AMENDED AND RESTATED
MASTER CLINICAL STUDY AGREEMENT

between

Pfizer Inc

and

The University of Texas Health Science Center at San Antonio

The University of Texas Health Science Center at Houston

The University of Texas Health Science Center at Tyler

The University of Texas M. D. Anderson Cancer Center

The University of Texas Medical Branch at Galveston

The University of Texas Southwestern Medical Center

The University of Texas at Austin

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AMENDED AND RESTATED MASTER CLINICAL STUDY AGREEMENT

This Amended and Restated Master Clinical Study Agreement ("Master Agreement") between

Pfizer Inc, a Delaware Corporation with a place of business at 235 East 42nd Street, New York, NY 10017-5755, ("Pfizer")

and

a) The University of Texas Health Science Center at San Antonio;
b) The University of Texas Health Science Center at Houston;
c) The University of Texas Health Science Center at Tyler;
d) The University of Texas M. D. Anderson Cancer Center;
e) The University of Texas Medical Branch at Galveston;
f) The University of Texas Southwestern Medical Center; and
g) The University of Texas at Austin;

Each is a member institution of The University of Texas System ("System") having a place of business at 201 West 7th Street, Austin, TX 78701. And each institution with a principal place of business and a contact person listed on the attached Appendix A ("Institution" or collectively, "Institutions").

Pfizer, System and its Institutions are hereinafter collectively referred to as the "Parties" or individually as a "Party".

This Master Agreement, when signed by all Parties, is effective as of December 1, 2015 "Effective Date").

Background
Pfizer sponsors a number of research projects related to the development of pharmaceutical products and medical devices.

Institution is a healthcare and research facility with expertise in the area of health research.

Pfizer wishes to establish a contractual relationship with Institution to facilitate the engagement of Institution from time to time for the conduct of Pfizer-sponsored clinical research projects that will benefit Pfizer and further the educational and research mission of Institution.

As of the Effective Date, this Master Agreement supersedes and replaces that certain Master Clinical Study Agreement effective September 1, 2008 ("2008 Master"), between Pfizer and

Institutions, and will govern and control all Studies undertaken by the Parties after the Effective Date. Any Study which began under the 2008 Master and which is still in progress as of the Effective Date will continue to be governed by the 2008 Master.

The Parties agree as follows:

1. Nature and Scope of Master Agreement

1.1 Services. Research projects contracted under this Master Agreement will consist of the conduct and reporting of Pfizer-sponsored clinical studies involving the use of a Pfizer product or drug (each a "Study"; "Pfizer Drug"; "Pfizer Product") to be conducted under Pfizer-provided clinical protocols (each a "Protocol"). For sake of clarity, the term 'Product' or "Pfizer Product" is used for a Pfizer Drug that has been approved in the market for a specific indication(s). Most of these Studies will be interventional, but some may be non-interventional (ie, observational studies involving participants who are receiving a prescribed Pfizer Drug as part of their standard medical care). A customized Study Order (as defined below) will be used for non-interventional Studies.

1.2 Nature of Master Agreement. As a master form of contract, this Master Agreement establishes the general terms under which each Study will be conducted and allows the Parties to contract for individual Studies through the execution of Study Orders (defined below) rather than full clinical study agreements. This Master Agreement does not obligate Pfizer to offer or Institution to accept engagement for any particular Study.

1.3 Study Order. Each Study will be initiated by the execution of a "Study Order." The Study Order will identify the Study and the Principal Investigator (defined below) and will also specify the funding and payment schedule. Studies conducted under a Study Order are subject to all applicable terms in this Master Agreement. The Study Order may also include terms and requirements that are specific to that Study. The Study Order must be signed by both Parties and by the Principal Investigator. Each Study Order is incorporated by reference into this Master Agreement upon its execution.

a. Study Order Templates. The format and content of a Study Order is illustrated in template form in Attachments B-1 (interventional studies) and B-2 (non-interventional studies) to this Master Agreement. Upon mutual agreement of the Parties, a Study Order template may be modified from time to time during the term of this Master Agreement or adapted on a project-specific basis to better meet the needs of a particular Study. The Study Order template for non-interventional studies (Attachment B-2) is customized to address the ways a non-interventional study differs from an

interventional study, including identifying provisions in this Master Agreement that are modified or omitted for purposes of the non-interventional Study.

b. Execution by Pfizer Affiliates and Agents. Any Affiliate (see Section 21.9, Affiliates) or authorized agent (such as a Contract Research Organization ("CROs")) of Pfizer may execute a Study Order under this Master Agreement without requiring Pfizer to be a signatory. If a Study Order is executed by an agent of Pfizer, the Study Order may indicate that Pfizer has also delegated responsibility for Study management, including Study monitoring, to that agent. Additionally, for Study Orders executed by an authorized agent or CRO of Pfizer, Pfizer will direct its CROs to use the then-current Master Agreement between Pfizer and Institutions. For Study Orders executed by a Pfizer Affiliate or agent, Pfizer remains responsible to Institution for the performance of all Pfizer duties under the Master Agreement and Study Order just as though Pfizer had performed them itself.

c. No Obligation Without Study Order. Neither Party has any obligation to the other in regard to a particular Study in the absence of an executed Study Order.

2. Responsibilities.

2.1 Investigators and Research Staff. Each Study contracted under this Master Agreement will be conducted by the Institution's investigator identified in the applicable Study Order as "Principal Investigator." Institution will ensure that only individuals who are appropriately trained and qualified assist in the conduct of the Study as sub-investigators or research staff.

2.2 No Substitution. Institution may not reassign the conduct of a Study to a different Principal Investigator without prior written consent from Pfizer.

2.3 Compliance Obligations. Institution is responsible to Pfizer for compliance by all Study personnel, including Principal Investigator, with the terms of this Master Agreement; the applicable Study Order; applicable law, regulations, and governmental guidance; and, for interventional studies, the International Conference on Harmonization Good Clinical Practice (ICH GCP) guidelines, in all cases as promulgated by the US Food and Drug Administration (FDA).

a. Ethical Transplantation Principles. Pfizer supports the ethical principles articulated in the World Health Organization's Guiding Principles for Human Cell, Tissue and Organ Transplantation. For any Study that

involves human cell, tissue, or organ transplantation, Institution agrees to abide by the ethical principles set forth in this document (WHA63.22) http://www.who.int/transplantation/en/.

b. Non-Interventional Studies. For any non-interventional Study conducted under this Master Agreement, Institution will comply with the principles of ICH GCP, as promulgated by the FDA to the extent relevant to that type of study and will also follow generally accepted research practices for non-interventional studies, such as the Good Pharmacoepidemiology Practices (GPP) issued by the International Society for Pharmacoepidemiology, the guidances issued by the International Society for Pharmaceconomics and Outcomes Research (ISPOR), the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) Code of Conduct for Scientific Independence and Transparency in the Conduct of Pharmacoepidemiological and Pharmacovigilance Studies, or the equivalent.

2.4 Pfizer GCP Training. Principal Investigator and any sub-investigators listed on Form FDA 1572 Statement of Investigator as "SubInvestigators" will complete a Pfizer-provided Good Clinical Practice training course ("Pfizer GCP Training") before enrollment of any Study Subjects (as defined in Section 5, Subject Enrollment) in a Study. Any investigators who later join the Study will complete the Pfizer GCP Training before performing Study-related duties. For studies of applicable duration, Principal Investigator and sub-investigators will complete Pfizer GCP Training every three years during the term of the Study, or more often if there are significant changes to the ICH GCP guidelines or course materials.

3. Funding. Pfizer will provide funding in support of each Study as delineated in the Study Budget and Payment Terms Exhibit to the applicable Study Order and subject to the terms specified in that Exhibit.

3.1 Payments. Each Pfizer Study payment under this Master Agreement will be identified by the Pfizer Protocol number and the name of the Principal Investigator for that Study.

3.2 Disclosure and Reporting by Pfizer. Pfizer is subject to certain US laws, including the federal Affordable Care Act of 2010, that require it to report or publicly disclose payments or other transfers of value to certain healthcare providers and teaching hospitals. These laws and their implementing regulations are collectively referred to as "Transparency Laws." To comply with applicable Transparency Laws and Pfizer policy relating to transparency in its financial relationships with investigators and study sites, Pfizer may disclose in any lawful manner the terms of any Study Order under this Master Agreement and the

support that Pfizer is providing under it.

a. Disclosure Content. In a transparency disclosure, Pfizer may identify both the Institution and the Principal Investigator, but will clearly differentiate between payments or other transfers of value to institutions and those made to individuals. Disclosures may include identifying information for institutions and investigators, such as name, business address, specialty, National Provider Identifier (NPI), and licensure numbers.

b. Agreement and Cooperation. Institution agrees to these disclosures on behalf of itself and its Principal Investigators. Institution further agrees to reasonably cooperate with Pfizer in Pfizer's collection and disclosure of information necessary to fulfill its transparency obligations, and to ensure such cooperation by its Principal Investigators or other affected personnel.

3.3 Investigator Meetings. If a Principal Investigator or other Study personnel are required to attend investigator meetings for a Study, Pfizer will arrange and pay directly for travel and accommodation and will cover the reasonable costs of meals in connection with those meetings, but does not provide compensation for attendance.

4. Protocol. Institution will conduct each Study and Study-related activities in accordance with the applicable Protocol including, but not limited to, the requirements relating to Institutional Review Board (IRB) approval and adverse event reporting.

4.1 Amendments. A Protocol may be modified only by a written amendment approved by Pfizer, the Principal Investigator, and the responsible IRB ("Amendment") except, as described in the Protocol, for emergency changes necessary to protect the safety of the Study Subjects (as defined in Section 5, Subject Enrollment).

