MASTER CLINICAL STUDY AGREEMENT

This Master Clinical Study Agreement ("Agreement"), effective as of the date of full execution hereof ("Effective Date") sets forth the terms and conditions by and between AbbVie Inc. ("AbbVie") and The University of Texas Health Science Center at Houston; The University of Texas Health Science Center at San Antonio, The University of Texas Health Science Center at Tyler; The University of Texas Medical Branch at Galveston; The University of Texas Southwestern Medical Center; The University of Texas Rio Grande Valley, and The University of Texas at Austin ("Institution" or collectively, "Institutions"), each a member institution of The University of Texas System ("System"). In consideration of the mutual promises set forth herein, the parties hereto agree as follows:

1. Scope of Agreement.

- (a) For purposes of the Agreement, "Affiliate" means an entity that, directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with the party being referenced, excluding, with respect to AbbVie, Pharmacyclics LLC. For purposes of this definition, "control" means the possession, direct or indirect, of the power to cause the direction of the management and policies of the applicable entity, whether through ownership of fifty percent (50%) or more of the voting securities of such entity, by contract or otherwise, The parties agree that AbbVie's Affiliates are hereby authorized to issue and execute Statements of Work pursuant to the terms of this Agreement in their own name, and shall accrue and be bound by the same rights and obligations AbbVie would under such an executed Statement of Work.
- (b) This Agreement allows the parties to specify distinct clinical studies to be performed by Institution through the issuance of multiple individual written agreements between AbbVie or an AbbVie Affiliate (an "AbbVie Party") and Institution related to the specific clinical study, forms of which are attached hereto and incorporated herein as **Exhibit A-1** (Standard Statement of Work Template). and Exhibit A-2 (ABT- 199 Statement of Work Template) (each a "Statement of Work"). This Agreement covers the provision of certain AbbVie-sponsored or AbbVie Affiliate-sponsored clinical studies (each, the "Study") in relation to certain AbbVie Party products identified in the Statement of Work (each, the "Study Product"). The AbbVie Party executing a Statement of Work shall be considered the "Sponsor," as that term is defined in 21 C.F.R. § 312.3(b), for the Study relating to such Statement of Work. AbbVie shall, in its sole discretion, determine when and whether to offer a Study under this Agreement to Institution including, without limitation, the decision whether or not to enter into a specific Statement of Work.
- 2. Statement of Work. The specific details and tasks of each Study shall be specified in writing in the Statement of Work. The Statement of Work shall be executed by an authorized representative of Institution and the applicable AbbVie Party and shall be acknowledged by the relevant qualified lead Institution employee responsible for the conduct of the Study at Institution (each a "Principal Investigator"). Each Statement of Work shall include, without limitation, identification of the Study Product, identification of the Principal Investigator, the title of the Study protocol, which may be amended from time to time (the "Protocol"), the detailed Study budget and payment schedule (the "Budget"); and term of Statement of Work (the "Study Term"). The Protocol shall be provided separately for each individual Study and shall be referred to and incorporated by reference into the Statement of Work. The Statement of Work shall be subject to all of the terms and conditions of this Agreement, in addition to the specific details set forth in the Statement of Work.

3. Conduct of Study.

(a) Institution shall conduct and shall require Principal Investigator, subinvestigator(s), and Institution's other employees, subcontractors and agents performing work in connection with the Study (collectively, "Institution Personnel") to conduct the Study in accordance with: (i) this Agreement and the relevant Statement of Work; (ii) the IRB-approved Protocol; (iii) all reasonable written instruction provided by AbbVie; (iv) Institution's ethical standards and/or policies; and (v) all applicable federal, state and local laws and regulations and guidelines (collectively, "Law(s)"), including without limitation (and each to the extent applicable to a Study), anti-bribery and anticorruption laws, International Conference on Harmonisation of Technical Requirements for

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Registration of Pharmaceuticals for Human Use E6 Good Clinical Practice as adopted by the FDA ("ICH-GCP"), regulations of the United States Food and Drug Administration (the "FDA"), the Patient Protection and Affordable Care Act of 2010, the Medicare/Medicaid Anti-kickback statute, the Social Security Act of 1935, the Controlled Substances Act, data protection and privacy laws, the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH"), and the Federal Food, Drug and Cosmetic Act of 1938, as each may be amended, from time to time. In furtherance of the foregoing obligations, Institution shall ensure that an Institution Review Board ("IRB") established and constituted in accordance with applicable Laws approves and oversees the conduct of the Study prior to the commencement of the Study. Institution will comply with the instructions of the IRB respecting the conduct of the Study, and will notify AbbVie to the extent any such instructions vary from the Protocol.

- (b) Prior to each Study subject's participation in the Study, Institution shall obtain a signed informed consent and/or authorization document (collectively, "ICF"), as reviewed by AbbVie and approved by the IRB. If Institution or Principal Investigator proposes to publish any Study subject recruitment advertisements, such advertisements require AbbVie's prior review in advance of submission to the applicable IRB. Institution and Principal Investigator shall report all serious adverse events or other safety concerns arising from the conduct of the Study that Principal Investigator becomes aware of as further specified in the Protocol and in accordance with applicable Laws.
- (c) Institution represents and certifies that Principal Investigator identified in a Statement of Work is an employee of Institution. Institution agrees that no other investigator may be substituted for the Principal Investigator without the prior written consent of AbbVie. If the Principal Investigator is no longer employed by Institution or becomes unwilling or unable to perform the duties required by this Agreement and relevant Statement of Work, Institution shall promptly notify AbbVie and reasonably cooperate with AbbVie to promptly find a mutually acceptable replacement Principal Investigator. If the parties cannot agree to a replacement Principal Investigator, either party may immediately terminate the relevant Statement of Work upon written notice to the other party.
- (d) Institution shall ensure that Principal Investigator and subinvestigator(s): (i) complete and return to AbbVie the FDA Form 1572 provided by AbbVie to ensure compliance with 21 C.F.R. Part 312.53 prior to the initiation of the Study and promptly notify AbbVie of any change in its accuracy during the Study Term of the applicable Statement of Work; and (ii) complete and return to AbbVie the Financial Disclosure Certification provided by AbbVie to ensure compliance with 21C.F.R. Part 54 prior to the initiation of the Study and promptly notify AbbVie of any change in the accuracy of the Financial Disclosure Certification during the Study Term of the applicable Statement of Work and for one (1) year following completion of the Study. Institution understands and agrees that Principal Investigator and subinvestigator(s), and their immediate families, may not, in violation of any applicable Law, have a direct ownership interest (including, without limitation, intellectual property rights or royalty rights) in the Study Product and may not be compensated with AbbVie securities in exchange for being a Principal Investigator or subinvestigator(s) in the Study.
- (e) Institution shall require Principal Investigator to comply with all applicable disclosure Laws relating to his/her relationship with AbbVie including, without limitation, full disclosure of the existence and nature of this relationship that (i) may be externally imposed on Principal Investigator based on his/her affiliation with any formulary, pharmacy and therapeutics (P&T) committee, or committee associated with the development of treatment protocols or standards (including clinical guidelines); or (ii) are required by any health care institution, medical committee or other medical or scientific organization with which Principal Investigator is affiliated. Institution shall require Principal Investigator to abide by such committee's or medical or scientific organization's procedures, which may include recusing himself/herself from decisions relating to any Study Product for which Principal Investigator is conducting the Study under the relevant Statement of Work. This disclosure requirement shall extend for one (1) year beyond the termination or expiration of the relevant Statement of Work.

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4. Sponsor Obligations.

- (a) AbbVie shall comply with applicable Laws in the performance of its activities relating to the Study and shall obtain all approvals required in connection with such activities.
- (b) AbbVie shall be responsible for data and safety monitoring as specified in the Protocol. During the performance of the Study at Institution and for two (2) years thereafter, AbbVie agrees to report promptly to the Institution any information (including without limitation any aspect of the Protocol, information discovered during site monitoring visits, or the Study Records/results) that AbbVie reasonably expects to affect, as applicable, (i) the well-being, medical care, health or safety of past or current Study subjects, (ii) Study subjects' willingness to continue participation in the Study, (iii) the conduct of the Study, or (iv) the IRB's approval to continue the Study. Notwithstanding anything to the contrary in this Agreement, Institution and Principal Investigator are free to communicate such information to each Study subject and the IRB.
- (c) AbbVie shall promptly register the Study on www.clinicaltrials.gov in accordance with the requirements described in Section 801 of the Food and Drug Administration Amendment Act.

