagnosis of an adverse reaction involving the Study Drug; and

(2) all reasonable costs for treating the adverse reaction of the subject if Lilly determines, with reasonable medical certainty, that such costs were due to the Study Drug administered in accordance with the Protocol.

Provided, however, Lilly will not reimburse costs that are covered by the patients' medical or hospital insurance or other governmental program providing such coverage. Lilly shall have the option of paying all of the above listed items directly to the provider of the service or product or to University.

Section 1.04. Cost of Additional Services. If Lilly makes changes to the Protocol, University and Lilly must agree on the cost, if any, to Lilly of such amendment prior to University performing the services required by such amendment.

Article II

Study Materials

Section 2.01. Materials. Lilly will provide, in a timely manner, sufficient amounts of all materials, clinical report forms, or other substances with which to perform the Study, and a Clinical Investigation Brochure as required by the Protocol.

Section 2.02. Documentation. University shall provide to Lilly a copy of each of the following documents received from the Principal Investigator. Study Drugs will not be provided to the Principal Investigator until these documents are received:

(1) a signed copy of the Principal Investigator's Statement of Investigation Form FD-1572 and Clinical Protocol Outline;

(2) an Exhibit C, "Principal Investigator's Assurance";

(3) a current Principal Investigator curriculum vitae; and

(4) written proof that the Principal Investigator's IRB has reviewed and approved the Study and the informed consent document.

Article III

Services of University

Section 3.01. Principal Investigator. University shall identify an investigator ("Principal Investigator") to conduct the Study. Lilly shall approve the Principal Investigator identified by University and obtain the Principal Investigator's commitment to conduct the Study in such capacity. If the Principal Investigator should become unable to complete the Study, University shall consult with and obtain Lilly's written consent before appointing a new Principal Investigator.

Section 3.02. University's and Principal Investigator's Commitments and Obligations. University represents that the Principal Investigator and all other investigators that may perform services hereunder are its employees and shall abide by the terms and conditions of this Agreement as if each were a party hereto. Such commitment will be in the form of a "Principal Investigator's Assurance" attached to this Agreement as Exhibit C and is incorporated herein by reference.

Section 3.03. Conduct of the Study. University and its Principal Investigator in conducting the Study agree to comply with: all conditions specified in the Protocol, including the statements required by Lilly in University's informed consent document; applicable requirements of the US IND regulations (Title 21, Part 312.1 et seq.); the conditions specified in the Statement of Investigator Form (FD-1572); the approval of University's Institutional Review Board ("IRB"); the Code of Federal Regulations (Title 21, Parts 50 and 56) governing informed consents and IRBs; provisions of the Generic Drug Enforcement Act of 1992 (Public Law 102-282, 102nd Congress); and all other applicable federal, state, and local laws or standards.

Section 3.03.1. Referral Fees. University agrees not to pay fees to another physician for the referral of patients.

Section 3.03.2. Inspections. University agrees that Lilly or Lilly-designated representatives may inspect University's procedures, facilities and Study records, and

that information obtained from such inspections may be shared with Lilly and Lilly-designated representatives.

Section 3.04. Study Drug Use and Record Retention. Drugs furnished for this Study ("Study Drugs") will be used solely under this Protocol; and any other use is expressly prohibited. All Study records must be retained for whichever period of time is greatest: fifteen (15) years after completion or termination of the Study; two (2) years after the date of marketing application approval for the drug indication investigated; or two (2) years after the FDA is notified by Lilly of discontinuation of the IND. Upon completion or termination of the Study, Lilly will notify University, and, if University determines that it is unwilling or unable to maintain Study records for the period outlined above, University agrees to advise Lilly and provide Lilly the opportunity to obtain the Study records from University for retention pursuant to FDA or other foreign regulatory and/or legal requirements.

