MASTER
INVESTIGATOR-INITIATED RESEARCH 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 Medical Branch at Galveston
The University of Texas Southwestern Medical Center
The University of Texas at Austin

TABLE OF CONTENTS

MASTER INVESTIGATOR-INITIATED RESEARCH AGREEMENT

This Master Investigator-Initiated Research ("IIR") Agreement ("Agreement") between

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

And each of the following member institutions of The University of Texas System:
The University of Texas Health Science Center at San Antonio
The University of Texas Health Science Center at Houston
The University of Texas Health Science Center at Tyler
The University of Texas Medical Branch at Galveston
The University of Texas Southwestern Medical Center
The University of Texas at Austin

Each identified "Institution" or collectively, "Institutions". The principal place of business and a contact person for each Institution are listed in Appendix A.

when signed by all parties, is effective as of December 1, 2015 ("Effective Date").

Pfizer is a research-based pharmaceutical company with an interest in research projects related to the development or further investigation of pharmaceutical products or medical devices. Pfizer has related interests in disease research and development or investigation of research or clinical methodologies.

Institution is an educational, healthcare and research facility with expertise in the area of health research.

Pfizer wishes to establish a contractual relationship with Institution to facilitate the provision by Pfizer, from time to time, of support to Investigator-Initiated Research ("IIR") projects conceived and conducted by Institution. "IIR Support" generally consists of free Pfizer product or compound, funding, use of capital equipment, or any combination of those.

As of the Effective Date, this Agreement supersedes and replaces that certain Master Investigator Initiated Research Grant Agreement effective June 1, 2010, as amended ("2010 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 2010 Master and which is still in progress as of the Effective Date will continue to be governed by the 2010 Master.

The parties agree as follows:

1. Nature and Scope of Agreement

1.1 Research Studies. IIR projects ("Studies") considered for support by Pfizer could include any of the following:

a. Interventional clinical studies
b. Prospective observational clinical studies
c. Retrospective (records based) human subject research
d. Preclinical studies (animal or in vitro)

1.2 Nature of Agreement. As a master form of contract, this Agreement establishes the general terms for the conduct and support of IIR Studies and allows the parties to contract for IIR Support to individual Studies through the execution of Study Orders (defined below) rather than full agreements. In addition to Studies conducted solely at Institution, multicenter Studies for which Institution will serve as sponsor and coordinator may also be contracted under this Agreement (see Section 12.1.a, Sub-contracting to Other Study Sites). This Agreement does not obligate Institution to request or Pfizer to provide IIR Support for any particular Study.

1.3 Study Order. IIR Support for each IIR will be contracted by the execution of an individual "Study Order." The Study Order will identify the Principal Investigator (as defined below in Section 2.1) and the project, and will describe the nature of the IIR Support (as defined above and in Section 5 below), including a payment schedule if the IIR Support includes funding. Studies conducted under a Study Order are subject to all applicable terms in this Agreement. In certain instances, the Study Order may also include terms and requirements that are specific to that Study and included in Section 8 of the Study Order. Each Study Order must be signed by authorized officials of both parties and acknowledged by the Principal Investigator and each Study Order is incorporated by reference into this Agreement upon its execution.

a. Study Order Template. The format and content of a Study Order is illustrated in template form in Exhibit 1 to this Agreement. Upon mutual agreement of the parties, the Study Order template may be modified from time to time during the term of this Agreement by amendment to this Agreement or adapted on a Study-specific basis to better meet the needs of a particular Study.

b. Execution by Affiliates. Any Affiliate of Pfizer (as defined in Section 15.2, Affiliates) may execute a Study Order under this Agreement, without requiring Pfizer to be a signatory to that Study Order.

c. No Obligation Without Study Order. Neither party has any obligation to the other for Study conduct or IIR Support related to a particular Study in the absence of an executed Study Order.

2. Investigators and Research Staff

2.1 Principal Investigator. Each Study supported under this Agreement will be conducted under the direction of the Institution investigator identified in the applicable Study Order as "Principal Investigator." For Studies that are clinical studies, Principal Investigator may delegate duties and responsibilities to sub-investigators or research staff only to the extent permitted by applicable laws governing the conduct of clinical investigations. If the Principal Investigator for a particular interventional clinical Study is not qualified to prescribe drugs (e.g., a Principal Investigator who is a PhD or PharmD), the Principal Investigator will ensure oversight of drug administration and subject safety by a medically qualified sub-investigator.

2.2 Obligations of Institution. Institution is responsible to Pfizer for compliance by all personnel who participate in the conduct of the Study, including the Principal Investigator and any contractors or consultants, with the terms of this Agreement and the applicable Study Order.

3. Protocol

3.1 Protocol. Each Study will be conducted in accordance with a protocol developed by the Principal Investigator ("Protocol"). Pfizer approval of the final Protocol is a condition of Pfizer support under any Study Order. Before the Study Results (see Section 10, Publications) are published, Pfizer will only share the Protocol with Pfizer employees, contractors, or consultants, will not disclose it to third parties, and will not make it available on any publicly available website or other public forum.

3.2 Amendments. If a Principal Investigator modifies the Pfizer-approved final Protocol, the Principal Investigator will promptly inform Pfizer in writing. Continued support by Pfizer will be contingent on Pfizer's review and acceptance of the Protocol changes.

4. Study Conduct

4.1 Sponsorship. Institution, not Pfizer, is the sponsor of the Studies. Institution will not represent to any third party, including Study subjects, that Pfizer is a sponsor.

4.2 Regulatory. Institution is solely responsible for any and all safety reporting and regulatory obligations associated with the conduct of each Study, including, but not limited to, obtaining and maintaining regulatory authorization for the conduct

of the Study, if required.

4.3 Standards. Principal Investigator will conduct each Study in accordance with the Protocol and all applicable law.

a. Studies Involving Human Subjects or Biological Sample Donors. Principal Investigator will comply with International Conference on Harmonization Good Clinical Practice (ICH GCP) guidelines to the extent applicable to the type of study being conducted.

1) Non-Interventional Studies. For prospective observational studies and retrospective human research studies (collectively, "non-interventional clinical studies"), Principal Investigator will also follow generally accepted research practices for this type of study, 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), or the equivalent.

2) 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 World Health Organization Guiding Principles on Human Cell, Tissue and Organ Transplantation (WHA63.22).

b. Studies Involving Research Animals. Principal Investigator will ensure that the Study is approved by and subject to continuing oversight by the responsible Institutional Animal Care and Use Committee (IACUC) and that any animals used in the Study are handled, housed, and, as appropriate, disposed of in accordance with recognized guidelines for research use of animals, such as those issued by the National Institutes of Health (NIH) or the Council for International Organizations of Medical Sciences (CIOMS).

c. Registration and Disclosure of Results. Pfizer encourages Institution to register any prospective clinical Study involving a Pfizer product on www.ClinicalTrials.gov or, for relevant non-interventional studies and as applicable, the European Union Post-Authorisation Study register www.encepp.eu/encepp_studies/indexRegister.shtml before enrollment of the first subject or the start of data collection. Pfizer further encourages Institution to publicly disclose the results of any Study through publication

(see Section 10, Publications), posting on a publicly available information repository, or other means.

4.4 IRB Approval. If required for a particular Study, Institution will ensure that the Study is approved and subject to continuing oversight by an appropriate Institutional Review Board (IRB). As a condition of Pfizer's IIR Support, Institution must provide Pfizer, for each Study for which IRB approval is required, with documentation of both the initial IRB approval of the final Protocol and annual renewals of that approval. Institution will notify Pfizer promptly of any withdrawal or suspension of such IRB approval during the term of the applicable Study Order.