5. Study Materials; Licenses; Equipment.

- (a) AbbVie will provide sufficient quantities of Study Product, investigator brochures, and if applicable, access to an electronic data capture system for completing Case Report Forms ("CRFs"), any other compounds, materials, and access to or copies of certain patient reported outcomes (electronic or paper) surveys, questionnaires, and/or scales (collectively, "PROs") that the Protocol specifies or that AbbVie deems necessary to conduct the Study at no cost to Institution (together, the "Study Materials"). All Study Materials and other information provided by AbbVie in connection with this Agreement and Statement of Work are and shall remain the sole property of AbbVie. AbbVie represents that the Study Product will have been manufactured in accordance with current Good Manufacturing Practices.
- (b) Institution shall maintain adequate records to account for the Study Materials including, without limitation and if applicable, dates, quantity, and use by Study subjects. Institution or Principal Investigator shall, if applicable, inspect the Study Materials upon receipt and notify AbbVie upon becoming aware that any Study Materials are damaged or that the supply of Study Materials is inadequate.
- (c) Study Materials shall (i) be stored and handled in accordance with the labeling, investigator brochure, or material data safety sheet, as applicable, of the applicable Study Materials, and in accordance with applicable Law, and AbbVie's reasonable written instructions, (ii) not be used past their respective labeled expiration dates, if any.
- (d) Neither Institution, Principal Investigator, nor any other Institution Personnel shall (i) publish any part of the PROs in any manuscript, poster, oral presentations, or otherwise, except to the extent information contained in the PROs constitutes Study data or results, in which case such information may be published in accordance with Section 12 (Publications and Presentations) below; (ii) remove or alter any notice contained in the PROs; or (iii) modify, transfer, distribute, or release the PROs to any third party, except in connection with performing the Study, in accordance with the Protocol or except as set forth in this Agreement.
- (e) Upon conclusion of the Study, termination of this Agreement or a Statement of Work, or at AbbVie's request, any remaining or expired Study Materials, as applicable, shall be returned to AbbVie at AbbVie's reasonable expense in accordance with the Protocol and AbbVie's

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reasonable written instructions and in compliance with applicable Law governing the shipment of such Study Materials. If the parties agree that the return of such Study Materials is not practicable or is prohibited under applicable Laws, any remaining or expired Study Materials, as applicable, will be destroyed in full compliance with applicable Laws. Upon any such destruction, Institution will promptly provide AbbVie with a certificate of destruction or similar document verifying the final disposition of the Study Materials.

- (f) If necessary for purposes of conducting the Study, AbbVie may provide Institution with certain equipment. Any equipment provided by AbbVie hereunder is described in **Exhibit B** of the Statement of Work (Equipment to be provided by AbbVie) ("<u>Equipment</u>"). For any Equipment provided by AbbVie, Institution shall (i) promptly inspect the Equipment following receipt and notify AbbVie upon becoming aware that any Equipment is damaged or malfunctioning; (ii) use the Equipment in accordance with the user manual and/or other reasonable instructions provided with the Equipment; (iii) maintain the Equipment in a secure manner designed to protect such Equipment from unauthorized use, theft, or damage and exercise the same degree of care with respect to the Equipment that Institution exercises with respect to its own equipment of similar type and value. If, due to the gross negligence of Institution or any Institution Personnel, any of the Equipment is lost, stolen, or damaged, then Institution shall pay the reasonable cost of replacement or repair, as applicable, which shall not exceed the estimated value of such Equipment set forth in **Exhibit B** of the Statement of Work. At AbbVie's direction and expense, the Equipment shall be returned to a location specified by AbbVie at the end of the Study or earlier termination of the Statement of Work.
- (g) In the event the Protocol requires Institution to provide Equipment to Study subjects for their use during the Study, Institution shall instruct the Study subjects as to the proper use of the Equipment. If any of the Equipment is lost, stolen, or damaged by a Study subject or while under the control of a Study subject, then AbbVie shall pay the reasonable cost of replacement or repair, as applicable.
- (h) Institution shall use the Study Materials and the Equipment solely for the conduct of the Study and not for any other study nor for any other use.

6. Monitoring of Study; Records; Reporting.

- (a) Upon the reasonable request of AbbVie, Institution shall submit oral or written reports on the progress of the Study at reasonable intervals during the Study Term. Within ninety (90) days following completion or termination of a Study at Institution, Institution shall furnish AbbVie with (i) a final report on the Study, which may be the final IRB Study report prepared by the Principal Investigator for the IRB; and (ii) all data, records CRFs, reports, and other information generated (excluding source documents, medical records, and Institution Records) in the conduct of the Study (collectively, "Records"), which shall be the exclusive property of AbbVie. Notwithstanding the foregoing, source documents, medical records, laboratory notebooks, Protected Health Information (as such term is defined by HIPAA), Institution's business records, regulatory and compliance documents, research notebooks, or any other information that is required by Law or regulation to be retained by Institution, (collectively referred to as "Institution Records") shall be considered the exclusive property of Institution. Institution agrees that, subject to Section 9 (Subject Confidentiality: Data Protection) of this Agreement, AbbVie shall have the right to use the information described in such source documents and medical records (i) to the extent permitted by the IRB approved ICF signed by the Study subject ("Subject ICF"), (ii) in accordance with any reasonable instructions from Institution's IRB that are consistent with the Protocol and such Subject ICF, and (iii) only in accordance with applicable Law. Notwithstanding the foregoing and subject to Section 8 (Confidentiality), Institution retains the right to use any Records for its internal and non-commercial research, teaching, patient care purposes and for publication purposes in accordance with **Section 12** (Publications and Presentations).
- (b) During normal business hours, Institution shall permit AbbVie and AbbVie's designees access to any facilities at which the Study is conducted to monitor the conduct of the Study and to audit the Records, source documents generated in the conduct of the Study, and other Study data CONFIDENTIAL

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(collectively, "Study Documents") to verify compliance with this Agreement, provided that Institution may redact such Study Documents as legally required to protect subject confidentiality. Except in cases where AbbVie requires immediate access to Study site in connection with audits and responses to requests made by regulatory authorities (in which case Institution shall permit access upon reasonable advance notice), monitoring visits shall be scheduled at mutually agreeable times.

- (c) If, as a result of Study monitoring, AbbVie identifies a significant audit finding that is not timely cured or is incapable of timely cure, AbbVie may immediately terminate any Statement of Work. AbbVie's rights in this Section shall be subject to Institution's reasonable measures for purposes of confidentiality, safety, and security, and will be further subject to AbbVie's compliance with Institution's premises rules that are generally applicable to all persons at Institution's facilities; provided, however, that all such policies and procedures are reasonable, and consistent with applicable Laws and regulations. Should AbbVie utilize one or more third party(s) in exercising its rights in this paragraph, AbbVie certifies that such party(s) shall be subject to an obligation of confidentiality consistent with the obligations of confidentiality required of AbbVie hereunder and such third party(s) shall be subject to any and all conditions upon AbbVie's rights that are set forth in this **Section 6**.
- (d) Institution shall, to the extent permitted by applicable Laws, promptly (i) notify AbbVie upon receiving any requests to inspect and have access to Study Documents by any regulatory authority having jurisdiction over the Study, and (ii) provide AbbVie with a copy of any relevant documents received from such regulatory authority that relate to the Study. In the event a regulatory citation or notice (including, without limitation, a FDA Form 483 or FDA warning letter) is issued relating to the Study, Institution agrees, to the extent permitted by applicable Laws, to furnish to AbbVie within thirty (30) days of receipt of such regulatory citation or notice (A) notification of such citation or notice, and (B) a summary of such citation or notice. AbbVie shall hold all such documents, citations, notice, and correspondence in confidence.
- (e) Institution shall retain the Study Documents in accordance with applicable Laws (the "Retention Period"). If AbbVie requests that Institution retain the Study Documents beyond the Retention Period, the parties shall cooperate in good faith in an effort to mutually agree upon the costs to be paid by AbbVie and the duration for such extended Retention Period.
- (f) If AbbVie obtains, learns of, comes in contact with, or otherwise has access to any protected health information, as defined in HIPAA ("PHI"), AbbVie shall, and shall ensure that AbbVie representatives or designees will keep such information confidential, and will collect, use, store, access PHI only in accordance with applicable Laws and to the extent permitted by the applicable IRB approved ICFs and any reasonable instructions from Institution's IRB.

7. Compensation.

- (a) In support of the conduct of each Study, AbbVie shall pay Institution in accordance with the Budget. Institution understands and agrees that none of Principal Investigator or subinvestigator(s) will receive any funds from AbbVie in connection with the performance of the Study other than the funds paid to Institution in accordance with the Budget. The parties agree that the amount for payments set forth in the Budget represents the fair market value for the services to be rendered and has not been determined in any manner that takes into account the volume or value of any referrals or business otherwise generated between Institution and AbbVie. Institution agrees that the overhead charged to AbbVie under a Statement of Work shall not exceed Institution's overhead rate applicable to that Statement of Work that is in effect as of the effective date of such Statement of Work.
- (b) In the event that the Agreement or Statement of Work is terminated, AbbVie shall pay Institution for work performed, expenses incurred and non-cancelable obligations made up to the effective date of termination. AbbVie shall not be obligated to reimburse Institution for expenses that are invoiced to AbbVie more than two hundred forty (240) days after the termination date of the relevant Statement of Work.

