MASTER CLINICAL STUDY AGREEMENT
BETWEEN MEMBER INSTITUTIONS
of
THE UNIVERSITY OF TEXAS SYSTEM

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

AND GENZYME CORPORATION
This Master Clinical Study Agreement (together with its Appendices, the “Agreement”) is made this 6th day of April, 2010 (“Effective Date”) between Genzyme Corporation, 500 Kendall Street, Cambridge, Massachusetts 02142 (“Genzyme”) and the following member institutions of The University of Texas System, located at 201 West 7th Street, Austin, Texas 78701 (“UT System”): The University of Texas Health Science Center at San Antonio, The University of Texas Health Science Center at Houston, The University of Texas M.D. Anderson Cancer Center, The University of Texas Southwestern Medical Center at Dallas, The University of Texas Medical Branch at Galveston, The University of Texas at Austin and The University of Texas Health Science Center at Tyler (Genzyme and each Institution referred to herein individually as “Party”, and collectively as “Parties”). The address and other information for each Institution can be found on Schedule B. Genzyme would like to sponsor one or more clinical studies (each, a “Study”) at Institution. One or more physicians employed by the Institution may desire to participate in a Study as a principal investigator (each, an “Investigator”).

1. Appendices. As a master form of contract, this Agreement establishes the general terms under which each agreed-upon Study will be conducted and allows the Parties to contract for individual Studies through the execution of abbreviated Appendices (as defined below) rather than full clinical study agreements. For each clinical Study that the Parties mutually agree will be conducted by Institution, a separate appendix to this Agreement, a sample form of which is attached as Schedule A, will be executed by Genzyme and the Institution, with the appropriate Investigator signing as read and understood (each, an “Appendix”). The name of the Investigator, the Study drug(s) to be used (the “Study Drug(s)”), the budget, the Study protocol (as may be amended from time to time by Genzyme, a “Protocol”), the physical location for the conduct of the Study if other than the Institution and other related matters will be specified in each Appendix (the place of business for the participating Institution shall be outlined in the applicable Appendix). Each Appendix shall incorporate by reference the terms and provisions of this Agreement and, taken together with this Agreement, shall be deemed a distinct and independent agreement separate from each other Appendix hereunder. This Agreement does not obligate Genzyme to offer, or Institution to accept, engagement for any particular clinical Study. Moreover, this Agreement pertains only to clinical studies initiated by
Genzyme and to be performed under protocols developed by Genzyme. Because this Agreement pertains only to Genzyme-initiated clinical studies, this Agreement does not contemplate that Institution will hold, and Institution will not hold, the Investigation New Drug application ("IND") for any Study under this Agreement. In the event an Investigator for a Study becomes unwilling or unable to perform the duties required by this Agreement or applicable Appendix, the Parties shall attempt to find a mutually acceptable replacement. In the event that a mutually acceptable replacement is not found, the relevant Appendix may be terminated in accordance with Section 2.1 of this Agreement without any further notice or waiting period. This Agreement will apply only to a Study for which an Appendix has been fully executed.

2. TERM

2.1 An Appendix to this Agreement will be effective upon its complete execution and will continue in force until the Study is completed or the Appendix is mutually terminated by Genzyme and Institution or by either Party giving the other Party thirty (30) days advance written notice of such termination. Either Party may immediately terminate an Appendix at Institution at any time by giving written notice to the other Party if necessary to protect the safety, health or welfare of subjects enrolled in the Study. The expiration or earlier termination of any Appendix will not terminate this Agreement or any other Appendix.

2.2 If an Appendix is terminated under 2.1 above, the applicable Study then in process will be reviewed, and a plan will be made for the reasonable and safe closeout of that Study, as well as the final settlement of all Study costs. Within ninety (90) calendar days of the termination of the Appendix, Institution and Investigator shall provide Genzyme with a final, written reconciliation of the Study costs relative to the budget set forth in the applicable Appendix. In the event that the compensation provided thereunder was not used in connection with the Study as set forth in the applicable budget/Appendix, Institution and Investigator will return to Genzyme such unused funds promptly upon delivery of the final reconciliation. Any costs owed to Institution will be adjusted pro
rata, including all reasonable non-cancelable commitment fees incurred up to date of the Study closeouts and terminations. Genzyme will pay the settlement amount, after agreeing to that amount with Institution, within forty-five (45) days of Genzyme’s receipt of a detailed invoice for that amount.