4.5 Informed Consent. If required for a particular Study, Principal Investigator will obtain informed consent for each subject in accordance with 21 Code of Federal Regulations Part 50 or, if appropriate, will obtain a waiver of informed consent for the Study from an appropriate IRB. If an informed consent is used, Principal Investigator will inform Study subjects that Pfizer is providing support for the Study. Pfizer has no obligation to participate in the development of, or to review or comment on, the informed consent form.

4.6 No Monitoring or Data Collection. Pfizer will not monitor the Study or receive any Study Data (as defined in Section 8, Study Data and Study Results), except as described in Section 4.7, Reporting of Serious Adverse Events or Section 4.8, Reporting of Nonclinical Adverse Findings.

4.7 Reporting of Serious Adverse Events. This Section 4.7 applies only to interventional clinical Studies that involve the use of a Pfizer Product (see Section 6, Pfizer Product or Compound), whether Pfizer supplies the product or not. Different requirements will apply to prospective or retrospective non-interventional studies that focus on a Pfizer Product or if an interventional study involves a certain type of Pfizer product (ie, a product that is or includes a medical device, certain long-marketed oncology products with a well established safety profile, and certain in-licensed products). Any such differing requirements will be documented in the Study Order for the affected Study.

a. Reporting Requirement. Within 24 hours of first awareness of the event (immediately if the event is fatal or life-threatening), Principal Investigator will report to Pfizer by facsimile any Serious Adverse Event ("SAE," as defined below) for which reporting is required under this provision. SAEs are to be reported for (1) Study subjects who are assigned or, in the case of a blinded Study, possibly assigned to receive the Pfizer Product (see Section 6, Pfizer Product or Compound) or (2) individuals otherwise exposed to the Pfizer Product as described below. A Principal Investigator should report an SAE as soon as it is determined to meet the definition, even if complete information is not yet available.

b. Reporting Forms. Principal Investigator will report SAEs using one of the following forms: (1) an FDA MEDWATCH form, (2) a CIOMS form, (3) a Pfizer-provided *Investigator-Initiated Research Serious Adverse Event Form* or (4) any other form prospectively approved by Pfizer. The *Reportable Event Fax Cover Sheet* provided by Pfizer must also be included with each SAE submitted.

c. SAE Definition. An SAE is any adverse event at any time, without regard to causality, that is life-threatening (ie, causes an immediate risk of death) or that results in any of the following outcomes: death; in-patient hospitalization or prolongation of existing hospitalization; persistent or significant disability or incapacity (ie, substantial disruption of the ability to conduct normal life functions); or a congenital anomaly or birth defect. Any other medical event that, in the medical judgment of the Principal Investigator, may jeopardize the subject or may require medical or surgical intervention to prevent one of the outcomes listed above is also considered an SAE. A planned medical or surgical procedure is not, in itself, an SAE.

d. Exposure or Lack of Effect. Even though there may not be an associated SAE, exposure to the Pfizer Product during pregnancy, exposure to the Pfizer Product during lactation, and occupational exposure to the Pfizer Product are reportable, and lack of effect of the Pfizer Product may also be reportable. These requirements are further explained in the training material provided by Pfizer (see Section 4.7.j, Pfizer-Provided Training). As used in this Agreement, the term SAE will be understood to include exposure during pregnancy, exposure during lactation, occupational exposure, and reportable instances of lack of effect.

e. Hy's Law Cases. For any interventional Study involving a Pfizer Product that is not yet approved for marketing in the US for the indication being studied, cases of potential drug-induced liver injury as assessed by laboratory test values ("Hy's Law Cases") are also reportable to Pfizer. If a Study subject develops abnormal values in aspartate transaminase ("AST") or alanine transaminase or both, concurrent with abnormal elevations in total bilirubin and no other known cause of liver injury, that event would be classified as a Hy's Law Case. This reporting requirement is further explained in the training material provided by Pfizer (see Pfizer-Provided Training, below). As used in this Agreement, the term SAE will be understood, for applicable Studies, to also include Hy's Law Cases. The Study Order for each interventional clinical Study will specify whether or not reporting of Hy's Law Cases is required for that Study.

f. Exclusions from SAE Reporting Requirements. Specifically excluded from the reporting requirements for SAEs under this provision are any SAEs identified in the Protocol as anticipated to occur in the Study population at some frequency independent of drug exposure, unless the Principal Investigator determines or concludes such an events as related to the Pfizer Product. Also specifically excluded from the reporting requirements, for oncology drugs only, is any SAE judged by the Principal Investigator to represent progression of the malignancy under study, unless it results in death within the SAE Reporting Period.

g. SAE Reporting Period. Unless the Protocol specifies a longer period, the SAEs subject to this reporting provision are those that occur from after the first dose of the Pfizer Product through 28 calendar days after the last administration of the Pfizer Product. In addition, if the Principal Investigator becomes aware of an SAE occurring any time after the end of this reporting period, Principal Investigator should report that SAE to Pfizer if the Principal Investigator suspects a causal relationship between the Pfizer Product and the SAE.

h. Follow-Up Information. Institution will assist Pfizer in investigating any SAE and will provide any follow-up information reasonably requested by Pfizer.

i. Regulatory Reporting. Reporting an SAE to Pfizer does not relieve Institution of responsibility for reporting it to FDA or other appropriate Regulatory Authorities as required.

j. Pfizer-Provided Training. Pfizer will make available training material that provides information about the SAE reporting requirements for IIR studies. Institution will ensure that the Principal Investigator will review this material and share it with any Study staff engaged in the reporting of SAEs.

4.8 Reporting of Preclinical Adverse Findings. This Section 4.8 applies only to preclinical Studies that involve the use of a Pfizer Compound or Product (see Section 6, Pfizer Product or Compound). Within 24 hours after discovery, Principal Investigator will report to Pfizer any adverse experience associated with the use of the Pfizer Compound or Product that is both serious and unexpected, as well as any finding that suggests a significant risk for human subjects, including reports of mutagenicity, teratogenicity or carcinogenicity. Principal Investigator will submit such a report to Pfizer by Email to CTPGrants@pfizer.com.

4.9 Biological Samples. For a laboratory Study that involves the use of human biological specimens such as blood, tissue, urine, saliva, skin, etc ("Biological

Samples"), the following terms apply.

a. Biological Samples Provided by Pfizer

(1) Source. Unless otherwise specified in the Study Order, Biological Samples provided by Pfizer will have been obtained from subjects participating in a Pfizer study ("Pfizer Study Subjects").

(2) Personal Data. Each Biological Sample may be marked with or accompanied by certain information that could include Personal Data, as that term is defined in Section 15.3, Personal Data, relating to the Pfizer Study Subject from which it was obtained.

(3) Consent. Pfizer will ensure that the transfer of the Biological Samples and any associated Personal Data to Institution and Institution's use of the Biological Samples and Personal Data as specified in the Protocol are both in compliance with any applicable privacy laws and are consistent with the informed consent or waiver of informed consent under which the Biological Samples and Personal Data were obtained.

(4) Standards. Principal Investigator will comply with all applicable laws and institutional and IRB requirements for studies involving the use of Biological Samples.

(5) Data Privacy and Security

(a) Compliance with Law. Institution will ensure compliance with applicable data privacy and security laws in regard to Institution's use and disclosure of any Personal Data relating to the Biological Samples.