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- (c) AbbVie shall not be responsible for: (i) data contained in a CRF which is intentionally misleading or inaccurate; or (ii) work performed in violation of the Protocol (provided, however, that actions (including deviations from the Protocol) taken by Institution or Institution Personnel that are based on generally accepted standards of clinical research and medical practice, necessary to treat a condition that poses an immediate risk to the safety, life or well-being of a Study subject shall not, in and of themselves, constitute a violation of the Protocol or this Agreement). If AbbVie has previously paid for such work, the payment shall be deducted from the final payment due under the Statement of Work (the "Final Payment").
- (d) In the event of any payment dispute under a Statement of Work, (i) AbbVie shall pay undisputed amounts upon receipt of an invoice therefor, and (ii) the parties shall cooperate in good faith to resolve such dispute in a timely manner. Following resolution of such dispute, Institution shall reinvoice AbbVie and AbbVie shall pay for the amounts the parties mutually agree are due. In no event may Institution or Institution Personnel withhold Study data or Records that are otherwise required to be submitted to AbbVie hereunder, pending resolution of a payment dispute.
- (e) AbbVie will make the Final Payment due under a Statement of Work and send a financial reconciliation to Institution after completion of the performance of all work contemplated thereunder and the delivery to AbbVie of all CRFs and all other items described in Section 6(a). If AbbVie has paid Institution less than Institution is entitled at the time of financial reconciliation, AbbVie shall pay the remaining amount due as part of the Final Payment. Any overpayment due AbbVie at the time of final reconciliation, shall be made payable to AbbVie Inc. within ninety (90) days of discovery of such overpayment along with an explanation of such overpayment, to the AbbVie Study Contact (as defined below) set forth in the Statement of Work.
- (f) Upon written notice to Institution, AbbVie may delegate certain payment obligations under a Statement of Work to a contract research organization ("<u>CRO</u>"). In such event, Institution agrees that as to any payments delegated by AbbVie to such CRO, Institution shall first seek redress from the CRO for compensation. If after seeking redress from the CRO for such payments Institution is not paid the amounts due under this **Section 7**, then AbbVie shall pay undisputed amounts. Additionally, for any Study in which AbbVie has delegated certain Study obligations to a CRO, AbbVie shall endeavor to require that its CROs either (a) use this Agreement or (b) conform its clinical study template to the substantive provisions from this Agreement.

8. Confidentiality.

- (a) The parties may wish, from time to time, in connection with work contemplated under this Agreement and a Study, to disclose confidential information to each other. During the Term of this Agreement, including any extensions thereof, and for a period of seven (7) years after expiration or termination of this Agreement, (i) Institution and Institution Personnel (collectively "Receiving Party") shall not disclose to any third party or use AbbVie Confidential Information (as defined below) for any purpose other than that indicated in this Agreement without AbbVie's prior written consent and (ii) AbbVie shall not use or disclose Institution's Confidential Information (as defined below) without Institution's prior written consent unless permitted hereunder. Notwithstanding the foregoing, Confidential Information identified as a trade secret will not be disclosed by AbbVie to Institution unless AbbVie first notifies Institution in writing that AbbVie wishes to disclose a trade secret and the nature of the trade secret, and Institution has then specifically agreed in writing in advance to receive such trade secret. In such event, Institution's obligations of confidentiality and non-use with respect to such disclosed trade secret shall survive for the period required by law.
- (b) "AbbVie Confidential Information" shall include any information provided to Receiving Party by or on behalf of AbbVie, including but not limited to the Protocol, Investigator Brochures, Study Materials, and Records. "Institution Confidential Information" shall include the information and materials provided to AbbVie by or on behalf of Institution, including any information concerning Institution and its business related to the Study. AbbVie Confidential Information and Institution Confidential Information shall be referred to herein collectively as "Confidential Information".
- (c) AbbVie Confidential Information shall not include information or any portion thereof which:

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- (i) is known to the Receiving Party prior to receipt thereof under this Agreement, as evidenced by its written records;
- (ii) is disclosed to the Receiving Party after acceptance of this Agreement by a third party who, to the knowledge of Receiving Party, has a right to make such disclosure in a nonconfidential manner;
- (iii) is or becomes part of the public domain through no fault of the Receiving Party; or
- (iv) is independently developed by the Receiving Party without use of, or reference to AbbVie Confidential Information.
- (d) Institution Confidential Information shall not include information or any portion thereof which:
 - (i) is known to AbbVie prior to receipt thereof under this Agreement, as evidenced by its written records;
 - (ii) is disclosed to AbbVie after acceptance of this Agreement by a third party who, to the knowledge of AbbVie, has a right to make such disclosure in a non-confidential manner;
 - (iii) is or becomes part of the public domain through no fault of AbbVie; or
 - (iv) is independently developed by or for AbbVie without use of or reference to the Institution Confidential Information, as evidenced by its written records.
- (e) Notwithstanding the foregoing, Institution may disclose AbbVie Confidential Information to the extent it is required to be disclosed (i) in order to obtain informed consent from subjects who may wish to enroll in the Study, provided, however, that the AbbVie Confidential Information will be disclosed only to the extent necessary and will not be provided in answer to unsolicited inquiries by telephone or to individuals who are not eligible Study candidates; (ii) to a Study subject for the safety or well-being of the Study subject; or (iii) is communicated to Institution's scientific and/or institutional review committees provided, however, that such persons are obligated to maintain the confidentiality of such information consistent with the terms of this Agreement.
- (f) Nothing in this Agreement will be construed to restrict either party from disclosing Confidential Information as required by Law or court order or other governmental order or request, provided in each case such party shall, to the extent practicable, give the other party written notice as soon as reasonably possible in order to allow the affected party to take whatever action it deems necessary to protect its Confidential Information. In the event that no protective order or other remedy is obtained, or either party waives compliance with the terms of this Section 8, a disclosing party shall furnish only that portion of the Confidential Information which it is legally required to disclose. In addition, each party will permit the affected party to attempt to limit such disclosure by appropriate legal means.
- (g) Neither party will disclose to the other party any information which is confidential or proprietary to a third party unless such party has first obtained the prior written approval of both such third party and the other party.
- (h) Within forty-five (45) days following completion or termination of the applicable Statement of Work, each party will return or destroy all tangible materials that contain the other party's Confidential Information, provided, however, that each party will be permitted to retain one (1) archival copy of the other's party's Confidential Information solely as required for regulatory, legal, or insurance purposes or as permitted by this Agreement.
- 9. Subject Confidentiality; Data Protection. Institution shall comply with all applicable Laws regarding Study subject confidentiality and data protection, including without limitation, HIPAA, HITECH, and applicable state privacy Laws, in the collection, use, storage and disclosure of PHI. Institution does not intend to provide any PHI to AbbVie, provided, however, that to the extent any Records, Study

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Documents, results or data of the Study or information provided to AbbVie or accessed by AbbVie may include any PHI, AbbVie shall and shall ensure that AbbVie's representatives shall hold such information in confidence, and collect, use, store, access and disclose such PHI only in accordance with applicable Law and to the extent permitted by the applicable Subject ICF and in accordance with any reasonable instructions from Institution's IRB that are consistent with the Protocol and such Subject ICF.

10. Publicity.

- (a) Except as required by Law or regulation or as permitted hereunder, including, but not limited to requirements set forth in **Section 12** (Publications and Presentations), neither party shall disclose the terms of this Agreement or make any public announcements regarding the existence of this Agreement without the other party's written consent.
- (b) Neither party shall use the trademark, servicemark, or logo of the other party or the other party's affiliates in any publicity, advertising, or other information intended to be disseminated to any third person or to the general public without the other party's prior written consent. Neither party shall use the name of the other party or the other party's affiliates in any publicity, advertising, or other information intended to be used for commercial or promotional purposes without the other party's prior written consent. Notwithstanding the foregoing, Institution and Principal Investigator may without prior written approval, disclose their participation in the Study (including the names of AbbVie or AbbVie's affiliates, name of the Study, funding source, and total funding amount) as required by applicable Laws, court order or state regulation, as required by Section 12 (Publications and Presentations), or in (i) curriculum vitae, (ii) internal reports, (iii) grant applications to government funding sources, (iv) required government reports and filings, (v) Institution's clinical trials website exactly as such information appears on clinicaltrials.gov, and (vi) conflict of interest disclosures. Institution understands and agrees that the terms and conditions of this Agreement and any Statement of Work and the amount of any payment made thereunder may be disclosed and made public by AbbVie to the extent required by AbbVie to comply with applicable Laws. As AbbVie reasonably requests, Institution shall cooperate in good faith with AbbVie to promptly provide accurate and complete information that is not already in AbbVie's possession in connection with such disclosures related to the Study. The parties understand that the terms and conditions of this Agreement may be disclosed and made public by AbbVie and/or Institution to the extent required by Law.

