

# MASTER CLINICAL STUDY AGREEMENT

## BETWEEN

### ABBOTT LABORATORIES AND SEVERAL MEMBER HEALTH INSTITUTIONS OF THE UNIVERSITY OF TEXAS SYSTEM

This Master Clinical Study Agreement (“Agreement”), effective as of the full execution hereof (“Effective Date”), sets forth the terms and conditions by and between **Abbott Laboratories** and its Affiliates (“Abbott”) and the following member health institutions of The University of Texas System (“UT System”):

The University of Texas Health Science Center at San Antonio;  
The University of Texas Health Science Center at Houston;  
The University of Texas Health Science Center at Tyler;  
The University of Texas Southwestern Medical Center;  
The University of Texas Medical Branch at Galveston;  
The University of Texas at Austin; and  
The University of Texas Rio Grande Valley

(each an “Institution” or collectively “Institutions”) to enable multiple clinical studies sponsored by Abbott (each, a “Study”) in relation to Abbott investigational or commercial products (“Study Product”) to be conducted at Institution upon mutual agreement and execution of individual Statements of Work (“SOWs”). In consideration of the mutual promises set forth herein, the parties agree as follows.

1. **Scope of Master Agreement.** This Agreement allows the parties to conduct individual clinical studies to be sponsored by Abbott through the issuance of multiple individual written agreements between Abbott and Institution, a form of which is attached hereto as **Exhibit A** (“Form of Statement of Work”). Each SOW shall be executed by an authorized representative of each party, and acknowledged by the applicable Investigator. Each SOW will include, as applicable: the name of the Study Product; the Study protocol, specifying the objective, design, methodology, statistical considerations and the organization of the Study as developed by Abbott (“Protocol”); the name of the qualified lead Institution employee responsible for the conduct of the Study at Institution (“Investigator”); the detailed Study budget and payment schedule (“Budget”); timeframes to enroll Study subjects; Investigator and Abbott contacts; compensation; and the Study term. The Protocol shall be provided separately for each individual Study and referred to and incorporated by reference in each SOW. Each SOW shall be subject to all the terms and conditions of this Master Agreement, in addition to the specific details set forth in the SOW. Abbott may execute individual SOWs in the names of any of its Affiliates, defined as entities controlled by or under common control with Abbott.
2. **Conduct of Individual Studies.**
  - 2.1 **Ethics Approval and Informed Consent.** Institution will ensure that an Institutional Review Board and/or an Independent Ethics Committee (collectively, “EC”), established and constituted in accordance with Applicable Law (defined below) approves and oversees the conduct of each Study. Institution will comply with the directives of the EC, as applicable, and will notify Abbott to the extent any such directives vary from the Protocol. Investigator shall obtain from each person enrolling in the Study, prior to the subject’s participation in the Study (a “Study Subject”) a valid written informed consent form (“ICF”) and document it as required by Applicable Law (defined below). The ICF must permit Abbott and its representatives to access, process, obtain copies, transfer and retain Study data. The Institution and the Investigator will comply with the terms of the consent, the Protocol, Abbott’s instructions, and any guidance provided by the EC. Institution will notify Abbott as soon as reasonably practicable if the EC withdraws approval for the Study.
  - 2.2 **Affiliated Institution Facilities.** Upon notification and consent from Abbott, and consistent with the terms of this Agreement, Institution may conduct Studies at an affiliated facility with common EC oversight.
  - 2.3 **Study Staff and Institution Oversight.** The Institution and Investigator shall supervise and ensure Study Staff are appropriately trained, qualified, certified, and abide by the applicable terms of this Agreement. Study Staff

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includes Investigator, sub-investigators and any other employees, contractors or agents performing or assisting with individual Studies ("Study Staff").

