

MASTER CLINICAL TRIAL AGREEMENT

BETWEEN

LILLY USA, LLC

AND

THE UNIVERSITY OF TEXAS SYSTEM AND ITS MEMBER INSTITUTIONS

THE UNIVERSITY OF TEXAS AT AUSTIN

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT SAN ANTONIO

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT TYLER

THE UNIVERSITY OF TEXAS M. D. ANDERSON CANCER CENTER

THE UNIVERSITY OF TEXAS MEDICAL BRANCH AT GALVESTON

THE UNIVERSITY OF TEXAS RIO GRANDE VALLEY

THE UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER

Confidential
CCGO MCTA Agmt #39644
December 5, 2017
UT System & Lilly Master CTA
OGC # 171577
Termination is 5 Years

TABLE OF CONTENTS

SCOPE OF AGREEMENT	1
ARTICLE I.....	1
STUDIES	2
Section 1.01. Studies	2
Section 1.02. Contract Research Organization Involvement.....	2
Section 1.03. Subsidiaries.....	3
ARTICLE II.....	3
INVESTIGATOR AND INSTITUTION OBLIGATIONS.....	3
Section 2.01. Study Obligations	3
Section 2.01.1 Compliance with Protocol, Laws, Regulations	3
Section 2.01.2. Financial Disclosure.....	4
Section 2.01.3. Licensed Physician	4
Section 2.01.4. HIV or Genetic Testing	4
Section 2.01.5. Investigator's Brochure	4
Section 2.01.6. Referral Fees	4
Section 2.01.7. IRB Approval and Informed Consent	4
Section 2.01.8. Samples for Independent Research	4
Section 2.01.9. Monitoring and Audit Access	5
Section 2.01.10. Adverse Event Reporting	5
Section 2.02. Clinical Trial Material and Record Retention	5
Section 2.02.1 Clinical Trial Materials.....	6
Section 2.02.2 Record Retention.....	6
Section 2.02.3 Record Destruction Notification	6
Section 2.03. Confidentiality and Non-Use.....	7
Section 2.04. Data.....	8
Section 2.05. Publications.....	8
Section 2.06. Inventions.....	9
Section 2.07. Publicity.....	9
Section 2.07.1. Solicitation of Patients	10
Section 2.07.2. Press Releases.....	10
Section 2.07.3. Inquiries From Media and Financial Analysts	10
Section 2.07.4. Use of Name.....	10
Section 2.08. Debarment Certification.....	10
Section 2.09. Controlled Drugs and Substances.....	10
Section 2.10. Equipment	11
ARTICLE III.....	11
LILLY OBLIGATIONS	11
Section 3.01. Lilly Study Support	11
ARTICLE IV	11
STUDY PATIENT INJURY REIMBURSEMENT.....	11
Section 4.01. Study Patient Injury Reimbursement.....	11
ARTICLE V	12
LIMIT OF STUDY PATIENT ENTRY OR ENROLLMENT AND STUDY TERMINATION.....	12
Section 5.01 Limit of Study Patient Entry or Enrollment and Study Termination.....	12
ARTICLE VI	12
SITE PERSONNEL DATA	12

Section 6.01. Site Personnel Data	13
ARTICLE VII	13
INDEMNIFICATION	13
Section 7.01. Indemnification	13
ARTICLE VIII	14
DISPUTES	14
Section 8.01. Law and Venue	14
Section 8.02. Alternative Dispute Resolution	14
Section 8.03. Entire Agreement	14
ARTICLE IX	14
NOTICES	14
Section 9.01. Notices	14
ARTICLE X	15
SURVIVORSHIP CLAUSE	15
Section 10.01. Survivorship Clause.....	15
ARTICLE XI	15
TERM AND TERMINATION	15
Section 11.01. Term and Termination	15
ARTICLE XII	16
MISCELLANEOUS	16
Section 12.01. Independent Contractor.....	16
Section 12.02. Binding Effect	16
Section 12.03. Amendments	16
Section 12.04. Counterparts.....	16
Section 12.05. Electronic Signature.....	16
Section 12.06. State Agency Limitations.....	16
Attachment 1. Administrative Contact of UT System and each Member Institution	20
APPENDIX A1	22
APPENDIX A1: SAMPLE CLINICAL RESEARCH AGREEMENT (CRA)	22
APPENDIX A2	24
APPENDIX A2: SAMPLE PAYMENT SCHEDULE FOR USE WITH A CRA	24
EXHIBIT B	26
EXAMPLE US ADVERTISING AND RECRUITMENT	26
APPENDIX B1	27
SAMPLE CLINICAL RESEARCH AGREEMENT FOR USE WITH A CLINICAL RESEARCH ORGANIZATION (CRO CRA)	27
APPENDIX B2	29
SAMPLE PAYMENT SCHEDULE FOR USE WITH A CRO CRA	29

MASTER CLINICAL TRIAL AGREEMENT

This Master Clinical Trial Agreement (hereinafter "Master Agreement") made effective December 5, 2017 ("Effective Date") is by and between **Lilly USA, LLC** (hereinafter "Lilly"), with its principal place of business at Lilly Corporate Center, Drop Code 1072, Indianapolis, Indiana, 46285 and **The University of Texas at Austin, The University of Texas Health Science Center at Houston, The University of Texas Health Science Center at San Antonio, The University of Texas Health Science Center at Tyler, The University of Texas M.D. Anderson Cancer Center, The University of Texas Medical Branch at Galveston, The University of Texas Rio Grande Valley, and The University of Texas Southwestern Medical Center** (each an "Institution" and collectively, "Institutions"), each with an office and place of business as set forth on Attachment 1 hereto and each a member institution of The University of Texas System ("UT System"), which has a principal office located at 201 West 7th St., Austin, Texas 78701. Both Lilly and the Institutions shall be collectively referred to herein as the "parties". This Master Agreement supersedes and replaces in its entirety the Master Clinical Trial Agreement ("MCTA") effective December 5, 1994, and the five (5) amendments thereto effective July 21, 1998, December 14, 1999, March 25, 2002, December 12, 2003 and November 18, 2004 between Lilly Research Laboratories, a Division of Eli Lilly and Company and the member/component institutions of The University of Texas System. Ongoing studies contracted under the prior MCTA shall remain in full force and effect pursuant to the terms of said prior MCTA. For sake of clarity, Lilly USA, LLC is the North American affiliate of Eli Lilly and Company.

SCOPE OF Master AGREEMENT

This Master Agreement sets forth the terms and conditions for the performance of Lilly-sponsored clinical trial studies in the United States pursuant to Lilly protocols. Observational studies and interventional studies (that do not use drug(s) or device(s)) sponsored by Lilly (unless accompanied by a modified clinical research agreement hereunder) and investigator initiated/sponsored studies and non-interventional/pre-clinical studies are out-of-scope of this Master Agreement. Oncology studies at The University of Texas M.D. Anderson Cancer Center within the scope of this Master Agreement are subject to special terms and conditions and must align with its strategic objectives. This Master Agreement is not an exclusive contract. Lilly retains the right to engage other institutions to perform any or all of the types of services contemplated by this Master Agreement, and Institutions may conduct research for or with any entity or person, including other outside sponsors, and Lilly will not gain any rights to that research (or research results) through this Master Agreement. Lilly acknowledges that this provision is intended to preserve the academic freedom and integrity of each Institution and its faculty, and to ensure that Institutions and their faculty are not regarded as exclusive researchers for Lilly. Moreover, this Master Agreement does not obligate Lilly to offer, or any Institution to accept, engagement for any Study as defined in Section 1.01 below.

The parties entering into this Master Agreement understand that an individual CRA or CRO CRA (as defined below) shall be executed by Lilly, Lilly representatives or Lilly subsidiaries and one or more Institutions for each Study to be performed under this Master Agreement.

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

Article I

Studies

Section 1.01. Studies. From time to time, Lilly may request Institution to perform a Lilly clinical trial study ("Study") pursuant to a Lilly protocol ("Protocol") and each such Study contemplated by this Master Agreement will be of mutual interest and benefit to Institution and Lilly. Lilly and Institution shall identify a principal investigator ("Principal Investigator") to conduct each Study. Each Study will be described in a Protocol and will be referenced in the Clinical Research Agreement ("CRA"). A sample CRA is attached hereto as Appendix A1. The CRA or CRO CRA (see Section 1.02 below) shall append to this Master Agreement for each Study to be conducted pursuant to the terms of this Master Agreement and shall be executed by the Investigator and an authorized official of Institution. Additionally, this Master Agreement shall be incorporated hereunder by reference in each individually executed CRA or CRO CRA. By execution of a CRA or CRO CRA, Institution shall be bound to the obligations contained in this Master Agreement. If the terms of a CRA or CRO CRA conflict with the terms of this Master Agreement, the terms of this Master Agreement shall control, unless specifically stated in the CRA (or CRO CRA) that the Master Agreement is being amended for the purposes of that certain CRA (or CRO CRA). For avoidance of doubt, the use of the term "Study" throughout this Master Agreement, whether preceded by the term "a", "the", "said", "any" or "each", shall refer to the named Study under an executed CRA or CRO CRA (defined below).

Clinical Trials Xpress (CTX) (www.clinicaltrialsxpress.org), a wholly owned initiative of UT System, is a central coordinating office and team established to provide site and study management services ("SMO Services") to support the Clinical Trials Xpress Network and promote efficient and streamlined study start-up processes of multi-institutional clinical trials. More specifically, the CTX network operating model accelerates study implementation by negotiating a single common clinical trial study budget; using pre-approved master clinical trial agreements; and by adopting the UT System IRB Reciprocity model or central IRBs for regulatory oversight. Lilly may engage the services of the CTX central coordinating office when more than one UT System Institution plans to participate in a Study under this Master Agreement. UT System authorizes CTX to enter into a modified SMO Services agreement (or other appropriate agreement) with Lilly, if requested by Lilly in writing, for the conduct of the Studies under this Master Agreement involving two (2) or more Institutions.