11. Intellectual Property.

- (a) Each party hereto retains all right, title and interest in any patent, patent application, trade secret, know-how and other intellectual property that was owned by such party prior to the Effective Date. No license grant or assignment, express or implied, by estoppel or otherwise, is intended by, or shall be inferred from this Agreement, except as specifically set forth herein.
- (b) Any invention, or discovery (whether patentable or not), conceived, reduced to practice, made, generated or developed by Institution or Institution Personnel that is made from use of the Study Materials provided hereunder or made in the conduct of the Study (collectively, "Intellectual Property") shall be promptly disclosed to AbbVie, and Institution hereby assigns to AbbVie all of Institution's rights, title, and interest in and to such Intellectual Property. Upon AbbVie's request and at AbbVie's expense, Institution shall require Institution Personnel to execute, or cause to have executed such documents and to take such other reasonable actions to obtain, record or enforce patents, assignments or other proprietary protection in AbbVie's name covering any such Intellectual Property. Subject to **Section 8** (Confidentiality) and **Section 12** (Publications and Presentations), AbbVie grants to Institution a free, non-transferable, non-sublicensable, non-exclusive license to use any Intellectual Property solely for its internal and non-commercial research, teaching, patient care purposes and for publication purposes.
- 12. <u>Publications and Presentations</u>. For purposes of this Agreement, "<u>Scientific Publication</u>" means any scientific publication or medical communication regarding Study results in any form that is intended

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for disclosure to third parties, including, without limitation, manuscripts, abstracts, posters, slides or other materials used for presentations.

- (a) AbbVie is committed to fostering the highest standard of conduct related to Scientific Publications and transparency, while at the same time, protecting its Confidential Information provided hereunder. Authorship related to Scientific Publications shall be determined in accordance with and governed by the criteria defined by the International Committee of Medical Journal Editors (ICMJE) "Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals", and Institution shall require that AbbVie's role in support of the Study be appropriately disclosed in any Institution Publications (as defined below).
- (b) Institution acknowledges that, as the Study sponsor, AbbVie retains the right to disclose the Study data and results first in a Scientific Publication based on the Study data and results from all appropriate sites ("Summary Publication").
- (c) Following the earliest of: (i) AbbVie's Summary Publication; or (ii) twelve (12) months after completion, abandonment or termination of the Study at all Study sites, Institution and Institution Personnel shall have the right to prepare and submit for public disclosure Institution's Study data through a Scientific Publication or other public disclosure (an "Institution Publication"). Institution shall provide AbbVie with a draft of any proposed Institution Publication at least thirty (30) days prior to submission of such publication for AbbVie to ascertain whether any patentable Intellectual Property or AbbVie Confidential Information (other than the data and/or results of the Study generated hereunder) are disclosed therein. AbbVie shall return comments to Institution within thirty (30) days after receipt of the draft Institution Publication ("Review Period"). Institution shall delay any proposed Institution Publication an additional sixty (60) days in addition to the Review Period in the event AbbVie so requests to enable AbbVie to secure patent or other proprietary protection for any Intellectual Property contained within such Institution Publication ("Delay Period"). Institution agrees to (A) keep the proposed Institution Publication confidential until expiration of the Review Period and, if elected by AbbVie, any Delay Period, and (B) delete AbbVie Confidential Information (other than data and/or results of the Study generated hereunder) from any Institution Publication. In the event that Institution or Institution Personnel and AbbVie differ in their conclusions or interpretation of Study data in the Institution Publication, the parties shall, during the Review Period, use good faith efforts to attempt to resolve such differences through appropriate scientific debate. Subject to Institution's and Institution Personnel's removal of AbbVie Confidential Information (other than data and/or results of the Study generated hereunder), Institution or Institution Personnel, as applicable, shall retain control over the final version of the Institution Publication.

13. Representations and Certifications.

- (a) Institution represents and certifies that during the Term of this Agreement, to the best of Institution's knowledge:
 - (i) the terms of this Agreement and Statement of Work are valid and binding obligations of Institution, and are not inconsistent with (A) any other contractual or legal obligation it may have; or B) policies and procedures of Institution;
 - (ii) Institution's and Institution Personnel's performance of the activities hereunder is in compliance with all policies and procedures of Institution, and Principal Investigator's performance of such activities does not present a conflict of interest with Principal Investigator's official duties;
 - (iii) Institution and Principal Investigator have, as applicable, adequate facilities, resources, training and expertise to conduct the Study in accordance with the Protocol and applicable Laws; and
 - (iv) Principal Investigator has a current and valid medical license in the jurisdiction in which the Study is being performed.

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Institution shall notify AbbVie promptly if at any time during the Term, Institution learns that Institution would no longer be able to truthfully make any of the representations and certifications in this **Section 13(a)** and AbbVie shall have the right to immediately terminate this Agreement.

- (b) Institution represents and certifies that neither Institution nor Institution Personnel are Debarred or, to the best of Institution's knowledge, have been Debarred or are the subject of a proceeding that could lead to Institution or any Institution Personnel becoming Debarred. For purposes of this Agreement, "Debarred" means (A) debarred by the FDA under 21 U.S.C. § 335a; (B) excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; (C) listed on the FDA's Disqualified and Restricted Lists for clinical investigators; or (D) convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible. In the event Institution receives notice of, or otherwise becomes aware of, the Debarment, proposed Debarment of itself or any Institution Personnel, Institution shall notify AbbVie immediately and AbbVie shall have the right to immediately terminate this Agreement. The obligations of this **Section 13(b)** shall survive termination or expiration of the Agreement for a period of one (1) year.
- (c) AbbVie represents and warrants that the Study Product that is delivered to Institution will be manufactured in accordance with current Good Manufacturing Practices and will meet the product specification identified in the product label at the time of delivery to Institution.

14. Term and Termination.

- (a) Unless terminated earlier as provided in **Section 14(b)** below, this Agreement shall be effective on the Effective Date and shall continue for five (5) years following the Effective Date ("<u>Term</u>").
- (b) This Agreement may be terminated:
 - (i) by either AbbVie or Institution upon written notice to the other party if the other party has breached a material term of this Agreement and fails to cure such breach within fifteen (15) days of receiving notice of such breach; or
 - (ii) by either party without cause upon thirty (30) days prior written notice to the other party; or (B) as otherwise permitted in this Agreement.
- (c) A Statement of Work may be terminated:
 - (i) by either AbbVie or Institution upon written notice to the other party if: (A) the other party has breached a material term of this Agreement or Statement of Work and fails to cure such breach within fifteen (15) days of receiving notice of such breach; (B) the Study is terminated or suspended by the IRB, FDA or any other governmental or regulatory authority; (C) if the Principal Investigator leaves Institution or is otherwise unable to continue to participate in the Study, and the parties are unable to find a mutually acceptable replacement principal investigator within thirty (30) days; or (D) if either AbbVie or an Institution, in its sole judgment, believes an adverse safety concern with respect to Study Product makes continued testing unadvisable, provided that if Institution terminates for this reason, it shall be after the Suspension Period (defined below) in accordance with Section 14(d).
 - (ii) by AbbVie (A) without cause upon thirty (30) days prior written notice to Institution; or (B) as otherwise permitted in the Statement of Work.
- (d) In the event Institution or Principal Investigator have concerns about the health, safety and welfare of the Study subject(s), Institution shall give prompt notice to AbbVie of such concerns, and may suspend enrollment of Study subjects for a period not to exceed thirty (30) calendar days ("Suspension Period"). During such Suspension Period, the parties shall evaluate the concerns raised by Institution or Principal Investigator to determine whether the Statement of Work should be terminated. In any event, Institution and Principal Investigator shall continue

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monitoring and follow-up in strict adherence to the Protocol for currently enrolled Study subjects during the Suspension Period. After the Suspension Period and following written notice including a detailed written explanation, to AbbVie, Institution may terminate a Statement of Work if Study subject health, safety, and welfare remain a concern to Institution of such magnitude to support such termination.