2.3 Upon any termination of an Appendix, the Investigator and the Institution will return to Genzyme the original of all Study data (excluding original medical records and laboratory notebooks) generated in that Study up to and including the time of termination, in whatever media that data exists. However, the Institution shall retain a copy of the Study data generated during the course of the Study, with the right to use the site data for regulatory compliance purposes, for its own internal non-commercial research, education and patient care purposes, subject to Institution’s obligations of Confidentiality under Section 9, and for Publication under Section 7.

2.4 This Agreement will terminate April 6, 2020, ten (10) years from the Effective Date. Any Party may terminate its participation in this Agreement at any time upon giving thirty (30) days prior written notice to the other Party. The expiration or termination of this Agreement will not automatically terminate any Appendix, and with respect to any Appendix entered into prior to such expiration or termination, this Agreement shall remain in effect until the expiration or earlier termination of such Appendix. Accordingly, the provisions of this Agreement will survive expiration or termination of this Agreement and will continue to be applicable to such Appendix until termination or expiration of the Appendix.

3. PAYMENT

3.1 Genzyme will pay the Institution for performance of the Study as detailed in the Appendix. The Investigator and Institution jointly and severally represent and certify to Genzyme that the amounts set forth in the budgets for the Study(s) constitute the fair market value of their Study activities. If Genzyme makes changes to the Protocol and such changes increase the cost of performance of the Study by Institution, the Parties
shall negotiate an amendment to the Appendix to adjust the Study budget to cover the additional costs.

3.2 Institution agrees and Investigator acknowledges that: (a) all claims that either Institution or Investigator submit for reimbursement to any federal healthcare program or third party payer for any procedure that involves any materials (including but not limited to, Study Drug) provided by or on behalf of Genzyme at no cost to Institution will accurately reflect the provision of those materials by or on behalf of Genzyme; (b) Institution and Investigator will not seek reimbursement from any federal healthcare program or third party payor for amounts paid by Genzyme; and (c) any equipment supplied by Genzyme or its designee for use in the Study will be used solely in connection with the Study and will be returned to Genzyme or its designee upon their request at the completion or termination of the Study, at the reasonable expense of either Genzyme or its designee.

3.3 Other than as required for their performance under this Agreement, neither the Investigator nor the Institution is under any obligation to solicit, refer, or solicit the referral of subjects for any Genzyme business. Except as provided by this Agreement, neither the Investigator nor the Institution will receive any benefit of any kind from Genzyme for such referrals, nor suffer any detriment for not making such referrals.

4. COMPLIANCE WITH PROTOCOL/LAW

a) Protocol/Law/AHRPP/HIPAA. The Investigator and the Institution will conduct each Study in accordance with relevant state and federal laws and regulations, including but not limited to the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") Privacy Regulations, Institutional policy, the provisions of the written Protocol (as it may be amended from time to time by Genzyme), and any other Study-specific written instructions or procedures provided by Genzyme. The Study will be supervised by the Investigator at the Institution, and may involve qualified healthcare personnel, as deemed necessary by the Investigator. Such personnel will be subject to and governed
by this Agreement. If Genzyme obtains, learns of, comes in contact with, or otherwise has access to any patient health or medical information, Genzyme will keep such information confidential and will comply with all applicable laws regarding the confidentiality of such information and will not use or disclose such patient health and medical information in a manner that would violate any applicable law (including HIPAA Privacy Regulations) if such use or disclosure were made by Institution. Further, Genzyme will maintain the confidentiality of, and will use or disclose Study subject’s health and medical information only as provided in the Study subject’s informed consent and authorization documents. Genzyme will promptly report to Institution, via the person identified in Schedule B, any finding, event, or information that could affect the safety of subjects or their willingness to continue participating in the Study, or influence the conduct of the Study, or affect the Institutional Review Board’s ("IRB"’s) approval to continue the Study. Genzyme shall promptly report to the Institution (a) any findings arising during or after a Study that may directly affect the safety or appropriate medical care for past or current Study subjects, and (b) any findings during the Study, including monitoring reports if Genzyme is monitoring the Study, that could affect the safety of Study subjects, affect the willingness of subjects to continue participation in the Study, influence the conduct of the Study, or alter the IRB’s approval to continue the Study. The Institution shall be free to communicate these findings to each Study subject and the IRB.