Section 1.02. Contract Research Organization Involvement. Lilly shall be entitled to authorize a contract research organization ("CRO") to perform certain sponsor obligations for any Study. Lilly agrees that if Lilly elects to utilize a CRO in connection with the Study and/or this Master Agreement that Lilly will inform Institution (named in Attachment 1) of such decision and that the terms and conditions of this Agreement shall also apply to CRO with regards to the delegated sponsor obligations. Institution, CTX and Investigator agree to cooperate with any Lilly-authorized CRO in performing the Study provided such cooperation is in alignment with the terms in this Master Agreement. In the event an Investigator and Institution are identified by a CRO and agree to conduct the Study, the CRO, Investigator and Institution shall execute a CRO clinical research agreement ("CRO CRA"), which CRO CRA shall append to this Master Agreement and incorporate the terms herein. Lilly will provide this Master Agreement to its CRO and will direct its CRO to enter into a CRO CRA under the terms of the Master Agreement. With the exception of provisions in this Master Agreement regarding Data (Section 2.04), Publications (Section 2.05), Confidentiality (Section 2.03), Inventions (Section 2.06), Publicity (Section 2.07), and Indemnification (Section 7.01), all

references to Lilly throughout this Master Agreement shall then refer to the CRO. A sample CRO CRA is attached hereto as Appendix B1.

Section 1.03. Subsidiaries. The parties agree that Lilly subsidiaries ("Lilly Subsidiary(ies)"), as well as, CROs that such Lilly Subsidiaries hire and delegate certain sponsor obligations to ("Subsidiary CRO(s)"), shall utilize the terms of this Master Agreement to collaborate with Institution for Lilly Subsidiaries' Study(ies) at the Lilly Subsidiaries'/Subsidiary CRO's and Institution's discretion. Institution and the Lilly Subsidiary/Subsidiary CRO shall execute a CRA or CRO CRA, which references and incorporates the terms of this Master Agreement therein. If needed, an individual CRA or CRO CRA may be modified as mutually agreed to by Lilly and/or the Lilly Subsidiary/Subsidiary CRO and Institution; provided however any proposed modifications to this Master Agreement (if any) and/or identification of the Lilly Subsidiary shall be explicitly described in the Study-specific CRA or CRO CRA and provided to the Intellectual Property Section of the Office of General Counsel, UT System for prior review and approval. The parties further agree that any reference to "Lilly" in this Master Agreement and in said CRA or CRO CRA shall then refer to the Subsidiary and/or the Subsidiary CRO.

Article II Institution Obligations

Section 2.01. Study Obligations. For each Study conducted under a CRA or CRO CRA, Institution and Investigator shall assume the following obligations, though for the avoidance of doubt, Investigator is not a party to this Master Agreement:

Section 2.01.1. Compliance with Protocol, Laws, Regulations. Institution will ensure that Investigator shall personally conduct or supervise the Study at Institution and any Lilly-approved sub-sites or satellite sites, if applicable (collectively "Study Site(s)"). Institution shall conduct a Study at the Study Site identified and named in the applicable CRA. If any portion of the Study is performed by Investigator or a sub-investigator at a facility or hospital other than Institution, Institution shall be responsible for ensuring that any such Study Site is aware that it is involved in the Study and consents to such participation. Institution shall comply with the following: all conditions, requirements and directions specified in the Protocol and the lab manual/sample flow chart, and any amendments and/or addenda thereof; applicable requirements of the U.S. investigational new drug ("IND") regulations (Title 21, Part 312.1 *et seq.*) and/or the Investigational Device Exemption Regulations (Title 21, Part 812.1 *et seq.*); Good Clinical Practice Guidelines; the conditions specified in the Statement of Investigator Form (FD-1572); the approval of the Institutional Review Board(s) ("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); provisions of the Generic Drug Enforcement Act of 1992 (Public Law 102-282, 102nd Congress); and all other applicable federal, state and local laws, regulations and standards. Institution shall ensure that all of Investigator's sub-investigators, associates, colleagues, employees, agents and contractors involved in the conduct of the Study at the Study Site(s) also understand and comply with these obligations and the provisions of this Master Agreement.

Section 2.01.2. Financial Disclosure. Institution shall also ensure that each Investigator and sub-investigator at the Study Site(s) provides Lilly with the appropriate financial information for compliance with 21 C.F.R. Part 54 and that they understand that regulations may require certain financial information to be submitted to the U.S. Food and Drug Administration ("FDA").

Section 2.01.3. Licensed Physician. If Investigator is not a licensed physician, Institution shall ensure that a licensed physician is an investigator or sub-investigator at the Study Site(s) and shall be responsible for patient care and other appropriate aspects of the Study.

Section 2.01.4. HIV or Genetic Testing. If the Study involves obtaining samples from Study patients for HIV or genetic testing, Institution shall be responsible for being familiar and complying with all applicable laws and regulations that may apply to this activity. These laws and regulations may include, without limitation, state and local laws related to written consent and counseling.

Section 2.01.5. Investigator's Brochure. Institution shall ensure that Investigator and any sub-investigator selected to participate in the Study shall read and understand all information in the clinical investigator's brochure provided to Investigator and/or Institution by Lilly, including the potential risks and side effects of the Study drug(s) or device(s).

Section 2.01.6. Referral Fees. Investigator and Institution shall not to pay fees to another physician for the referral of patients. Additionally, Institution shall ensure that Investigator shall not to pay fees to another physician for the referral of patients.

Section 2.01.7. IRB Approval and Informed Consent. Prior to beginning the Study, Institution shall obtain approval from the IRB for the Study and the informed consent document. Institution shall only use an informed consent document that has been reviewed and approved by Lilly and the IRB.

Section 2.01.8. Biological Samples; Definition. The parties agree that certain biological specimens, as further described and specified in the applicable Protocol, Protocol Amendments and/or Addenda ("Biological Samples") may be transferred from Institution to Lilly. Lilly agrees to abide by the following conditions with respect to any Biological Samples received by Lilly under a Study Protocol: (a) Lilly will not use the Biological Samples other than the specific uses set forth in the Protocol, Protocol Amendment and/or Addenda, and/or Informed Consent Document or as allowed by applicable law; (b) such Biological Samples shall not be for use in humans; and (c) all Biological Samples will be handled, stored and disposed of in accordance with the Protocol, Protocol Amendments and/or Addenda and/or Informed Consent Document or as allowed by applicable law. Lilly further agrees that if the Study patient withdraws consent and upon written notification from Institution, Lilly will return or destroy such Biological Samples. For the purposes of this Master Agreement, Biological Samples include but are not limited to any human biological material, blood, body tissue, plasma and any other material containing human cells.

Section 2.01.9. Biological Samples for Independent Research. Institution agrees that if Institution collects any Biological Samples for independent research from Study

patients on an individual Study, Institution shall obtain separate informed consent documents as well as distinct IRB approval for such independent research and shall comply with all applicable privacy laws related to such Biological Samples. Institution shall not disclose any Lilly Confidential Information (defined in Section 2.03 below) to any researcher who has access to and is authorized to use the Biological Samples for such independent research. Furthermore, Institution shall ensure that any researchers who have access to and are authorized to use the Biological Samples understand they cannot analyze the Biological Samples for the purpose of identifying or isolating the Lilly Study drug(s), its simple derivatives or metabolites (including antibody fragments), or reverse engineer the Lilly Study drug(s), its simple derivatives or metabolites (including antibody fragments) and shall ensure compliance with the same.

Nothing herein prohibits the collection of or use of Biological Samples as needed for patient care purposes.

Section 2.01.10. Monitoring and Audit Access. Lilly, Lilly-designated representatives, and any domestic or foreign regulatory agencies may inspect the procedures, facilities and Study records (including portions of other pertinent records for all patients in the Study) and those procedures, facilities or Study records of any contractor, agent or Study Site(s) that is used in conducting the Study. Institution shall provide Lilly with prompt notice of any governmental or regulatory review, audit or inspection of a facility or processes related to the Study. To the extent allowed by applicable law, Lilly can be present during such review, audit or inspection, and that Lilly shall be given the opportunity to provide assistance to Institution in preparing for and responding to any such review, audit or inspection. When the data are reviewed by an on-site scheduled visit of a Lilly-designated representative, Institution shall have all reasonably available data obtained through the preceding day complete and ready for evaluation. Information obtained from such reviews, audits or inspections may be shared with Lilly and Lilly-designated representatives. In the event that there is a lack of compliance with this Master Agreement, Lilly is entitled to secure compliance or discontinue shipments of Study drug(s) and device(s) and end Institution's participation in the Study.

Section 2.01.11. Adverse Event Reporting. Institution shall report all adverse events, serious adverse drug reactions, serious unexpected adverse drug reactions and pregnancy events that Investigator or Institution become aware of during the Study to Lilly in accordance with the reporting procedures specified in the Protocol. Institution shall follow Institution's policies and procedures regarding the reporting of such adverse events to the IRB and Lilly. In the event there is a conflict between the Protocol and Institution's adverse event reporting policies, Institution shall promptly notify Lilly and agrees to work with Lilly to resolve such discrepancies in a timely manner. Lilly agrees to comply with all applicable laws and regulatory authority responsibilities regarding sponsor obligations for reporting adverse events. Nothing herein or in the Protocol limits Institution from reporting such events to the IRB or local regulatory authorities in accordance with applicable laws and regulations and/or the requirements of such entities.