4.2 No Additional Research. No additional research may be conducted on Study Subjects (as defined in Section 5, Subject Enrollment) during the conduct of the Study that: (a) is prohibited by the Protocol or informed consent document; or (b) makes use of any unpublished Study Data specifically collected for the Study. In addition, unless prospectively approved by CRO and documented as described above, and/or except as permitted under Section 12.2(d) hereunder, no additional research of any kind may be conducted or on biological samples collected during the conduct of the Study unless it is approved by Pfizer and documented as an Amendment to the Protocol or made subject to mutually agreeable terms otherwise documented by the Parties. For any additional research that is not prohibited under this Section, Institution commits to ensure: (1) compliance with applicable regulations; and (2) use of an informed consent document that is

separate from that used for the Study and that does not state or imply that CRO or Pfizer is the sponsor of, or has any responsibility for, the additional research.

5. Subject Enrollment. The Study Order may specify the time period during which qualified participants may be enrolled in the Study, the minimum and maximum numbers of qualified participants to be enrolled, or both. A qualified participant is one who meets all Protocol criteria for full participation in the Study. After enrollment in the Study, such a qualified participant is considered a "Study Subject."

5.1 Multi-Center Studies. Pfizer may end Study Subject enrollment early by written notice to Institution if the total enrollment needed for a multi-center Study has been achieved before the end of the enrollment period for that Study or before Institution has enrolled the minimum number of Study Subjects.

6. Study Conduct.

6.1 Charging Study Subjects. Institution will not charge a Study Subject or third party payer for Investigational Drug (see Section 9, Investigational Drug) or for any services reimbursed by Pfizer under the Study Order.

6.2 Safety Measures and Serious Breaches. Institution will inform Pfizer immediately of (a) any urgent safety measures taken by a Principal Investigator to protect Study Subjects against immediate hazard and (b) any serious breaches of the Protocol or of ICH GCP guidelines of which Institution becomes aware.

6.3 Medical Coverage for Phase I Studies. For any Phase I clinical study conducted under this Master Agreement, Institution will ensure that appropriate medical coverage is available during Study conduct. Such coverage will be consistent with accepted standards of care and should include the following:

a. Ready availability of a licensed physician during dosing.

b. Written procedures governing the conduct of emergency response.

b. Ready availability of an emergency response team trained in cardiopulmonary resuscitation and advanced cardiac life support (ACLS)

c. Appropriate medications and equipment to handle medical emergencies (e.g., a "crash cart" or equivalent).

d. Arrangements in place to ensure prompt medical intervention should a potentially life-threatening event occur (e.g., ready access to a hospital Emergency Room).

e. Presence of medical staff in the clinic with Study Subjects at all times during any Protocol-specified confinement period (e.g., overnight clinic stays). For overnight clinic stays, at least two staff members possessing the following minimum qualifications must be present:

(1) One staff member must be (a) certified in ACLS, (b) able to access an emergency response system, such as activating the emergency team of an associated hospital or activating the locally available emergency medical system, and (c) competent in basic first aid.

(2) A second staff member must be (a) certified in basic life support (BLS), and (b) able to access an appropriate emergency response system, such as the emergency team of an associated hospital or a locally available emergency medical system.

7. Protected Health Information.

7.1 Study Data PHI. Data collected in a Study may include Protected Health Information ("PHI") as that term is defined in the Privacy Rule enacted pursuant to the Health Insurance Portability and Accountability Act of 1996 ("HIPAA Privacy Rule"). Institution will comply with the Privacy Rule in its conduct and reporting of a Study. Pfizer will use any PHI collected about Study Subjects only as permitted by the HIPAA Authorization and informed consent document signed by that Study Subject (see Section 8, HIPAA Authorization, Informed Consent, and Subject Recruitment).

7.2 MMSEA Reporting Obligations. Institution acknowledges that, under Section 111 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 ("MMSEA"), Pfizer has an obligation to submit certain reports to the Centers for Medicare & Medicaid Services about Medicare beneficiaries who participate in the Study and experience a Research Injury (as defined in Attachment A, Indemnification and Research Injury Policy) for which diagnosis or treatment costs are incurred. Institution therefore agrees to provide to Pfizer the information listed in Study Order Exhibit 1 (Study Budget and Payment Terms) for any Study Subject who incurs medical costs associated with a Research Injury. Institution further agrees to provide Pfizer or a third party vendor designated by Pfizer (e.g., Medical Research Consultants), on request, certain individually identifiable information about such Study Subjects and to otherwise cooperate with Pfizer or the vendor as necessary for Pfizer to meet its MMSEA reporting obligations.

8. HIPAA Authorization, Informed Consent, and Subject Recruitment

8.1 HIPAA Authorization and Informed Consent. Institution will obtain a written authorization to use and disclose health information ("HIPAA Authorization") and a written informed consent for each Study Subject in a form approved by the IRB. The HIPAA Authorization may be incorporated into the informed consent document or handled as a separate document. Institution will provide Pfizer an opportunity to review and approve the content of the HIPAA Authorization and the informed consent document (including any revisions made during the course of the Study) before they are used.

8.2 Subject Recruitment. Institution will provide Pfizer an opportunity to review and approve the content of any Study recruitment materials directed to potential Study Subjects before such materials are used. This requirement applies to all such materials, regardless of medium.

9. Investigational Drug. Pfizer will provide Institution, at no charge, with sufficient quantities of the Pfizer Drug or Pfizer Product that is being studied to conduct the Study. Unless otherwise indicated in a Study Order, Pfizer will also provide at no charge, or cover the costs of, any other Protocol-required drugs (e.g., placebo, comparator drug, concomitant drug). Any other Protocol-required drug that Pfizer provides or covers the cost of is, together with the Pfizer Drug, considered "Investigational Drug."

9.1 Custody and Dispensing. Institution will maintain appropriate control of supplies of Investigational Drug and will not administer or dispense it to anyone who is not a Study Subject, or provide access to it to anyone except Study personnel.

9.2 Use. Institution will use Investigational Drug only as specified in the Protocol. Any other use of Investigational Drug constitutes a material breach of this Master Agreement.

9.3 Ownership of Pfizer Drug. Pfizer Drug is and remains the property of Pfizer. Except for, and limited to, the use specified in the Protocol, Pfizer grants Institution no express or implied intellectual property rights in the Pfizer Drug or in any methods of making or using the Pfizer Drug.

10. Equipment or Materials. Pfizer may provide, or arrange for its agent or a vendor to provide, certain equipment (“Equipment”) or proprietary materials for use by Institution during the conduct of a Study. Such proprietary materials may include computer software, methodologies, rating scales and other instruments that are owned or licensed for use by Pfizer (collectively, “Materials”).

10.1 Equipment and Materials Exhibit to Study Orders. Any Equipment or Materials to be provided for the Study and requirements relating to them will be described in an Equipment and Materials Exhibit to the applicable Study Order (see Attachment B, Exhibit 2).

11. Confidential Information. During the course of a Study, Institution may receive or generate information that is confidential to Pfizer, a Pfizer agent, or a Pfizer Affiliate.

11.1 Definition. Except as specified in Section 11.2, Exclusions, below, "Confidential Information" includes

a. the Protocol,

b. the Investigator Brochure,

c. Study Data (as defined in Section 12, Study Data, Biological Samples, and Study Records, below),

d. Biological Sample Analysis Data (as defined in Section 12, Study Data, Biological Samples, and Study Records, below),

e. The Study Order, including its Exhibits, and

f. any other information related to a Study, the Pfizer Drug, or Pfizer, Pfizer Affiliate, or Pfizer agent technology, research, or business plans that Pfizer, a Pfizer Affiliate, or a Pfizer agent provides to Institution (including Institution's Principal Investigator) in writing or other tangible form and marks as CONFIDENTIAL or initially discloses orally and then summarizes and confirms in writing as CONFIDENTIAL within 30 days after the date of oral disclosure. Information of the type described in this Section 11.1.f. that Pfizer discloses orally will also be considered Confidential Information even if not later confirmed in writing if the confidential nature of the disclosure is reasonably apparent to the other Party.

11.2 Exclusions. Confidential Information does not include information that

a. is in the public domain at the time of disclosure or during the term of this confidentiality obligation by means other than breach of this Master Agreement by Institution,

b. is already known to Institution at the time of disclosure and is free of any obligations of confidentiality,

c. is obtained by Institution, free of any obligations of confidentiality, from a third party who has a lawful right to disclose it,

d. is independently developed, as documented by written records, by individuals within Institution without reference to or reliance upon Confidential Information.

11.3 Obligations of Confidentiality. Unless Pfizer provides prior written consent, Institution may not use Confidential Information for any purpose other than that authorized in this Master Agreement, nor may Institution disclose Confidential Information to any third party except as authorized in this Master Agreement or as required by law, including applicable regulations.

a. Pfizer specifically authorizes any required disclosure of Confidential Information to the IRB or to FDA representatives.

b. Permitted uses and disclosures of Study Data and Biological Sample Analysis Data are described in Sections 12 (Study Data, Biological Samples, and Study Records) and 17 (Publications) of this Master Agreement.

c. Permitted uses and disclosures for Confidential Information include where ethically required to be disclosed to participants because of an unforeseen risk identified by either Party during or after completion on the Study.

11.4 Disclosure Required by Law. If disclosure of Confidential Information beyond that expressly authorized in this Master Agreement is required by law, regulation, or court order, that disclosure does not constitute a breach of this Master Agreement so long as Institution

a. notifies Pfizer in writing as far as possible in advance of the disclosure so as to allow Pfizer to take legal action to protect the Confidential Information,

b. discloses only that Confidential Information required to comply with the legal requirement, and

a. continues to maintain the confidentiality of this Confidential Information with respect to all other third parties.

11.5 Survival of Obligations. For Confidential Information other than Study Data and Biological Sample Analysis Data (as defined in Section 12, Study Data, Biological Samples, and Study Records), these obligations of nonuse and nondisclosure survive termination of the Study Order under which the Confidential Information was disclosed and continue for a period of five years after such termination, unless a longer period of time is specified in the applicable Study Order. Confidentiality obligations for Study Data and Biological Sample Analysis Data survive for as long as Institution retains that information, subject to the permitted uses and disclosures described in Sections 12, 16 (Institution Inventions), and 17 (Publications) of this Master Agreement.