(b) Safeguards. Institution will apply adequate, commercially reasonable electronic, physical, and other safeguards appropriate to the nature of the information to prevent any unauthorized or unlawful use, access, alteration, loss, or disclosure of Personal Data relating to the Biological Samples ("Security Breach"). Institution will also implement appropriate internal policies, procedures, or protocols to minimize the risk of occurrence of a Security Breach.

(c) Security Breach. Institution will notify Pfizer within ten (10) days of discovery of any Security Breach. Institution will also take immediate steps to consult with Pfizer in

good faith in the development of remediation efforts to rectify or mitigate the Security Breach. Institution will undertake remediation efforts at its sole expense or will reimburse Pfizer for Pfizer's reasonable expenses incurred in connection with Pfizer-performed remediation efforts.

(d) Identification of Study Subjects. If Institution receives key-coded or otherwise de-identified or anonymized data relating to the Biological Samples, Institution will not attempt to identify the Pfizer Study Subjects to which the data relates and will implement appropriate internal policies, procedures, or protocols to minimize the risk of any such identification. If Institution receives or obtains from Pfizer any information that unintentionally reveals the identity of a Pfizer Study Subject, Institution will notify Pfizer within ten (10) days of discovery of the identification. Institution will then cooperate with Pfizer to remedy the unintentional disclosure and to minimize the risk of recurrence.

(6) Ownership, Use, and Disposition. Biological Samples and Personal Data provided to Institution by Pfizer are and remain the property of Pfizer. Institution will use Biological Samples and Personal Data only as specified in the Protocol. Institution will not allow access by, nor will Institution transfer Biological Samples or Personal Data to, any third party without prospective written approval from Pfizer. If Pfizer grants such approval, Institution will ensure that the third party is bound by terms regarding the protection and use of the Biological Samples and Personal Data that are no less restrictive than those set forth in this Agreement. Any other transfer or use of the Biological Samples or Personal Data constitutes a material breach of this Agreement. At the conclusion of the Study, Institution will retain any unused Biological Samples and Personal Data until instructed by Pfizer as to return or destruction. Any unauthorized research use of Pfizer-provided Biological Samples is subject to the Unauthorized Research provision of this Agreement (see Section 7, Unauthorized Research).

(a) No Genetic Testing. Unless such testing is specified in the Protocol, Institution will not perform any Genetic Test on the Biological Samples. As used in this Agreement, the term "Genetic Test" includes any testing or analysis of human genes, gene products, DNA, RNA, chromosomes, proteins, or metabolites that detect genotypes, mutations,

chromosomal changes, abnormalities, or deficiencies, including carrier status, that (i) are linked to physical or mental disorders or impairments, (ii) indicate a susceptibility to illness, disease, impairment, or other disorders, whether physical or mental, or (iii) demonstrate genetic or chromosomal damage due to environmental factors. Genetic Test does not include routine physical measurements; chemical, blood and urine analyses that are widely accepted and in use in clinical practice; tests for presence of drugs; tests for the presence of the human immunodeficiency virus; analyses of proteins or metabolites that do not detect genotypes, mutations, chromosomal changes, abnormalities, or deficiencies; or analyses of proteins or metabolites that are directly related to a manifested disease, disorder, or pathological condition that could reasonably be detected by a health care professional with appropriate training and expertise in the field of medicine involved. If the Protocol includes any Genetic Tests, Institution will perform only those tests specified.

(7) Significant Individual Research Results. If Protocol-specified testing of the Biological Samples yields results relating to a specific Pfizer Study Subject that a reasonable physician would consider to have significant implications for an individual's health, Institution will promptly report to Pfizer the results and the key-code identification numbers of the Biological Samples for which those results were found.

b. Biological Samples Provided by Institution

(1) Consent. Principal Investigator will (a) obtain informed consent from each individual who donates Biological Samples ("Sample Donor") in accordance with 21 Code of Federal Regulations Part 50, (b) ensure that informed consent that covers the research to be conducted has already been obtained, or (c) obtain a waiver of informed consent for the use of the Biological Samples in the Study from an appropriate IRB. Principal Investigator will also ensure compliance with applicable privacy laws in regard to the use and disclosure of Personal Data relating to the Sample Donors. If an informed consent is used, Principal Investigator will inform Sample Donors that Pfizer is providing support for the Study. Pfizer has no obligation to participate in the development of, or to review or comment on, an informed consent form, authorization, or

waiver request.

(2) Standards. Principal Investigator will comply with all applicable laws and institutional and IRB requirements for studies involving the use of Biological Samples.

(3) Ownership and Disposition. Pfizer makes no claim of ownership to Biological Samples provided for the Study by Institution. Institution is responsible for appropriate disposition of any remaining Biological Samples at the end of the Study.

4.10 Status Updates. The Principal Investigator for each Study will provide Pfizer with an update of Study status, in the form requested by Pfizer, at least once a year during the term of the relevant Study Order, or more frequently if so indicated in the Study Order or as mutually agreed in writing by the parties. Each status update will include information on subject enrollment or Study progress, publication plans, any adjustments in estimated Study conduct completion date, and any other information reasonably requested by Pfizer.

4.11 Notifications to Pfizer. If a Principal Investigator becomes aware during the conduct of a clinical Study involving a Pfizer Product of any of the following information or circumstances relating to the Pfizer Product, the Principal Investigator will promptly notify Pfizer. Principal Investigator is to provide such notification upon awareness, even if complete information is not yet available.

a. Imposition by an applicable competent regulatory authority in any area of the world in which the Pfizer Product is marketed of any prohibition or restriction of the Pfizer Product's use.

b. Any new information that might influence the evaluation of the risks and benefits of the Pfizer Product. This could include both positive and negative results from clinical trials or other studies in relation to all indications and populations, whether or not use of the product in that indication or population is approved under the relevant marketing authorization.

5. Investigator-Initiated Research Support ("IIR Support"). The IIR Support provided by Pfizer for a particular Study may include funding, free Pfizer Product or Compound (as defined in Section 6, Pfizer Product or Compound), use of capital equipment, or any combination of those. If IIR Support for a particular Study includes free Pfizer Product or Compound, use of such material is governed by Section 6 (Pfizer Product or Compound). If IIR Support includes Pfizer funding, Pfizer will provide that funding as delineated in Attachment A (Payment Schedule) of the applicable Study Order and subject to any additional terms specified in that Attachment. If IIR Support includes the use of equipment for Study conduct, that equipment will be identified in Attachment C

(Capital Equipment) of the applicable Study Order and its use will be subject to the requirements in that Attachment.

5.1 Basis of Support. IIR Support is not conditioned on any pre-existing or future business relationship between Pfizer and Institution or any Principal Investigator. It is also not conditioned on any business or other decisions a Principal Investigator or Institution has made, or may make, relating to Pfizer or Pfizer products.

5.2 Submission of Required Documents. Pfizer will not provide any component of the IIR Support until Pfizer has received the required documents identified in Attachment B (Study Documentation Requirements) of the relevant Study Order.

5.3 Use of IIR Support. The Principal Investigator and Institution will use IIR Support solely for purposes of the Study for which it was provided. At the completion of each Study, Principal Investigator will confirm in writing that the IIR Support has been used only to support that Study by completing a *Certification of Study Closure* form provided by Pfizer. For Studies that are prospective clinical trials, IIR funds may not be used to pay physicians for referring potential subjects for enrollment in the Study.