Section 2.01.12. Safety Reporting. Lilly shall include in the Protocol (or in a separate safety monitoring plan) to be reviewed and approved by Institution's IRB a plan for data and safety monitoring for the Study. Lilly will comply with 21 CFR 312.55 which requires

that as the overall investigation proceeds, Lilly shall keep Investigator informed of new observations discovered by or reported to Lilly on the Study Drug, including but not limited to findings from monitoring reports at the Institution, particularly with respect to adverse events and safe use and, thereafter, in accordance with applicable FDA requirements regarding reporting that could affect the safety or medical care of current or former Study patients, influence the conduct of the Study, or alter the IRB's approval. Such information will be promptly provided to Investigator and may be distributed to Investigator by means of periodically revised investigator brochures, reprints of published studies, reports or letters to clinical investigators, through a portal (provided by Lilly to Investigator) or other appropriate means. Important safety information shall be relayed to Investigator in accordance with 21 CFR 312.32. Institution and Investigator shall review safety information in whatever form Lilly provides it. For a period of two years after the completion of the study under this Master Agreement, Lilly will promptly notify Investigator in the event that Lilly determines, in its sole discretion in good faith, that significant new findings from the study data directly impact the safety of former Study patients, where such findings may not be reasonably inferred from previous safety notifications and which have not been otherwise published in a readily accessible format. Both Lilly and Institution/Investigator shall comply with their own respective reporting requirements to regulatory authorities, including, for example, the Food and Drug Administration, the Office for Human Research Protections, and other authorities as required. Institution or Investigator and/or the IRB, as appropriate, shall inform Study patients of the above important information Investigator receives from Lilly in accordance with the IRB-approved informed consent form.

Section 2.02. Clinical Trial Material and Record Retention

Section 2.02.1. Clinical Trial Materials. Clinical trial materials, including Study drug(s), device(s) and other clinical trial materials furnished for the Study shall be used solely for the Study under the Protocol and may not be used for any other purposes. Institution shall follow Lilly's written instructions related to disposition of such Study drug(s), device(s) and clinical trial materials, which shall be at Lilly's sole expense for all reasonable and necessary actual costs incurred by Institution. Institution shall be responsible for compliance with all laws and regulations applicable to any destruction or disposition of such Study drug(s), device(s) or clinical trial materials at the Study Site(s).

Section 2.02.2. Record Retention. All Study records must be retained for fifteen (15) years after completion or termination of the given Study; provided, however, that in the unlikely event that ICH or FDA record retention requirements, (i.e., two (2) years after the date of marketing application approval by FDA for the Study drug(s) indication investigated; or, if an application is not approved, two (2) years after the FDA is notified by Lilly of discontinuation of the IND) are longer than fifteen (15) years, Lilly shall notify Institution regarding any additional length of time that records must be retained to meet such requirements and will reasonably compensate Institution for any such additional retention unless storage fees for the additional duration have already been provided in the Study Budget.

Section 2.02.3. Record Destruction Notification. Notwithstanding the above, Institution shall contact Lilly in writing at the address below prior to the destruction of

Study records. Institution may only dispose of Study records if confirmation is obtained from Lilly that it is appropriate to do so. In the event that Lilly notifies Institution that such Study records must be retained for an additional retention period for necessary business reasons, Lilly shall pay Institution for or provide alternative storage at Lilly's expense and Institution shall either continue to retain such records or to ship records to a location specified by Lilly, at Lilly's expense.

Attention: Record Retention Specialist (SAM)
Eli Lilly and Company
Global Clinical Operations Site Activation Management
Lilly Corporate Center, DC1707
Indianapolis, IN 46285

Section 2.03. Confidentiality and Non-Use for Master Agreement and Each Individual CRA or CRO CRA. All information provided to Institution by Lilly or Lilly-designated representatives, or generated by Investigator and/or Institution in connection with this Master Agreement and/or any Study, including, but not limited to, discussions and correspondences related to potential services to be provided pursuant to this Master Agreement and the specific Study (for example, discussion of clinical plans and potential trials) and/or any information provided to an Investigator with regard to a Lilly publication or presentation related to such Study ("Confidential Information"), shall be kept in confidence and not used for any purpose not expressly provided for in this Master Agreement and/or any applicable CRA or CRO CRA for seven (7) years after the termination or conclusion of the Study, except to the extent that Lilly gives Institution written permission or particular Confidential Information is required by laws or regulations to be disclosed to the IRB, the Study patient, local regulatory agencies or the FDA. To the extent, disclosure is requested by any other person or entity, Institution shall promptly notify Lilly and shall not disclose any Confidential Information without Lilly's prior written consent. If such disclosure is sought by a third party under a claim of legal right, Institution shall reasonably cooperate with Lilly in the event Lilly wishes to take legal action to challenge such claim or the disclosure; provided, however, in no event shall Institution be obligated to defy any law, regulation or judicial or governmental order. Institution shall be responsible for ensuring that their employees, sub-investigators, contractors and agents are obligated to these same or substantially similar terms of confidentiality and non-use. The terms of confidentiality and non-use set forth herein shall supersede any prior terms of confidentiality and non-use agreed to by the parties in connection with the Study. The terms of this Master Agreement shall also be considered Confidential Information and may be disclosed only to the extent required by law (including the Texas Public Information Act), necessary for approval of the Study or as permitted by Lilly in writing. This obligation survives the expiration, cancellation or termination of this Master Agreement and any CRA or CRO CRA for a specific Study. Notwithstanding anything to the contrary, if and when such new information is subject to one of the exclusions mentioned below or is no longer confidential as a result of an authorized disclosure of such information under the terms of this Master Agreement, then Institution will not have any additional restriction upon its use or disclosure of such information. Nothing contained in this provision negates or voids Institution's rights to publish its own Study results in accordance with **Section 2.05 Publications** of the Master Agreement.

The foregoing obligations of confidentiality and non-use shall not apply to Confidential Information that:

- (a) is or later becomes part of the public domain other than through an act or omission of Investigator and/or Institution;
- (b) was known by Investigator and/or Institution prior to disclosure by Lilly or becomes known from an independent source who is in rightful possession and not under an obligation of confidentiality with respect to such Confidential Information, as can be shown by prior written documentation; or
- (c) is independently developed, as shown by written documentation, by Investigator and/or Institution or their personnel without use or reliance on Confidential Information.

Nothing herein shall restrict or prohibit disclosures to other healthcare providers to the extent necessary to provide urgent patient care for any patient participating in the Study. In the event the patient's medical complaint is not of an urgent nature, Investigator and Institution shall contact Lilly to discuss what information, if any, may be disclosed to another healthcare provider as it relates to the diagnosis and/or treatment of the patient.

In addition, Lilly may provide Confidential Information to Institution regarding its compounds or its clinical development plans for the purposes of determining whether Institution is interested in participating in future research with Lilly. In the event that Institution does not participate in research related to such information and therefore no CRA is executed, Institution agrees to hold such Confidential Information in confidence for five (5) years from the date of such disclosure.

Section 2.04. Data. Data generated in connection with the Study, excluding patient medical records not recorded as case report forms, shall be the sole property of Lilly and shall be subject to the obligations of Confidentiality and Non-Use set forth herein.

Institution shall enter all data within five (5) business days from the end of the patient visit/cycle or receipt of the underlying data (e.g., local lab results) which shall not be unreasonable delayed. Additionally, Institution shall complete all data queries within five (5) business days of the request date. Notwithstanding the foregoing, Lilly may request shortened timelines (to the extent reasonable) based on Study needs, such as for interim analysis and database lock, and Institution will use reasonable efforts to meet such shortened timelines.

Section 2.05. Publications. Notwithstanding the obligations of Confidentiality and Non-Use set forth herein, Institution shall be free to publish and present their results of the Study subject to the following conditions: Lilly shall be furnished with a copy of any proposed publication or presentation for review and comment at least thirty (30) days prior to such presentation or submission for publication. Such thirty (30) day period does not begin until receipt of the proposed publication or presentation at Lilly in the Indianapolis, Indiana office noted in Section 9.01 Notices. At the expiration of such thirty (30) day period, Institution may proceed with the presentation or submission for publication; provided, however, that in the event Lilly has notified Institution in writing that Lilly reasonably believes that prior to such publication or presentation it must take action to protect its intellectual property interests, such as the filing of a patent application claiming an invention or a trademark registration

application, Institution shall either (1) delay such publication or presentation for an additional sixty (60) days or until the foregoing action(s) have been taken, whichever shall first occur; or (2) if Institution is unwilling to delay the publication, Institution shall remove from the publication or presentation the information which Lilly has specified it reasonably believes would jeopardize its intellectual property interests. Notwithstanding the foregoing, scientific conclusions and professional judgments regarding the results of a Study in any publication submitted by Investigator shall be determined solely by Investigator and will adhere to the policies and principles of the International Committee of Medical Journal Editors and other major medical journals and will not be subject to censor or control or unreasonable delay by Lilly. Under certain circumstances, a shorter review period may be granted in writing by Lilly. Institution shall assist Lilly in obtaining reprints of Institution's and/or Investigator's publication(s) resulting from the Study.

Additionally, if the Study is part of a multi-center Study, Institution shall delay publication of their results of the Study until the results of the multi-center Study are published or presented, provided that if the results of the multi-center Study are not published or presented within twelve (12) months of the termination, conclusion, or abandonment of the Study by all sites, Institution may publish their results of the Study without further delay subject to the terms above. For sake of clarity regarding the preceding sentence, Lilly acknowledges that this sentence is not intended to control or restrict Institution's publication rights.