- 2.4 Delivery of Reports. Upon reasonable request, Institution will submit oral or written reports on the progress of each Study. Institution will ensure that Study data, as required by the Protocol, is entered into the Case Report Forms within 10 business days of Study Subject visits. Within 45 days following the completion or termination of the Study, Institution will provide Abbott the final report prepared by the Investigator for the EC.
- 2.5 Competitive Enrollment. Institution and Investigator acknowledge that (a) a Study may involve participation of multiple sites; (b) recruitment is competitive; and (c) when the enrollment goal for the entire Study is reached enrollment will be closed at all sites, including the Institution, regardless of whether the Institution and Investigator have reached their individual enrollment goal. Institution will use reasonable best efforts to meet enrollment targets provided by Abbott. Upon notice of enrollment closure, Institution and Investigator shall immediately cease enrollment of new subjects.
- 2.6 Study Product and Study Materials. Abbott will provide sufficient quantity of Study Product (the "Study Product"), as well as any other supplies and information specified by the Protocol as necessary to conduct each Study (the "Study Materials"). All Study Product and Study Materials provided will remain the sole property of Abbott. Neither Institution nor Investigator will use any Study Product or Study Materials for any purpose other than to conduct the applicable Study. Investigator shall supervise the testing of Study Product and maintain accurate records that include receipt and disposition. Each of Institution and Investigator shall notify Abbott in the event the supply of Study Product or Study Materials needs replenishing and will ensure Products are stored and handled in accordance with the labeling, applicable regulatory requirements, and Abbott's written instructions. Institution and Investigator will return at Abbott's reasonable expense any unused or expired Study Product and Study Materials to Abbott upon conclusion of a Study, termination of this Agreement, or at Abbott's written request. Any transportation of Study Product shall be conducted in accordance with all applicable regulatory requirements. If any Study Product are required to be destroyed, Institution shall carry out such disposal at Abbott's reasonable expense and in compliance with all Applicable Law. Final disposition of Study Product and Study Materials shall be documented by Institution to include dates, quantities and use by Study Subjects. Institution shall not bill any third party for Study Product or Study Materials provided by Abbott.
- 2.7 Safety Reporting. Institution and Investigator shall notify Abbott of any information concerning Study Product deficiency and any serious or unexpected event or injury in accordance with the applicable Protocol and regulatory requirements. Abbott agrees to provide Institution with any data and safety monitoring reports as required by Applicable Law, and Institution agrees they will be submitted to the EC as required. Abbott shall provide Institution and Investigator with the written report of any findings, including Study results and any routine monitoring findings, and data and safety analyses. During and for a period of 2 years after completion or termination of a Study, Abbott shall promptly and within a reasonable time after becoming aware, provide Institution and Investigator any Study information that may affect the safety and welfare of current or former Study Subjects, affect the willingness of Study Subjects to continue participating in a Study, materially influence the conduct of a Study, or alter EC approval to continue a Study, and in each case, Institution or Investigator shall be free to communicate such Study information to each Study Subject and to the EC.

### **3 Monitoring, Audit and Record Retention.**

- 3.1 Monitoring and Audits by Abbott. Institution will permit Abbott and any Abbott designee access to Study sites during normal business hours agreed by the parties in advance to monitor the Study and to audit records and data relating to the Study. Institution may redact records, source documents, and other data as legally required to protect Subject confidentiality. If Abbott requests corrective and/or preventive action relating to its monitoring or audits, Institution shall timely create and implement a corrective and/or preventive plan. Abbott's right to audit shall survive expiration of this Agreement for two years.

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3.2 Audits by Regulatory Authorities. If legally permissible, Institution will notify Abbott within two business days upon receipt of any requests by a regulatory authority to inspect or have access to Study documents and will promptly provide Abbott with a copy of any such request, to include copies of any documents received from or provided to regulatory authorities. If legally permissible, Abbott may attend or request to be present during any inspection. Abbott agrees not to alter or interfere with any documentation or practice of Institution. Upon receipt of a regulatory citation or notice relating to this Agreement, Institution agrees to produce a summary within 10 business days that includes an explanation of the issues identified by the regulatory authority and any response thereto.

3.3 Records Retention. Institution shall retain Study documents in accordance with Applicable Law or the Protocol, whichever retention period is longer. At Abbott's request and expense, Institution shall retain the documents for an additional period.

#### **4 Compliance and Transparency**

4.1 Legal and Regulatory Standards. The parties will conduct each Study in accordance with all applicable laws, regulations and international standards, including but not limited to International Conference on Harmonization, Good Clinical Practice (ICH-GCP), the Declaration of Helsinki, ISO 14155, the regulations of the United States Food and Drug Administration or its foreign equivalent governing clinical investigations and the protection of human subjects ("Applicable Law").

4.2 Anticorruption. The parties acknowledge and agree that all compensation provided for in this Agreement represents 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 between Institution, Investigator and Abbott. Neither this Agreement, nor any payment hereunder, is in exchange for any explicit or implicit agreement or understanding that Institution or Investigator purchase, lease, order, prescribe, recommend or otherwise arrange for the use of Abbott products.