5.4 No Charge to Study Subjects. Institution will not charge Study subjects, insurers, or any other third parties for any product provided by Pfizer or any Study services covered by IIR funding.

5.5 Disclosure and Reporting by Pfizer. Pfizer is subject to certain U.S. 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, including their implementing regulations, are collectively referred to as "Transparency Laws." To comply with applicable Transparency Laws as well as Pfizer policy relating to transparency in its financial relationships with investigators and study sites, Pfizer may disclose in any lawful manner the terms of a Study Order and the support that Pfizer provides 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.

6. Pfizer Product or Compound. If IIR Support for a particular Study includes a Pfizer product ("Pfizer Product") or a Pfizer compound ("Pfizer Compound"), Pfizer will provide, free of charge, sufficient supplies of that Pfizer Product or Compound to conduct that Study. Pfizer Products are finished goods formulations suitable for use in human subjects. Pfizer Compounds consist of active drug substance in a form other than finished goods and are not to be used in humans. When providing Pfizer Product for human use, Pfizer will perform a quality release for the intended use, and will also provide relevant safety information, including expiration dating.

6.1 Packaging and Labeling. Pfizer may choose to provide commercial supplies of Pfizer Product (ie, product that is packaged and labeled for sale in the U.S.). As Study sponsor, Institution is responsible for any re-labeling or special packaging of such Product needed to make it appropriate for use in the Study. Institution will ensure that any packaging, labeling, or testing of Pfizer-provided Product performed by or at the direction of the Institution is in compliance with applicable law.

6.2 Custody and Dispensing. The Principal Investigator will maintain appropriate control of supplies of the Pfizer Product or Compound and will not provide it to anyone else except research staff who are directly involved in Study conduct at that Study site.

6.3 Expired or Unused Supplies. The Principal Investigator will monitor the expiration status of all supplies of Pfizer-provided Pfizer Product, ensure that Study subjects only receive Pfizer Product that is within its expiration dating, and provide Pfizer with sufficient notice (as defined by mutual agreement of the parties before Study initiation) if resupply is needed because of pending expiration of existing supplies. If Pfizer provides expiration dating for Pfizer Compound, the Principal Investigators will monitor the expiration status of the supplies and ensure that only Pfizer Compound that is within its expiration dating is used in the Study. Unless otherwise instructed by Pfizer in writing, Institution will destroy any supplies of Pfizer Product or Compound that expire during the term of this Agreement, as well as all supplies that remain unused at the termination of this Agreement. Institution will destroy these materials in accordance with all applicable law and institutional policies.

6.4 Product Complaints. Principal Investigator will promptly report to Pfizer any suspected quality defect in the Pfizer Product or its Pfizer-provided packaging or labeling (collectively, "Product Complaint"). Principal Investigator will report Product Complaints for all Studies that involve a Pfizer Product, whether Pfizer has supplied the Pfizer Product used in the Study or not. Pfizer will investigate and assess the Product Complaint and Institution will reasonably cooperate with

Pfizer in this activity.

6.5 Product Recalls. Should Pfizer decide to institute a product recall, for any reason, Pfizer will coordinate the recall for any ongoing Study for which Pfizer has supplied Pfizer Product. Institution will reasonably cooperate with Pfizer in this process and, for multicenter Studies (see Section 12.1.a, Sub-contracting to Other Study Sites), will ensure the cooperation of Participating Sites.

6.6 Ownership and Permitted Use. Except for, and limited to, the use specified in the Protocol, Pfizer grants Principal Investigator or Institution no express or implied intellectual property rights in the Pfizer Product or Compound or in any methods of making or using the Pfizer Product or Compound. Principal Investigator will use the Pfizer Product or Compound only as specified in the Protocol. Any other use of the Pfizer Product or Compound constitutes a material breach of this Agreement. Any unauthorized research use of a Pfizer Product or Compound is subject to the Unauthorized Research provision of this Agreement (see Section 7, Unauthorized Research).

6.7 Confidential Product Information. Pfizer or a Pfizer Affiliate (see Section 15.2, Affiliates) may provide Institution certain confidential information about a Pfizer Product or Compound, a Pfizer clinical trial from which Biological Samples were obtained, or Pfizer or Pfizer Affiliate technology, research, or business plans relating to a Pfizer Product or Compound. Pfizer or a Pfizer Affiliate may provide such information to Institution in writing or other tangible form marked as CONFIDENTIAL or may initially disclose such information orally and then summarize and confirm it in writing as CONFIDENTIAL within thirty (30) days after the date of oral disclosure ("Confidential Information").

a. Exclusions. Confidential Information does not include information that
   1) is known or open to the public or otherwise in the public domain at the time of disclosure,
   2) becomes part of the public domain by any means other than breach of this Agreement by Institution,
   3) is already known to Institution at the time of disclosure and is free of any obligations of confidentiality,
   4) is independently developed by individuals within Institution without use of or reference to the Confidential Information, or
   5) is obtained by Institution, free of any obligations of confidentiality, from a third party that has a lawful right to disclose it.

b. Obligations of Confidentiality. Unless Pfizer provides prior written consent, Institution may not use Confidential Information for any purpose except to conduct the Study, nor may Institution disclose Confidential Information to any third party except as authorized in this Agreement or as required by law.

1) Pfizer specifically authorizes any necessary disclosure of Confidential Information to IRB or regulatory authority representatives.
2) For a multicenter Study (see Section 12.1.a, Sub-contracting to Other Study Sites), Pfizer also specifically authorizes Institution to disclose Confidential Information as appropriate to Participating Investigators and Participating Sites.

c. Disclosure Required by Law. If disclosure of Confidential Information other than as expressly permitted under this Agreement is required by law, regulation, or court order that disclosure does not constitute a breach of this Agreement so long as Institution
1) notifies Pfizer in writing as far as possible in advance of the disclosure so as to allow Pfizer to take legal action to protect its Confidential Information,
2) discloses only that Confidential Information required to comply with the legal requirement, and
3) continues to maintain the confidentiality of this Confidential Information with respect to all other third parties.

d. Survival of Obligations. These obligations of nonuse and nondisclosure of Confidential Information survive termination of the Study Order under which the Confidential Information was disclosed and continue for a period of five (5) years after such termination.

7. Unauthorized Research. If Institution or Principal Investigator uses, or permits others to use, Pfizer-provided Product, Compound, or Biological Samples for any research not authorized by the Protocol, Pfizer will be the exclusive owner of the results of that research ("Unauthorized Research Results"), including any inventions or discoveries that arise out of it, whether patentable or not ("Unauthorized Inventions"). Institution will assign to Pfizer, or ensure assignment to Pfizer, all interest in Unauthorized Research Results and Unauthorized Inventions and will cooperate with Pfizer to ensure execution and delivery of all documentation that Pfizer reasonably deems necessary to perfect Pfizer's rights in the Unauthorized Research Results and Unauthorized Inventions.

7.1 Assignment Prohibited. If Institution or any inventor is prohibited by law from assigning its interest in an Unauthorized Invention to Pfizer, Institution will instead grant, or ensure that all inventors grant, to Pfizer a fully paid, perpetual, worldwide, royalty-free exclusive license for all purposes, including full rights to sublicense and assign, to each such Unauthorized Invention.

8. Study Data and Study Results. For purposes of this Agreement, "Study Data" means the raw, non-aggregated data collected during the course of the Study. "Study Results" refers to aggregated or summarized Study Data and conclusions about the Study, as would be included in a study report or publication. Principal Investigator is free to publish the Study Results, subject to the provisions in Section 10 (Publications) and

Principal Investigator and Institution are free to use Study Results for any other purpose. Institution owns and is free to use Study Data for its own research, educational, and patient care purposes and programs. However, in consideration of the Pfizer IIR Support, Principal Investigator and Institution will not use or permit others to use the Study Data for the commercial benefit of any third party.