11.6 Return of Confidential Information. If requested by Pfizer in writing, Institution will, at Pfizer's expense as memorialized in the applicable Study Order, return all Confidential Information relating to a completed Study except that required to be retained at the Study site by FDA regulation. However, Institution may retain a single archival copy of the Confidential Information to determine the scope of obligations incurred under this Master Agreement and may retain Study Data for the exercise of the non-exclusive license under Section 12.1.b.

12. Study Data, Biological Samples, and Study Records.

12.1 Study Data. During the course of a Study, Institution will collect certain data, as specified in the Protocol, and submit it to Pfizer or as directed by Pfizer ("Study Data"). Institution will ensure accurate and timely collection, recording, and submission of Study Data, including adhering to timelines for data entry set out in the Pfizer-provided *CRF Completion Requirements* document or an equivalent document provided by a Pfizer agent.

a. Ownership of Study Data. Subject to Principal Investigator's right to use Study Data to publish the results of a Study (see Section 16, Publications) and the non-exclusive license that permits certain uses (see Section 12.1.b, below), Pfizer is the exclusive owner of all Study Data.

b. Non-Exclusive License. Pfizer grants Institution a royalty-free non-exclusive license, with no right to sublicense, to use Study Data for internal research, educational, or patient care purposes.

c. Medical Records. Study Subject-related medical records that are not submitted to Pfizer may include some of the same information as is included in Study Data; however, Pfizer makes no claim of ownership to those documents or the information they contain.

d. Data Review by Pfizer. Pfizer will review the Study Data it receives on an ongoing basis. Pfizer will comply with applicable federal regulations requiring notification of participating investigators of new safety information about the Pfizer Drug. Pfizer further commits to notify Principal Investigator of any other new information of which Pfizer becomes aware that could affect the safety of the Study Subjects or influence the conduct of the Study. To the extent required by applicable law, to include but not be limited to 21 C.F.R. § 312.50 and 21 C.F.R. § 312.55, Pfizer shall promptly notify Institution and Principal Investigator of new observations discovered by or reported to Pfizer relating to a Pfizer Drug, particularly with respect to adverse effects and safe use, and shall ensure that Institution and Principal Investigator is promptly informed of significant adverse effects or risks with respect to the Pfizer Drug. Further, Pfizer shall promptly notify the applicable Institution and Principal Investigator of any findings of (1) new and unexpected serious adverse safety events arising from Pfizer's monitoring of a Study that could affect the safety of Study Subjects, and (2) trends or patterns of non-serious or expected adverse events that occur at a specificity or severity that is inconsistent with prior observations, all in accordance with the obligations set forth in 21 C.F.R. 312.32(c), 21 C.F.R. 312.55(b), 21 C.F.R. 56.108(b) and FDA's Guidance on Adverse Event Reporting to Institutional Review Boards in Clinical Trials (January 2009).

e. Study Results. After analysis of Study Data from all sites is complete, Pfizer will provide Principal Investigator with a summary of the overall results of the Study. Pfizer encourages Principal Investigator to communicate the results, as appropriate, to the Study Subjects. Institution shall ensure that Principal Investigator promptly reports any such information to the IRB, per the IRB's policies. In addition, after a Study has ended, if the results of the multi-center study reveal issues that directly affect the safety of the Study Subjects, Pfizer shall notify the applicable Institution and Principal Investigator. When participant safety or medical care could be directly affected by such findings, Institution shall provide to Study participants a written communication of such information.

12.2 Biological Samples. If so specified in a Protocol and the informed consent document, Institution may collect and provide to Pfizer or its designee biological samples (e.g., blood, urine, tissue, saliva, etc.) obtained from Study Subjects for

testing that is not directly related to Study Subject care or safety monitoring, such as pharmacokinetic, pharmacogenomic, or biomarker testing ("Biological Samples").

a. Use. Institution will not use Biological Samples collected under the Protocol in any manner or for any purpose other than that described in the Protocol. Pfizer will use Biological Samples only in ways permitted by the informed consent and HIPAA Authorization under which they were obtained.

b. Analysis Data. Pfizer or its designees will test Biological Samples as described in the Protocol. Unless otherwise specified in the Protocol, and as approved by the IRB, Pfizer will not provide the results of these tests ("Biological Sample Analysis Data") to the Institution or Study Subject. If Pfizer provides Biological Sample Analysis Data to the Institution, that data will be subject to the permitted use provisions of Section 12.1 (Study Data) of this Master Agreement.

c. Ownership. Pfizer is the exclusive owner of all Biological Samples and Biological Sample Analysis Data.

d. Secondary Biological Samples. Notwithstanding any other provision of this Master Agreement, Institution may collect and/or reserve additional quantities of Biological Samples ("Secondary Biological Samples") for purposes of testing or use in research not described in the Protocol, including pharmacokinetic, pharmacogenomic, and biomarker testing and research, so long as such collection complies with all applicable laws, regulations and acceptable clinical trial practices, including, but not limited to, patient privacy and informed consent laws. Institution will be the owner of all Secondary Biological Samples. At least three (3) months before undertaking any research with the Secondary Biological Samples, Institution will inform Pfizer, on a confidential and non-use basis, of such research so that Pfizer can review and provide to Institution comments upon the proposed research. Institution will be the owner of all data and results arising from Institution's research on and testing of the Secondary Biological Samples (the "Secondary Biological Samples Analysis Data"). Institution, however, will provide the Secondary Biological Samples Analysis Data to Pfizer. Institution will have the right to publish the Secondary Biological Samples Analysis Data but will not publish such results and data until three months after providing the Secondary Biological Samples Analysis Data to Pfizer so that Pfizer may review and comment upon the results and data. Pfizer will treat the Secondary Biological Samples Analysis Data as confidential information and will not

use or disclose the results and data until they have been made public by Institution. Without regard to the other provisions of this Master Agreement, Institution will own all inventions and discoveries arising from Institution's research on and testing of the Secondary Biological Samples.

12.3 Study Records. Institution will retain each Study Subject's Study records, which include the Institution's copies of all Study Data as well as relevant source documents (collectively, "Study Records"), under storage conditions conducive to their stability and protection, for that period of time that is required by law or for a longer period as may be set forth in the Study Order unless Pfizer authorizes, in writing, earlier destruction. Institution agrees to contact Pfizer at InvestigatorRecords@Pfizer.com prior to destroying any Study Records and further agrees to permit Pfizer to ensure that the Study Records are retained for a longer period if necessary, at Pfizer expense, under an arrangement that protects the confidentiality of the records (e.g., secure off-site storage).

13. Monitoring, Inspections, and Audits.

13.1 Monitoring. Pfizer intends to monitor Study conduct. Upon reasonable written notice at mutually agreeable times and during regular business hours, Institution will permit Pfizer representatives access to the premises, facilities, Study Records, investigators, and research staff as required to monitor Study conduct. If the Parties are unable to agree on a mutual agreeable time within thirty (30) days of Pfizer's written notice to Institution, then Pfizer, working with Institution's availability, shall determine in its sole discretion which day such visit during regular business hours will occur and shall so inform Institution of such date in writing. Pfizer will promptly notify Principal Investigator of any monitoring findings that could affect the safety of Study Subjects or influence the conduct of the Study. Principal Investigator will inform Study Subjects of such findings as appropriate.

13.2 Inspections and Audits. Institution acknowledges that Studies conducted under this Master Agreement are subject to inspection by regulatory agencies worldwide, including the FDA, and that such inspections may occur after completion of the Study and may include auditing of Study Records. Pfizer may also audit Study Records during or after the Study as part of its monitoring of Study conduct.

a. Notification. Institution will notify Pfizer as soon as reasonably possible if the site is inspected or scheduled to be inspected by a regulatory agency in relation to a Study.

b. Cooperation. Institution will cooperate with regulatory agency or Pfizer representatives in the conduct of inspections and audits and will ensure that Study Records are maintained in a way that facilitates such activities.

c. Resolution of Discrepancies. Institution will promptly resolve any discrepancies that are identified between the Study Data and the Study Subject's medical records.

d. Inspection Findings and Responses. Institution will promptly forward to Pfizer copies of any inspection findings (e.g., Establishment Inspection Report or FDA Form 483) that Institution receives from a regulatory agency in relation to a Study. Whenever feasible, Institution will also provide Pfizer with an opportunity to prospectively review and comment on any Institution responses to regulatory agency inspections in regard to a Study.

14. Remedies for Breach of Certain Study Obligations. If Institution fails to comply, for any Study, with any of its obligations set out in Sections 4 (Protocol), 8 (HIPAA Authorization, Informed Consent, and Subject Recruitment), 12 (Study Data, Biological Samples, and Study Records) and 13 (Monitoring, Inspections, and Audits) of this Master Agreement, or the requirements of the Protocol relating to adverse event reporting, ethical conduct of the study, and IRB review, in addition to its right to terminate the Study immediately under Section 20.5, Pfizer will have recourse to either or both of the following alternative remedies:

a. Suspension of Study Subject enrollment, if the Study is not yet fully enrolled, and
b. Suspension of payment to Institution under that Study Order.

Any suspension of enrollment or payment will continue until Institution returns to compliance with its Study obligations, as determined by Pfizer. Use of either or both of the above remedies does not preclude Pfizer from exercising its right to immediately terminate the Study if Institution does not become compliant.

15. Pfizer Inventions

a. Notification. If the conduct of Study results in any invention or discovery, whether patentable or not, that relates to the Pfizer Drug, including any that contemplates either a new use or new formulation of the Pfizer Drug (a "Pfizer Invention"), Institution will promptly inform Pfizer.

b. Assignment. Institution will assign all interest in any such Pfizer Invention to Pfizer, free of any obligation or consideration, provided,

however, that Institution will retain a royalty-free, non-exclusive, irrevocable, perpetual, worldwide license, with no right to sublicense, to make and use each Pfizer Invention for internal research, academic and educational, and patient care purposes.

c. Assistance. Institution will provide reasonable assistance to Pfizer in filing and prosecuting any patent applications relating to a Pfizer Invention, at Pfizer's expense.