b) Use of Study Drug(Device). Neither the Institution nor the Investigator will use the Study Drug (and/or Device) for any purpose other than that outlined in the Protocol. To the extent authorized by the Constitution and laws of the State of Texas, the Institution takes full responsibility for (a) the use and tracking of the Study Drug (and/or Device) at the Institution, (b) maintaining record on use and disposition of the Study Drug and (c) disposing of Study Drug at the completion or termination of the Study according to Genzyme’s instructions.
c) **Biological Samples.** "Biological Samples" means blood, fluid, and tissue samples collected pursuant to the requirements of the Protocol from subjects enrolled in a Study, including any tangible materials derived from such samples. The Institution and Investigator will collect, retain, use and transfer Biological Samples only in accordance with the Protocol and the applicable Informed Consent Form. Institution and Investigator will not use Biological Samples except as provided for in the applicable Protocol. Upon completion of the Study, Institution and Investigator will deliver or dispose of the Biological Samples according to Genzyme’s direction.

5. **INDEMNIFICATION/SUBJECT INJURY.** To the extent authorized by the Constitution and laws of the State of Texas, Institution shall indemnify and hold harmless Genzyme against any and all claims, demands, damages, liabilities and costs incurred by Genzyme resulting from the negligent acts or omissions of UT System, Institution, its officers, Regents, agents or employees pertaining to the activities to be carried out pursuant to the obligations of this Agreement; provided, however, that Institution shall not hold Genzyme harmless from claims arising out of the negligence or willful malfeasance of Genzyme, its officers, agents, or employees, or any person or entity not subject to Institution’s supervision or control. Genzyme shall indemnify and hold harmless Institution, UT System, their Regents, officers, agents, and employees against any and all claims, demands, damages, liabilities and costs which result from judgments or claims against them arising out of the activities to be carried out pursuant to the obligations of this Agreement and the use by Genzyme of the results of the Study; provided, however, that Genzyme will have no indemnification obligations to hold harmless for i) Institution’s failure to adhere to the Protocol, or ii) failure by the Institution to comply with applicable FDA or other governmental regulations and requirements or iii) negligence or willful malfeasance of the Institution, UT System, its Regents, officers, agents and employees or iv) any claim, demand, damages, liability or cost arising from a compound or drug that is not the Study Drug under investigation and that is not required to be used under the Protocol of the applicable Study.
Genzyme will be responsible for reasonable medical care costs associated with injuries to subject(s) that result from interventions, drugs or devices that the subject(s) would not have been exposed to, had he/she not volunteered to participate in the Study Protocol, and that are not the result of negligence, reckless or willful malfeasance of the Investigator, sub-Investigator(s), Institution or their employees, agents, officers, assigns or other affiliated persons, or failure of same to follow the Protocol. Genzyme's responsibility does not extend to medical care costs for the normal progression of the subject(s) disease, or interventions, drugs or devices that the subject(s) would have received in the provision of standard medical care.

6. **INSURANCE.** The Parties shall have sufficient insurance or financial resources to meet their obligations under this Agreement. Such insurance shall be in the form of one or more commercial insurance policies and/or self-insurance programs. Upon request, each Party shall provide a certificate or proof of such insurance to the other Party before commencing work under an Appendix, or within thirty (30) days thereafter.