Section 2.06. Inventions. If during the course of the Study or within one (1) year after termination or expiry of the CRA or CRO CRA, Institution conceives or actually reduces to practice what Institution believes to be a new invention (including, without limitation, new uses, processes, formulations, therapeutic combinations or methods) occurring as a result of the performance of the Study covered by this Master Agreement and/or any applicable CRA or CRO CRA or involving the Study drug(s), device(s), or simple derivatives of the Study drug(s) (e.g., but not limited to, antibody fragments, analogs, salts, solvates, conformers, stereoisomers, racemic mixtures, amorphous forms, crystal forms, crystal habits, metabolites, prodrugs, free acids, chelates, complexes, synthetic intermediates, isotopic or radiolabeled equivalents or mixtures thereof), Institution shall promptly notify Lilly. The new invention or use shall be the sole property of and shall be assigned to Lilly. Lilly hereby grants Institution a non-exclusive, perpetual, royalty-free license, without the right to grant sub-licenses, to use the Study data and results and know-how generated in the performance of this Master Agreement and/or any applicable CRA or CRO CRA for its own internal non-commercial (i) research and/or patient care and/or (ii) educational purposes. For clarity, Institution can only use Study information in accordance with the terms of this Master Agreement.

Each party shall retain all right, title and interest in any patent, patent application, trade secret, know-how, improvement and other intellectual property that was owned by such party prior to the execution of an applicable CRA or CRO CRA under this Master Agreement and no license, grant or assignment, express or implied, by estoppel or otherwise, is intended by, or shall be inferred from this Master Agreement.

Section 2.07. Publicity. Consistent with the obligations of Section 2.03 Confidentiality and Non-Use of this Master Agreement and set forth herein, the parties shall comply with the following:

Section 2.07.1. Solicitation of Patients. Lilly and the IRB must approve, in writing, the text of any communication soliciting patients for the Study before placement, including, but not limited to, newspaper and radio advertisements, direct mail pieces, internet advertisements or communications and newsletters. Such communications must comply with applicable laws and guidelines.

Section 2.07.2. Inquiries From Media and Financial Analysts. During and after the Study, Investigator and/or Institution may receive inquiries from reporters or financial analysts regarding Lilly, the Study and/or Study drug(s) or device(s). Institution and Investigator shall contact Lilly's Corporate Communications Department at Lilly in Indianapolis, Indiana (317-276-2000) to discuss such inquiries before responding. During and after the Study, Lilly may receive inquiries from reporters or financial analysts regarding Institution. Lilly shall contact UT System's and Institution's Public Relations Department by obtaining such phone numbers from the Study Site to discuss such inquiries before responding.

Section 2.07.3. Use of Name. Lilly and Institution shall not use the name or names of another party or their employees in any advertising or sales promotional material or in any publication without prior written permission; provided, however, Investigator's and Institution's names may be used in Study publications and communications, including clinical trial web sites and Study newsletters, and Lilly may disclose Investigator's and Institution's names, the type of services performed for Lilly under this Master Agreement, the existence and terms of this Master Agreement and any CRA or CRO CRA for a specific Study, and the amount of compensation Lilly paid in exchange for the services. Notwithstanding the foregoing, Institution and/or Investigator may disclose for internal, noncommercial reporting purposes Lilly's identity, the Study title, Investigator's name, the Study budget and duration of the Study.

Section 2.08. Debarment Certification. Institution agrees that it and Investigator is not and have not been debarred or disqualified from participating in clinical research by any United States regulatory authority or by any other regulatory authority, and that it/they shall not use or involve any person or organization in connection with the Study that is or has been debarred or disqualified by any regulatory authority from participating in clinical research. In the event that Investigator and/or Institution, or any person or organization it/they use or involve in connection with the Study should become debarred or disqualified during the course of the Study, Institution shall promptly notify Lilly in writing.

Section 2.09. Controlled Drugs and Substances. If the Study involves the use of a controlled drug or substance, Institution shall provide Lilly a photocopy of the appropriate, current Drug Enforcement Agency ("DEA") registration certificate before Study drug(s) or device(s) is shipped to the investigational Study Site(s). The certificate must bear the address of the investigational Study Site(s) where the Study drug(s) or device(s) shall be received, stored and dispensed. The certificate must also show authorization to handle the controlled drug or substance involved. If the drug shipment address changes or the DEA registration certificate expires, Institution shall provide Lilly a photocopy of an updated DEA registration certificate before any further shipment of Study drug(s) or device(s) shall be made by Lilly. If there has been a change in circumstance affecting the validity of the certificate, Institution shall promptly notify Lilly before any further shipment of Study drug(s) or device(s). Additionally, Institution shall comply with all applicable laws regarding the

handling, storage and security of any controlled drugs or substances used in the Study, including any necessary screening of Study personnel.

Section 2.10. Equipment. If Lilly is providing Institution with leased or Lilly owned equipment ("Equipment") for use in the Study, such Equipment shall be and remain the sole and exclusive property of Lilly and/or the lessor. Institution shall comply with all manuals and instructions from Lilly and/or the lessor regarding the use, care and return or disposition of the Equipment. The Equipment shall only be used for conducting the specific Study, and shall not be used for any other clinical or commercial purposes. The Equipment shall remain in the same condition as provided, ordinary wear and tear excepted. Institution shall be responsible for any loss or damage (including but not limited to maintenance, repair or replacement but excluding reasonable and normal wear-and-tear) to the Equipment due to Institution's negligence or mistreatment.

Article III Lilly Obligations

Section 3.01. Lilly Study Support. For each Study, Lilly shall provide Institution with Study drug(s) and/or device(s) applicable to the Study. In addition, Lilly shall provide financial support for the Study up to a total maximum fee as set forth in the CRA Payment Schedule, a sample of which is attached hereto as Appendix A2, and a budget ("Budget") that will be mutually agreed upon for each Study. A sample Payment Schedule for use with a CRO CRA is attached hereto as Appendix B2. A sample US Advertising and Recruitment documents which may be applicable for Study-specific CRAs is attached hereto as Appendix A3. Payment Schedule and Budget (and US Advertising and Recruitment, if applicable) shall be attached as exhibits to each Study-specific CRA or CRO CRA. Institution understands and acknowledges that the appendixes/exhibits attached hereto are examples only, and may be updated or changed pursuant to changes in Lilly's policies, or as pertinent to a specific CRO's policies.

Article IV Study Patient Injury Reimbursement

Section 4.01. Study Patient Injury Reimbursement. Lilly shall reimburse Institution or the service provider for the following additional costs:

- (a) All reasonable and customary costs incurred that are associated with the diagnosis of an adverse event involving the Study drug(s), device(s), or a Protocol procedure; and
- (b) All reasonable and customary costs incurred for treatment of physical injury to the Study patient if Lilly determines after consulting with Institution that the adverse event was reasonably related to administration of the Study drug(s), device(s), or Protocol procedure; provided, however, that:
 - (1) the adverse event is not attributable to the negligence or misconduct of Institution or any of their agents, contractors or employees;
 - (2) the adverse event is not attributable to the natural progression of any underlying illness, whether previously diagnosed or not; and

- (3) Investigator and Institution have adhered to and complied with the written specifications of the Protocol and all written recommendations furnished by Lilly for the use and administration of any drug or device used in the Study.

To the extent that the informed consent form provided to a patient in the Study states that the Study patient shall be provided with any treatment or compensation beyond what Lilly has agreed to reimburse pursuant to this Study Patient Injury Reimbursement provision, Lilly shall have no obligation with respect to such treatment or compensation.

In order for Lilly to comply with reporting requirements under the Centers for Medicare and Medicaid Services (CMS) Section 111 of the Medicare, Medicaid and SCHIP Extension Act of 2007 (MMSEA 111), Institution shall submit, upon request, documentation required by Lilly regarding any request for payment of Study patient injury costs. Such documentation must be provided to Lilly prior to Lilly making any such payment, however, the failure to provide such documentation shall not relieve Lilly of its obligations unless it is materially adversely affected by such failure; it being understood that information necessary to determine whether the injury was related to the Study drug and/or Protocol procedure (or was due to an exclusion set forth above, e.g., Institution/Investigator negligence, etc.) and information required to be reported under MMSEA are both material in nature.

Article V

Limit of Patient Entry or Enrollment and Study Termination

Section 5.01. Limit of Patient Entry or Enrollment and Study Termination. Lilly reserves the right to limit entry or enrollment of additional patients in the Study at any time. This may occur in a competitive-enrollment Study because sufficient patients have been entered by other investigators to complete the needs of the Study. Lilly also reserves the right to terminate Institution's participation in the Study or the Study itself at any time for any reason. Institution may terminate the Study upon thirty (30) days written notice in the event (a) there is a breach of a material provision of this Master Agreement by Lilly, which breach is not cured by Lilly within ninety (90) days following receipt from Institution of written notice thereof; (b) if the Investigator becomes unavailable due to death, disability, or is no longer affiliated with Institution, and Lilly and Institution are unable to agree upon an acceptable replacement; or (c) if the authorization and approval to perform the Study is withdrawn by the FDA or by the IRB.

In the event Institution's participation in the Study or the Study itself is terminated, Institution shall return, retain or dispose of all Study drug(s) and/or device (s) in accordance with instructions to be provided by Lilly and regulatory requirements. Payments shall be made for all work that has been performed up to the date of termination and shall be limited to reasonable non-cancelable costs which were incurred by Investigator and/or Institution in connection with the Study as required under the Protocol and contemplated in the Study-specific Payment Schedule and Budget.