16. Institution Inventions.

a. Notification. If the conduct of Study results in any invention or discovery, whether patentable or not, that does not meet the definition of a Pfizer Invention, Institution will promptly inform Pfizer. Such an invention will be termed an "Institution Invention" and ownership will be determined in accordance with U. S. patent law. Pfizer will accept notification of an Institution Invention in confidence and, for a period of one year or until Institution files a patent application directed to the Institution Invention, whichever occurs first, Pfizer will not disclose it to any third party without written consent from Institution unless required by law (including FDA regulations).

b. Nonexclusive License to Pfizer. Institution will grant Pfizer a worldwide royalty-free non-exclusive license for research purposes to each Institution Invention.

c. Option to a Royalty-Bearing License. With respect to any Institution Invention, Institution hereby grants to Pfizer a first option to negotiate, in good faith, the terms of an exclusive or nonexclusive license for such invention. Pfizer may exercise each such option by submitting a written request to Institution at any time within 1 year following the disclosure of the Invention to Pfizer (such 1-year period, an "Option Term"). If Pfizer fails to exercise its option with respect to the particular Invention within the applicable Option Term, Institution will then be free to grant a non-exclusive license to the invention to any other entity or person on any terms the Institution so chooses. For the period of each Option Term plus any period in which the parties are negotiating a License, Institution hereby grants to Pfizer and all Affiliates the necessary rights and license for exclusive use of the Invention that are the subject of such Option Term and negotiating period for internal evaluation purposes, including without limitation, research and development of prototype products, services or processes (such rights and licenses referred to collectively as the "Evaluation License"). If Pfizer timely exercise its option and notifies

Institution of its desire to enter into a license agreement, a license agreement containing commercially reasonable terms will be negotiated in good faith by the Parties within a period not to exceed 180 days from Pfizer' notification to Institution of its desire to enter into a license agreement, or such period of time as to which the Parties will mutually agree. The license will provide for a commercially competitive royalty on net sales from all processes, products, and services that incorporate the Invention and which are sold by Pfizer and/or its Affiliates and include reasonable terms, to be negotiated in good faith and based on relevant industry standards and the respective contributions of the Parties. If Institution and Pfizer are unable to agree upon the terms of a license during the good faith negotiations, Institution will be free to enter into a license with any other Party, provided, however, that for a period of twelve (12) months after the termination of the Parties' negotiation of a license agreement, Pfizer will have a right of first refusal as to any exclusive licensing terms that are offered by Institution to a third party that are more favorable licensing terms than those offered to Pfizer. Consequently, before accepting an offer from a third party to acquire any exclusive license rights in such invention, Institution will inform Pfizer of such offer and will allow Pfizer a period of thirty (30) days thereafter in which to elect whether to acquire the exclusive right to the invention under such terms as are offered to Institution by the third party.

17. Publications. Pfizer supports the exercise of academic freedom and has no objection to publication by Principal Investigators of the results of a Study based on information collected or generated by a Principal Investigator under a Study Order ("Study Results"), whether or not the results are favorable to the Pfizer Drug. As used in this Master Agreement, "Publication" means any journal article, abstract, presentation, or other type of public disclosure that reports any Study Results.

17.1 Prepublication Review. Principal Investigators will provide Pfizer an opportunity to review any Publication before it is submitted or otherwise disclosed. Pfizer will review for unprotected Inventions (see Section 15, Pfizer Inventions) and may also provide comments on content. Principal Investigators will consider any such comments in good faith but is under no obligation to incorporate any Pfizer suggestions.

a. Submission to Pfizer. Principal Investigators will provide any Publication to Pfizer at least 30 days before it is submitted for publication or otherwise disclosed. If any patent action is required to protect intellectual property rights, Principal Investigators will delay the disclosure for a period not to exceed an additional 60 days.

b. Redaction of Confidential Information. Principal Investigators will, on request, remove any previously undisclosed Confidential Information before disclosure, except for any Study- or Pfizer Drug-related information necessary to the appropriate scientific presentation or understanding of the Study Results.

17.2 Multi-Center Studies. If a Study is part of a multi-center trial, Institution agrees and Principal Investigators acknowledge that the first Publication is to be a joint Publication covering all Study sites, and that any subsequent Publications by the Principal Investigator will reference that primary Publication. However, if a joint manuscript has not been submitted for publication within 12 months of completion or termination of the Study at all participating sites, the Principal Investigator is free to publish separately, subject to the other requirements of this Publications Section.

17.3 Standards. For all Publications, Principal Investigators will, where appropriate, comply with the authorship guidelines in the *Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals* (http://www.icmje.org/icmje-recommendations.pdf) established by the International Committee of Medical Journal Editors.

17.4 Disclosure of Support. Principal Investigators will disclose Pfizer sponsorship and financial support of the Study in any Publication.

17.5 Study Registration by Pfizer. Pfizer commits to register, on the National Institutes of Health Clinical Trials Data Bank (www.clinicaltrials.gov) , all Pfizer-sponsored Phase 1 through 4 interventional and non-interventional studies that involve the use of a Pfizer Product and/or Pfizer Drug and evaluate the safety or efficacy of that product. Pfizer will also register Pfizer-sponsored studies on other listings of ongoing studies maintained by competent regulatory authorities where there is a regulatory requirement to do so.

18. Indemnification and Research Injury. The Pfizer Indemnification and Research Injury Policy applicable to Studies conducted under this Master Agreement is appended as Attachment A.

19. Assignment and Delegation.

19.1 By Institution. Institution may not assign its rights or delegate or subcontract any duties under this Master Agreement or any Study Order without written permission from Pfizer. If Pfizer authorizes delegation or subcontracting in a Study Order, Institution remains responsible to Pfizer for the performance of all delegated or subcontracted duties.

19.2 By Pfizer. Pfizer may freely delegate and assign Study-related duties and rights to any Pfizer Affiliate and may also, upon advance notice to Institution, freely delegate and assign duties and rights to a Pfizer agent. As indicated in Section 1.3.b (Execution by Pfizer Affiliates and Agents), Pfizer's delegation of duties for a particular Study to a Pfizer agent may include authorization for that agent to negotiate and execute Study Orders in its own name for the benefit of Pfizer. Pfizer may not otherwise assign its rights or delegate its duties under this Master Agreement without written permission from Institution. If Pfizer delegates or subcontracts any duties, Pfizer remains responsible to Institution for the performance of those duties.

20. Term and Termination.

20.1 Term of Master Agreement. This Master Agreement will remain in effect for seven (7) years from the Effective Date (from December 1, 2015 to November 30, 2022).

20.2 Extensions to Master Agreement. This Master Agreement may be extended by mutual agreement of the Parties. Any extension will be executed as a written Amendment to this Master Agreement.

20.3 Early Termination of Master Agreement. This Master Agreement may be terminated early

a. by 90 day advance written notice by Pfizer to Institution for any reason,

b. by notification by either Party of an uncured breach by the other Party. The Party alleging breach must first provide notice that specifically identifies the breach and must provide the breaching Party 30 days in which to cure it.

20.4 Effect of Termination of Master Agreement on Ongoing Study Orders. If this Master Agreement is terminated (either by expiration or early termination), all still-active Study Orders will remain in effect under the terms of that Study Order and this Master Agreement until terminated in accordance with Section 20.5, Termination of Study Orders, below.

20.5 Termination of Study Orders. Each Study Order will terminate upon the earlier of any of the following events:

a. Disapproval by IRB. If a Study cannot be initiated because of IRB disapproval, the Study Order will terminate immediately.

b. Study Completion. For purposes of this Master Agreement, a Study is considered complete after conclusion of all Protocol-required activities for all enrolled Study Subjects.

c. Early Termination of Study. The Study Order will terminate if the Study is terminated early as described below.

a. Termination of Study Upon Notice by Pfizer. Pfizer may terminate a Study for any reason upon 30 days written notice to Institution.

b. Immediate Termination of Study by Pfizer. Pfizer may terminate a Study immediately upon written notification to Institution for causes that include failure to enroll Study Subjects at a rate sufficient to achieve Study performance goals; material unauthorized deviations from the Protocol or reporting requirements; circumstances that in Pfizer's opinion pose risks to the health or well-being of Study Subjects; or regulatory agency actions relating to the Study or the Pfizerl Drug.

c. Immediate Termination of Study by Institution. Institution will have the right to terminate a Study immediately upon notification to Pfizer: (i) if the Principal Investigator at Institution for such Study is no longer affiliated with the Institution or is no longer able to perform the duties required of Principal Investigator and the Institution is unable to identify a replacement Principal Investigator acceptable to Pfizer, (ii) if requested to do so by the responsible IRB or for regulatory reasons, or (iii) for considerations of the health, welfare, or safety of the Study subjects, which considerations in the reasonable and good faith opinion of Principal Investigator or Institution support immediate termination of the Study.

20.6 Effective Date of Study Order Termination. If termination of a Study Order is triggered by any of the events described in Section 20.5, above, the termination will be effective after receipt by Pfizer of all Protocol-required Study Data and Biological Samples generated up until termination; receipt of all payments due either Party; and completion by both Parties of any remaining applicable Master Agreement obligations.

20.7 Payment upon Termination of a Study Order. If a Study is terminated early in accordance with Section 20.5.c, Early Termination of Study, above, Pfizer will

provide a termination payment equal to the amount owed for work already performed, in accordance with the Study Budget in the Study Order, less payments already made. The termination payment will include any non-cancelable expenses other than future personnel costs, so long as they were properly incurred and prospectively approved by Pfizer and only to the extent they cannot reasonably be mitigated. If a Study was never initiated because of disapproval by the IRB (see Section 20.5.a, Disapproval by IRB, above), through no fault of Institution, Pfizer will reimburse Institution for IRB fees and for any other expenses that were prospectively approved, in writing, by Pfizer.

20.8 Return of Materials. Unless Pfizer instructs otherwise in writing, upon termination of the Study Order, Institution will promptly return all materials supplied by Pfizer for Study conduct, including unused Pfizer Drug, unused case report forms, and any Pfizer-supplied Equipment and Materials.