4.3 Financial Disclosure Certification. Prior to the initiation of each Study, Institution will ensure that Investigator and any subinvestigators complete and return to Abbott the Financial Disclosure Certification, as applicable. Each individual certifying will promptly notify Abbott of any change in the accuracy of the Certification during the Term and for one year following completion of the applicable Study. Investigator understands and will be required to certify that Investigator, any subinvestigators and their immediate families may not have a direct ownership interest (e.g., intellectual property rights) in any Study Products, nor may they be compensated with Abbott securities in exchange for serving as an Investigator or subinvestigator. Institution and Investigator will comply with all applicable requirements regarding reporting and management of conflicts of interest.

4.4 Transparency Reporting. Abbott may be required to report and publish certain direct and indirect transfers of value made to healthcare providers pursuant to Applicable Law. Institution and Investigator shall provide Abbott with any information necessary to satisfy transparency reporting obligations. Institution agrees to provide all relevant healthcare providers with notice that the types of information referenced herein will be shared with Abbott so that Abbott may report transfers of value as necessary, and that such information will be made available to the public.

4.5 Study Registration. Abbott shall register Studies at either [www.clinicaltrials.gov](http://www.clinicaltrials.gov) or any other registry as applicable or required by law and consistent with the guidelines of the International Committee of Medical Journal Editors ("ICMJE") on trial registrations.

#### **5 Confidentiality and Data Protection**

5.1 Confidential Information. Information exchanged in anticipation of or during the Term of this Agreement, including but not limited to the Protocol, Study Products and Materials, data, results and other information concerning or developed as a result of individual Studies shall be deemed Confidential Information. During the Term of this Agreement and each SOW, and for a period of 5 years after expiration or termination of each, no

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party, including their respective employees or agents, shall disclose Confidential Information without the non-disclosing party's prior written consent. Should it be necessary to disclose a trade secret under this Agreement for the purposes of a Study, the disclosing party will provide written notice of its intent to disclose the trade secret by way of the particular Study SOW or other writing and the trade secret will be marked as such by the disclosing party. Obligations of confidentiality and non-use with respect to any Confidential Information identified in writing as a trade secret, including any additional period of confidentiality beyond the 5-year period described in this section, will be mutually agreed by the parties and specified in writing by the disclosing party. Confidential Information shall not include any information that is known to a party prior to receipt or is independently developed by the receiving party, as evidenced by its written records; becomes part of the public domain; or is received from a third party having no obligation of confidentiality to the disclosing party.

5.2 Permitted Use and Disclosure. A party may use and/or disclose Confidential Information of another party with prior written consent or for the limited purpose of performing obligations under this Agreement, complying with a legal order to disclose, of ensuring patient safety or informed consent, or complying with government reimbursement billing requirements. Upon receipt of a legal order to disclose, the receiving party will give the non-disclosing party prompt written notice (no less than 5 business days) to enable the non-disclosing party to take action to protect its Confidential Information.

5.3 Data Protection. The parties will comply with all Applicable Law regarding Study Subject and Study Staff confidentiality and data protection, including but not limited to the Health Insurance Portability And Accountability Act (HIPAA) and the General Data Protection Regulation (GDPR), as applicable. The parties, as appropriate for their respective roles, shall maintain appropriate safeguards to ensure the confidentiality and security of information identifying or, in combination with other information, identifiable to a living individual ("Personal Data") and any Processing associated with it. "Processing" (and its conjugates, including without limitation "Process") shall mean any operation or set of operations that is performed upon Personal Data, including without limitation any collection, recording, retention, organization, storage, adaptation, alteration, retrieval, consultation, blocking erasure use, disclosure, access, transfer, or destruction, whether or not by electronic means. The provisions of this section will survive termination or expiration of this Agreement.

5.4 Data Security Breaches. In the event of a breach of Institution's data system, Institution or Investigator shall report to Abbott, within fourteen (14) calendar days, any confirmed unauthorized or unintentional access to, acquisition of, or disclosure of personal health information as defined under HIPAA ("Security Breach"). The report shall include the timing and nature of the Security Breach. Institutions' notice to Abbott and report of a confirmed breach shall be treated as Confidential Information under this Agreement. Institution shall take all reasonable and necessary steps to remedy and mitigate any harm arising from the Security Breach.