Article VI

Site Personnel Data

Section 6.01. Site Personnel Data. Lilly may collect information from Investigator and Institution personnel, including names, titles and business contact information ("Site Personnel Data") and may provide that information to Lilly's business partners and vendors working with Lilly on matters related to the Study, to fulfill Lilly's business purposes including:

- a) Compliance with U.S. regulations regarding possible financial conflicts of interest;
- b) Assessment of personnel qualifications to conduct the Study;
- c) Quality control and Study management; and
- d) Disclosures to IRBs or federal or foreign regulatory authorities in connection with their performance of review or oversight responsibilities for the Study.

Site Personnel Data may also be aggregated with data from other Lilly sources and evaluated for business decisions including those involving future research. Lilly may store or process such Site Personnel Data in the U.S. or other countries at Lilly or Lilly-associated facilities, as long as a business need or legal obligation exists. Lilly shall comply with all applicable laws and regulations regarding Lilly's use of Site Personnel Data. Investigator and/or Institution personnel may have access to Site Personnel Data about themselves that Lilly has collected and may have corrections made to Site Personnel Data about themselves that is inaccurate. Investigator and/or Institution may contact Lilly with inquiries regarding Lilly's collection or use of Site Personnel Data.

Article VII Indemnification

Section 7.01. Indemnification. Lilly agrees to indemnify, hold harmless, and defend UT System, its Board of Regents, Institution and their staff, officers, agents and employees (including Investigator) ("Indemnitees") from and against loss, damage, cost and expense of claims and suits (including reasonable attorneys' fees) resulting from (1) an injury to a patient seeking damages alleged to have been directly caused or contributed to by any substance or procedure administered in accordance with Study Protocol or (2) by Lilly's use of results obtained from activities performed by Institution under this Master Agreement or under an individual CRA or individual CRO CRA, including the cost and expense of handling such claims and defending such suits; provided, however, (a) that Indemnitees have adhered to and complied with all applicable federal, state and local regulations (including, without limitation, obtaining informed consents and IRB approvals), the written specifications of the Protocol and all written recommendations furnished by Lilly for the use and administration of any drug or device described in the Protocol; (b) that Lilly is promptly notified of any such claim or suit, however, the failure to provide such prompt notification shall not relieve Lilly of its indemnification obligations unless such failure impairs Lilly's ability to defend the claim or suit; (c) that the Indemnitees cooperate fully in the investigation and defense of any such claim or suit; (d) that Lilly retains the right to defend the lawsuit in any manner it deems appropriate, including the right to retain counsel of its choice; and (e) that Lilly shall have the sole right to settle the claim or suit; provided, however, that Lilly shall not admit fault on Indemnitees' behalf without Indemnitees' advance written permission. In addition, Lilly's

obligation of indemnification shall not extend to any loss, damage or expense arising from the negligence, willful malfeasance or unlawful act or malpractice by the Indemnitees, it being understood that the administration of any substance in accordance with the Protocol shall not constitute negligence, willful malfeasance or unlawful act or malpractice for purposes of this Master Agreement. This Section 7.01 is subject to the applicable statutory duties of the Texas Attorney General.

Article VIII Disputes

Section 8.01. Law and Venue. The parties agree to remain silent regarding law and venue governing this Master Agreement.

Section 8.02. Alternative Dispute Resolution. In the event a dispute arises between or among the parties over the interpretation and application of this Master Agreement, the parties shall attempt to settle such a dispute first by negotiation and consultation between themselves. The parties also will consider alternative dispute resolution as a means of resolving any such dispute.

Section 8.03. Entire Agreement. This Master Agreement represents the entire understanding between the parties and supersedes all other agreements, express or implied, between the parties concerning the subject matter hereof. This Master Agreement has been thoughtfully considered by the parties and, consequently, shall not be strictly construed against any party.

Article IX Notices

Section 9.01. Notices. All communication and notices required to be in writing under this Master Agreement shall be delivered personally, electronically or by facsimile with proof of transmittance or sent by certified or registered mail or courier (e.g. UPS), return receipt requested, postage prepaid, to the appropriate party at the address set forth below or at such other address as a party may give to the other in the manner set forth in this section.

If to Lilly:
Lilly USA, LLC

To Institution:
See Attachment 1

Global Clinical Operations Site
Activation
Lilly Corporate Center, Drop Code
1707
Indianapolis, IN 46285
ATTN: Clinical Contracts and Grants
Office
eMail:
Contracts_Lilly_CCGO@Lilly.com
Fax: 317-453-8500; toll free 866-
922-2854
Phone: (888) 651-2501

Notice shall be deemed given when delivered in person or electronically or by facsimile with proof of transmittance or three (3) days after being sent by certified or registered mail or courier. The parties may change their respective addresses where notice has been given by prior written notice to the other, as provided herein.

Article X Survivorship Clause

Section 10.01. Survivorship Clause. Notwithstanding any termination of this Master Agreement, the obligations with respect to Confidentiality and Non Use Section 2.03, Data Section 2.04, Publications Section 2.05, Publicity Section 2.07, Institution Obligations Article 2, Study Patient Injury Reimbursement Section 4.01, Site Personnel Data Section 6.01, and Indemnification Article 7, respectively, shall survive the expiration, termination or cancellation of this Master Agreement or any CRA or CRO CRA executed under this Master Agreement.

Article XI Agreement Term and Termination

Section 11.01. Term and Termination. This Master Agreement shall be effective upon the Effective Date and shall continue in effect for five (5) years after the Effective Date (from December 5, 2017 to December 5, 2022) unless terminated by either party upon giving the other party not less than thirty (30) days prior written notice of termination. Provided however, Studies being conducted at the time of termination shall continue pursuant to the terms of this Master Agreement and the specific CRA or CRO CRA until completed, except that Lilly and Institution shall be entitled to terminate the CRA or CRO CRA for any such Study as set forth in the Limit of Patient Entry or Enrollment and Study Termination Section 5.01 of this Master Agreement. If after termination of this Master Agreement or any CRA or CRO CRA Lilly decides to proceed on a project without the further services of Institution, Lilly shall have the right to do so, utilizing, if it so desires, the data generated by Institution. Institution shall have no liability arising out of the use of such data. The term of a specific CRA or CRO CRA shall be stated in the individual specific CRA or CRO CRA.

**Article XII
Miscellaneous**

Section 12.01. Independent Contractor. Institution and Lilly will be acting as independent contractors and not as an agent, partner or employee of the other party. Neither Institution nor Lilly will have any authority to make agreements with third parties that are binding on the other party.

Section 12.02. Binding Effect. By signing this Master Agreement and/or any CRA or CRO CRA, Investigator and Institution represent and warrant that they have the authority and ability to or shall otherwise contractually bind any individual or entity that performs services in connection with the Study hereunder to the terms and conditions of this Master Agreement and any CRA or CRO CRA.

Section 12.03. Amendments. This Master Agreement may only be amended by an instrument in writing signed by the parties hereto.

Section 12.04. Counterparts. This Master Agreement is legally binding when, but not until, each party has received from the other a counterpart of the Master Agreement signed by the authorized representative. The parties' representatives may sign separate, identical counterparts of this document; taken together, they constitute one agreement. A signed counterpart may be delivered by any reasonable means, including facsimile or other electronic transmission.

Section 12.05. Electronic Signature. The parties agree that execution of this Master Agreement by industry standard electronic signature software and or by exchanging PDF signatures shall have the same legal force and effect as the exchange of original signatures, and that in any proceeding arising under or relating to this Master Agreement, each party hereby waives any right to raise any defense or waiver based upon execution of this Master Agreement by means of such electronic signatures or maintenance of the executed agreement electronically.

Section 12.06. State Agency Limitations. Lilly acknowledges each Institution is an agency of the State of Texas and, under the Constitution and laws of the State of Texas, 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 laws of the State of Texas. Notwithstanding any provision hereof, nothing in this Master 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 on 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 Master Agreement as they pertain to Institution are enforceable only to the extent authorized by the Constitution and laws of the State of Texas.

Rest of page intentionally left blank.

IN WITNESS WHEREOF, the parties hereto have authorized their officers or representatives to execute this Master Agreement in duplicate and it shall be effective as of the Effective Date written in the Preamble.

AGREED AND ACCEPTED:
LILLY USA, LLC

Anna Pinkhas

Anna Pinkhas, Esq., Consultant
Clinical Contracts and Grants Office
Global Clinical Operations Site Activation
12/6/17

(Date)

This Master Agreement Prepared by:
Robert C Fisher III, Associate Consultant
Clinical Contracts and Grants Office
Global Clinical Operations Site Activation

AGREED AND ACCEPTED:
The University of Texas System

Raymond S. Greenberg
(Signature of Authorized Official)

Raymond S. Greenberg, MD, PhD
(Typed or Printed Name and Title)
Executive Vice Chancellor For Health Affairs

January 4, 2018
(Date)

AGREED AND ACCEPTED:
The University of Texas Health Science
Center at Houston

(Signature of Authorized Official)

(Typed or Printed Name and Title)

(Date)

AGREED AND ACCEPTED:
The University of Texas Health Science
Center at Tyler

David Anderson

(Signature of Authorized Official)

David Anderson, Director, Sponsored Programs
(Typed or Printed Name and Title)

12/8/17
(Date)

IN WITNESS WHEREOF, the parties hereto have authorized their officers or representatives to execute this Master Agreement in duplicate and it shall be effective as of the Effective Date written in the Preamble.