20.9 Survival of Obligations. Obligations relating to Funding, Confidential Information, Study Records, Inventions, Publications, Indemnification and Research Injury, and Debarment and Exclusion survive termination of this Master Agreement and any Study Order, as does any other provision in this Master Agreement, including Attachments, Study Orders, and Exhibits, that by its nature and intent remains valid after termination.

21. Other Terms

21.1 Debarment. Institution certifies that it is not debarred under subsections 306(a) or (b) of the Federal Food, Drug, and Cosmetic Act and that it will not use in any capacity the services of any person debarred under such law with respect to services to be performed under this Master Agreement and each Study Order. During the term of this Master Agreement and for three years after its termination, Institution will notify Pfizer promptly if this certification, as it relates to either Institution or a Principal Investigator, needs to be amended in light of new information.

21.2 Exclusion. Institution certifies that it is not excluded from any federal health care program, including Medicare and Medicaid and that it will not use any Principal Investigator that is so excluded for a Study under this Master Agreement. During the term of this Master Agreement and for three years after its termination, Institution will notify Pfizer promptly if this certification, as it relates to Institution or any Principal Investigator, needs to be amended in light of new information. Pfizer certifies that it is not excluded from any federal health care program, including Medicare and Medicaid and that it will promptly notify Institution if it becomes excluded during the term of this Master Agreement.

21.3 Investigations, Inquiries, Warnings, or Enforcement Actions Related to Conduct of Clinical Research. Institution certifies that it is not the subject of any past or pending governmental or regulatory investigation, inquiry, warning, or enforcement action (collectively, "Agency Action") related to its conduct of clinical research that has not been disclosed to Pfizer. Institution will notify Pfizer promptly if it or any Principal Investigator performing under a Study Order receives notice of or becomes the subject of any Agency Action regarding its/his/her compliance with ethical, scientific, or regulatory standards for the conduct of clinical research if the Agency Action relates to events or activities that occurred before or during the period in which the Study was conducted.

21.4 Use of Name. For each Study conducted under this Master Agreement, Pfizer reserves the right to identify the Principal Investigator and Institution in association with a listing of the Protocol in the National Institutes of Health (NIH) Clinical Trials Data Bank, other publicly available listings of ongoing clinical trials, or other Study Subject recruitment services or mechanisms. Neither Party will otherwise use the name of the other Party or any of its employees for promotional or advertising purposes without written permission from the other Party. And Institution will have the right to acknowledge Pfizer as the sponsor of a Study in scientific or academic publications and other scientific or academic communications, without Pfizer's prior approval. In any such statements, Institution will describe the scope and nature of their participation in the Study accurately and appropriately. Notwithstanding anything herein to the contrary, Institution may, in addition to the above, (i) acknowledge the existence of the Agreement; (ii) the Protocol title (without any specific Study Drug information); and (iii) the aggregate amount of funding provided by Pfizer in support of the Study as necessary.

21.5 Relationship of the Parties. The relationship of Institution to Pfizer is one of independent contractor and not one of partnership, agent and principal, employee and employer, joint venture, or otherwise.

21.6 Modifications. Any modification to this Master Agreement must be in writing, signed by authorized officials of the Parties, and identified as an Amendment to this Master Agreement. Any modification, to an executed Study Order must be in writing and signed by authorized officials of the Parties and identified as an Amendment to the Study Order, except for certain mutually agreeable Study Budget changes that may be identified in Exhibit 1 (Study Budget and Payment Terms) of the relevant Study Order.

21.7 No Waiver. Failure to exert a right under this Master Agreement does not constitute a waiver of that right in the future. No waiver of any right is effective unless in writing and signed by the Party who waives the right.

21.8 Conflict with Attachments , Study Orders, or Protocol. If there is any conflict between this Master Agreement and any Attachments to it, the terms of this Master Agreement control. If there is any conflict between this Master Agreement and any executed Study Order, the terms of this Master Agreement will control unless the Study Order expressly states that it is intended to control over specified inconsistent terms of the Master Agreement. If there is any conflict between this Master Agreement and the Protocol, the Protocol will control as to any issue regarding treatment of Study Subjects, and the Master Agreement will control as to all other issues.

21.9 Affiliates. As used in this Master Agreement, the term "Affiliate" means any entity that directly or indirectly controls, is controlled by, or is under common control with the named Party.

21.10 Successors and Assigns. This Master Agreement will bind and inure to the benefit of the successors and permitted assigns of each Party.

21.11 Entire Agreement. This Master Agreement, including any Study Orders, Attachments, and Exhibits, represents the entire understanding between the Parties relating to this subject matter. This Master Agreement supersedes all previous agreements between the Parties (oral and written) relating to this subject matter, including but not limited to the 2008 Master, except for any obligations that, by their terms, survive independent of this Master Agreement.

21.12 Notices. The Parties will deliver notices and other communications relating to this Master Agreement by hand, by courier, or by a postage-paid traceable method of mail delivery to the address below, or such other address that a Party may later designate by notice to the other Party in accordance with this subsection:

Pfizer:

For Contract Issues:

Pfizer Inc
WRD/Development & Clinical Alliance Management
Attention: Business Operations Strategy Lead
235 E. 42nd Street
New York, New York 10017

Each Study Order will provide Pfizer contact information for submission of Publications relating to that Study.

Institution: See Appendix A for the name of an administrative contact person for each Institution

21.13 Institution as a State Agency. 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 and only such authority as is granted to it under the Constitution and laws of the State of Texas. Notwithstanding any provision hereof, nothing herein is intended to be, nor will it be construed to be, a waiver of the sovereign immunity of the State of Texas or a prospective waiver or restriction of any of the rights, remedies, claims, and privileges of the State of Texas. Moreover, notwithstanding the generality or specificity of any provision hereof, the provisions of this agreement as they pertain to Institution are enforceable only to the extent authorized by the Constitution and laws of the State of Texas.

21.14 Subordination and Conformance to Law. Neither Party will be required to perform any act or to refrain from any act or be bound to any act that would violate any state or federal law applicable to it. In this regard, this Master Agreement is subject to, and the Parties agree to comply with, all applicable local, state, federal, national and international laws, statutes, rules and regulations. Any provision of any law, statute, rule or regulation that invalidates any provision of this Master Agreement, that is inconsistent with any provision of this Master Agreement, or that would cause one or any of the Parties hereto to be in violation of law will be deemed to have superseded the terms of this Master Agreement. The Parties, however, will use all reasonable efforts to accommodate the terms and intent of this Master Agreement to the greatest extent possible consistent with the requirements of the law and negotiate in good faith toward amendment of this Master Agreement in such respect. If the Parties cannot reach agreement on an appropriate amendment, then this Master Agreement may be immediately terminated by either Party.

21.15 Consulting Arrangements. Principal Investigators and Pfizer may be parties to a consulting agreement or other outside agreement to which Institution is not a Party. Pfizer acknowledges and agrees that Institution has no involvement with or responsibility for these consulting or outside agreements.

21.16 Force Majeure. Neither Party will be liable for nonperformance or delays in performance that result from causes that are beyond its reasonable control and not attributable to its own acts or omissions, such as acts of God, fire, strikes, embargo, acts of terrorism, acts of government, acts by regulatory agencies or ethics committees, or other similar causes ("Force Majeure"). However, such nonperformance or delay is excused under this provision only for the duration of the qualifying event.

a. Notice and Attempts to Remedy. Upon the occurrence of a Force Majeure event, the Party whose performance is delayed or prevented will promptly give written notice to the other Party of the event, the expected duration, and its anticipated effect on the ability of the Party to perform its obligations. The Party whose performance is affected by the event will also make reasonable efforts to remedy the cause of the delay or work stoppage.

21.17 Contract Research Organizations**.** For Study Orders executed by an authorized agent or CRO of Pfizer, the following conditions shall apply:

a. **Assignment and Delegation by CRO.** CRO may freely assign any or all of its rights and delegate any or all of its duties under this Study Order to Pfizer Inc or any Pfizer Affiliate. If CRO assigns all rights and delegates all duties to a Pfizer entity, CRO or Pfizer will notify Institution in writing. CRO may also freely delegate and assign Study-related duties and rights to an external provider upon advance notice to Institution. CRO may not otherwise assign its rights or delegate its duties under this Master Agreement without written permission from Institution. If CRO delegates or subcontracts any duties to anyone other than a Pfizer entity, CRO remains responsible to Institution for the performance of those duties. Pfizer is ultimately responsible to Institution for the performance of all duties under the Master Agreement and each Study Order that Pfizer has delegated to CRO for this Study.

b. **Third Party Beneficiary**. Pfizer is an intended third party beneficiary to each Study Order and is entitled to enforce directly any and all of its rights under it.

c. **Disclaimer of Warranties by CRO**. The Parties Acknowledge that Pfizer has engaged CRO to provided Services in Regard to the Pfizer-sponsored clinical Study under the Study Order. Pfizer certifies that CRO has not performed any independent research or analysis regarding the safety of efficacy of any investigational drug or other materials or treatment procedures to be used in the Study under the Study Order and therefore certifies that CRO makes no warranties, expressed or implied, concerning those drugs, materials, or treatment procedures, the results to be obtained by administering them pursuant to the Protocol, or to their fitness for any particular purpose, or to any other Pfizer obligations under the Protocol or this Master Agreement.