Section 3.05. Data and Confidentiality. All information which is disclosed in writing by Lilly to the University and marked "Confidential," or disclosed visually or orally and subsequently confirmed in writing within thirty (30) days after first disclosure, will be maintained in confidence by the University and will not be disclosed to any third party except to employees of the University under similar obligations of confidentiality, without the written consent of Lilly, for a period of five (5) years from the effective date of this Agreement. The University will use reasonable efforts to maintain the confidentiality of the information. The obligations of this section do not apply to:

(1) information which is in the public domain or comes in to the public domain through no fault of the University;

(2) information learned by the University from a third party not subject to a duty to Lilly not to disclose such information;

(3) information developed by the University independently of knowledge or information obtained by the University from Lilly;

(4) information already known to the University before receipt from Lilly, as shown by the University's prior written records; and

(5) information which the University is required by laws or regulations to disclose to the IRB, the patient, local regulatory agencies, or the FDA, or any other person or body entitled by law to such disclosure, provided that in the event that information is required to be disclosed pursuant to this subsection (5), University shall immediately notify Lilly to allow Lilly to assert whatever exclusions or

exemptions may be available to it under such law or regulations.

Subject to the University's right to publish the results of the Study as set forth in Section 3.06 below, data emanating from the Study shall be the sole property of Lilly and shall be transmitted promptly to Lilly. Lilly shall keep the data from the Study confidential with the following exceptions:

(1) Lilly may report such data to the FDA, and other federal, state, and local governmental and regulatory authorities and agencies, domestic and foreign;

(2) when disclosure is required by or in accordance with any applicable federal, state, or local laws or regulations, domestic or foreign;

(3) descriptions of safety data from the Study may be shared with all investigators conducting studies with the same products; and

(4) data pooled from several investigators may be published or otherwise made publicly available by Lilly.

However, this commitment is not intended nor does it prevent Lilly from providing the data to a third party under a confidentiality agreement at least as restrictive as the confidentiality commitment provided herein.

Section 3.06. Publications. University reserves the right to publish the results of the Study. University will, however, notify Lilly at least forty-five (45) days prior to submission of an abstract or manuscript from the Study for publication or oral presentation. Lilly shall notify University in writing within thirty (30) days of receipt whether the abstract or manuscript contains information requiring the filing of a patent application(s) covering an invention in which Lilly owns full or part interest, or intends to obtain an interest from University pursuant to this Agreement. Lilly shall have the right to request a delay and University agrees to delay said publication for a period not exceeding ninety (90) days to allow Lilly to protect its intellectual property or data package exclusivity interests. Information related to Lilly's experimental drugs will not be transmitted to nonscientific journals, newspapers, radio or television without Lilly's written consent. Under certain circumstances, a shorter review period may be granted in writing by Lilly. Should Lilly need assistance in obtaining reprints of University's publication resulting from the Study, University will provide such assistance as it is allowed to provide.

Section 3.07. Inventions. If during the course of the Study under this Agreement the University or the Principal Investigator discovers what is believed to be a new invention or use involving Lilly's product, the University or Principal Investigator will promptly notify Lilly.

Lilly shall have an option, for one (1) year from the date of disclosure, to acquire a worldwide exclusive license to the new invention or use, under terms to be negotiated in good faith, provided any royalty shall not exceed five percent (5%) of Lilly's net sales of any product employing such new invention or use.

Section 3.08. Publicity.

(1) Advertisement for patients. Lilly and University's IRB must approve, in writing, the text of advertisements soliciting patients for the Study before placement. Such advertisements shall not name the Study Drug, contain therapeutic claims or mention Lilly.

(2) Press releases. Lilly must approve, in writing, press statements by University or Principal Investigator regarding the Study or the Study Drug before the statements are released. Except as required by applicable laws or governmental regulation, the parties agree not to release or distribute any materials or information containing the name of the other party without prior written approval by an authorized representative of the non-releasing party.

(3) Inquiries from media and financial analysts. During and after the Study University may receive inquiries from reporters or financial analysts. Lilly requests that University confer with a Lilly Research Physician or Lilly's Corporate Communications Department (317-276-3655), before responding to such inquiries.

Section 3.09. Debarment Certification (Generic Drug Enforcement Act of 1992). University agrees to submit to Lilly upon completion or termination of the Study a certification that it has not been debarred by the FDA under the provisions of the Act and that it did not and will not use in any capacity the services of any individual or person (as defined in the Act) debarred by the FDA, in connection with the Study.