(e) Termination or expiration of this Agreement or Statement of Work shall not affect any rights or obligations which have accrued prior thereto or any other rights or remedies provided at law or equity which either party may otherwise have. If the Study Term of a Statement of Work extends beyond the termination or expiration date of this Agreement, the applicable terms and conditions of this Agreement shall extend automatically for such Statement of Work until such Statement of Work's termination or expiration date. In the event of premature termination of a Statement of Work, Institution shall (i) appropriately withdraw and discontinue all then-enrolled subjects if medically permissible (ii) complete the Study for then-enrolled Study subjects where required by accepted medical practice, or (iii) reasonably cooperate with AbbVie to arrange for then-enrolled Study subjects to enroll at an alternative Study site.

15. Subject Injury; Indemnification.

- (a) If under a Study any injury or illness occurs to a Study subject as a result of (i) the administration of the Study Materials or (ii) the performance of Protocol- mandated procedures on Study subjects that such Study subjects would not have received but for their participation in the Study ("Procedures") in each case in accordance with the Protocol ("Study Injury"), AbbVie agrees to pay all reasonable medical expenses necessary to treat such Study Injury, provided that such Study Injury is not due to the natural progression of any pre-existing disease or any underlying illness. Institution shall not submit claims for such medical expenses for a Study Injury paid by AbbVie to a third party payor.
- (b) AbbVie shall indemnify, defend and hold harmless Institution, System, their Regents, officers, agents employees, Institution Personnel and Institution's officers, trustees, and IRB members ("Indemnitees") in the conduct of a Study, for any liability, loss, and expense resulting from judgments or claims against them (collectively, "Losses") as a result of any claim or lawsuit made by a third party as a result of (i) a Study Injury; (ii) AbbVie's or its representatives negligent acts or omissions, recklessness, or intentional misconduct during and/or in connection with the Study; (iii) AbbVie's use of the Study data and results (including Records); or (iv) AbbVie's breach of any provision of this Agreement. AbbVie's indemnification obligation applies only if (A) Study Materials are administered by Institution Personnel and Procedures are performed during the Study in accordance with the Protocol (provided, however, that actions (including deviations from the Protocol) taken by Institution or Institution Personnel that are based on generally accepted standards of clinical research and medical practice, necessary to treat a condition that poses an immediate risk to the safety, life or well-being of a Study subject shall not, in and of themselves, constitute a violation of the Protocol), with accepted medical practice, and with any other reasonable written instructions furnished by AbbVie, and (B) Study data and results communicated to AbbVie by Institution Personnel are not intentionally misleading or, inaccurate.
- (c) The foregoing agreement to indemnify, defend, and hold harmless Indemnitees is conditioned upon the following obligations of Indemnitees to:
 - (i) advise AbbVie of any claim or lawsuit, in writing addressed to AbbVie Inc., Attention: Risk Management, Dept. 317, Bldg. AP34, 1 N. Waukegan Road, North Chicago, Illinois 60064-3500, with a copy to Attention: Legal R&D, Alliance Management and Transactions, Dept. V323, Bldg. AP34, 1 N. Waukegan Road, North Chicago, Illinois 60064, promptly after Indemnitees has received notice of said claim or lawsuit within such time frame so that AbbVie's ability and rights to defend or settle such claim or lawsuit are not materially prejudiced, provided, however, the failure to promptly notify AbbVie shall not relieve AbbVie of its indemnification obligations unless the AbbVie is materially adversely affected by such failure;

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- (ii) reasonably assist AbbVie and its representatives in the investigation and defense of any lawsuit or claim for which indemnification is provided; and
- (iii) not compromise or otherwise settle any such claim or lawsuit without AbbVie's prior written consent.
- (d) AbbVie's obligations to pay reasonable medical expenses in connection with a Study Injury or to indemnify, defend, or hold harmless shall not apply in the event any Losses or Study Injury, respectively, are attributable to (i) the negligence, recklessness or willful misconduct of, or failure to follow the Protocol (provided, however, that actions (including deviations from the Protocol) taken by Institution or Institution Personnel that are based on generally accepted standards of clinical research and medical practice, necessary to treat a condition that poses an immediate risk to the safety, life or well-being of a Study subject shall not, in and of themselves, constitute a violation of the Protocol), by, any of the Indemnitees or (ii) Institution's or Institution Personnel's breach of any obligations under this Agreement or Statement of Work.
- (e) **Section 15** is subject to the statutory duties of the Texas Attorney General.
- 16. <u>Insurance</u>. Each party shall maintain a policy or program of insurance or self-insurance with policy limits sufficient to support its obligations under this Agreement. Upon request by a party, the other party shall furnish evidence of such party's applicable insurance. Each party's insurance coverage shall comply with applicable Laws and insurance guidelines. Each member of The University of Texas System is self-insured pursuant to The University of Texas Professional Medical Liability Benefit Plan under the authority of Chapter 59, Texas Education Code.
- 17. <u>Independent Contractor</u>. Each party's relationship to the other party is that of an independent contractor, and neither party has authority to bind or act on behalf of the other party.
- 18. <u>Assignment</u>. Neither party may assign this Agreement to any other party without the other party's prior written consent; provided, however, that upon prior written notice to the other party, either party may assign this Agreement without consent to any successor by merger, de-merger or sale of substantially all of the assets to which this Agreement relates; provided further that any successor of Institution is a hospital or other health care facility or patient treatment center. Any attempted assignment except in accordance with this **Section 18** shall be null and void and shall constitute a material breach of this Agreement.
- 19. <u>Subcontracting</u>. In the event Institution subcontracts any aspect of Study performance to a subcontractor, Institution shall (a) ensure each subcontractor's compliance with the requirements of this Agreement and Statement of Work, and (b) be responsible for any subcontractor's non-compliance with the terms and conditions of this Agreement and Statement of Work to the same extent that Institution would be responsible if Institution were performing the subcontracted services directly. If a subcontractor does not strictly adhere to the provisions of this Agreement and Statement of Work, Institution shall promptly notify AbbVie and AbbVie may immediately terminate this Agreement or relevant Statement of Work.

20. Notices.

- (a) Routine communications regarding the conduct of the Study shall be sent to the AbbVie individual identified to Institution by AbbVie as the primary contact for the Study ("AbbVie Study Contact") set forth in the Statement of Work.
- (b) Communications related to the assignment of this Agreement shall be made by email, mail or recognized national or international courier and shall be sent to the AbbVie notice address set forth below.
- (c) All legal notices under this Agreement shall be in writing, refer to this Agreement, and be sent by recognized national or international overnight courier or registered or certified mail, postage prepaid, return receipt requested, or delivered by hand to the legal notice address set forth below.

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If to Institution:

See Appendix A for the name and address of an administrative contact for each Institution

With a copy to: The University of Texas System Office of General Counsel 201 West 7th Street Austin, TX 78701

ATTN: OGC Intellectual Property Assistant

General Counsel and IP Legal Expert

If to AbbVie:

Director, Contract Management Dept. R479, Bldg. AP04-2 AbbVie Inc. 1 N Waukegan Road North Chicago, IL 60064

If to AbbVie (legal notices) Divisional Vice President and Associate General Counsel, Legal R&D, Alliance Management and Transactions AbbVie Inc.

Dept. V323, Bldg. AP34 1 North Waukegan Road North Chicago, IL 60064-6011

Legal notices under this Agreement shall be deemed to be duly given: (i) when delivered by hand; (ii) two (2) days after deposit with a recognized national or international courier; or (iii) on the delivery date indicated in the return receipt for registered or certified mail. A party may change its legal notice address immediately by sending written notice to the other party's legal notice address as set forth in this Section 20.

- 21. Survival. Any other terms which by their intent or meaning are intended to survive termination or expiration of this Agreement shall so survive, including, without limitation, the parties' obligations with respect to financial disclosure reporting and conflict of interest disclosure and management, record retention and audit rights, confidentiality, publicity, intellectual property, publications, notification requirements with respect to such party's representations and certifications as set forth in Section 13(b), indemnification, and Study Injuries.
- 22. Severability. If any provision, right or remedy provided for herein or any Statement of Work is held to be unenforceable or inoperative by a court of competent jurisdiction, the validity and enforceability of the remaining provisions shall not be affected thereby.
- 23. Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed to be an original, and all of which together shall constitute one and the same agreement. Each party acknowledges that an original signature or a copy thereof transmitted by facsimile or by PDF shall constitute an original signature for purposes of this Agreement.
- 24. Entire Agreement. This Agreement including, without limitation, all Exhibits hereto, contains the entire understanding of the parties with respect to the subject matter herein and supersedes all previous agreements and undertakings with respect thereto. In the event of a purchase order is issued to provide for payment of the services under a Statement of Work, the terms and conditions of this Agreement and relevant Statement of Work shall control over any conflict between terms and conditions of the purchase order and this Agreement or Statement of Work. In the event of a conflict between provisions of the Protocol and this Agreement or any Exhibits hereto, the Protocol shall control with respect to matters of science, medical practice, and Study subject safety. In all other matters, the provisions of this Agreement shall control. In the event of any conflict between the terms and provisions of this Agreement and those in the Exhibits hereto or any Statement of Work, the provisions of this Agreement shall control, unless a particular Statement of Work specifically acknowledges the conflict and expressly states that the conflicting term or provision found in the Statement of Work controls for that Statement of Work only (but then only with respect to that particular Statement of Work and with respect only to such matter). Neither this Agreement nor any of

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its terms, including any attachment or Exhibit hereto, may be amended, restated or otherwise altered except by written agreement signed by the parties.