AGREED TO AND ACCEPTED BY:

Pfizer Inc **By:** _____ Signature Phillip Paone, Esq. Printed Name Associate Director Pfizer Inc Title 11/25/2015 Date	**The University of Texas Health Science Center at Houston** **By:** _____ Signature Karen S. Niemeier Printed Name Director, Contracts Sponsored Projects Administration Title 11/20/2015 Date
The University of Texas Health Science Center at San Antonio **By:** _____ Signature _____ Printed Name _____ Title _____ Date	**The University of Texas Southwestern Medical Center** **By:** _____ Signature Angela R. Charboneau Wishon, J.D. Vice President for Research Administration _____ Date
The University of Texas Medical Branch at Galveston **By:** _____ Signature _____ Printed Name _____ Title	**The University of Texas Health Science Center at Tyler** **By:** _____ Signature _____ Printed Name _____ Title

AGREED TO AND ACCEPTED BY:

Pfizer Inc **By:** _____ Signature _____ Printed Name _____ Title _____ Date	**The University of Texas Health Science Center at Houston** **By:** _____ Signature _____ Printed Name _____ Title _____Date
The University of Texas Health Science Center at San Antonio **By:** Chris G. Green Signature Chris G. Green, CPA Director, Office of Sponsored Programs Printed Name 11-23-15 Title _____ Date	**The University of Texas Southwestern Medical Center** **By:** _____ Signature Angela R. Charboneau Wishon, J.D. Vice President for Research Administration _____ Date
The University of Texas Medical Branch at Galveston **By:** _____ Signature _____ Printed Name _____ Title _____	**The University of Texas Health Science Center at Tyler** **By:** _____ Signature _____ Printed Name _____ Title _____

AGREED TO AND ACCEPTED BY:

Pfizer Inc **By:** _____ Signature _____ Printed Name _____ Title _____ Date	**The University of Texas Health Science Center at Houston** **By:** _____ Signature _____ Printed Name _____ Title _____Date
The University of Texas Health Science Center at San Antonio **By:** _____ Signature _____ Printed Name _____ Title _____ Date	**The University of Texas Southwestern Medical Center** **By:** _____ Signature Angela R. Charboneau Wishon, J.D. Vice President for Research Administration 11-20-2015 Date
The University of Texas Medical Branch at Galveston **By:** _____ Signature _____ Printed Name _____ Title _____	**The University of Texas Health Science Center at Tyler** **By:** _____ Signature _____ Printed Name _____ Title _____

Agreed to and Accepted by:

Pfizer Inc **By:** _____ Signature _____ Printed Name _____ Title _____ Date	**The University of Texas Health Science Center at Houston** **By:** _____ Signature _____ Printed Name _____ Title _____ Date
The University of Texas Health Science Center at San Antonio **By:** _____ Signature _____ Printed Name _____ Title _____ Date	**The University of Texas Southwestern Medical Center** **By:** _____ Signature Angela R. Charboneau Wishon, J.D. Vice President for Research Administration _____ Date
The University of Texas Medical Branch at Galveston **By:** Angela Cook **Signature** Angela Cook, PhD Director, Office Clinical Research _____ Title 11/23/2015 Date	**The University of Texas Health Science Center at Tyler** **By:** _____ **Signature** _____ Printed Name _____ Title _____ Date

AGREED TO AND ACCEPTED BY:

Pfizer Inc **By:** _____ Signature _____ Printed Name _____ Title _____ Date	**The University of Texas Health Science Center at Houston** **By:** _____ Signature _____ Printed Name _____ Title _____Date
The University of Texas Health Science Center at San Antonio **By:** _____ Signature _____ Printed Name _____ Title _____ Date	**The University of Texas Southwestern Medical Center** **By:** _____ Signature Angela R. Charboneau Wishon, J.D. Vice President for Research Administration _____ Date
The University of Texas Medical Branch at Galveston **By:** _____ Signature _____ Printed Name _____ Title _____	**The University of Texas Health Science Center at Tyler** **By:** _____ Signature David Anderson Printed Name Director, Sponsored Programs Title 11/20/15

Date	Date
The University of Texas at Austin **By:** _____ Signature DAVID HAWKINS Printed Name ASSOCIATE DIRECTOR, OSP Title 11.20.2015 Date	**The University of Texas M. D. Anderson Cancer Center** **By:** _____ Signature _____ Printed Name _____ Title _____ Date

Date	Date
The University of Texas at Austin **By:** _____ Signature _____ Printed Name _____ Title _____ Date	**The University of Texas M. D. Anderson Cancer Center** **By:** Jaime Farias Signature Jaime Farias, MBA Assistant Director, Sponsored Program _____ Printed Name _____ Title 11/20/15 Date

Reviewed and Approved by
UTMDACC Legal Services for
UTMDACC Signature:
5/894
11/20/15

Appendix A – Administrative Contact Person and Address for Each Institution
For Master Clinical Study Agreement between Pfizer Inc.
and the Member Institutions of The University of Texas System

David Hawkins or Courtney F. Swaney 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	Angela R. Charboneau Wishon, J.D. Vice President for Research Administration **The University of Texas Southwestern Medical Center** 5323 Harry Hines Blvd. Dallas, TX 75390-9105 Phone: 214-648-6449 Fax: 214-648-4474 Tax ID: 75-6002868
Mr. 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	Karen Niemeier 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
David Anderson Director, Office of Pre-Award Services **The University of Texas Health Science Center at Tyler** 11937 U.S. Hwy. 271 Tyler, TX 75708-3154 Phone: 903-877-7585 Fax: 903-877-7558 Email: david.anderson@uthct.edu Tax ID: 75-6001354	Toni D'Agostino Associate VP for Research Office of Sponsored Projects **The University of Texas Medical Branch at Galveston** 301 University Boulevard 4.40 Rebecca Sealy Hospital Galveston, TX 77555-0156 Phone: 409-266-9413 Fax: 409-266-9469 Tax ID: 74-6000949
Houston Mitchell Director, Research Agreements **The University of Texas M. D. Anderson Cancer Center** 1515 Holcomb Boulevard, Houston, TX 77030 Phone: 713-563-3881 Fax: 713-794-4535 Email: hmitchel@mdanderson.org Tax ID: 74-6001118	

Attachment A
INDEMNIFICATION AND RESEARCH INJURY POLICY

For each Study contracted under this Master Agreement, Pfizer agrees to indemnify, defend or cover costs of defense for, and hold harmless ("Indemnify") the following individuals and entities, along with their officers, agents, and employees: the Study investigators; System; its Board of Regents, any Institution at which Study activities are conducted, and the Institutional Review Board that approved the Study (collectively, "Indemnified Parties") against any third party demand or claim for damages ("Claim") arising out of a Research Injury (defined below), the design of the Study, the specifications of the Study Protocol, or Pfizer's use of Study Data and/or Study Results.

Excluded from this agreement to Indemnify are any Claims to the extent resulting from

(a) failure by any Indemnified Party to comply with the Protocol,[1]*

(b) failure of any Indemnified Party to comply with any applicable FDA or other governmental regulations, or

(c) negligence or willful misconduct by any Indemnified Party.

Pfizer further agrees to be responsible for the actual cost of diagnostic procedures and medical treatment necessary to treat a Research Injury. Institution agrees, upon payment from Pfizer, to directly pay the providers of all such services, whether or not the provider is affiliated with the Institution. Institution acknowledges that Pfizer will not directly interface with or make payments to treatment providers or Study Subjects in connection with treatment or procedures necessary to treat a Research Injury.

Research Injury. For purposes of this Indemnification and Research Injury Policy, the term "Research Injury" means an adverse event, physical injury, or illness caused by treatment or procedures required by the Protocol that the Study Subject would not have received if the Study Subject had not participated in the Study. Institution agrees to provide or arrange for prompt diagnosis and medical treatment (if needed) of any Research Injury experienced by a Study Subject. Institution further agrees to promptly notify Pfizer of any Research Injury.

Notice and Cooperation. Institution agrees to provide Pfizer with prompt notice of, and full cooperation in handling and resolving, any Claim that is subject to Indemnification. However, failure to provide timely notice will not relieve Pfizer of its obligation to Indemnify except to the extent that Pfizer is prejudiced by the delay. Cooperation will include reasonably assisting Pfizer

* [1]Slight deviations that do not contribute to the injury or jeopardize the validity of the Study will not be considered a failure to adhere to the Protocol.

in the management of a Claim until it is fully resolved, which may entail Pfizer requesting and reviewing medical bills and records related to a Research Injury. If so requested by Pfizer, and subject to the statutory duties of the Texas Attorney General, Institution agrees to authorize Pfizer to carry out the sole management of defense of an Indemnified Claim. However, any Indemnified Party, at its sole expense, will have the right to representation by separate counsel and to participate in the defense of any claim or suit.

Settlement or Compromise. No settlement or compromise of a Claim subject to Indemnification will be binding on Pfizer without Pfizer's prior written consent. Pfizer will not unreasonably withhold such consent of a settlement or compromise. Neither Party will admit fault on behalf of the other Party or enter into a non-monetary settlement that places future obligations on the other Party without the written approval of the affected Party.

Attachment B-1
STUDY ORDER FOR INTERVENTIONAL STUDY
UNDER PFIZER MASTER CLINICAL STUDY AGREEMENT

Use this Study Order template for interventional studies contracted by an Alliance Partner or other CRO under a Pfizer US Master Clinical Study Agreement (MCSA) when the contracting party is an Institution

Pfizer Protocol Number: _____
Protocol Title: _____

This Study Order ("Study Order") is an agreement between

[Name and address of Alliance Partner/CRO] ("CRO") and

[Name and address of Institution] ("Institution")

This Study Order is issued under the Amended and Restated Master Clinical Study Agreement between Pfizer Inc ("Pfizer") and Institution with an Effective Date of December 1, 2015 (the "Master Agreement"). Together with the Master Agreement, this Study Order governs the conduct of the Pfizer-sponsored interventional clinical study ("Study") identified above.

Pfizer has delegated to CRO responsibility for the management and monitoring of this Study, including negotiation and execution of this Study Order. Pfizer has further authorized CRO to bind Pfizer to all relevant commitments within the Master Agreement and this Study Order. Except as otherwise specified in this Study Order, any communication initiated by Institution in regard to the Study should be directed to CRO instead of Pfizer.

1. Term. When signed by all parties, this Study Order has an effective date of _____ and will continue until terminated in accordance with the *Termination of Study Orders* provisions in the Master Agreement.

2. Principal Investigator. The Study will be conducted by Institution's investigator _____ *[include mailing address]* ("Principal Investigator").

3. Protocol. Institution and Principal Investigator acknowledge their previous receipt of a copy of the Protocol for the Study that is the subject of this Study Order.