Section 3.10. Controlled Substance. Should the Study involve the use of a Schedule II, III, IV, or V controlled substance, the University agrees to provide to Lilly a photocopy of University current DEA registration certificate before Study Drug is shipped to the investigational site. The certificate must bear the address of the investigational site where the Study Drug will be received, stored and dispensed by the Principal Investigator. The certificate must also show that the Principal Investigator is authorized to handle Schedule II, III, IV, or V substances. University agrees that if the Principal Investigator moves, or if the Principal Investigator's DEA registration certificate expires, University shall provide to Lilly a photocopy

of an updated DEA registration certificate before any further shipment of Study Drug will be made by Lilly.

Article IV

VA Contracts

Section 4.01. U.S. Department of Veterans Affairs. Lilly has contracts with the U.S. Department of Veterans Affairs. If the U.S. Department of Veterans Affairs facilities, employees (full or part-time), or patients are to be utilized in the Study, please provide written confirmation from the director of the U.S. Department of Veterans Affairs facility involved that:

(1) the research to be conducted is authorized under Department of Veterans Affairs policies;

(2) the amount and manner of payment is appropriate; and

(3) the designated payee is appropriate under U.S. Department of Veterans Affairs requirements.

Article V

Limit of Patient Entry or Enrollment and Study Termination

Section 5.01. Limit of Patient Entry or Enrollment. Lilly reserves the right to limit entry or enrollment of additional patients at any time. Lilly also reserves the right to terminate University's participation in the Study or the Study itself at any time.

Section 5.02. Termination. Lilly may terminate this Agreement at any time upon written notice to University; provided, however, that when the reason for termination is the safety of subjects, then it can be terminated immediately by telephone.

In the event this Agreement is terminated by Lilly for any reason, unless University is then in default, Lilly shall pay University for reasonable costs incurred for all work performed up to the time of termination, which costs shall be limited to non-cancelable costs incurred as required under the Protocol, and contemplated in the Schedule of Financial Support, Exhibit B, related to the Study. Such amounts shall
take into account the advance payment and other payments made by Lilly, under this Agreement. In the event the advance payment, and any other payments made by Lilly, exceed the final fees owed to University at time of termination, University shall within thirty (30) days of termination reimburse such excess to Lilly.

Section 5.03. Materials Return. Promptly upon termination of this Agreement for any

reason, University shall deliver to Lilly all available subject clinical data, all unused drug supplies, all data forms required for the Study as well as any other data requested by the Federal Food and Drug Administration.

Article VI

Indemnification

Section 6.01. Indemnification.

(1) Lilly shall indemnify and hold harmless The University of Texas System, the University, their regents, officers, agents and employees from any liability, loss, damage, costs and expenses of claims and suits (including the costs and expenses of handling such claims and defending such suits) resulting from:

(a) an injury to a patient or subject seeking damages alleged to have been directly caused by or attributed to any substance dispensed or administered or any procedure performed in accordance with the provisions of the protocol; or

(b) the use by Lilly of the results of the Study;

(2) PROVIDED, HOWEVER, that the following is excluded from Lilly's obligation to indemnify and hold harmless:

(a) the failure of the University to comply with any applicable governmental requirements or to adhere to the terms of the protocol; or

(b) the negligence of the University, a regent, officer, agent or employee of the University.

(3) Lilly's obligation to indemnify and hold harmless are subject to the following conditions:

(a) that Lilly is promptly provided with written notice of any claim or lawsuit;

(b) that Lilly retains the right to defend the lawsuit, in any manner it deems appropriate, subject to the Texas Attorney General's statutory duty, including the right to retain the counsel of its choice;

(c) that Lilly has the sole right at its expense to settle the claim; and

(d) that subject to the Texas Attorney General's statutory duty, the indemnified party will cooperate fully in the investigation and with

defense of any such claim or lawsuit.

Not in any limitation of the foregoing provisions of 6.01 above, Lilly will reimburse the costs of extra unanticipated tests, treatments, and hospitalizations of patients required as a result of adverse events which Lilly determines with reasonable medical certainty, to have resulted from the substances dispensed or administered properly and in accordance with the Study Protocol. The University will obtain promptly, for Lilly, all records of such extra tests and treatments. Lilly will not reimburse for those costs covered by the subject's or patient's medical or hospital insurance or by governmental programs providing such coverage.