9. Study Report. Within six (6) months after completion of Study conduct or termination of the applicable Study Order, whichever occurs first, Principal Investigator will provide Pfizer with a written report of the Study Results ("Study Report"). Unless otherwise agreed in writing by the parties, the Study Report may take the form of a manuscript for publication (see Section 10, Publications). For a multicenter Study (see Section 12.1.a, Sub-contracting to Other Study Sites), the Study Report will include the Study Results of the Study as a whole. If the Study Order is terminated early, the Study Report must include, at minimum, the results of the Study up until the date of termination.

10. Publications. Pfizer supports the exercise of academic freedom and encourages Institution to publish the Study Results of each Study, whether or not the results are favorable to Pfizer or any Pfizer product. As used in this Agreement, "Publication" means any journal article, abstract, presentation, or other type of public disclosure that reports any Study Results.

10.1 Pre-Publication Review. The Principal Investigator or other appropriate Institution authors ("Authors") will provide Pfizer an opportunity (a minimum of sixty (60) days before submission or other public disclosure) to prospectively review any proposed Publication. Pfizer may provide comments on content and will, for Studies involving the use of a Pfizer Product or Compound, review for unprotected Product-Related Inventions (see Section 11, Inventions). Authors will consider any Pfizer comments in good faith but are under no obligation to incorporate any Pfizer suggestions. Before any publication, Pfizer will not use the proposed Publication for any purpose other than internal review, will disclose it only to Pfizer employees, contractors, or consultants with a need to know, and will not disclose it publically or to any third parties.

10.2 Redaction of Confidential Information. If the Study involves the use of a Pfizer Product or Compound and Pfizer has provided any Confidential Information, the Authors will, on written request, remove any previously undisclosed Confidential Information from the Publication before disclosure, except for any such information necessary to the appropriate scientific presentation or understanding of the Study Results.

10.3 Standards. For all Publications, Authors will 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.

10.4 Disclosure of Support. Authors will disclose Pfizer IIR Support of the Study in any Publication.

10.5 Multicenter Studies. For a multicenter Study (see Section 12.1.a, Sub-contracting to Other Study Sites), the first Publication will present the overall Study Results from all Participating Sites, including Institution. Institution will provide the data analysis and oversee the preparation of this joint Publication. After such Publication of the overall Study Results, each Participating Site is free to publish separately, subject to the terms of this Section 10.

11. Inventions. Rights to any invention or discovery, whether patentable or not, that results from the conduct of the Study ("Invention") will be determined according to this provision.

11.1 Ownership. Any Invention made solely by one or more employee or contractor (collectively, "staff") of Institution or, in the case of a multicenter Study, a Participating Site (see Section 12.1.a, Sub-contracting to Other Study Sites), will be solely owned by Institution or Participating Site. Any Invention made solely by Pfizer staff will be solely owned by Pfizer. Inventions made jointly by Institution/Participating Site staff and Pfizer staff will be jointly owned by Institution/Participating Site and Pfizer. Inventorship will be determined according to United States (U.S.) law. Institution/Participating Site and Pfizer will each retain its right to practice and exploit its undivided interest in any jointly owned Invention without the consent of and without accounting to its co-owner.

11.2 Product-Related Inventions

a. In a Study involving use of a Pfizer Product, a "Product-Related Invention" is any Invention (as defined in Section 11, above) that encompasses treatment with, or the delivery, manufacture, form, formulation, or use of, the Pfizer Product (including use in combination with other products or agents), or that is or relates to a biomarker useful in selecting patients for treatment with the Pfizer Product.

b. In a Study involving use of Pfizer Compound, a "Product-Related Invention" is any Invention that encompasses treatment with, or the delivery, manufacture, form, formulation, or use of, any Pfizer product that contains the active ingredient found in the Pfizer Compound (including use in combination with other products or agents), or that is or relates to a biomarker useful in selecting patients for treatment with such a Pfizer product.

11.3 Non-Exclusive License to Pfizer. Institution will grant, or, for a multicenter Study (see Section 12.1.a, Subcontracting to Other Study Sites) in which Inventions are not assigned to Institution, ensure that the relevant Participating Site grants, to Pfizer a fully paid, perpetual, worldwide, non-exclusive, royalty-free license for all purposes to each Product-Related Invention owned by Institution or a Participating Site. Such non-exclusive license will include the rights to (1) sublicense to Pfizer Affiliates (see Section 15.2, Affiliates), contractors, or collaborators working for the benefit of Pfizer or in connection with a Pfizer, Pfizer Affiliate, or collaboration product or service, and (2) sublicense or assign to a successor in interest to some or all rights in a Pfizer product to which the Product-Related Invention is relevant.

11.4 Option to an Exclusive License. Institution further grants, or will ensure that the relevant Participating Site grants Pfizer an option to negotiate an exclusive worldwide license if legally able to do so for all purposes, with full rights to sublicense and assign, to each Product-Related Invention owned in whole or in part by Institution or Participating Site, under terms to be negotiated in good faith between the parties.

11.5 Confidentiality of Disclosed Inventions. Until the earlier of (1) action has been taken to protect the Product-Related Invention's patentability, or (2) the Product-Related Invention owner or owners have notified Pfizer that they will not pursue a patent, Pfizer will not use the information it receives about any Product-Related Invention on which Pfizer is not a joint inventor for any purpose other than internal review, will disclose it only to Pfizer employees, contractors, or consultants with a need to know, and will not disclose it publically or to any third parties without written consent from an owner of the Product-Related Invention unless required by law, including applicable regulations.

12. Assignment and Delegation

12.1 By Institution. Unless authorized in the Study Order, Institution may not assign any rights nor may Institution delegate or subcontract ("delegate") any duties under this Agreement or any Study Order without written permission from Pfizer. If Pfizer authorizes any delegation of duties, Institution remains responsible to Pfizer for the performance of those duties.

a. Subcontracting to Other Study Sites. A Study Order may authorize Institution to identify appropriate principal investigators and study sites ("Participating Investigators" and "Participating Sites") and to contract with those investigators or sites to perform the same Study to be performed by Institution. The Institution's Principal Investigator will serve as the "Coordinating Investigator" for the multicenter Study. In such a circumstance the following terms apply, unless agreed otherwise by

the parties and documented in the applicable Study Order.

(1) Written Agreements. Institution will enter into written agreements with each Participating Site or Participating Investigator or both in regard to the conduct of the Study. Institution will ensure that such agreements require compliance with applicable provisions of this Agreement and the applicable Study Order.

(2) Obligation of Institution. Institution is responsible to Pfizer for compliance by all personnel at all Participating Sites, including any contractors or consultants, with applicable terms of this Agreement.

(3) Anti-Corruption Requirements for Non-US Participating Sites. The provisions in Exhibit 2, Anti-Corruption, are applicable to a multicenter Study that includes any non-U.S. Participating Sites.