   3.1 Pfizer GCP Training. Principal Investigator and any sub-investigators listed on Form FDA 1572 Statement of Investigator as "SubInvestigators" will complete a Pfizer-provided Good Clinical Practice training course ("Pfizer GCP Training") before

enrollment of any Study Subjects (as defined in Section 5, Subject Enrollment, Master Agreement) in a Study. Any investigators who later join the Study will complete the Pfizer GCP Training before performing Study-related duties. For studies of applicable duration, Principal Investigator and sub-investigators will complete Pfizer GCP Training every three years during the term of the Study, or more often if there are significant changes to the ICH GCP guidelines or course materials.

4. Subject Enrollment. Institution agrees use reasonable efforts to enroll in Study a minimum of _____ but no more than _____ Study Subjects by _____, unless CRO modifies this enrollment period by written notice. However, the Parties understand and acknowledge that enrollment numbers are subject to the individuals patients' best interest and/or willingness to participate, and therefore cannot be guaranteed. As used in this Study Order, "Study Subject" means a participant who is both enrolled in the Study and has met all the Protocol criteria for full participation.

Alternative Section 4:

Subject Enrollment. Institution agrees to use reasonable efforts to enroll Study Subjects in the Study during the CRO-specified enrollment period, unless CRO modifies the enrollment period by written notice. As used in this Study Order, "Study Subject" means a participant who is both enrolled in the Study and has met all the Protocol criteria for full participation.

5. Payee Information *(Specify if different from that provided in the Master Agreement. If unchanged, reference the Funding section of the Master Agreement as follows:* CRO will make all payments under this Study Order payable as specified in the *Funding* section of the Master Agreement.

6. Pfizer Contact for Study Publications. Principal Investigator will use the address below to submit Publications relating to this Study directly to Pfizer, as described in the *Publications* section of the Master Agreement.

Pfizer Contact for Submission of Publications:
Insert contact information for Pfizer Study Clinician
_____
_____
Telephone: _____
Email: _____

7. Pfizer Contact for Study Records Retention Issues. Institution will contact Pfizer directly at InvestigatorRecords@Pfizer.com before destroying any Study Records relating to this Study.

8. Exhibits. The Exhibits included in this Study Order are identified below.

Exhibit 1 Study Budget and Payment Terms
Exhibit 2 Equipment and Materials *(include only if applicable)*

9. Conflicts. If any Exhibits to this Study Order conflict with the terms of this Study Order, the Study Order will control. If this Study Order or any Exhibit conflicts with the terms of the Master Agreement, the Master Agreement will control except as specified in Section 10 (Additional Terms) below.

10. Additional Terms. The following provisions are added to or updated from the Master Agreement for purposes of this Study. Any and all such revisions to the Master Agreement listed under this section must be approved in advance by the Institution and the UT System Office of General Counsel.

Add any additional Study-specific terms as needed. Include identification of any prospectively authorized assignment or delegation by Institution. If the additional term is intended to override an inconsistent provision of the Master Agreement, identify the inconsistent Master Agreement provision and obtain prospective approval to override it from Alliance Partner Legal (AP studies) or Pfizer Legal (CRO studies).

11. CRO Contact Information. Institution may deliver to CRO notices and other communications relating to this Study Order by hand, by courier, or by a postage-paid traceable method of mail delivery to the mailing address below, or such other address that CRO may later designate by written notice to Institution.

CRO:

_____
_____
_____

Attention: _____
Telephone: _____
Email: _____

Rest of page intentionally left blank.

AGREED TO AND ACCEPTED BY:

[NAME OF AP or OTHER CRO]	[INSTITUTION NAME]
_____	_____
_____	_____
Printed Name	Printed Name
_____	_____
Printed Title	Printed Title
Date:_____	Date: _____

I confirm that I have received a copy of the Master Agreement under which this Study Order is issued. I confirm that I have read and understand the Master Agreement and this Study Order and that I accept the terms as they relate to my activities as Principal Investigator.

_____ Date: _____

[Insert Name]
Principal Investigator

Attachment B-2
STUDY ORDER FOR NON-INTERVENTIONAL STUDY
UNDER PFIZER MASTER CLINICAL STUDY AGREEMENT

Use this Study Order template for an observational study (ie, prospective non-interventional study involving a Pfizer Product) contracted by an Alliance Partner or other CRO under a Pfizer US Master Clinical Study Agreement (MCSA) when the contracting party is an Institution. For sake of clarity, the term 'Product' or 'Pfizer Product' is used for a Pfizer Drug that has been approved in the market for a specific indication(s).

Pfizer Protocol Number: _____
Protocol Title: _____

This Study Order ("Study Order") is an agreement between

[Name of Alliance Partner or other CRO] ("CRO"), and

[Name and address of Institution] ("Institution")

This Study Order is issued under the Master Clinical Study Agreement between Pfizer Inc and Institution with an effective date of December 1, 2015 (the "Master Agreement"). Together with the Master Agreement, this Study Order governs the conduct of the Pfizer-sponsored non-interventional clinical study ("Study") identified above.

Pfizer has delegated to CRO responsibility for the management and monitoring of this Study, including negotiation and execution of this Study Order. Pfizer has further authorized CRO to bind Pfizer to all relevant commitments within the Master Agreement and this Study Order. Except as otherwise specified in this Study Order, any communication initiated by Institution in regard to the Study should be directed to CRO instead of Pfizer.

The Study to which this Study Order relates is non-interventional and consists of prospective data collection on patients who are receiving treatment with the Pfizer product _____ ("Pfizer Product") as part of their standard medical care for [*insert medical condition*]. *If Study will involve protocol-required tests, other types of patient monitoring, or data collection that would not have been performed as part of standard medical care, so indicate and provide a very brief general description of what will be done. If the additions constitute interventions, replace or qualify the description of the study as non-interventional (e.g., "…is non-interventional except for the performance of XXXXX testing, which requires collection of blood samples).*

1. Term. When signed by all parties, this Study Order has an effective date of _____ and will continue until terminated in accordance with the *Termination of Study Orders* provisions in the Master Agreement.

2. Principal Investigator. The Study will be conducted by Institution's investigator _____ *[include mailing address]* ("Principal Investigator").

3. Protocol. Institution and Principal Investigator acknowledge their previous receipt of a copy of the Protocol for the Study that is the subject of this Study Order.

4. Subject Enrollment. Institution agrees to use reasonable efforts to enroll Study Subjects during the CRO-specified enrollment period, unless CRO modifies the enrollment period by written notice. As used in this Study Order, "Study Subject" means a participant who is both enrolled in the Study and has met all the Protocol criteria for full participation. Only patients for whom the Pfizer Product has already been prescribed as part of standard medical care are eligible for inclusion in the Study. The opportunity for a patient to participate in the Study will play no role in the clinician's decision to prescribe the Pfizer Product.

Alternative Section 4:

Subject Enrollment. Institution agrees to use reasonable efforts to enroll in Study a minimum of _____ but no more than _____ Study Subjects by _____, unless CRO modifies this enrollment period by written notice. However, the Parties understand and acknowledge that enrollment numbers are subject to the individuals patients' best interest and/or willingness to participate, and therefore cannot be guaranteed. As used in this Study Order, "Study Subject" means a participant who is both enrolled in the Study and has met all the Protocol criteria for full participation. Only patients for whom the Pfizer Product has already been prescribed as part of standard medical care are eligible for inclusion in the Study. The opportunity for a patient to participate in the Study will play no role in the clinician's decision to prescribe the Pfizer Product.

5. Payee Information *Specify if different from that provided in the Master Agreement. If unchanged, reference the Funding section of the Master Agreement as follows:* CRO will make all payments under this Study Order payable as specified in the *Funding* section of the Master Agreement.

6. Pfizer Contact for Study Publications. Principal Investigator will use the address below to submit Publications relating to this Study directly to Pfizer, as described in the *Publications* section of the Master Agreement.

Pfizer Contact for Submission of Publications:
Insert contact information for Pfizer Study Clinician
_____
_____
Telephone: _____
Email: _____

7. Pfizer Contact for Study Records Retention Issues. Institution will contact Pfizer directly at InvestigatorRecords@Pfizer.com before destroying any Study Records relating to this Study, as further described in the *Study Records* section of the Master Agreement.

8. Exhibits. The Exhibits included in this Study Order are identified below.

Exhibit 1	Study Budget and Payment Terms
Exhibit 2	Equipment and Materials *(include only if applicable)*

9. Conflicts. If any Exhibits to this Study Order conflict with the terms of this Study Order, the Study Order will control. If this Study Order or any Exhibit conflicts with the terms of the Master Agreement, the Master Agreement will control except as specified in Section 10 (Additional Terms) below.

10. Additional Terms. Because this is not an interventional study and it is being contracted and managed by CRO instead of Pfizer, the following provisions are added to or modified from the Master Agreement for purposes of this non-interventional Study. Any and all such revisions to the Master Agreement under this section must be approved in advance by the Institution and the UT System Office of General Counsel.

If any "catch-up" entries will be included in Section 10 (see instructional text following Section 10.13 below), modify the Section 10 text above to read as follows: Because this is not an interventional study, it is being contracted and managed by CRO instead of Pfizer, and there have been certain changes in the external environment, the following provisions are added to or modified from the Master Agreement for purposes of this non-interventional Study.

10.1 The *Pfizer GCP Training* provision is omitted, in its entirety, because this requirement does not apply to this type of Study. *Revise or omit if the study team will, by exception, require GCP training for this observational study.*

10.2 The *Funding* section is supplemented to include the following new provision:

Basis of Study Participation. Institution's participation in the Study is not based on any pre-existing or future business relationship between CRO or Pfizer and either the Principal Investigator or Institution. It is also not

conditioned on any business or other decisions the Principal Investigator or Institution has made, or may make, relating to CRO, Pfizer, or Pfizer Products.

10.3 The *Charging Study Subjects* provision in the *Study Conduct* section is revised to read, in its entirety, as follows:

Charging Study Subjects. Institution will ensure that no Study Subject or third party payer is charged for any services reimbursed by CRO under this Study Order.

