**CLINICAL RESEARCH AGREEMENT**

This Agreement, effective as of \_\_\_\_\_\_\_\_\_\_\_\_, is made between Genentech, Inc. ("Genentech"), 460 Point San Bruno Boulevard, South San Francisco, California 94080, and The University of Texas \_\_\_\_\_\_\_\_\_ ("Study Center") Dallas, Texas (collectively the "Parties") for the purpose of conducting clinical research. Citations to the Code of Federal Regulations ("C.F.R.") in this Agreement are citations to regulations governing investigations of new drugs.

**1.0 DEFINITIONS**

For purposes of this Agreement:

1.1 "Investigational New Drug," as that term is defined in 21 C.F.R.  Section 312.3(b), is \_\_\_\_\_\_\_\_.

1.2 "Investigator," as that term is defined in 21 C.F.R. Section 312.3(b), is \_\_\_\_\_\_\_\_\_, who agrees to direct the administration of the Investigational New Drug in accordance with the Protocol.

1.3 "Protocol" means the protocol, number \_\_\_\_\_\_\_\_\_, which is entitled , and which is attached as Exhibit A. Exhibit A is made a part of this Agreement as though fully set forth. Any statement in the Protocol which is inconsistent with this Agreement is superseded by the Agreement.

1.4 The "Sponsor," as that term is defined in 21 C.F.R. Section 312.3(b), is Genentech.

1.5 "Study" or "Clinical Investigation" means the work performed by the Investigator and any Subinvestigators in connection with the Protocol.

1.6 "Subinvestigator," as that term is defined in 21 C.F.R. Section 312.3(b), is any individual designated by the Investigator in the event the clinical investigation is conducted by a team.

1.7 "Subject," as that term is defined in 21 C.F.R. Section 312.3(b), is a human being who participates in the Study.

**2.0 THE STUDY**

2.1 The Study shall be conducted in accordance with the Protocol and no changes in the Protocol will be made unless agreed upon in advance by Genentech or unless necessary to protect the safety, rights or welfare of the Subjects.

2.2 Enrollment for the Study will begin on or about \_\_\_\_\_\_\_\_\_.   The planned enrollment is approximately Subjects.  The Study is to be completed by \_\_\_\_\_\_\_\_\_, unless the Parties mutually agree to a different date.

**3.0 PAYMENT AND PAYMENT SCHEDULE**

Genentech agrees to make payments totaling $         per patient to The Study Center.

Initial reimbursement of $          will be made \_\_\_\_\_\_\_\_\_\_\_\_\_. After Genentech has received copies of the completed case report forms for each of the final Subjects participating in the Study, Genentech agrees to make the final payment.

**4.0 INVESTIGATIONAL NEW DRUG**

Genentech shall provide, without charge, the Investigational New Drug to Study Center to be used in the Study. Such drug shall be shipped to Study Center in appropriately marked containers in accordance with 21 C.F.R. Section 312.6.

**5.0 HUMAN SUBJECTS**

Informed consent of the Subjects participating in the Study shall be obtained in accordance with 21 C.F.R. Part 50 and Institutional Review Board ("IRB") review and approval of the Protocol, including the Informed Consent form, shall be obtained in accordance with 21 C.F.R. Part 56. Study Center agrees to supply Genentech with evidence of IRB approval, a copy of the Informed Consent form which is IRB approved and a copy of any modified Informed Consent form later approved by the IRB and used.

**6.0 RECORD KEEPING AND ACCESS TO RECORDS**

6.1 Study Center agrees to maintain adequate and accurate records as required under 21 C.F.R. Section 312.62 relating to the disposition of the Investigational New Drug and the treatment of Subjects in the Study.

6.2 Study Center agrees to maintain the records required by 21 C.F.R. Section 312.62 for two (2) years following the date a marketing application is approved for the drug for the indication which is being investigated, or until two (2) years after Genentech has provided written notice to the Investigator that the investigation has been discontinued.

6.3 Study Center further agrees to permit Genentech access to the records maintained pursuant to paragraph 6.1 upon request at reasonable times.