(4) Special Requirements for Non-Interventional Studies with Participating Sites in the European Union. If Institution conducts a multicenter non-interventional Study (prospective or retrospective), special requirements relating to reporting of Adverse Events will apply to any Participating Site located in the European Union ("EU"). Requirements relating to retention of Study records and availability of those records to audit may also apply to the EU site and the Institution, depending on the nature of the Study. These additional requirements, based on applicable EU legislation, will be identified in the Study Order for each such Study. If Institution wishes to add a Participating Site located in the EU after execution of a Study Order that did not contemplate inclusion of an EU site, Institution will notify Pfizer. Addition of an EU Participating Site to such a Study will require amendment of Section 8 of the Study Order to reflect these additional requirements.

(5) IIR Support. Pfizer will provide any IIR Support only to Institution. Institution is responsible for appropriate dispersal of such funds to the Participating Sites or Participating Investigators with which Institution has contracted. For multicenter Studies for which IIR Support includes Pfizer Product or Compound, the Study Order will specify whether Pfizer will provide the Pfizer Product or Compound solely to Institution or directly to each Participating Site. Institution will not disperse any type of Pfizer IIR Support to a Participating Site, or request Pfizer to ship Pfizer Product or Compound to a Participating Site, until all required contractual and regulatory documentation is in place for that Site

(e.g., subcontract, IRB approval, completed FDA 1572 form, etc).

(6) Overall Analysis and Joint Report. Institution will obtain Study Data from all Participating Sites and will arrange for the analysis of the overall Study Results. The Study Report that Institution provides to Pfizer (see Section 9, Study Report) will include those overall Study Results.

(7) Publication. Institution will ensure that Participating Sites agree that the first Publication will reflect the overall Study Results from all Participating Sites (see Section 10.5, Multicenter Studies).

12.2 By Pfizer. Under any Study Order, Pfizer may freely assign and delegate Study-related rights and duties to a Pfizer Affiliate (see Section 15.2, Affiliates) or to a successor in interest in the Pfizer Product, Pfizer Compound, or area of research interest to which the Study Order relates. Upon advance written notice to Institution, Pfizer may also freely assign rights and delegate duties relating to a Study Order to a Pfizer research or business partner or to a contracted service provider. As indicated in Section 1.3.b (Execution by Affiliates), Pfizer Affiliates are authorized to contract for the support of an IIR Study under this Agreement by means of a Study Order executed by that Affiliate. Pfizer may also authorize a service provider to negotiate and execute a particular Study Order on Pfizer's behalf. However, if Pfizer authorizes a service provider to negotiate and execute a particular Study Order on Pfizer's behalf, then Pfizer will direct such service provider to honor and use the substantive terms of this Agreement or to conform the terms of its template documents to the substantive terms in this Agreement. Pfizer may not otherwise assign its rights or delegate its duties under this Agreement without written permission from Institution. If Pfizer delegates any duties, Pfizer remains responsible to Institution for the performance of those duties.

13. Indemnification

13.1 By Pfizer. The Studies for which Pfizer provides IIR Support are not designed, sponsored, or managed by Pfizer, therefore Pfizer provides no indemnification for Study conduct. However, Pfizer will indemnify and hold harmless ("Indemnify") The University of Texas System, its Board of Regents, the Institution, any other Participating Sites, and all investigators, along with their officers, agents, and employees (collectively, "Institution Indemnified Parties") from any losses (including reasonable costs of defense) from any third-party demand, claim, fine, or penalty (collectively "Claim") that arises from (1) Pfizer's use of the Study Report or of any Invention licensed to Pfizer under this Agreement, (2) defects in the manufacture of the Pfizer Product, or (3) Pfizer's use of Personal Data supplied to Pfizer by Institution (see Sections 15.3, Personal Data and 15.4, Processing of Personal Data by Pfizer), except to the extent that any of these types

of Claim results from

a. failure of any Institutional Indemnified Party to use the Pfizer Product in accordance with the Protocol;

b. negligence or willful misconduct on the part of any Institution Indemnified Party;

c. a breach of any applicable law or regulation by any Institution Indemnified Party; or

d. failure by any Institution Indemnified Party to comply with material obligations under this Agreement or the applicable Study Order relevant to that party.

13.2 By Institution. To the extent authorized by the Constitution and laws of the State of Texas, Institution will Indemnify Pfizer, its officers, directors, employees and agents (collectively, "Pfizer Indemnified Parties") against any Claim that arises from a Security Breach by Institution involving Personal Data associated with Biological Samples obtained from Pfizer under this Agreement (see Section 4.9.a, Biological Samples Provided by Pfizer), except to the extent that the Claim results from the negligence, willful misconduct, or failure by any Pfizer Indemnified Party to comply with its material obligations under this Agreement or the applicable Study Order.

14. Term and Termination

14.1 Term of Agreement. This Agreement will remain in effect for five (5) years from December 1, 2015 until November 30, 2020.

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

14.3 Early Termination of Agreement. This Agreement may be terminated early

a. by ninety (90) day advance written notice by either party for any reason,

b. by notification by either party of a material 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 thirty (30) days in which to cure it.

14.4 Effect of Termination of Agreement on Ongoing Study Orders. Unless the Agreement is terminated because of a material uncured breach, termination of this

Agreement (either by expiration or early termination) will have no effect on any ongoing Study Orders unless otherwise agreed by the parties. Each such ongoing Study Order will continue until terminated in accordance with Section 14.5 (Termination of Study Orders), below, and will remain subject to the terms of this Agreement until the Study Order terminates.

14.5 Termination of Study Orders

a. Termination Events. Termination of a Study Order will be triggered by the earlier of the following events.

(1) Completion of Agreement Obligations. The Study Order will terminate when the Study is completed, which means the completion of all Protocol-required activities ("Study Completion"), and the parties have received all deliverables and payments owed under that Study Order.

(2) Early Termination by Institution. If Institution terminates the Study early, for any reason, Institution may terminate the Study Order upon notice to Pfizer.

(3) Early Termination by Pfizer. Pfizer may terminate a Study Order early in any of the following circumstances after providing written notice to Institution:

(a) The Protocol is modified in a way unacceptable to Pfizer (see Section 3.2, Amendments).
(b) Study conduct is not completed within six (6) months after the target date provided in the Study Order;
(c) The Study does not start within six (6) months of the effective date of the Study Order;
(d) Subject enrollment rate or Study progress is significantly slower than that outlined in the Protocol or proposal or needed to complete Study conduct by the target date;
(e) The Study design or objectives are no longer scientifically relevant.

(4) Termination for Cause. Either party may terminate a Study Order immediately upon notification for cause, including but not limited to an uncured material breach of the terms of this Agreement or Study Order by the other party. The party alleging breach must first provide notice that specifically identifies the breach and must provide the breaching party thirty (30) days in which to cure it.

(a) Multinational Studies. Also considered adequate cause for termination by Pfizer under this provision would be failure by Institution to comply with, or a demonstrated intent to fail to comply with, the warranties in Exhibit 2 (Anti-Corruption) in regard to a non-U.S. Participating Site in a multicenter Study.

b. Effective Date of Termination. If termination of a Study Order is triggered by events described in Sections 14.5.a. (2) or (3) above, termination will be effective after completion by both parties of any remaining applicable Study Order obligations.

c. Payment upon Early Termination. The terms in this Section 14.5.c, Payment upon Early Termination, apply only if a Study Order involving Pfizer IIR Support is terminated early for a reason other than a termination by Pfizer for cause (see Section 14.5.a.(4), Termination for Cause). Upon early termination of the Study Order, Pfizer will pay a pro rata portion of the total funding, less payments already made. Institution will refund to Pfizer any funding already received in excess of this calculated amount except to the extent that such funds have already been used, or are committed and unable to be canceled, in a manner consistent with the Study budget upon which the IIR Support is based or as prospectively approved by Pfizer.

d. Reconciliation upon Study Completion. At Study Completion, the parties will cooperate to perform a financial reconciliation to confirm consistency between total Pfizer milestone payments and the agreed-upon milestones and deliverables. The parties agree to make any adjustment (e.g., refund or additional payment) that is revealed by this analysis to be warranted.