- 25. <u>State Agency</u>. Institution is an agency of the State of Texas and under the Constitution and the laws of the State of Texas possesses certain rights and privileges, is subject to certain limitations and restrictions, and only has such authority as is granted to it under the Constitution and laws of the State of Texas. Notwithstanding any provision hereof, nothing in this Agreement is intended to be, nor will it be construed to be, a waiver of the sovereign immunity of the State of Texas or a prospective waiver or restriction of any of the rights, remedies, claims, and privileges of the State of Texas. Moreover, notwithstanding the generality or specificity of any provision hereof, the provisions of this Agreement as they pertain to Institution are enforceable only to the extent authorized by the Constitution and laws of the State of Texas; accordingly, to the extent any provision hereof conflicts with the Constitution or laws of the State of Texas or exceeds the right, power or authority of Institution to agree to such provision, then that provision will not be enforceable against Institution or the State of Texas.
- 26. Clinical Trials Xpress ("CTX") [www.clinicaltrialsxpress.org], a wholly-owned initiative of the System, is the central coordinating office and team established to promote efficient and streamlined study start-up processes of multi-institutional clinical trials. More specifically, the CTX network operating model accelerates study implementation by negotiating a single, common clinical trial study budget; using pre-approved master clinical trial agreements; and by adopting the System IRB Reciprocity model or central IRBs for regulatory oversight. AbbVie may engage the services of the CTX central coordinating office when the applicable Study contemplated by this Agreement will be considered for participation by more than one Institution.

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IN WITNESS WHEREOF, the parties have caused this Agreement to be executed by their duly authorized representatives.

ABBVIE INC.	THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON
By: Panela Schroede	By: Christopher Denman
Name: Pamela Schroeder	Assistant Director, Contracts
Title: Assistant Director	Sponsored Projects Administration
Date: 27 Sept 2016	Date: 10/17/16
THE UNIVERSITY OF TEXAS SCIENCE CENTER AT SAN ANTONIO	THE UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER
Ву:	By:
Name:	Name:
Title:	Title:
Date:	Date:
THE UNIVERSITY OF TEXAS MEDICAL BRANCH AT GALVESTON	THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT TYLER
By:	By:
Name:	Name:
Title:	Title:
Date:	Date:
THE UNIVERSITY OF TEXAS AT AUSTIN	THE UNIVERSITY OF TEXAS RIO GRANDE VALLEY
By:	Ву:
Name:	Name:
Title:	Title:
Date:	Date:

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IN WITNESS WHEREOF, the parties have caused this Agreement to be executed by their duly authorized representatives.

ABBVIE INC.	THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON
By: Tamela Schroede	Ву:
Name: Pamela Schroeder	Name:
Title: Assistant Director	Title:
Date: 27 Sept 2016	Date:
THE UNIVERSITY OF TEXAS SCIENCE CENTER AT SAN ANTONIO	THE UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER
By: CMP/8-8um	Ву:
Name: Chris G. Green, CPA	Name:
Title: Director, Office of Sponsored Programs	Title:
Date: 05 October 2016	Date:
THE UNIVERSITY OF TEXAS MEDICAL BRANCH AT GALVESTON	THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT TYLER
Ву:	Ву:
Name:	Name:
Title:	Title:
Date:	Date:
THE UNIVERSITY OF TEXAS AT AUSTIN	THE UNIVERSITY OF TEXAS RIO GRANDE VALLEY
Ву:	Ву:
Name:	Name:
Title:	
	Title:

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IN WITNESS WHEREOF, the parties have caused this Agreement to be executed by their duly authorized representatives.

ABBVIE INC.	THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON
By: Jamela Schroede	Ву:
Name: Pamela Schroeder	Name:
Title: Assistant Director	Title:
Date: 27 Sept 2016	Date:
THE UNIVERSITY OF TEXAS SCIENCE CENTER AT SAN ANTONIO	THE UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER DOCUSTIGNED by:
Ву:	By: Dong
Name:	Name: Davifdenegge4ed
Title:	Title: Assistant Vice President, Sponsored Programs Adm
Date:	Date: 10/20/2016
THE UNIVERSITY OF TEXAS MEDICAL BRANCH AT GALVESTON	THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT TYLER
Ву:	Ву:
Name:	Name:
Title:	Title:
Date:	Date:
THE UNIVERSITY OF TEXAS AT AUSTIN	THE UNIVERSITY OF TEXAS RIO GRANDE VALLEY
Ву:	Ву:
Name:	Name:
Title:	Title:
Date:	Date:

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Five Year Term

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed by their duly authorized representatives.

ABBVIE	INC.	THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON
By:	tamela Schroede	Ву:
Name:	Pamela Schroeder	Name:
Title:	Assistant Director	Title:
Date:	27 Sept 2016	Date:
	IIVERSITY OF TEXAS SCIENCE R AT SAN ANTONIO	THE UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER
Ву:		Ву:
Name:		Name:
Title:		Title:
Date:		Date:
	IIVERSITY OF TEXAS MEDICAL H AT GALVESTON	THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT TYLER
Ву:	for Cyra	Ву:
Name:	Toni D'Agostino	Name:
Title:	Assoc. VP, Research Admin	Title:
Date:	10/05/2016	Date:
THE UN	IIVERSITY OF TEXAS AT AUSTIN	THE UNIVERSITY OF TEXAS RIO GRANDE VALLEY
Ву:		Ву:
Name:		Name:
Title:		Title:
Date:		Date:

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IN WITNESS WHEREOF, the parties have caused this Agreement to be executed by their duly authorized representatives.

ABBVIE INC.	THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON
By: tamela Schroede	Ву:
Name: Pamela Schroeder	Name:
Title: Assistant Director	Title:
Date: 27 Sept 2016	Date:
THE UNIVERSITY OF TEXAS SCIENCE CENTER AT SAN ANTONIO	THE UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER
Ву:	Ву:
Name:	Name:
Title:	Title:
Date:	Date:
THE UNIVERSITY OF TEXAS MEDICAL BRANCH AT GALVESTON	THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT TYLER
Ву:	By:
Name:	Name: David Anderson
Title:	Title: Director, Sponsored Programs
Date:	Date: 10/13/16
THE UNIVERSITY OF TEXAS AT AUSTIN	THE UNIVERSITY OF TEXAS RIO GRANDE VALLEY
Ву:	Ву:
Name:	Name:
Title:	Title:
Date:	Date:

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Five Year Term Includes StemCentrx as Affiliate

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed by their duly authorized representatives.

ABBVIE INC.	THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON
By: Tamela Schroede	Ву:
Name: Pamela Schroeder	Name:
Title: Assistant Director	Title:
Date: 27 Sept 2016	Date:
THE UNIVERSITY OF TEXAS SCIENCE CENTER AT SAN ANTONIO	THE UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER
Ву:	Ву:
Name:	Name:
Title:	Title:
Date:	Date:
THE UNIVERSITY OF TEXAS MEDICAL BRANCH AT GALVESTON	THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT TYLER
Ву:	Ву:
Name:	Name:
Title:	Title:
Date:	Date:
THE UNIVERSITY OF TEXAS AT AUSTIN	THE UNIVERSITY OF TEXAS RIO GRANDE VALLEY
By:	Ву:
Mr. David Hawkins, Associate Director	Name:
Titlehe University of Texas at Austin	Title:
Date: 10 13 2016	Date:

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IN WITNESS WHEREOF, the parties have caused this Agreement to be executed by their duly authorized representatives.

ABBVIE INC	THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON
By: Jamels Sch	voede By:
Name: Pamela Sch	roeder Name:
Title: Assistant D	irector Title:
Date: 27 Sept 20	Date:
THE UNIVERSITY OF TEXAS SCIE CENTER AT SAN ANTONIO	NCE THE UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER
Ву:	Ву:
Name:	
Title:	
Date:	D
THE UNIVERSITY OF TEXAS MED BRANCH AT GALVESTON	THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT TYLER
By:	Ву:
Name:	
Title:	Tido:
Date:	
THE UNIVERSITY OF TEXAS AT A	
By:	
Name:	
Title:	Title: Associate Vice President for Research
Date:	Date: October 5, 2016

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APPENDIX A

Administrative contact person and address for each Institution named in Agreement between AbbVie Inc. and the System.