6.4 Genentech shall not at any time disclose the name of any Subject or any information which identifies a Subject to a third party unless specifically required to do so by law or the Food and Drug Administration.

**7.0 CONFIDENTIALITY**

7.1 Study Center agrees that

a. all confidential information received from Genentech, including but not limited to the Investigator's Brochure and the Protocol, and

b. all confidential information developed by Genentech during the Study, including but not limited to the case reports and safety information, is "Confidential Information" which is the sole and exclusive property of Genentech during the period of this Agreement and subsequent thereto.

Alternative

7.1 Study Center agrees that all information received from Genentech which is designated confidential which shall include but shall not be limited to the Protocol is "Confidential Information" which is the sole and exclusive property of Genentech during the period of this Agreement and subsequent thereto.

7.2 For a period of three (3) years from completion of the study, the Investigator and Study Center agree not to disclose Genentech`s Confidential Information to any person, except the Investigator, Subinvestigators, members of the Institutional Review Board or, as required, to the Food and Drug Administration, without the prior written consent of Genentech, and further agrees to take all reasonable precautions to prevent the disclosure by the Investigator, Subinvestigators and the IRB of Genentech's Confidential Information to a third party.

7.3 Except as otherwise provided herein, the Investigator agrees to use Genentech's Confidential Information only in the conduct of the Study and evaluation of its results.

7.4 The provisions of this Section 7.0 do not apply to any information which:

a. was known to Study Center or the Investigator prior to receiving that information either directly or indirectly from Genentech, or

b. is generally known to the public or which becomes generally known to the public through no act or omission on the part of Study Center or the Investigator, or

c. is disclosed to Study Center or the Investigator at any time by a third party who had a legal right to disclose it,

d. is independently derived by Study Center or by component institutions of The University of Texas System, or

e. is required by law or regulation to be disclosed.

**8.0 PUBLICATION**

The Investigator is free to communicate and/or publish with respect to the results of the Study being conducted hereunder without the prior approval of the Sponsor. However, with respect to any proposed publication of the results of the Study, the Investigator agrees to submit to the Sponsor a summary of the proposed publication at least two (2) months prior to the submission thereof for publication. The purposes for such prior submission are: (i) to provide the Sponsor with the opportunity to review and comment on the contents of the proposed publication; and (ii) to identify any trade secret or confidential information belonging to Genentech to be deleted from the proposed publication. Sponsor shall provide any comments to Investigator or identify any of Sponsor's trade secret or confidential information to be deleted from the proposed publication within thirty (30) days of receipt of the proposed publication.

**9.0 REPORTING**

Study Center agrees to report to Genentech within 24 hours all adverse experiences that may be associated with the administration of the Investigational New Drug that occur during the course of the Study. Failure to comply with this paragraph provides Genentech with good cause for terminating this Agreement as provided in paragraph 13.2.

**10.0 INDEMNIFICATION**

10.1 Genentech agrees to indemnify and hold harmless The University of Texas System, the Study Center and the Investigator and their officers, employees, and agents from any and all liability, loss (including attorneys' fees), or damage they may suffer as the result of claims, demands, costs, or judgments against them arising out of the activities to be carried out pursuant to the Protocol, except to exclude from this agreement to indemnify any claims, demands, costs or judgments which are, or are alleged to be, arising from

a. a failure to adhere strictly to the terms of the Protocol;

b. negligence or willful misconduct on the part of Study Center, the Investigator or any Subinvestigator; or

c. a breach of any applicable federal, state or local law by Study Center, the Investigator or any Subinvestigator.

10.2 Genentech's agreement to indemnify and hold harmless in paragraph 10.1 is conditioned on the Study Center and Investigator

a. obtaining from each of the Subjects participating in the study informed consent in compliance with 21 C.F.R. Part 50; and

b. obtaining Institutional Review Board (IRB) review and approval in compliance with 21 C.F.R. Part 56,

c. providing written notice to Genentech of any claim, demand or action arising out of the activities to be carried out pursuant to the Protocol within such a period of time as not to materially prejudice the rights of Genentech (or "the indemnifying party") after Study Center or the Investigator has knowledge of such claim, demand or action.