7. **PUBLICATION.** The Parties contemplate that the Studies under this Agreement will be multi-site Studies, and the Parties recognize that there is a need for a coordinated approach to any publication or public disclosure of the data or results of such multi-site Studies. To that end, there will be no publication or public disclosure of such data or results by the Institution or Investigator without Genzyme's prior review of any such publication or public disclosure. Therefore, Institution agrees not to independently publish the results of the Study from their site before the publication of the multi-site paper; but in no event shall Institution be so restricted after the expiration of eighteen (18) months from completion, termination, or abandonment of the Study at all sites. If the Institution wishes to publish or publicly disclose Study data or results, it will submit any proposed manuscript or publication to Genzyme for comment at least sixty (60) days prior to its submission for publication or other disclosure. The Institution will make reasonable attempts to incorporate comments received from Genzyme during such 60-day period. The Institution will not use Genzyme's Confidential Information (as defined in Section 8 below of this Agreement) in any publication without the prior written consent of Genzyme, provided, however, that for publication purposes, such Genzyme
Confidential Information shall not include the results of the Study. Genzyme will notify Institution within sixty (60) days of receipt of the proposed publication if it desires to file patent applications on any inventions contained in the proposed publication. If Genzyme decides to pursue such patent protection, Genzyme may request that publication be delayed for an additional sixty (60) days to permit the filing of any desired patent applications. Upon expiration of the initial sixty (60) day review period or the extended sixty (60) day patent filing period, if applicable, Institution may proceed with its publication. Study data and results shall remain the sole property of Genzyme, provided, however, that original medical records and laboratory notebooks are not included within the meaning of Study data and results.

8. **CONFIDENTIAL INFORMATION.** For the duration of the Study and for five (5) years after the completion, termination, or abandonment of the Study (at all sites, in the case of a multi-center Study), each Party will hold in confidence any information provided by another Party or that Party’s designee in connection with the Study ("Confidential Information"). Subject to Institution’s publication rights as set forth in Section 7 above and to the extent permitted by law, (a) the terms of this Agreement (including all Protocols and Appendices), (b) Genzyme’s investigator brochure and (c) all information and all data generated in connection with the Study including without limitation the case report forms and data contained therein, shall be deemed Confidential Information belonging to Genzyme. Notwithstanding the aforementioned, Institution may publish the Study data and results in accordance with Section 7 above and may use Study data and results for internal non-commercial research and for educational and/or patient use in accordance with this Agreement. The receiving Party agrees that it shall: (a) protect the Confidential Information with the same degree of care as it normally uses to preserve and safeguard its own Confidential Information of like nature, but not less than a reasonable degree of care; (b) use Confidential Information solely for the purposes of this Agreement and related Appendices; and (c) disclose Confidential Information only on a need-to-know basis to effect the purposes of this Agreement and related Appendices and only to its employees, advisors, agents and affiliates who are under an obligation of confidentiality substantially similar to that contained herein. However there is no such obligation of confidentiality or restriction on use as to any information (i) that was part of the public domain
prior to its receipt by receiving Party, or (ii) that becomes part of the public domain without fault of the receiving Party, or (iii) that is rightfully obtained without obligation of confidentiality from a third party having the right to disclose the information, or (iv) that was known to the receiving Party prior to disclosure, as proven by the written records of that Party, or (v) that was developed independently by the receiving Party without any reference to or use of any Confidential Information. Also, information shall not be deemed to be in the public domain simply because one or more portions of it are in the public domain.

Notwithstanding any other provision of this Agreement, Institution or the Principal Investigator may disclose Confidential Information:

(i) to the extent such disclosure is required by law, provided, however, that to the extent reasonably possible, Institution or Principal Investigator promptly provides to Genzyme notice of such required disclosure and reasonably cooperates with Genzyme, so that Genzyme can file a motion for a protective order or otherwise seek alternate legal relief it deems desirable or appropriate to protect its interests in the Confidential Information, and provided, further, that they will disclose only the minimum amount necessary to comply with the compelled disclosure and will continue to maintain the confidentiality of such disclosed Confidential Information; and

(ii) in order to obtain informed consent from patients or subjects who may wish to enroll in the Study, provided, however, that the information will be disclosed only to the extent necessary to answer such candidate’s queries in relation to his/her participation in the Study and will not be provided to answer unsolicited inquiries by telephone or to individuals who are not eligible Study candidates.

Notwithstanding any other provision of this Agreement, if and when any Confidential Information is no longer confidential as a result of an authorized public disclosure of such information under the terms of this Agreement, including any permitted publication, or because...
it has otherwise been made public through no wrongful act of Institution, then Institution will no longer have any restrictions upon its use or disclosure of such information, including as restricted under Section 8 or Section 9 below.