David Hawkins Associate Director, Office of Sponsored Projects The University of Texas at Austin P.O. Box 7726 Austin, Texas 78713-7726 Phone: 512-471-6424 Fax: 512-471-6564 Tax ID: 74-600023	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
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	Christopher Denman Assistant Director, Contracts The University of Texas Health Science Center at Houston P.O. Box 20036 Houston, TX 77225 Phone: 713-500-3166 Fax: 713-383-3746 Tax ID: 74-1761309 Overnight address is: 7000 Fannin Street, Suite UCT 1007-2 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
Glorimar Colon Research Liaison Officer Office of the Senior VP for Research, Innovation, and Economic Development The University of Texas Rio Grande Valley 1201 West University Drive Edinburg, TX 78539 Phone: 965-665-3008 Fax: 956-665-2940 Email: glorimar.colon@utrgv.edu Tax ID: 46-5292740	

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EXHIBIT A-1

STANDARD STATEMENT OF WORK TEMPLATE

This Statement of Work ("Statement of Work"), effective as of the full execution hereof ("Effective Date") is entered into by and between Insert Name of UT Campus(es) ("Institution") and Insert Name of AbbVie Legal Entity ("Sponsor"), and is issued under that certain Master Clinical Study Agreement (AbbVie Contract Number C103262) effective Insert Date MCSA was fully executed (the "Agreement") by and between AbbVie Inc. ("AbbVie") and The University of Texas Health Science Center at Houston; The University of Texas Health Science Center at San Antonio, The University of Texas Health Science Center at Tyler; The University of Texas Medical Branch at Galveston; The University of Texas Southwestern Medical Center; The University of Texas Rio Grande Valley and The University of Texas at Austin. This Statement of Work includes the terms and conditions of the Agreement, which are hereby incorporated herein by reference.

WHEREAS, for purposes of this Statement of Work, the defined term "AbbVie" in the Agreement shall refer to and mean "Sponsor," as defined in this Statement of Work.

- 1. Protocol. The Study is to be conducted in relation to the Sponsor product Insert Sponsor Study Product (individually and collectively, the "Study Product") pursuant to Protocol No. Insert Protocol No. entitled "Insert Protocol Title," which may be amended from time to time (the "Protocol"), the terms of the Agreement and this Statement of Work.
- 2. <u>Principal Investigator</u>. Sponsor is entering into this Statement of Work with the understanding that <u>Insert Investigator's Name</u> ("<u>Principal Investigator</u>"), an employee of the <u>Insert Campus</u>, shall be responsible on Institution's behalf for the conduct of the Study.
- 3. <u>Equipment</u>. Sponsor will provide Institution with the equipment described in **Exhibit B** (Equipment to be provided by Sponsor) ("Equipment") in accordance with the terms of the Agreement.
- 4. <u>Compensation</u>. Sponsor shall pay Institution in accordance with the Budget attached hereto and incorporated herein as **Exhibit A** (Budget Summary and Payment Schedule) and with the terms of the Agreement.
- 5. <u>Study Term</u>. This Statement of Work shall be effective upon the Effective Date and shall terminate on the earlier of: (i) one (1) year from the Effective Date, if there is no subject enrollment at Institution under this Statement of Work; or (ii) upon completion of the Study at Institution (the "<u>Study Term</u>"), unless terminated earlier pursuant to the terms of the Agreement.

6. Notices.

- (a) Routine communications regarding the conduct of the Study shall be sent to the Sponsor individual identified by Institution to Sponsor as the primary contact for the Study ("Sponsor Study Contact").
- (b) Communications related to the replacement of the individuals identified on FDA Form 1572 shall be made by email, mail, or recognized national or international courier and shall be sent to the Sponsor Study Contact [If AbbVie is the party, please include the following; otherwise please delete or include the appropriate name] with a copy to Assistant Director, Outsourcing, AbbVie Research and Development, Dept. R479, Bldg. AP04, 1 N. Waukegan Road, North Chicago, Illinois 60064, email: pamela.schroeder@abbvie.com.]
- (c) All legal notices under this Statement of Work shall be in writing, refer to this Statement of Work, and be sent by recognized national or international overnight courier or registered or certified mail, postage prepaid, return receipt requested, or delivered by hand to the legal notice address set forth below.

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If to Institution:

See Appendix A for the name and address of an administrative contact for each Institution.

With a copy to:

The University of Texas System Office of General Counsel 201 West 7th Street Austin, TX 78701

ATTN: OGC Intellectual Property Assistant

General Counsel and IP Legal Expert

If to Sponsor:

[If AbbVie is the Sponsor, include the following. Otherwise, insert applicable notices recipient.]

Assistant Director, Outsourcing Dept. R479, Bldg. AP04 AbbVie Inc. 1 N Waukegan Road North Chicago, IL 60064

If to Principal Investigator:

Insert Name Insert Title Insert Address Insert City, State Zip

If to Sponsor (legal notices):

[If AbbVie is the Sponsor, include the following. Otherwise, insert applicable notices recipient.]

Divisional Vice President and Associate General Counsel, Legal R&D, Alliance Management and Transactions AbbVie Inc. Dept. V323, Bldg. AP34 1 North Waukegan Road North Chicago, IL 60064-6011

Legal notices under this Statement of Work shall be deemed to be duly given: (i) when delivered by hand; (ii) two (2) days after deposit with a recognized national or international courier; or (ii) on the delivery date indicated in the return receipt for registered or certified mail. A party may change its legal notice address immediately by sending written notice to the other party's legal notice address as set forth in this **Section 6** of this Statement of Work.

- 7. <u>Counterparts</u>. This Statement of Work may be executed in any number of counterparts, each of which shall be deemed to be an original, and all of which together shall constitute one and the same agreement. Each party acknowledges that an original signature or a copy thereof transmitted by facsimile or by PDF shall constitute an original signature for purposes of this Statement of Work.
- 8. Entire Agreement. This Statement of Work including, without limitation, all Exhibits hereto and the Agreement contain the entire understanding of the parties with respect to the subject matter herein and supersedes all previous agreements and undertakings with respect thereto. In the event of a conflict between the provisions of the Protocol and the terms and provisions of this Statement of Work or any Exhibits hereto, the Protocol shall control with respect to matters of science, medical practice and Study subject safety. In all other matters, the terms and provisions of this Statement of Work shall control. In the event of any conflict between the terms and provision of this Statement of Work and those of the Agreement, the terms and provisions of the Agreement shall control, unless this Statement of Work specifically acknowledges the conflict and expressly states that the conflicting term or provision found in this Statement of Work controls for this Statement of Work only. This Statement of Work may be modified only by written agreement signed by the parties to this Statement of Work.

IN WITNESS WHEREOF, the parties have caused this Statement of Work to be executed by their duly authorized representatives.

INSERT ABBVIE LEGAL ENTITY NAME	INSERT C	AMPUS
Ву:	Ву:	DRAFT – NOT FOR SIGNATURE
Name:	Name:	
	-	

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The University of Texas System September 27, 2016	
Title:	Title:
Date:	Date:
	I have read the Agreement and this Statement of Work and acknowledge the obligations under the provisions of the Agreement and this Statement of Work.
	By: DRAFT – NOT FOR SIGNATURE
	Name: Insert Name of Principal Investigator
	Title: Principal Investigator

Date:

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EXHIBIT A TO STATEMENT OF WORK

BUDGET SUMMARY AND PAYMENT SCHEDULE

(See accompanying PDF attachment)

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EXHIBIT B TO STATEMENT OF WORK

EQUIPMENT TO BE PROVIDED BY SPONSOR

Manufacturer	Model #	Basic Description	Replacement Value
Intentionally omitted – Sponsor will not be providing any equipment for this Study			

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EXHIBIT A-2

ABT-199 STATEMENT OF WORK TEMPLATE

This Statement of Work ("Statement of Work"), effective as of the full execution hereof ("Effective Date") is is entered into by and between Insert Name of UT Campus(es) ("Institution") and AbbVie Inc. ("AbbVie"), and is issued under that certain Master Clinical Study Agreement (AbbVie Contract Number C103262) effective Insert Date MCSA was fully executed (the "Agreement") by and between AbbVie and The University of Texas Health Science Center at Houston; The University of Texas Health Science Center at San Antonio, The University of Texas Health Science Center at Tyler; The University of Texas Medical Branch at Galveston; The University of Texas Southwestern Medical Center; The University of Texas Rio Grande Valley and The University of Texas at Austin. This Statement of Work includes the terms and conditions of the Agreement, which are hereby incorporated herein by reference.