AGREED AND ACCEPTED:
LILLY USA, LLC

AGREED AND ACCEPTED:
The University of Texas System

Anna Pinkhas

Anna Pinkhas, Esq., Consultant
Clinical Contracts and Grants Office
Global Clinical Operations Site Activation
12/6/17

(Date)

(Signature of Authorized Official)

(Typed or Printed Name and Title)

(Date)

This Master Agreement Prepared by:
Robert C Fisher III, Associate Consultant
Clinical Contracts and Grants Office
Global Clinical Operations Site Activation

AGREED AND ACCEPTED:
The University of Texas Health Science
Center at Houston

AGREED AND ACCEPTED:
The University of Texas Health Science
Center at Tyler

Kathleen M. Kreidler

(Signature of Authorized Official)

Kathleen M. Kreidler,
Assoc. VP, Sponsored Projects Admin

(Typed or Printed Name and Title)

12/20/2017

(Date)

(Signature of Authorized Official)

(Typed or Printed Name and Title)

(Date)

AGREED AND ACCEPTED:
The University of Texas Health Science
Center at San Antonio

Chris G. Green

(Signature of Authorized Official)
Chris G. Green, CPA
Director, Office of Sponsored Programs

(Typed or Printed Name and Title)

07 December 2017
(Date)

AGREED AND ACCEPTED:
The University of Texas M.D. Anderson
Cancer Center

(Signature of Authorized Official)

(Typed or Printed Name and Title)

(Date)

AGREED AND ACCEPTED:
The University of Texas Medical Branch
at Galveston

(Signature of Authorized Official)

(Typed or Printed Name and Title)

(Date)

AGREED AND ACCEPTED:
The University of Texas Southwestern
Medical Center

(Signature of Authorized Official)

(Typed or Printed Name and Title)

(Date)

AGREED AND ACCEPTED:
The University of Texas Rio Grande
Valley

(Signature of Authorized Official)

(Typed or Printed Name and Title)

AGREED AND ACCEPTED:
The University of Texas at Austin

(Signature of Authorized Official)

(Typed or Printed Name and Title)

AGREED AND ACCEPTED:
The University of Texas Health Science
Center at San Antonio

(Signature of Authorized Official)

(Typed or Printed Name and Title)

(Date)

AGREED AND ACCEPTED:
The University of Texas Medical Branch
at Galveston

(Signature of Authorized Official)

(Typed or Printed Name and Title)

(Date)

AGREED AND ACCEPTED:
The University of Texas Rio Grande
Valley

(Signature of Authorized Official)

(Typed or Printed Name and Title)

AGREED AND ACCEPTED:
The University of Texas M.D. Anderson
Cancer Center

(Signature of Authorized Official)

Wesley Hartott
Associate Vice President, Research Administration

(Typed or Printed Name and Title)

(Date)

12/12/17

Reviewed and Approved by
UTMDACC Legal Services for
UTMDACC Signature: (CL)
Johel #55298
12-9-17

AGREED AND ACCEPTED:
The University of Texas Southwestern
Medical Center

(Signature of Authorized Official)

(Typed or Printed Name and Title)

(Date)

AGREED AND ACCEPTED:
The University of Texas at Austin

(Signature of Authorized Official)

(Typed or Printed Name and Title)

AGREED AND ACCEPTED:
The University of Texas Health Science
Center at San Antonio

AGREED AND ACCEPTED:
The University of Texas M.D. Anderson
Cancer Center

(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:
The University of Texas Medical Branch
at Galveston

AGREED AND ACCEPTED:
The University of Texas Southwestern
Medical Center



(Signature of Authorized Official)

(Signature of Authorized Official)

(Lori Simon
Director, Office of Clinical Research Title)

(Typed or Printed Name and Title)

18 Dec 2017

(Date)

(Date)

AGREED AND ACCEPTED:
The University of Texas Rio Grande
Valley

AGREED AND ACCEPTED:
The University of Texas at Austin

(Signature of Authorized Official)

(Signature of Authorized Official)

(Typed or Printed Name and Title)

(Typed or Printed Name and Title)

CLOSE

The University of Texas Health Science
Center at San Antonio

The University of Texas M.D. Anderson
Cancer Center

(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:
The University of Texas Medical Branch
at Galveston

AGREED AND ACCEPTED:
The University of Texas Southwestern
Medical Center

(Signature of Authorized Official)

DocuSigned by:
Megan Marks, Ph.D.

(Signature of Authorized Official)

(Typed or Printed Name and Title)

Megan G. Marks, Ph.D.

(Typed or Printed Name and Title) JS

(Date)

12/11/2017 | 7:15 PM CST

(Date)

AGREED AND ACCEPTED:
The University of Texas Rio Grande
Valley

AGREED AND ACCEPTED:
The University of Texas at Austin

(Signature of Authorized Official)

(Signature of Authorized Official)

(Typed or Printed Name and Title)

(Typed or Printed Name and Title)

AGREED AND ACCEPTED:
The University of Texas Health Science
Center at San Antonio

AGREED AND ACCEPTED:
The University of Texas M.D. Anderson
Cancer Center

(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:
The University of Texas Medical Branch
at Galveston

AGREED AND ACCEPTED:
The University of Texas Southwestern
Medical Center

(Signature of Authorized Official)

(Signature of Authorized Official)

(Typed or Printed Name and Title)

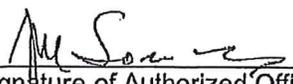
(Typed or Printed Name and Title)

(Date)

(Date)

AGREED AND ACCEPTED:
The University of Texas Rio Grande
Valley

AGREED AND ACCEPTED:
The University of Texas at Austin



(Signature of Authorized Official)

Juan M. Sanchez, Ph.D.
Interim Sr. VP for Research, Innovation and Economic Development

(Typed or Printed Name and Title)

(Signature of Authorized Official)

(Typed or Printed Name and Title)

AGREED AND ACCEPTED:
The University of Texas Health Science
Center at San Antonio

AGREED AND ACCEPTED:
The University of Texas M.D. Anderson
Cancer Center

(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:
The University of Texas Medical Branch
at Galveston

AGREED AND ACCEPTED:
The University of Texas Southwestern
Medical Center

(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:
The University of Texas Rio Grande
Valley

AGREED AND ACCEPTED:
The University of Texas at Austin

(Signature of Authorized Official)



(Signature of Authorized Official)

(Typed or Printed Name and Title)

Bill Catlett, Director, Office of Industry Engagement

(Typed or Printed Name and Title)

(Date)

(Date)

12/08/2017

If this Master Agreement is acceptable, please sign and return all pages (including attachments) to the Lilly Clinical Contracts and Grants Office in one of the three methods outlined below. If you have questions, please call the Lilly Clinical Contracts and Grants Office at (888) 651-2501.

- (1) Forward the scanned (.pdf) or electronically signed document to
Contracts_Lilly_CCGO@Lilly.com
- (2) Send by facsimile transmission to (317) 453-8500 or toll free at (866) 922-2854
- (3) Mail to: Global Clinical Operations Site Activation, ATTN: Clinical Contracts and
Grants Office, Lilly Corporate Center, Drop Code 1707, Indianapolis, Indiana, 46285

**Attachment 1
Administrative Contact for UT System and Each Member Institution**

<p>David Hawkins Associate Director Office of Sponsored Projects The University of Texas at Austin P.O. Box 7726 Austin, Texas 78713-7726 Phone: 512-471-6424 Fax: 512-471-6564 Tax ID: 74-600023 Email: dhawkins@austin.utexas.edu</p>	<p>Arriel Stevens Sponsored Programs Administrator The University of Texas Southwestern Medical Center 5323 Harry Hines Blvd. Dallas, TX 75390-9105 Phone: 214-648-4139 Fax: 214-648-4474 Email: arriel.stevens@UTSouthwestern.edu Tax ID: 75-6002868</p>
<p>Chris G. Green, CPA Director, Office of Sponsored Programs The University of Texas Health Science Center at San Antonio 7703 Floyd Curl Dr, Mail Code 7828 San Antonio, TX 78229-3900 Phone: 210-567-2340 Fax: 210-567-8107 Email: contracts@uthscsa.edu Tax ID: 74-1586031</p>	<p>Kathleen Kreidler Director, Contracts The University of Texas Health Science Center at Houston P.O. Box 20036 Houston, TX 77225 Phone: 713-500-3999 Fax: 713-500-4939 Tax ID: 74-1761309 Overnight address is: 7000 Fannin Street, Suite 1006 Houston, TX 77030 Email: kathleen.kreidler@uth.tmc.edu</p>
<p>David Anderson Director, Office of Sponsored Programs The University of Texas Health Science Center at Tyler 11937 U.S. Hwy. 271 Tyler, TX 75708-3154 Phone: 903-877-7486 Fax: 903-877-7558 Email: david.anderson@uthct.edu Tax ID: 75-6001354</p>	<p>Toni D'Agostino Associate VP for Research Office of Sponsored Projects The University of Texas Medical Branch at Galveston 301 University Boulevard 5.106 W Admin. Building Galveston, TX 77555-0133 Phone: 409-772-2138 Fax: 409-266-9469 Email: todayost@utmb.edu Tax ID: 74-6000949</p>
<p>Houston Mitchell Director, Sponsored Programs The University of Texas M. D. Anderson Cancer Center 1515 Holcomb Boulevard, Unit 1676 Houston, TX 77030 Phone: 713-563-3881 Fax: 713-794-4535 Email: hmitchel@mdanderson.org Email: osp@mdanderson.org Tax ID: 74-6001118</p>	<p>Rita Garza AVP/Exec. Director, Sponsored Programs The University of Texas Rio Grande Valley Office of Sponsored Programs 1201 West University Drive Edinburg, TX 78539 Phone: 956-665-3883; 956-882-4161 Email: rita.garza@utrgv.edu Email: sponpro@utrgv.edu Tax ID: 46-5292740</p>

<p>BethLynn Maxwell Chief Health Research Officer and Associate General Counsel The University of Texas System 210 West 7th Street – 14th Floor Austin, TX 78701 Phone: 512-499-4518 Fax: 512-499-4523 Email: bmaxwell@utsystem.edu</p>	
--	--

Appendix A1

Sample Clinical Research Agreement ("CRA")

This Clinical Research Agreement ("CRA") will serve to append to the Master Clinical Trial Agreement ("Master Agreement") effective the 14th day of November, 2017, between Lilly USA, LLC ("Lilly"), with its principal place of business at Lilly Corporate Center, Drop Code 1072, Indianapolis, Indiana, 46285 and [Enter name of Institution] ("Institution"), with its principal place of business at [Enter Address of Institution], for the clinical trial study to be performed entitled "[insert study title]" [Protocol [protocol ID]] ("Protocol"), which Protocol is incorporated herein by reference] ("Study"). The Study is to be performed by [name of Investigator], M.D., an employee of Institution, as principal investigator ("Investigator").