Genzyme agrees to ensure that the Study is registered on a publicly accessible internet site in accordance with all laws and regulations required for clinical trial registration and under the guidelines of the International Committee of Medical Journal Editors ("ICMJE").

9. **USE OF DATA.** Subject to Institution’s publication rights as set forth in Section 7 above, Institution and/or Investigator will not use data generated during the Study or results of the Study for any purpose other than internal, non-commercial research purposes or in connection with educational or patient care uses. or in connection with publication. Genzyme will have the unrestricted right to use all data resulting from each Study for any and all purposes subject to any and all laws and regulations, provided that if any results or data of the Study includes Protected Health Information (as defined by HIPAA), Genzyme may only use such Protected Health Information in accordance with the subject’s informed consent and authorization documents; it being understood that subject confidentiality will be maintained.

10. **INVENTIONS.** Any inventions, discoveries, suggestions, innovations, ideas, reports or the like (whether or not patentable or copyrightable) ("Inventions") developed, made, conceived or otherwise reduced to practice by Investigator or the Institution in the direct conduct of a Study and arising from the performance of the Study shall be promptly and fully disclosed to Genzyme in writing. Further, the Investigator and the Institution will do what is reasonably necessary, jointly and severally, and at Genzyme’s reasonable expense, to ensure that all rights to and ownership of any such Inventions are assigned to Genzyme as set forth below.

(a) Inventions related to the Study Drug, Study Protocol, other information or materials supplied by Genzyme or improvements of any of the foregoing. Any Inventions, developed, made, conceived or otherwise reduced to practice by Institution,
Investigator or other personnel of Institution, as a result of or in connection with conducting the Study and which are related to: the Study Drug, the Study Protocol, or other information or materials supplied by Genzyme, or any improvements of the foregoing (including but not limited to Inventions relating to any use, dosage or modification of the Study Drug or Study Protocol), shall be promptly and fully disclosed to Genzyme in writing and shall be the sole property of Genzyme subject to Institution having a royalty-free right to internally use any Invention for non-commercial research, and academic and patient care purposes. Institution agrees on behalf of itself, Investigator, and other Institution personnel to take such actions, at Genzyme’s expense, as Genzyme may reasonably request to secure its proprietary rights in any of the foregoing and vest ownership in Genzyme. The Investigator and the Institution agree to execute and deliver any documents of assignment or conveyance to effectuate the ownership rights of Genzyme.

(b) Other Inventions. For any other Inventions made, conceived or otherwise reduced to practice by Institution, Investigator or other personnel of Institution, in connection with or during the conduct of the Study (“Other Inventions”), ownership shall follow inventorship and inventorship shall be determined in accordance with United States patent laws. With regard to such Other Inventions, Institution shall grant and hereby grants to Genzyme the first option to obtain an exclusive, worldwide royalty-bearing license under Institution’s rights in any such Other Invention. Any such license shall contain commercially reasonable terms and conditions to be negotiated in good faith between the Parties. Genzyme shall have three (3) months after receiving a complete written description of such Other Invention to exercise its option. If Genzyme and Institution fail to execute a license agreement within six (6) months after Genzyme notifies Institution of its intent to exercise its option, Institution shall be free to license the Other Invention to any party upon such terms as Institution deems appropriate, without any further obligation to Genzyme.
(c) In the event that any Invention is made in breach of Institution’s or Investigator’s obligations under this Agreement, Genzyme shall be the sole and exclusive owner. Institution and Investigator shall execute and deliver any documents necessary to effectuate Genzyme’s ownership rights, at Genzyme’s expense.

11. MISCELLANEOUS

11.1 This Agreement, including its Appendices constitutes the entire and only agreement between the Parties with respect to the subject matter of this Agreement. All prior negotiations, representations, agreements and understandings are superseded by this Agreement. In the event of a conflict between the terms and conditions of this Agreement and those set forth in an Appendix or an exhibit, the terms and conditions of this Agreement shall govern and control. A Protocol will govern the scientific conduct of the Study and patient care and may not alter or add to the business terms of this Agreement or an Appendix. No amendment to this Agreement including its Appendices may be made unless that amendment is in writing and signed by an authorized representative of each Party.