WHEREAS, Institution acknowledges that AbbVie has advised Institution that AbbVie has a collaboration agreement with Genentech Inc. ("Genentech") relating to the AbbVie product ABT-199 (the "Study Product") and the Study will involve use of the Study Product. This AbbVie-Genentech collaboration agreement imposes certain non-negotiable conditions on conduct of the Study and use of the Study Product as set forth below. Retention by AbbVie of Institution to conduct the Study described below is conditioned on Institution's agreement to these conditions. Genentech is an intended third party beneficiary of this Statement of Work and, for purposes of this Statement of Work, the Agreement.

NOW, THEREFORE, the parties hereby agree as follows:

- 1. <u>Protocol</u>. The Study is to be conducted in relation to the Study Product pursuant to Protocol No. <u>Insert Protocol No.</u> entitled "<u>Insert Protocol Title</u>," which may be amended from time to time (the "<u>Protocol</u>"), the terms of the Agreement and this Statement of Work.
- 2. <u>Principal Investigator</u>. AbbVie is entering into this Statement of Work with the understanding that <u>Insert Investigator's Name</u> ("<u>Principal Investigator</u>"), an employee of the <u>Insert Campus</u>, shall be responsible on Institution's behalf for the conduct of the Study.
- 3. <u>Equipment</u>. AbbVie will provide Institution with the equipment described in **Exhibit B** (Equipment to be provided by AbbVie) ("<u>Equipment</u>") in accordance with the terms of the Agreement.
- 4. <u>Compensation</u>. AbbVie shall pay Institution in accordance with the Budget attached hereto and incorporated herein as **Exhibit A** (Budget Summary and Payment Schedule) and with the terms of the Agreement.
- 5. Pursuant to **Section 24** of the Agreement and only with respect to this Statement of Work, the first two sentences of **Section 10(b)** (<u>Publicity</u>) of the Agreement shall be replaced in its entirety and superseded by the following language:
 - "Neither party shall use the trademark, servicemark, or logo of the other party or the other party's affiliates or of Genentech in any publicity, advertising, or other information intended to be disseminated to any third person or to the general public without the prior written consent of such other party or of Genentech, as applicable. Neither party shall use the name of the other party or the other party's affiliates or of Genentech in any publicity, advertising, or other information intended to be used for commercial or promotional purposes without the prior written consent of such other party or of Genentech, as applicable."
- 6. Pursuant to **Section 24** of the Agreement and only with respect to this Statement of Work, **Section 11(b)** (Intellectual Property) shall be superseded and replaced in its entirety by the following language:

"Any invention, discovery (whether patentable or not), conceived or first reduced to practice, made, generated or developed by Institution or Institution Personnel that is made in the conduct of the Study or made from use of any of the Study Materials provided hereunder, or from using biological samples obtained from the Study subjects as part of the Study (collectively, "Intellectual

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<u>Property</u>") shall be promptly disclosed to AbbVie, and Institution hereby assigns to AbbVie all of Institution's rights, title, and interest in and to such Intellectual Property. Inventorship of Intellectual Property constituting inventions shall be determined according to U.S. patent laws. Upon AbbVie's request and at AbbVie's expense, Institution shall require Institution Personnel to execute, or cause to have executed such documents and to take such other reasonable actions to obtain, record or enforce patents, assignments or other proprietary protection in AbbVie's and Genentech's name covering such Intellectual Property. Subject to **Section 8** (Confidentiality) and **Section 12** (Publications and Presentations), AbbVie grants to Institution a free, non-transferable, non-sublicensable, non-exclusive license to use any Intellectual Property solely for its internal and non-commercial research, teaching, patient care purposes and for publication purposes."

7. Pursuant to **Section 24** of the Agreement and only with respect to this Statement of Work, the first sentence of **Section 12(c)** (Publications and Presentations) of the Agreement shall be superseded and replaced in its entirety by the following sentence:

"Following the earliest of: (i) AbbVie's Summary Publication; or (ii) eighteen (18) months after completion, abandonment or termination of the Study at all Study sites, Institution and Institution Personnel shall have the right to prepare and submit for public disclosure Institution's Study data through a Scientific Publication or other public disclosure (an "Institution Publication")."

8. <u>Study Term</u>. This Statement of Work shall be effective upon the Effective Date and shall terminate on the earlier of: (i) one (1) year from the Effective Date, if there is no subject enrollment at Institution under this Statement of Work; or (ii) upon completion of the Study at Institution (the "<u>Study Term</u>"), unless terminated earlier pursuant to the terms of the Agreement.

9. Notices.

- (a) Routine communications regarding the conduct of the Study shall be sent to the AbbVie individual identified by Institution to AbbVie as the primary contact for the Study ("AbbVie Study Contact").
- (b) Communications related to the replacement of the individuals identified on FDA Form 1572 shall be made by email, mail, or recognized national or international courier and shall be sent to the AbbVie Study Contact with a copy to Assistant Director, Outsourcing, AbbVie Research and Development, Dept. R479, Bldg. AP04, 1 N. Waukegan Road, North Chicago, Illinois 60064, email: pamela.schroeder@abbvie.com.
- (c) All legal notices under this Statement of Work shall be in writing, refer to this Statement of Work, and be sent by recognized national or international overnight courier or registered or certified mail, postage prepaid, return receipt requested, or delivered by hand to the legal notice address set forth below.

If to Institution:

See Appendix A for the name and address of an administrative contact for each Institution.

Insert Name
Insert Title

With a copy to:

The University of Texas System Office of General Counsel 201 West 7th Street Austin, TX 78701

ATTN: OGC Intellectual Property Assistant General Counsel and IP Legal Expert

If to AbbVie:

Assistant Director, Outsourcing Dept. R479, Bldg. AP04 AbbVie Inc. 1 N Waukegan Road North Chicago, IL 60064

If to Principal Investigator:

Insert Name
Insert Title
Insert Address
Insert City, State Zip

If to AbbVie (legal notices):

Divisional Vice President and Associate General Counsel, Legal R&D, Alliance Management and Transactions AbbVie Inc.

ADD VIG IIIC.

Dept. V323, Bldg. AP34

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1 North Waukegan Road North Chicago, IL 60064-6011

Legal notices under this Statement of Work shall be deemed to be duly given: (i) when delivered by hand; (ii) two (2) days after deposit with a recognized national or international courier; or (ii) on the delivery date indicated in the return receipt for registered or certified mail. A party may change its legal notice address immediately by sending written notice to the other party's legal notice address as set forth in this **Section 9** of this Statement of Work.

- 10. <u>Counterparts</u>. This Statement of Work may be executed in any number of counterparts, each of which shall be deemed to be an original, and all of which together shall constitute one and the same agreement. Each party acknowledges that an original signature or a copy thereof transmitted by facsimile or by PDF shall constitute an original signature for purposes of this Statement of Work.
- 11. Entire Agreement. This Statement of Work including, without limitation, all Exhibits hereto and the Agreement contain the entire understanding of the parties with respect to the subject matter herein and supersedes all previous agreements and undertakings with respect thereto. In the event of a conflict between the provisions of the Protocol and the terms and provisions of this Statement of Work or any Exhibits hereto, the Protocol shall control with respect to matters of science, medical practice and Study subject safety. In all other matters, the terms and provisions of this Statement of Work shall control. In the event of any conflict between the terms and provision of this Statement of Work and those of the Agreement, the terms and provisions of the Agreement shall control, unless this Statement of Work specifically acknowledges the conflict and expressly states that the conflicting term or provision found in this Statement of Work controls for this Statement of Work only. This Statement of Work may be modified only by written agreement signed by the parties to this Statement of Work.

IN WITNESS WHEREOF, the parties have caused this Statement of Work to be executed by their duly authorized representatives.

ABBVIE INC.	INSERT CAMPUS
Ву:	By: DRAFT – NOT FOR SIGNATURE
Name:	Name:
Title:	Title:
Date:	Date:
	I have read the Agreement and this Statement of Work and acknowledge the obligations under the provisions of the Agreement and this Statement of Work.
	By: DRAFT – NOT FOR SIGNATURE
	Name: Insert Name of Principal Investigator
	Title: Principal Investigator
	Date:

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EXHIBIT A TO STATEMENT OF WORK

BUDGET SUMMARY AND PAYMENT SCHEDULE

(See accompanying PDF attachment)

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EXHIBIT B TO STATEMENT OF WORK

EQUIPMENT TO BE PROVIDED BY ABBVIE

Manufacturer	Model #	Basic Description	Replacement Value
Intentionally omitted – AbbVie will not be providing any equipment for this Study			

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