Article VII

EPA or FDA Visits

Section 7.01. Visitation. At Lilly's request, a representative of University shall accompany Lilly to EPA or FDA to explain or discuss any and all aspects of the Study. Such visit or visits to the EPA or FDA shall be arranged at times mutually agreeable to Lilly and University. All reasonable travel and living expenses incurred by University in connection with such visits shall be reimbursed by Lilly.

Section 7.02. Notification. University shall notify Lilly of any request from FDA, EPA, other federal or state agencies or any other third party to inspect or otherwise gain access to the information, data or materials pertaining to the Study performed by University under this Agreement. University shall notify Lilly of such requests prior to permitting any third party access unless prior notice is not possible.

Section 7.03. Inspection. University agrees to permit inspection of such information, data and materials relating to the Study by authorized representatives of FDA or EPA and as otherwise required by law. During such inspections, University shall provide appropriate scientific and quality assurance support for the Study. If warranted, Lilly will provide additional scientific and quality assurance support during regulatory inspections.

Article VIII

Force Majeure

Section 8.01. Force Majeure. A party shall be excused from performing its obligations under this Agreement if its performance is delayed or prevented by any cause beyond such party's control, including but not limited to, acts of God, fire, explosion, disease, weather, war, insurrection, civil strife, riots, government action, or power failure. Performance shall be excused only to the extent of and during the reasonable continuance of such disability. Any deadline or time for performance specified in the Protocol which falls due during or subsequent

to the occurrence of any of the disabilities referred to herein shall be automatically extended for a period of time equal to the period of such disability. University will immediately notify Lilly if, by reason of any of the disabilities referred to herein, University is unable to meet any deadline or time for performance specified in the Protocol.

In the event that any part of the Study is rendered invalid as a result of such disability, University will, upon written request from Lilly, repeat that part of the Study affected by the disability.

Nothing contained in this force majeure section shall affect Lilly's right to terminate this Agreement at any time.

Article IX

Reports Regarding Application of Funds

Section 9.01. Summary of Payments. In order that Lilly may comply with applicable federal tax laws and regulations, University agrees that if requested by Lilly, University will report to Lilly within sixty (60) days after the close of each calendar year the dollar amount of the budget funds which University and/or the Principal Investigators expended during the year on research activities covered by this Agreement. In order to assist University in completing the statement, Lilly will endeavor to provide University with a summary of payments made to it during such year for this and other studies or research activity conducted by it during such year.

Article X

Disputes

Section 10.01. Disputes. It is the intention of the parties that in the event disputes should arise between the parties over the interpretation and application of this Agreement, the parties will attempt to settle such disputes by negotiation and consultation between themselves. The parties will also consider but are not bound to commit to arbitration as a means of resolving any such disputes.

Section 10.02. Litigation. In the event that either party commences legal proceedings against the other party in connection with this Agreement, the prevailing party shall be entitled to recover its costs and expenses of litigation (including reasonable attorney's fees) from the other party.

Article XI

Notices

Section 11.01. Notices. All notices required or permitted by this Agreement shall be in writing and shall be delivered in person or sent by certified or registered mail, return receipt requested, postage prepaid, to each party at the address set forth in the Study Protocol, the Study identification letter or at such other address as a party may give to the other in the manner set forth in this section. Notices shall be deemed effective on the date of receipt.

Article XII

Amendments

Section 12.01. Amendments. Any amendments or revisions to this Agreement or the Protocol must be proposed in writing by either party and accepted in writing by the other party as provided in the Notices provision contained herein, before they shall become effective and binding.

Article XIII

Waiver

Section 13.01. Waiver. No waiver of any term, provision, or condition of this Agreement, whether by conduct or otherwise in any one or more instances, shall be deemed to be or construed as a further or continuing waiver of any such term, provision, or condition or of any other term, provision, or condition of this Agreement.

Article XIV

Binding Effect

Section 14.01. Binding Effect. This Agreement shall be binding upon and inure to the benefit of the parties hereto and their successors and assigns, provided, however, that neither party shall have the right to assign this Agreement or any of the rights or obligations hereunder without the prior written consent of the other party. This Agreement may be executed in one or more counterparts, each of which shall be an original and all of which shall constitute together the same document.