15. Other Provisions

15.1 Modifications. Any modification to this Agreement must be in writing, signed by authorized officials of both parties, and identified as an Amendment to this Agreement. Any modification to an executed Study Order must be in writing, signed by each of the parties, and identified as an Amendment to the Study Order.

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

15.3 Personal Data. Information that could be used by itself or in combination with other available information to identify a specific individual is considered "Personal Data." For purposes of this Agreement, key-coded data is considered Personal Data even if the holder of the Personal Data does not have access to the

key that links the data to the identity of an individual.

15.4 Processing of Personal Data by Pfizer. Pfizer uses global electronic systems for processing certain information in connection with IIR studies. These systems may include certain Personal Data provided to Pfizer by Institution that relates to persons who participate in or perform work in connection with the conduct of the Study. The Personal Data used in such systems generally includes information such as name, specialization, and contact information. Pfizer may transfer such Personal Data to Pfizer Affiliates, to Pfizer's research or business partners, to Pfizer-contracted service providers or consultants, or to relevant governmental authorities. Such recipients may be located outside the country in which the Study was performed.

15.5 Pfizer Affiliates as Third-Party Beneficiaries. In regards to the processing and use of Personal Data associated with Pfizer-provided Biological Samples (see Section 4.9.a, Biological Samples Provided by Pfizer), any Pfizer Affiliate may enforce relevant terms of this Agreement as an intended third-party beneficiary to the Agreement. This Agreement does not confer any other benefits or rights on any person or entity other than the parties to the Agreement.

15.6 Debarment and Exclusion. Institution certifies that it is not debarred under subsections 306(a) or (b) of the Federal Food, Drug, and Cosmetic Act and that it has not and will not use in any capacity the services of any person debarred under such law with respect to services to be performed under this Agreement. Institution also certifies that it is not excluded from any federal health care program, including but not limited to Medicare and Medicaid. Institution will notify Pfizer promptly if either of these certifications needs to be amended in light of new information.

15.7 Entire Agreement. This Agreement, including its Exhibits and Attachments and Appendix A, represents the entire understanding between the parties relating to this subject matter. This Agreement supersedes all previous agreements between the parties (oral and written) relating to this subject matter, including but not limited to the 2010 Agreement, except for any obligations that, by their terms, survive independent of this Agreement.

15.8 No Waiver. Failure to exert a right under this 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.

15.9 Conflict with Attachments or Protocol. If there is any conflict between this Agreement and any of its Attachments, the terms of this Agreement will control. If there is any conflict between the Agreement and the Protocol, the Agreement will control except with respect to medical, scientific, or clinical matters relating to Study conduct, for which the Protocol will take precedence.

15.10 Notices. The parties will deliver notices and other communications relating to this 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.
Contracts, Compliance,
& Vendor Management
Attn: Contract Development Lead Pfizer Inc
235 E. 42nd Street
MS 150/2/4
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 and address of an administrative contact person for each Institution.

With a copy to:

The University of Texas System
Office of General Counsel
201 West 7th Street
Austin, TX 78701
Attn: IP Section Assistant General Counsel

15.11 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.

Rest of page intentionally left blank

Agreed to and Accepted by:

Pfizer Inc **By:** _____ Signature _____ Printed Name _____ Title _____ Date	**The University of Texas Health Science Center at Houston** **By:** Karen S. Niemeier 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 _____ Date	**The University of Texas Health Science Center at Tyler** **By:** _____ Signature _____ Printed Name _____ Title _____ Date

Agreed to and Accepted by:

Pfizer Inc By: R E A Signature Rakiyya E Ali Printed Name Director Title 24 November 2015 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 _____ 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:** Angela R Wishon 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 _____ 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:** 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 _____ Date	**The University of Texas Health Science Center at Tyler** **By:** _____ Signature David Anderson Printed Name Director, Sponsored Projects Title 11/20/15 Date

The University of Texas at Austin By: Bill Catlett Signature Bill Catlett Printed Name Director, Office of Industry Engagement Title 23 NOV 15 Date	

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

EXHIBIT 1
Study Order Template
NOTE: Laboratory studies involving the use of human biological samples may not be contracted under this Master IIR and will require a standalone IIR.

STUDY ORDER
PROTOCOL TITLE: _____
PFIZER TRACKING # _____

STUDY TYPE: _____

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

Pfizer Inc, a Delaware Corporation with a place of business at 235 E. 42nd Street, New York, NY 10017 ("Pfizer"), and

_____ ("Institution").

This Study Order is issued under the Master Investigator-Initiated Research Agreement ("Agreement") between Pfizer and Institution with an effective date of _____. Together with the Agreement, this Study Order governs the conduct of the IIR project identified above ("Study") and Pfizer's support of the Study by means of IIR Support.

1. Term. When signed by both parties, this Study Order has an effective date of _____ and will continue until terminated in accordance with Section 14.5 Termination of Study Order provision of the Agreement.

2. Principal Investigator. The Study was designed and will be conducted by Institution's investigator _____ ("Principal Investigator").

3. Duration of Study Conduct. Principal Investigator expects to complete Study conduct (completion of all protocol activities) by _____.

4. Investigator-Initiated Research Support

product only: Pfizer will provide, free of charge, the Pfizer product (compound) _____ ("Pfizer Product") ("Pfizer Compound") to be used in the Study. This free Pfizer Product (Compound) constitutes the IIR Support for this Study.

funding only: Pfizer will provide funding in support of the Study in the amount of _____, in accordance with Attachment A, Payment Schedule. This funding constitutes the IIR Support for this Study.

product and funding: Pfizer will provide funding in support of the Study in the amount of _____, in accordance with Attachment A, Payment Schedule. Pfizer will also provide, free of charge, the Pfizer product (compound) _____ ("Pfizer Product") ("Pfizer Compound") to be used in the Study. Together the funding and free Pfizer Product (Compound) constitute the IIR Support for this Study.

If Pfizer will provide equipment, the appropriate option above will be supplemented with the following: Pfizer will also provide certain equipment for use by Institution in the conduct of the Study, as specified in Attachment C, Capital Equipment and subject to the terms of that Attachment.

For Studies involving funding, one of the following provisions will be included, as appropriate to the circumstances:

Option 1 - no funding for costs of publishing Study Results

4.1 Study Budget. Institution represents that the Institution-provided study budget upon which this IIR Support is based reflects an informed estimate of all funds required to complete the Study**.**

Option 2 - publication costs included in original budget

4.1 Study Budget. Institution represents that the Institution-provided study budget upon which this IIR Support is based reflects an informed estimate of all funds required to complete and report the Study, including expenses relating to the publication of Study Results.

5. Principal Investigator Debarment and Exclusion. Institution certifies that Principal Investigator is not debarred under subsections 306(a) or (b) of the Federal Food, Drug, and Cosmetic Act or excluded from any federal health care program, including but not limited to Medicare and Medicaid. Institution will notify Pfizer promptly if either of these certifications needs to be amended in light of new information.

For a multicenter Study, "Principal Investigator" will be revised to "Coordinating Investigator," duration of Study conduct will specify Study conduct "at all Participating Sites" and, if applicable, a section entitled "Distribution of Pfizer Product" will specify where Pfizer will ship the Pfizer Product.