Institution shall be bound to the terms of the Master Agreement, and this CRA. The Master Agreement and all terms and conditions thereof are incorporated herein by reference.

[INSERT THIS LANGUAGE IF EXHIBIT B IS N/A TO THIS STUDY: Lilly agrees to provide payment to Institution in accordance with Payment Schedule attached hereto as Exhibit 1, and the Budget attached hereto as Exhibit A. Exhibits 1 and A are incorporated herein by reference and made a part hereof for all purposes.

[INSERT THIS LANGUAGE IF EXHIBIT B IS APPLICABLE TO THIS STUDY:] Lilly agrees to provide payment to Institution in accordance with Payment Schedule attached hereto as Exhibit 1, the Budget attached hereto as Exhibit A, and the Advertising/Recruitment exhibit attached hereto as Exhibit B. Exhibits 1, A and B are incorporated herein by reference and made a part hereof for all purposes.

If Lilly desires to amend the terms of the Master Agreement for this individual CRA, (1) Lilly acknowledges and agrees that the Office of General Counsel, UT System must first review and approve the added text and (2) Institution will ensure that the Office of General Counsel, UT System first reviews and approves of such revision.

By signing this CRA, Institution represents and certifies that it has the authority and ability to or will otherwise contractually bind any individual or entity that performs services for them in connection with the Study hereunder to the terms and conditions of this Master Agreement. This CRA is legally binding when, but not until, each party has received from the other a counterpart of the CRA signed by an authorized representative. The parties' representatives may sign separate, identical counterparts of this document; taken together, they constitute one agreement. A signed counterpart may be delivered by any reasonable means, including facsimile or other electronic transmission. Additionally, the parties agree that facsimile, electronic and/or email copies of this CRA are considered to be a legal original and signatures thereon shall be legal and binding agreement.

This CRA represents the entire understanding between the parties and supersedes all other agreements, express or implied, between the parties concerning the subject matter hereof. This CRA has been thoughtfully considered by the parties and, consequently, shall not be strictly construed against any party.

AGREED AND ACCEPTED:
LILLY USA, LLC

AGREED AND ACCEPTED:
[Enter name of Institution]

(Signature of Authorized Official)

(Signature of Authorized Official)

(Typed or Printed Name and Title -
Required)

(Typed or Printed Name and Title -
Required)

(Date)

(Date)

This CRA Prepared by:
[CCGO PROCESSOR NAME]
Clinical Contracts and Grants Office
Global Clinical Operations Site Activation

READ AND ACKNOWLEDGED BY:
Investigator

[Name of Investigator]

(Date)

If this CRA is acceptable, please sign and return all pages (including attachments) to the Lilly Clinical Contracts and Grants Office in one of the three methods outlined below. If you have questions, please call the Lilly Clinical Contracts and Grants Office at (888) 651-2501.

- (1) Forward the scanned (.pdf) or electronically signed document to
Contracts_Lilly_CCGO@Lilly.com
- (2) Send by facsimile transmission to (317) 453-8500 or toll free at (866) 922-2854
- (3) Mail to: Global Clinical Operations Site Activation, ATTN: Clinical Contracts and
Grants Office, Lilly Corporate Center, Drop Code 1707, Indianapolis, Indiana, 46285

**Appendix A2
(Exhibit 1 of CRA)**

Sample Payment Schedule for use with a CRA

Payee and Payments:

Payment in connection with the Study shall be made to Institution as Institution is named in an IRS W-9 form and to the address listed in the Lilly Supplier Information Form provided by Institution to Lilly.

The following information shall be provided to Institution regarding each payment designated for patient services: Protocol alias, Investigator name, patient number, patient visit number and visit payment amount. For each payment made in reimbursement of invoiceable expenses, Lilly shall provide a remittance advice containing either a description of the reimbursement and/or Institution's invoice number. Inquiries regarding payment status or clarification should be addressed to Lilly at: P2P Answer Center@lilly.com or by calling (317) 655-2700 or (877) 511-1529.

Investigator and Institution represent and warrant that payments under the terms of this CRA shall not violate any policy or agreement they may have with a third party with which they are affiliated.

Payment Schedule:

- (1) **Procedure Costs:** In connection with the Study, Institution shall be paid in accordance with the terms set forth in the budget ("Budget"), attached hereto as Exhibit A. Institution is responsible for payment to the Investigator and Lilly shall have no direct liability to Investigator for such payments. For those amounts designated for patient services, Institution shall 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 will be made at monthly intervals and is limited to payment for the number of patients designated in the Budget who are enrolled in the Study during the enrollment period, unless Lilly gives Institution written approval to enroll additional patients or extend the enrollment period. In the event that such approval is granted, Institution shall be paid in accordance with the fees set forth in the Budget for the additional patients. Lilly shall pay Institution for screen failures that occur in accordance with the Protocol in the amount designated on the Budget. The number of screen failures listed on the Budget is an estimate. Lilly shall pay for all screen failures provided that such screen failures are performed in accordance with the Protocol.
- (2) **Invoiceable Expenses:** Upon receipt of a fully executed CRA, Lilly shall provide Institution with the purchase order number and information on how to invoice through the Lilly web invoicing system as well as the required reimbursement submission for those who prefer paper invoicing. Within forty-five (45) days of proper submission of an invoice(s) detailing the work performed or actual costs incurred consistent with the Budget, Lilly shall reimburse Institution for such invoiceable expenses. Invoiceable amounts in the Budget represent the maximum amount payable. Increases to such invoiceable expenses shall

only be paid upon advance, written approval from Lilly. Requests for payment for services provided by a third party shall require submission, by Institution, of that third party's invoice which shall serve as the basis for payment to Institution. Lilly shall reimburse Institution for all reasonable and customary local IRB fees actually incurred during the course of the Study as supported by Institution providing Lilly with the IRB fee schedule, official costing documentation from the IRB department or the IRB third party invoice in accordance with the invoiceable process set forth above. Additionally, reasonable and customary costs incurred for required unscheduled visits or for additional Protocol-required procedures that are not related to adverse events shall be paid by Lilly in accordance with the invoiceable process outlined above, provided that Lilly agrees to the visit or procedure in advance. Costs for adverse events shall be evaluated in accordance with the Study Patient Injury Reimbursement section of the Master Agreement.

[Insert the following for all non-Oncology studies. If study is Oncology DELETE THIS LANGUAGE AND EXHIBIT B] If applicable to this Study, for any amounts designated on the Budget specified as either patient advertising or recruitment activities, Lilly shall pay Institution for such activities up to the maximum amounts set forth for each such activity on the Budget. In addition, only those advertising or recruitment activities that are of the type and nature of those set forth on Exhibit B shall be compensated by Lilly. In order to receive payment for advertising or recruitment activities, the submission requirements that are set forth in Exhibit B must be met, as well as an invoice detailing the services performed or costs incurred must be submitted to Lilly in accordance with the terms above.

- (3) Payment Eligibility: To be eligible for payment, the procedures must be performed in full compliance with the Protocol, the Master Agreement and this CRA, and the data submitted must be complete and correct. For data to be complete and correct, each patient must have signed an IRB-approved 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 Lilly has agreed to provide compensation, Lilly shall be the sole source of compensation. Institution shall not seek payment from any third party payor, whether public or private, for any costs covered by payments made by Lilly under this Agreement. If any payments exceed the amount owed for work performed under the Protocol, Institution shall return the excess balance to Lilly. To the extent Institution shall provide reimbursement to Study patients in excess of or in addition to what is set forth in the Budget, Institution is responsible for making such payments and Lilly is not liable for such payments. Matters in dispute shall be payable upon mutual resolution of such dispute.
- (4) Meetings and Training: In addition, if Lilly requests Institution's personnel to attend the Study startup meeting or other meeting necessary to provide information regarding the Study or Study drug(s) or device(s), Lilly shall provide reimbursement for reasonable and necessary travel and lodging expenses (including meals and snacks) that are incurred to attend such meeting(s), provided that attendance at such meeting(s) has been approved in advance by Lilly. Such travel and lodging expenses shall not exceed the maximum amounts that Lilly would reimburse its own employees for comparable travel. Lilly shall make such reimbursements within thirty (30) days of receiving acceptable detailed documentation of such expenses, provided that Lilly receives such documentation within sixty (60) days of the date that the expenses were incurred