11.2 By entering into this Agreement, each Party attests that it understands what is required of it for the Study under all applicable laws and regulations, and commits to meeting those requirements. The Institution and the Investigator also represent and certify that no person or entity among their agents or employees working under this Agreement and on the Study is barred from doing so by any relevant government or regulatory authority. Further, the Institution and the Investigator represent that they will not knowingly, after reasonable inquiry, employ or engage any debarred person or entity to perform any services under this Agreement.

11.3 Neither Institution nor Investigator shall assign or transfer any of their respective rights or obligations hereunder, or any part hereof, without the prior written consent of Genzyme. However Genzyme reserves the right to assign to its Affiliates (as defined below) or to procure the performance by its Affiliates of some or all of its rights and
obligations under this Agreement, including payment or receipt of monies due hereunder. In addition Genzyme reserves the right to assign a particular Appendix to a third party in connection with Genzyme assigning the associated drug program to such third party. Genzyme shall be solely liable for the acts and omissions of its Affiliates, which are not parties to this Agreement. In addition to the foregoing, the Parties hereby agree that Affiliates of Genzyme may from time to time execute Appendices to this Agreement with respect to a particular Study and that the terms and conditions of this Agreement shall govern such Study just as if such Affiliates had been signatories to this Agreement. By their execution of such Appendices, Genzyme Affiliates agree for purposes of such Study to be bound by the terms and conditions of this Agreement just as if they were signatories to this Agreement. “Affiliates” means any person or entity that controls or is controlled by or is under common control with Genzyme. The term control means the possession, directly or indirectly, of at least 50% of the share capital or voting rights or of the power to direct or cause the direction of the management and policies of an entity, whether through the ownership of voting securities, by contract or to otherwise. Genzyme may also assign this Agreement and any attached Appendix(s) in connection with the merger, consolidation or sale of any of its assets.

11.4 The relationship between the Parties is that of independent contractors. This Agreement creates no agency in Institution or in Investigator. Institution and Investigator may use Genzyme’s name as necessary to conduct a Study and may acknowledge Genzyme’s support and provision of funding and/or Study Drug for a Study in scientific or academic publications and presentations relating to the applicable Study without Genzyme’s approval. Except for the foregoing, or otherwise in connection with patient recruitment, or except as required by law or regulation, no Party shall release or distribute any materials or information containing the name of another Party or any of its employees without prior written approval by that other Party; this approval will not be unreasonably withheld or delayed.
11.5 Any notice or other communication required or permitted by this Agreement, including but not limited to legal/contractual matters will be in writing, and will be considered given as of the date it is received by the addressee. Such notice will be given to the Parties at these addresses:

To the Institution: See Schedule B attached hereto.

To Genzyme:
General Counsel
Attn: Master Clinical Study Agreement
Genzyme Corporation
500 Kendall Street
Cambridge, MA 02142

11.6 Paragraphs 2.2, 2.3, 5, 7, 8, 9, 10, 11.2, 11.3 and 11.5 will survive any termination of this Agreement.

11.7 Nothing in this Agreement will limit or prohibit Institution or any of its personnel, including the Investigator, from conducting any research or for performing research for or with any entity or person, including outside supporters. Genzyme acknowledges that this provision is intended to preserve the academic freedom and integrity of Institution and its faculty and acknowledges that Institution and its faculty are not regarded as exclusive researchers for Genzyme.

11.8 A facsimile, telecopy, pdf, email or other reproduction of this Agreement may be executed by one or more Parties to this Agreement, and an executed copy of this Agreement clearly showing the signature of or on behalf of such Party may be delivered by one or more Parties to this Agreement by facsimile, pdf email or similar instantaneous electronic transmission device. The execution and delivery of this Agreement shall be considered valid, binding and effective for all purposes. At the request of any Party to this Agreement, all Parties to this Agreement agree to execute
an original of this Agreement as well as any facsimile, telecopy or other reproduction of this Agreement.