6. Attachments. This Study Order includes the following Attachments:

ATTACHMENT A	Payment Schedule
ATTACHMENT B	Study Documentation Requirements
ATTACHMENT C	Capital Equipment *(included only if applicable)*

7. Conflicts. If any Attachments to this Study Order conflict with the terms of this Study Order, the Study Order will control. If this Study Order or any Attachment conflicts with the terms of the Agreement, the Agreement will control except as specified in Section 8

(Additional Terms) below.

8. Additional Terms ***ANY TERMS ADDED TO THIS SECTION 8, INCLUDING BUT NOT LIMITED TO SECTIONS 8.1, 8.1, AND 8.2 BELOW, MUST FIRST BE REVIEWED AND APPROVED BY THE OFFICE OF GENERAL COUNSEL OF THE UNIVERSITY OF TEXAS SYSTEM AND THE APPLICABLE INSTITUTION TO BE VALID.***

For clinical studies involving the use of a Pfizer Product, include one or more of the following provisions -- as applicable to the circumstances.

8.1 Adverse Event Reporting Requirements. Because the Pfizer Product used in this interventional study is approved for marketing in the U.S. for the indication under study, potential drug-induced liver injury as assessed by laboratory test values ("Hy's Law Cases", as discussed in the Reporting of Serious Adverse Events section of the Agreement) are not reportable to Pfizer unless the Principal Investigator classifies such an occurrence as a serious adverse event.

8.1 Adverse Event Reporting Requirements. Because the Pfizer Product used in this interventional study is not yet approved for marketing in the U.S. for the indication under study, potential drug-induced liver injury as assessed by laboratory test values ("Hy's Law Cases") are reportable to Pfizer as discussed in the Reporting of Serious Adverse Events section of the Agreement.

8.2 Adverse Event Reporting Requirements. Because this [is a prospective non-interventional study] [is a retrospective non-interventional study] [Study involves the use of a Pfizer product that includes a device component] [Study involves the use of a Pfizer product that is a mature marketed oncology product with a well-established safety profile], the requirements for reporting serious adverse events ("SAEs") to Pfizer differ somewhat from the standard interventional-study requirements included in the Agreement. Requirements applicable to this Study are as follows: *[Insert the Adverse Event text appropriate to the circumstances]*

Section 8 (Additional Terms) may also include any authorized assignment or delegation by Institution, identification of source of Biological Samples to be used in the Study, terms applicable to multicenter studies, special requirements for multicenter studies that include any participating sites located within the European Union, etc.

9. Pfizer Contact Information for Submitting Publications (Section 15.10 Master)

Name: _____
Title: _____
Phone: _____
Email: _____

ACCEPTED AND AGREED TO BY:

PFIZER INC	[INSTITUTION NAME]
_____	_____
_____	_____
Printed Name	Printed Name
_____	_____
Title	Title
Date:_____	Date:_____

I confirm that I have received a copy of the Agreement under which this Study Order is issued and that I have read and understand the Agreement and this Study Order (with or without Attachment A). I agree to comply with the terms of the Agreement and this Study Order as they relate to my activities as Principal Investigator.

_____ Date: _____

PRINCIPAL INVESTIGATOR **DATE**

[Insert Typed Name]

Template Version Date: October 2014

Attachment A
PAYMENT SCHEDULE

PROTOCOL TITLE: _____

PFIZER TRACKING # _____

Study-Specific Content

Attachment B
STUDY DOCUMENTATION REQUIREMENTS

PROTOCOL TITLE: _____

PFIZER TRACKING # _____

Study-Specific Content

Attachment C
CAPITAL EQUIPMENT
[Included Only if Applicable]

PROTOCOL TITLE: _____
PFIZER TRACKING # _____

Pfizer Equipment

As part of its IIR Support, Pfizer will provide the equipment identified below ("Pfizer Equipment") for use by Institution in the conduct of the Study.

#	Equipment	Model #	Serial #	Pfizer Asset Tag # (if applicable)	Estimated Original Value	Estimated Depreciated Value at Study Completion
1						
2						

Permitted Use

Institution may use Pfizer Equipment only for purposes of the Study.

Disposition of Equipment

Alternative #1 – Return to Pfizer
After completion of Study conduct, Institution will arrange for return of Pfizer Equipment, at Pfizer's expense, to Pfizer or a location designated by Pfizer

Alternative #2 – Donation to a Non-Profit
After completion of Study conduct, Institution will donate the Pfizer Equipment to a non-profit organization other than Institution itself or any Institution Affiliate. Institution will provide Pfizer with documentation of this donation.

Alternative #3 - Purchase of Pfizer Equipment by Institution
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 document any transfer of ownership in writing.

If ownership of any Pfizer Equipment is transferred to Institution, Pfizer transfers the Pfizer Equipment 'as is' and does not make any representation or provide any warranty of any kind concerning the Equipment.

Template Version Date: 19 July 2010

EXHIBIT 2

Anti-Corruption Requirements for Non-US Participating Sites (Section 12.1 a. (3))

1. Anti-Corruption

1.1 Definitions

b. Government. As used in this Agreement, "Government" includes all levels and subdivisions of governments (ie, local, regional, and national; administrative, legislative, and executive).

c. Government Official. As used in this Agreement, "Government Official" includes (1) any elected or appointed non-US Government official (e.g., a legislator or a member of a non-US Government ministry), (2) any employee or individual acting for or on behalf of a non-US Government official, non-US Government agency, or enterprise performing a function of, or owned or controlled by, a non-US Government (e.g., a healthcare professional employed by a non-US Government hospital or researcher employed by a non-US Government university), (3) any non-US political party officer, candidate for non-US public office, or employee or individual acting for or on behalf of a non-US political party or candidate for public office, (4) any employee or individual acting for or on behalf of a public international organization, and (5) any member of a royal family or member of a non-US military.

1.2 Representations and Certifications. Institution represents and certifies to Pfizer the following:

a. Any information provided by Institution to Pfizer as part of Pfizer's anti-corruption due diligence process is complete and accurate.

b. The funding provided by Pfizer under this Agreement will not cause Institution or individuals affiliated with Institution to do anything that would result in Pfizer improperly obtaining or retaining business or gaining any improper business advantage.

c. Institution will not, and will take measures to ensure that individuals affiliated with Institution will not, use any portion of the Pfizer funding to directly or indirectly offer or pay any money or anything of value in an effort to influence any Government Official or any other person in order for

1) Pfizer to improperly obtain or retain business or to gain an improper business advantage, or

2) Institution or the affiliated individual(s) to improperly obtain or retain business or gain a business advantage.

d. Neither Institution nor, to Institution's knowledge, any individuals associated with Institution have accepted a payment intended to improperly obtain or retain business for Pfizer or to gain an improper business advantage for Pfizer.

e. Institution will not, and will take measures to ensure that individuals associated with Institution will not, accept in the future any payment intended to improperly obtain or retain business for Pfizer or to gain an improper business advantage for Pfizer.

1.3 Non-Compliance. Failure to comply with, or a demonstrated intent to fail to comply with, any of the representations and certifications in Section 10.2, above, will constitute adequate cause for Pfizer to immediately terminate the Agreement under Section 8.1.d, Termination for Cause. In such a circumstance, Pfizer is under no obligation to provide Institution an opportunity to cure before termination or to provide any further payment upon termination, including any payment for non-cancelable commitments by Institution relating to the Study.