10.3 To the extent permitted under the Constitution and the laws of the State of Texas, Study Center agrees to hold Genentech harmless to the full extent permitted by and subject to any restrictions imposed by the Constitution and laws of the state of Texas, from any and all liability, loss, or damage it may suffer as the result of claims, demands, costs, or judgments which are, or are alleged to be, arising out of

a. a negligent failure to adhere strictly to the terms of the protocol;

b. negligence on the part of Study Center, the Investigator or any Subinvestigator; or

c. a negligent breach of any applicable federal, state or local law by Study Center, the Investigator or any Subinvestigator.

10.4 Each Party's agreement to indemnify and hold the other harmless is conditioned on the indemnified party (i) providing written notice to the indemnifying party of any claim, demand or action arising out of the indemnified activities within such a period of time as to not materially prejudice the rights of the indemnifying party after the indemnified party has knowledge of such claim, demand or action (ii) subject to the statutory duty of the Texas Attorney General, permitting the indemnifying party to assume full responsibility to investigate, prepare for and defend against any such claim or demand, (iii) assisting the indemnifying party, at the indemnifying party's reasonable expense, in the investigation of, preparation for and defense of any such claim or demand, and (iv) not compromising or settling such claim or demand without the indemnifying party's written consent, which shall not be unreasonably withheld.

**11.0 INVENTIONS**

All inventions made by Study Center or Investigator arising from the conduct of the study in strict conformity with the protocol during the course of the Study ("Inventions") shall be the property of the Study Center. Study Center hereby grants to Sponsor a right of first refusal to obtain an exclusive or non-exclusive (as Sponsor may elect), royalty-bearing license to practice any Invention made by Study Center or Investigator during the term of this Agreement or to practice any patent anywhere in the world arising out of any such Invention. Said option shall remain exercisable by Sponsor until a period of one (1) year following the filing of a United States patent application on said Invention. Study Center shall provide notice of such filing to Sponsor promptly after such filing has been made. Sponsor may exercise the option by providing written notice of such to Study Center, and the parties shall meet within thirty (30) days thereafter to negotiate in good faith a license agreement based on commercially reasonable terms and provisions. The license shall bear a reasonable royalty which shall be determined with a view to whether the license is exclusive or non-exclusive, the scope of the patent claims in the involved patent, the standard in the industry and other relevant commercial factors. If Sponsor does not exercise its option before expiration of the option, Study Center shall be free to grant such licenses as it may choose under the Inventions or patents subject to this provision.

**12.0 COMPLIANCE WITH STATUTES**

Study Center and the Investigator agree to conduct the Study in accordance with the applicable portions of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. Section 301 et seq., and its implementing regulations and other applicable federal and state statutes and regulations.

**13.0 TERMINATION**

13.1 With the exception of Sections 8.0 and 10.0, Genentech and the Study Center, by mutual agreement, may terminate the Study and this Agreement at any time.

13.2 Except for Sections 8.0 and 10.0, Genentech has the right to terminate this Agreement at any time for good cause upon thirty (30) days written notice.

13.3 Section 7.0 will remain in full force and effect without regard to whether the Parties have fully performed their obligations under this Agreement and as long as Study Center or the Investigator are in possession of Genentech's "Confidential Information."

**14.0 CHANGES, GOVERNING LAW AND NOTICE**

14.1 This Agreement constitutes the entire understanding of Genentech and Study Center. No changes, amendments or alterations shall be effective unless in writing and signed by the Parties.

14.2 Any notice required to be given under this Agreement shall be sent to the other Party by certified mail, return receipt requested and shall be deemed given three (3) days after the date of postmark. Notice shall be given to each Party at the address set forth at the beginning of this Agreement and in the case of Genentech shall be addressed to the Corporate Secretary.

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| University of Texas \_\_\_\_\_\_\_\_\_\_\_\_ By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_                                Name Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  | Genentech, Inc. By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_                                Name Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  |

I have read this Agreement and understand
my obligations hereunder.

By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
                   (Principal Investigator)

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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