11.9 Institution is an agency of the State of Texas, and under the Constitution and the laws of the State of Texas, Institution possesses certain rights and privileges, is subject to certain limitations and restrictions, and only has such authority as is granted to it under the Constitution and the laws of the State of Texas. Notwithstanding any provision hereof, nothing in this Agreement is intended to be, nor will it be construed to be, a waiver of the sovereign immunity of the State of Texas or a prospective waiver or restriction of any of the rights, remedies, claims, and privileges of the State of Texas. Moreover, notwithstanding the generality or specificity of any provision hereof, the provisions of this Agreement as they pertain to Institution are enforceable only to the extent authorized by the Constitution and laws of the State of Texas; accordingly, to the extent any provision hereof conflicts with the Constitution or laws of the State of Texas or exceeds the right, power or authority of Institution to agree to such provision, then that provision will not be enforceable against Institution or the State of Texas. Finally, Institution will not be required to perform any act or to refrain from any act in violation of any applicable law.

As witness to this Agreement, each Party’s authorized representative has signed below on behalf of that Party. This Agreement may be executed in multiple counterparts, each of which shall be considered one and the same original.

Genzyme Corporation

[Signature]
Richard Moscicki, M.D.
Senior Vice President and
Chief Medical Officer

Date: 4/8/10
The University of Texas Medical Branch at Galveston

By: Susan E. Ramsey

Printed Name: Susan E. Ramsey
Manager of Research Operations

Title: ________________________________

Date: 4/19/10

The University of Texas Health Science Center at San Antonio

By: Jane A. Ypungers

Printed Name: Jane A. Ypungers

Title: Assistant Vice President for Research

Date: 4-15-2010

The University of Texas M.D. Anderson Cancer Institute

By: Melinda Cotten, CRA

Printed Name: Melinda Cotten, CRA
Executive Director, Sponsored Programs

Title: ________________________________

Date: 4/21/10

The University of Texas Southwestern Medical Center at Dallas

By: Suzanne M. Rivera, Ph.D., M.S.W.

Printed Name: Suzanne M. Rivera, Ph.D., M.S.W.

Title: VP for Research Administration

Date: 4/23/10

Master CSA UT TEXAS 06APRIL10 Genzyme-Initiated Protocols

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The University of Texas Health Science Center at Tyler

By: [Signature]

Printed Name: Conna Sutton  
Director, Pre-Award Services

Date: 4/26/2010

The University of Texas Health Science Center at Houston

By: [Signature]

Printed Name: Jodi S. Ogden 
Title: Contracts Director

Date: April 20, 2010

The University of Texas at Austin

By: [Signature]

Printed Name: Susan Wyatt Sedwick 
Title: Associate VP for Research  
Director, Office of Sponsored Projects

Date: April 28, 2010
SCHEDULE A – SAMPLE FORM
STUDY APPENDIX TO MASTER CLINICAL STUDY AGREEMENT
APPENDIX #

Study Protocol No.__________________________

MCSA EFFECTIVE DATE: 06APRIL10

Effective date of Appendix:

Study Drug:

Study Title:

Investigator:

Institution:

Institution (identified above) and Genzyme Corporation (“Genzyme”) have signed the Master Clinical Study Agreement (“MCSA”) identified above. Institution and Genzyme agree that the terms in this Appendix and the MCSA will apply to the Study that is the subject of this Appendix.

Study Budget & Payment Schedule

The Study Budget is based on (XXX) patients completing this Study at $________ per subject. The Study Budget is attached within this Appendix. Subject enrollment is competitive. The Study Budget includes all research-required direct subject care for the enrolled subjects and the personnel costs of the Investigator, the Co-Investigator, the Clinical Study Coordinator and all other study related personnel for the Study along with all other Study related expenses (including but not limited to Institutional fees). Also included in the above per subject amount are any fringe benefits and overhead amounts associated with the Study-required direct subject care (as applicable), personnel and other direct costs.

One-time payments outlined below will be paid once this Appendix is fully executed and IRB approval for the Study is obtained.