10.4 The heading of the *Safety Measures and Serious Breaches* provision in the *Study Conduct* section is changed to "*Serious Breaches*" and this provision is revised to read, in its entirety, as follows:

Serious Breaches. If Institution becomes aware of any serious breaches of (1) the Protocol or (2) any aspects of ICH GCP guidelines relevant to this type of study, Institution will inform CRO immediately.

If use of subject-directed recruitment materials will not be permitted in this Study, include the subsection 10.5 that follows. If recruitment materials will be permitted, do not include.

10.5 The heading of the *HIPAA Authorization, Informed Consent, and Subject Recruitment* section is revised to omit the reference to "Subject Recruitment." Also, the *Subject Recruitment* provision is omitted in its entirety as are subsequent references within the Master Agreement to that provision.

10.6 The *Investigational Drug* section is replaced, in its entirety, with the following:

Pfizer Product. Because this is a non-interventional study, CRO and Pfizer will not provide the Pfizer Product. Study Subjects will receive the Pfizer Product by prescription as part of their standard medical care.

10.7 The *Study Data* provision in the *Study Data, Biological Samples, and Study Records* section of the Master Agreement is replaced, in its entirety, with the following:

Study Data. During the course of the Study, Institution will collect certain data, as specified in the Protocol, and submit it to CRO ("Study Data"). Institution will ensure accurate and timely collection, recording, and submission of Study Data, consistent with CRO instructions. *IMPORTANT – If necessary, customize this subsection to accurately reflect the nature of the*

data to be collected and, if appropriate, how data collection will work and allocation of responsibility among the parties.

a. Ownership of Study Data. Subject to Principal Investigator's right to use Study Data to publish the results of the Study (see the *Publications* section of the Master Agreement) and the non-exclusive license that permits certain uses (see the *Non-Exclusive License* provision below), Pfizer is the exclusive owner of all Study Data.

b. Non-Exclusive License. Pfizer grants Institution a royalty free non-exclusive license, with no right to sublicense, to use Study Data for internal research, educational, or patient care purposes.

c. Medical Records. Study Subject-related medical records that are not submitted to CRO or Pfizer may include some or all of the same information as is included in Study Data; however, Pfizer makes no claim of ownership to those documents or the information they contain.

10.8 The *Monitoring* provision in the *Monitoring, Inspections, and Audits* section of the Master Agreement is replaced, in its entirety, with the following:

Monitoring. CRO and Pfizer reserve the right to monitor Study conduct in the manner that CRO or Pfizer deems appropriate to the circumstances, and Institution will reasonably cooperate with such activities. Upon reasonable notice and during regular business hours, Institution will permit CRO and Pfizer representatives access to the premises, facilities, Study Records, investigators, and research staff if and as required to monitor Study conduct.

10.9 The *Research Injury* definition in the *Indemnification and Research Injury* Attachment is supplemented for purposes of this Study as follows (added text shown in bold italics):

Research Injury. For purposes of this Indemnification and Research Injury Policy, the term "Research Injury" means adverse event, physical injury, or illness caused by treatment or procedures required by the Protocol that the Study Subject would not have received if the Subject had not participated in the Study. ***Because this is an observational study involving Study Subjects who are receiving prescribed treatment with the Pfizer Product as part of their standard medical care, an adverse reaction to the Pfizer Product would not be a Research Injury.*** Institution agrees to provide or arrange for prompt diagnosis and medical treatment of any Research Injury experienced by a Study Subject. Institution further agrees to promptly notify CRO of any Research Injury.

If any study-specific terms are needed for this Study, add them here. Include identification of any prospectively authorized assignment or delegation by Institution. If an additional term is intended to override an inconsistent provision of the Master Agreement, identify the inconsistent Master Agreement provision and obtain prospective approval to override it from Alliance Partner Legal (AP studies) or Pfizer Legal (CRO studies).

11. CRO Contact Information. Institution may deliver to CRO notices and other communications relating to this Study Order by hand, by courier, or by a postage-paid traceable method of mail delivery to the mailing address below, or such other address that CRO may later designate by written notice to Institution.

CRO:

_____
_____
_____
Attention: _____
Telephone: _____
Email: _____

AGREED TO AND ACCEPTED BY:

[NAME OF AP or OTHER CRO]	[INSTITUTION'S NAME]
_____	_____
_____	_____
Printed Name	Printed Name
_____	_____
Printed Title	Printed Title
Date:_____	Date: _____

I confirm that I have received a copy of the Master Agreement under which this Study Order is issued. I confirm that I have read and understand the Master Agreement and this Study Order and that I accept the terms as they relate to my activities as Principal Investigator.

_____ Date: _____

[Insert Name]
Principal Investigator

Exhibit 1
STUDY BUDGET AND PAYMENT TERMS

Pfizer Protocol Number: _____
Protocol Title: _____

Use the current AP-specific – or Pfizer/CRO-agreed upon -- Attachment A that is used with stand-alone Clinical Study Agreements (CRO and Institution version)

Before use, change the title and footer from "Attachment A" to "Exhibit 1"

Exhibit 2
EQUIPMENT AND MATERIALS

Pfizer Protocol Number _____
Protocol Title: _____

Pfizer-Provided Equipment and Materials

Pfizer-Provided Equipment

Pfizer will provide the equipment identified below ("Pfizer Equipment") for use by Institution in the conduct or reporting of the Study:

[If no equipment is being provided, the table below will be omitted and "NONE" will be entered after the colon above.]

#	Equipment	Serial #	Asset Tag #	Estimated Original Value	Estimated Depreciated Value at Study Completion
1					
2					
3					
4					
5					

[Estimated Original Value and Estimated Depreciated Value Columns are not needed if disposition Alternative #1 (return to Pfizer) is selected.]

Pfizer-Provided Materials

Pfizer will provide the proprietary materials owned or licensed by Pfizer and identified below ("Pfizer Materials") for use by Institution in the conduct or reporting of the Study.

Materials Supplied: _____

[If no Materials are being provided, "NONE" will be entered after the colon above.]

[If neither Pfizer Equipment nor Pfizer Materials will be provided, the subsections below will be omitted down to "Vendor-Provided Equipment or Materials."]

Permitted Uses of Pfizer Equipment and Pfizer Materials

Institution may use any Pfizer Equipment and Pfizer Materials only for purposes of this Study. *[Alternatively, specify permitted uses. If use for non-study patients is permitted for Pfizer*

Equipment, specify that (1) a charge will be assessed (deducted from Study funding) based on estimated or actual usage or (2) Institution agrees that use of the Pfizer Equipment for non-study patients will not be charged to the patient or third party payer. Non-study use of Pfizer Materials is generally not permitted.]

Disposition of Pfizer Equipment and Pfizer Materials

Alternative #1 – Return to Pfizer

After completion of Study conduct or at an earlier time specified by Pfizer, Institution will arrange for return of any Pfizer Equipment and Pfizer Materials, at Pfizer's expense, to Pfizer or a location designated by Pfizer.

Alternative #2 – Return of Materials to Pfizer and transfer of Equipment to Institution with value included in grant.

After completion of Study conduct or at an earlier time specified by Pfizer, Institution will arrange for return of any Pfizer Materials, at Pfizer's expense, to Pfizer or a location designated by Pfizer.

The total compensation for Study conduct has been calculated to include the depreciated value of Pfizer Equipment at the termination of this Master Agreement. Pfizer will transfer or arrange for transfer of title in Pfizer Equipment to Institution at the termination of this Master Agreement, provided that Institution has enrolled the targeted number of Study Subjects (or some lesser number of Study Subjects agreeable to Pfizer), has complied with the terms of the Master Agreement, and has satisfactorily completed all Protocol requirements. Pfizer will ensure that this transfer is documented in writing, and the parties hereby agree that the depreciated value of Pfizer Equipment at termination of this Master Agreement is part of the total compensation payable for Study conduct.

If any Pfizer Equipment is so transferred, it will be transferred 'as is' and Pfizer does not make any representation or provides any warranty of any kind concerning it.

Alternative #3 – Return of Materials to Pfizer and purchase of Equipment by Institution

After completion of Study conduct or at an earlier time specified by Pfizer, Institution will arrange for return of any Pfizer Materials, at Pfizer's expense, to Pfizer or a location designated by Pfizer.

After completion of Study conduct, Pfizer will make Pfizer Equipment available for purchase by Institution at its then depreciated value. If Study conduct is completed significantly earlier or later than originally estimated, the depreciated value identified in the table above will be adjusted accordingly. Pfizer will ensure that any transfer of ownership is documented in writing.

If any Pfizer Equipment is so transferred, it will be transferred 'as is' and Pfizer does not make any representation or provides any warranty of any kind concerning it.

Vendor-Provided Equipment or Materials

Pfizer will arrange for a vendor to provide the following equipment or proprietary materials ("Vendor Property") for use in this Study: _____

[If no Vendor Property is being provided, "NONE" will be entered after the colon above and e the two subsections that follow will be omitted.]

Permitted Uses of Vendor Property

Institution will use Vendor Property only for purposes of this Study. *[Alternatively, specify permitted uses.]*

Disposition of Vendor Property

The vendor will determine the disposition of Vendor Property after completion of Study conduct.

Ownership, Responsibilities, and Liability

Ownership. Pfizer Equipment, Pfizer Materials, and Vendor Property are and remain the property of Pfizer, the vendor, or the licensor, as the case may be.

Institution Responsibilities. Institution will bear the risk of loss or damage due to its negligence to Pfizer Equipment, Pfizer Materials, and Vendor Property. If any Pfizer Equipment, Pfizer Materials, or Vendor Property must be replaced by Pfizer or vendor during Study conduct as the result of loss or damage by Institution due to its negligence, Pfizer reserves the right to deduct, from future Study funding payments, the cost to Pfizer of the replacements.

Liability. Pfizer has no liability for damages of any sort, including personal injury or property damage, resulting from the use of Pfizer Equipment, Pfizer Materials, or Vendor Property except to the extent that (1) such damages were caused by the negligence or willful misconduct of Pfizer or the vendor or (2) a personal injury constitutes a Research Injury to a Study Subject, as described in Attachment A to this Master Agreement.