Section 14.02. Survival of Obligations. Notwithstanding any termination of this Agreement, the obligations with respect to the protection, non-use and non-disclosure of confidential information pursuant to Section 3.05, 3.06, 3.08 and Article VI shall survive and continue to be enforceable in accordance with their terms.

Article XV

Entire Agreement

Section 15.01. Agreement. This Agreement represents the entire understanding between the parties, and supersedes all other agreements, express or implied, between the parties concerning the subject matter hereof.

IN WITNESS WHEREOF, the parties hereto have authorized their officers or representatives to execute this Agreement in duplicate as of the date and year written.

LILLY RESEARCH LABORATORIES
A DIVISION OF
ELI LILLY AND COMPANY

BY:_____
ALECIA A. DECOUDREAUX
EXECUTIVE DIRECTOR

AGREED AND ACCEPTED:
THE UNIVERSITY OF TEXAS HEALTH
SCIENCE CENTER AT SAN ANTONIO

BY:_____
(SIGNATURE OF AUTHORIZED OFFICIAL)

_____
(PRINTED NAME AND TITLE)

_____
(DATE)

AGREED AND ACCEPTED:
THE UNIVERSITY OF TEXAS HEALTH
SCIENCE CENTER AT HOUSTON

BY:_____
(SIGNATURE OF AUTHORIZED OFFICIAL)

_____
(PRINTED NAME AND TITLE)

_____
(DATE)

AGREED AND ACCEPTED:
THE UNIVERSITY OF TEXAS M.D.
ANDERSON CANCER CENTER

BY:_____
(SIGNATURE OF AUTHORIZED OFFICIAL)

_____
(PRINTED NAME AND TITLE)

_____
(DATE)

AGREED AND ACCEPTED:
THE UNIVERSITY OF TEXAS SOUTHWESTERN
MEDICAL CENTER AT DALLAS

BY:_____
(SIGNATURE OF AUTHORIZED OFFICIAL)

_____
(PRINTED NAME AND TITLE)

_____
(DATE)

AGREED AND ACCEPTED:
THE UNIVERSITY OF TEXAS MEDICAL
BRANCH AT GALVESTON

BY:_____
(SIGNATURE OF AUTHORIZED OFFICIAL)

_____
(PRINTED NAME AND TITLE)

_____
(DATE)

EXHIBIT A

PROTOCOL

EXHIBIT B

SCHEDULE OF FINANCIAL SUPPORT

EXHIBIT C

PRINCIPAL INVESTIGATOR'S ASSURANCE

FORM OF

EXHIBIT C
TO
MASTER CLINICAL TRIAL AGREEMENT

Principal Investigator's Assurance

Clinical Trial Study Title: _____

_____

I, Dr. _____, the Principal Investigator for The University of Texas _____ _____, ("University") have read and I understand my obligations under the Master Clinical Trial Agreement ("Agreement") for the above-referenced Clinical Trial Study. I agree to abide by the terms of the Agreement whether such obligations are imposed upon the University, Principal Investigator or both, to which Agreement this Principal Investigator's Assurance is attached as Exhibit C.

The University of Texas _____

_____
(Signature)

_____
(Printed Name and Title)

_____
(Date)

AMENDED
FORM OF

EXHIBIT C
TO
MASTER CLINICAL TRIAL AGREEMENT

Principal Investigator's Assurance

Clinical Trial Study Title: _____
_____

I, Dr. _____, the Principal Investigator for The University of Texas _____, ("University") have read and I understand my obligations under the Master Clinical Trial Agreement ("Agreement") for the above-referenced Clinical Trial Study. I agree to abide by the terms of the Agreement as may be amended with respect to the term of confidentiality as set forth below, whether such obligations are imposed upon the University, Principal Investigator or both, to which Agreement this Principal Investigator's Assurance is attached as Exhibit C.

The term of confidentiality shall be:

____ as set forth in the Master Clinical Trial Agreement.
____ _____ years.

The University of Texas _____

_____
(Signature)

_____
(Printed Name and Title)

_____
(Date)