**Appendix A3
(Exhibit B of CRA)**

**Example US Advertising and Recruitment
Version Date 11 April 2014**

**(Note – Not applicable for all Studies – included only for non-oncology studies)
NON NEGOTIABLE TERMS**

Advertising (Third Party Invoice Required) :	Submission Requirements:
Media- Television, Radio	Site required to submit a copy of the vendor invoices along with the Clinical Investigator Reimbursement Form. Payable up to the maximum indicated on the Advertising line item on the budget.
Print Media- Newspaper	Site required to submit a copy of the vendor invoices along with the Clinical Investigator Reimbursement Form. Payable up to the maximum indicated on the Advertising line item on the budget.
Internet (Google, Facebook, Web MD)	Site required to submit a copy of the vendor invoices along with the Clinical Investigator Reimbursement Form. Payable up to the maximum indicated on the Advertising line item on the budget.
Vendor Recruitment Services: Examples: Contact of potential subjects, recruitment planning, recruitment material distribution, etc.	Site required to submit a copy of the vendor invoices along with the Clinical Investigator Reimbursement Form. Payable up to the maximum indicated on the Advertising line item on the budget.
Site Recruitment Activities (Reimbursement is intended for activities prior to subject contact):	Submission Requirements:
Site Recruitment and Outreach Activities: Reimbursement for site staff time to create, distribute and educate on study-related information to increase study awareness. Examples: Meetings with external MD practices, creating and posting flyers. Lilly does not reimburse for referrals, providing food/beverage, any transfer of value items, or conference registrations. Subject Recruitment presentations may include limited disease state background for context, but must be transparent on the purpose of the presentation and predominantly focused on the requirements for the study.	Site required to submit an invoice for the staff hours utilized and date of activity. Invoice must be accompanied by supporting documentation (i.e. name of external practice receiving protocol education, type of material created and where it was distributed.) Reimbursed at \$100/hour for MD, DO, and PhD and \$40/hour for all other staff within study-approved recruitment budget. Payable up to the maximum indicated on the Site Recruitment Activities item on the budget less any dollars utilized for Internal Subject Search.
Internal Subject Search: Reimbursement for staff time to perform an internal search for potential subjects qualifying for a Lilly study (electronic medical record queries, existing database search, limited chart review of identified subjects). Reimbursement is intended for activities prior to subject contact and does not include costs associated with contacting subjects, receiving calls from potential subjects and prescreening activities.	Site required to submit an invoice for the staff hours utilized and date of search. Invoice must be accompanied by supporting documentation (i.e. number charts and/or files reviewed). Reimbursed at \$40/hour within study-approved recruitment budget, payable up to a maximum of \$600 or as noted on the budget Exhibit A. (Chart reviews are paid at a minimum of 6 records/hour.)

Appendix B1
Sample Clinical Research Agreement
for use with a Clinical Research Organization ("CRO CRA")

Whereas, Lilly USA, LLC ("Lilly"), with its principal place of business at Lilly Corporate Center, Drop Code 1072, Indianapolis, Indiana, 46285 and [Enter name of Institution] ("Institution"), with its principal place of business at [Enter Address of Institution], entered into a Master Clinical Trial Agreement ("Master Agreement") effective the 14th day of November, 2017

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

Whereas, [PI Name], M.D. ("Investigator"), an employee of Institution, shall conduct the study entitled, "[Study title]," protocol [Protocol ID] ("Protocol"), which Protocol is incorporated herein by reference ("Study");

Now, therefore, CRO, and Institution shall abide by the terms of the Master Agreement for conducting the Study. This CRO CRA shall serve as the Clinical Research Agreement referenced in the Master Agreement. The Master Agreement and all terms and conditions thereof are incorporated herein by reference.

Lilly shall remain responsible to Institution for the obligations of Indemnification of the Master Agreement.

CRO and Institution acknowledge that all references, except references to the Data, Publications, Inventions, Publicity and Indemnification sections throughout the Master Agreement shall be understood as referring to "Lilly and/or CRO," provided, however, that CRO shall be directly responsible for any reimbursement due under Study Patient Injury Reimbursement.

CRO and Lilly reserve all rights to terminate this CRO CRA at any time in accordance with the Termination provisions of the Master Agreement.

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

If Lilly desires to amend the terms of the Master Agreement for this individual CRO CRA, (1) Lilly acknowledges and agrees that the Office of General Counsel, UT System must first review and approve the added text and (2) Institution will ensure that the Office of General Counsel, UT System first reviews and approves of such revision.

By signing this CRO CRA, Institution represents and certifies that they have the authority and ability to or will otherwise contractually bind any individual or entity that performs services for them in connection with the Study hereunder to the terms and conditions of this CRO CRA. This CRO CRA is legally binding when, but not until, each party has received from the other a counterpart of the CRO CRA signed by an authorized representative. The parties' representatives may sign separate, identical counterparts of this document; taken together,

they constitute one agreement. A signed counterpart may be delivered by any reasonable means, including facsimile or other electronic transmission. Additionally, the parties agree that facsimile, electronic and/or email copies of this CRO CRA are considered to be a legal original and signatures thereon shall be legal and binding agreement.

This CRO CRA represents the entire understanding between the parties and supersedes all other agreements, express or implied, between the parties concerning the subject matter hereof. This CRO CRA has been thoughtfully considered by the parties and, consequently, shall not be strictly construed against any party.

AGREED AND ACCEPTED:
[Insert Name of CRO]

AGREED AND ACCEPTED:
[Enter name of Institution]

(Signature of Authorized Official)

(Signature of Authorized Official)

(Typed or Printed Name and Title -
Required)

(Typed or Printed Name and Title -
Required)

(Date)

(Date)

READ AND ACKNOWLEDGED:
Investigator

[Name of Investigator]

(Date)

If this CRO CRA is acceptable, please sign and return it to CRO by: [insert means (e.g. fax, email and/or postal mail) and appropriate addresses and/or numbers]. If you have any questions, please call CRO at [insert phone number]

**Appendix B2
(Exhibit 1 of CRO CRA)**

**Sample Payment Schedule for use with a CRO CRA
(Note – CRO may have different payment terms)**

Payee and Payments

Payment in connection with the Study will be made to Institution as Institution is named in an IRS W-9 form provided by Institution to CRO.

The following information shall be provided to Institution regarding each payment designated for patient services: Protocol alias, Investigator name, patient number, patient visit number and visit payment amount. For each payment made in reimbursement of invoiceable expenses, CRO shall provide a remittance advice containing either a description of the reimbursement and/or Institution's invoice number. Inquiries regarding payment status or clarification should be addressed to CRO at: **[INSERT CRO INFORMATION]**.

Institution represents and certifies that to the best of its knowledge, payments under the terms of this CRO CRA will not violate any policy or agreement they may have with a third party with which they are affiliated.

Payment Schedule

- (1) **Procedure Costs**: In connection with the Study, Institution shall be paid in accordance with the terms set forth in the budget ("Budget"), attached hereto as Exhibit A. Institution is responsible for payment to the Investigator and that CRO shall have no direct liability to Investigator for such payments. For those amounts designated for patient services, Institution shall 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 shall be made at monthly intervals and is limited to payment for the number of patients designated in the Budget who are enrolled in the Study during the enrollment period, unless CRO gives Institution written approval to enroll additional patients or extend the enrollment period. In the event that such approval is granted, Institution will be paid in accordance with the fees set forth in the Budget for the additional patients. CRO shall pay Institution for screen failures that occur in accordance with the Protocol in the amount designated on the Budget. The number of screen failures listed on the Budget is an estimate. CRO shall pay for all screen failures provided that such screen failures are performed in accordance with the Protocol.

- (2) **Invoiceable Expenses**: In addition to the payments set forth above, CRO will also reimburse Institution for invoiceable expenses as set forth in the Budget. Increases to invoiceable expenses shall only be paid upon advance, written approval from CRO. Budgeted line item amounts represent the maximum payable amounts unless such advance, written approval is obtained. Requests for payment for services provided by a third party will require submission, by Institution, of that third party's invoice which will serve as the basis for payment to Institution. All payments for invoiceable expenses shall be made within thirty (30) days of receipt of an invoice detailing the work performed or actual costs incurred consistent with the Budget and the amount due. CRO agrees to

reimburse Institution for all reasonable and customary local IRB fees actually incurred during the course of the Study as supported by Institution providing CRO with the IRB fee schedule and official costing documentation from the IRB department or the IRB third party invoice. Additionally, reasonable and customary costs incurred for required unscheduled visits or additional Protocol-required procedures that are not related to adverse events shall be paid by CRO in accordance with the invoiceable process outlined above, provided that CRO agrees to the visit or procedure in advance. Costs for adverse events will be evaluated in accordance with the Patient Injury Reimbursement section of the Master Agreement.

- (3) Payment Eligibility: To be eligible for payment, the procedures must be performed in full compliance with the Protocol and this CRO CRA, and the data submitted must be complete and correct. For data to be complete and correct, each patient must have signed an IRB-approved 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 shall be the sole source of compensation. Institution shall not seek payment from any third party payor, whether public or private, for any costs covered by payments made by CRO under this CRO CRA. If any payments exceed the amount owed for work performed under the Protocol, Institution shall return the excess balance to CRO. To the extent, Institution shall provide reimbursement to Study patients in excess of or in addition to what is set forth in the Budget, Institution is responsible for making such payments and neither CRO nor Lilly are liable for such payments. Matters in dispute shall be payable upon mutual resolution of such dispute.
- (4) Meetings and Training: In addition, if CRO requests Institution's personnel to attend the Study startup meeting or other meeting necessary to provide information regarding the Study or Study drug(s) or device(s), CRO shall provide reimbursement for reasonable and necessary travel and lodging expenses (including meals and snacks) that are incurred to attend such meeting(s), provided that attendance at such meeting(s) has been approved in advance by CRO. Such travel and lodging expenses shall not exceed the maximum amounts that CRO would reimburse its own employees for comparable travel. CRO shall make such reimbursements 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.