- Start-up Fee: $________
- IRB Fee: $________
- Pharmacy (Fixed Costs): $ If Applicable
- (also include additional institution specific fees that may apply)
  Total Start up fee to be paid upon execution of this Appendix: $

OPTIONAL LANGUAGE IF SCREEN FAILURES ARE APPROVED FOR THE STUDY --
THIS MAY BE ADDED AT THAT TIME TO THE APPENDIX BUDGET
Invoices will be sent to:

Genzyme Corporation
Accounts Payable Dept.
PO Box 9322
Framingham, MA 01701-9322
Protocol Number:
Study Manager:
Account Code:

Payments will be made to:

Attn:_____________________
Address:_____________________

_____________________

Tax Identification number: _______________

Study Procedural and Nonprocedural Payments will be based upon completed subject visits and will be administered upon Genzyme’s receipt of all completed CRFs and resolution of all data clarification requests to Genzyme’s satisfaction, on or about 45 days after Genzyme’s receipt of this information. See attached Study Budget for payment amount for each completed per-subject visit.

The following criteria must be met for the subject payments to be made:

a. Subjects meet eligibility criteria as specified in the Protocol, or as approved by Genzyme.
b. Subjects treated according to the Protocol.
c. Required Case Report Forms (CRFs) are accurately completed and forwarded to Genzyme.

NOTE: Every effort shall be made to have each enrolled Study subject complete the Study. If subject fails to complete the Study, the per subject payment will be amended to reflect the actual Study costs incurred for that subject. If the Study is terminated early, i.e., before its anticipated completion, payment will be made based upon prorated costs and resolution of final data queries. If there is a reduction or increase in the schedule of assessments, the Study Budget will be adjusted accordingly by the amount allotted for that procedure. Genzyme is not liable to either the Investigator or the Institution for any costs not explicitly set forth in this Appendix.
Study Budget

* Attach final excel spreadsheet (dated) or Budget Table here
Agreed to:
Genzyme Corporation

By: __________________________
Name: _________________________
Title: _________________________
Date: _________________________

Institution

By: __________________________
Name: _________________________
Title: _________________________
Date: _________________________

As part of the Investigator's obligations under this Appendix, the Investigator will notify Genzyme of any material changes in the "Certification of Investigator Financial Interests and Arrangements" statement the Investigator signed for this Study. Such material changes include: (a) the Investigator's financial arrangements with Genzyme; (b) the Investigator's or the Institution's receipt of funds from Genzyme not connected to this Study; (c) the Investigator's proprietary interest in Genzyme or any products of Genzyme; and (d) the Investigator's equity interest in Genzyme.

I have read this Appendix and the MCSA and agree to abide by all the terms and obligations of both documents.

Investigator:

By: __________________________
Name: _________________________
Date: _________________________
### SCHEDULE B – INSTITUTIONAL CONTACT INFORMATION

<table>
<thead>
<tr>
<th>Susan Sedwick</th>
<th>Suzanne M. Rivera, Ph.D., M.S.W.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Director</td>
<td>Vice President for Research Administration</td>
</tr>
<tr>
<td>Office of Sponsored Projects</td>
<td>Clinical Trials Office</td>
</tr>
<tr>
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<td>The University of Texas Southwestern Medical</td>
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<tr>
<td>P.O. Box 7726</td>
<td>Center at Dallas</td>
</tr>
<tr>
<td>Austin, Texas 78713-7726</td>
<td>5323 Harry Hines Blvd.</td>
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<tr>
<td>Phone: 512-471-6424</td>
<td>Dallas, TX 75390-9016</td>
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<td>Phone: 214-648-6449</td>
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<tr>
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<tr>
<td>Tax ID: 74-600023</td>
<td>Email: <a href="mailto:clinicaltrials@UTSouthwestern.edu">clinicaltrials@UTSouthwestern.edu</a></td>
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<tr>
<td>Overnight address is:</td>
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<tr>
<td>North Office Building, Suite 4.300</td>
<td>6303 Forest Park Road, BPB212</td>
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<tr>
<td>101 E. 27th Street</td>
<td>Dallas, TX 75390-9016</td>
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<tr>
<td>Austin, TX 78712</td>
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<table>
<thead>
<tr>
<th>Jane A. Youngers</th>
<th>Jodi Ogden</th>
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<tbody>
<tr>
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<td>Contracts Director</td>
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<td>7000 Fannin Street, Suite 1006</td>
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<td></td>
<td>Houston, TX 77030</td>
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</tbody>
</table>
### SCHEDULE B – INSTITUTIONAL CONTACT INFORMATION

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<th>Conna Sutton</th>
<th>Susan Ramsey</th>
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