5.5 Study Staff Consents. Investigator acknowledges and consents, and shall cause all Study Staff to acknowledge and consent, to Abbott's collection, use, processing, and disclosure of Investigator's and any sub-investigator's Personal Data, including details of his/her name, address, qualifications and clinical trials experience. Additional uses or disclosures may include financial information (including compensation and reimbursement payments), public registration of each Study on web sites designed for this purpose (such as [www.clinicaltrials.gov](http://www.clinicaltrials.gov)), assessments by Abbott of Investigator's suitability for future studies, and for compliance with Applicable Law. Institution and Investigator understand and agree and shall cause all Study Staff to agree that this information may, as necessary for the purposes of the Study be made available to the EC, government authorities and other Abbott companies or authorized agents, and may be transmitted outside the country of origin to the United States or elsewhere as required.

## 6 Data Ownership and Intellectual Property.

6.1 Use and Ownership of Data. Data and results generated by Institution in conducting each Study shall belong to Abbott, and Abbott shall have the right to use the data in accordance with Applicable Law and the terms of this Agreement. Institution shall retain the right to use the data and results for its publication, regulatory, and non-

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commercial internal research, educational, and patient-care purposes. Individual patient medical records and source documents shall belong to Institution.

6.2 Inventions. Any information, invention, data, innovation, modification, or discovery (whether patentable or copyrightable or not), communication or report, and all intellectual property appurtenant thereto, conceived, reduced to practice, made, generated or developed by the Institution or Investigator, solely or with others, that either results from use of any of the Study Product, Study Materials, or Abbott Confidential Information, or results from conduct of each Study (“Invention”) will be promptly disclosed to Abbott, is hereby assigned to Abbott, and will be the sole property of Abbott. Institution and Investigator each agree, upon Abbott’s request and at Abbott’s expense, to execute or cause to have executed such documents and to take such other actions as Abbott deems necessary or appropriate to obtain patent or other proprietary protection in Abbott’s name covering any of the foregoing.

## 7 Publications.

7.1 Requirements. Institution may publish or present results of its performance of Studies consistent with the terms of this section. If a Study is part of a multi-center clinical study, Institution agrees that the first publication of results will be made as a joint multi-center publication with investigators from all sites contributing data. Institution may publish data and results individually from its site after any of the following, (1) a multi-center publication is published, (2) no multi-center publication is submitted within eighteen months after closure of the Study at all sites, or (3) Abbott confirms in writing there will be no multi-center publication. The parties agree that any publications concerning each Study shall abide by the guidelines of the ICMJE.

7.2 Review Periods. Institution shall provide or shall require Investigator to provide Abbott with a draft of any Study-related publication, presentation or other disclosure (“Publication”) at least 45 days prior to any submission for Abbott’s review and comment to ascertain whether any patentable subject matter or Abbott Confidential Information (other than the results of the Study) are disclosed therein. Abbott shall return comments to Institution or Investigator within 45 days after receipt of the draft (“Review Period”). Upon Abbott’s request, Institution or Investigator shall delay any proposed Publication an additional 60 days in addition to the Review Period to enable Abbott to secure patent or other proprietary protection (“Delay Period”). Institution agrees and shall require Investigator to agree to keep the proposed Publication confidential until the Review Period and, if requested by Abbott, the Delay Period has expired. Institution agrees and shall require Investigator to agree that due consideration will be given to Abbott comments; and further, Abbott Confidential Information (other than the results of the Study and information that is necessary to allow for the complete and accurate presentation and interpretation of such data and results in accordance with scientific and/or academic requirements) shall be deleted from any Publication. If Institution or Investigator and Abbott differ in their opinion or interpretation of data in the Publication, the parties shall resolve such differences in good faith through appropriate scientific debate.

7.3 License to Abbott. Institution and Investigator agree that, if either publishes the results of a Study, Abbott is hereby granted an irrevocable, royalty-free license to make and distribute copies of any such publication under any copyright privileges that the Institution and Investigator may have, if any. Abbott shall have the right to independently publish the results of the Study.

## 8 Compensation.

8.1 Budget. Abbott shall compensate Institution for all services completed and data received in accordance with the budget attached to each SOW. Abbott will not provide compensation for data contained in a Case Report Form (“CRF”) that is not complete and accurate. Abbott will not be obligated to compensate or reimburse Institution for invoices issued more than 180 days after termination of the applicable SOW. In the event of a payment dispute, Institution shall not withhold Study data or information pending resolution.

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8.2 Reimbursements. Study Staff will be reimbursed for reasonable and necessary expenses related to Abbott-approved travel consistent with Abbott's travel policy (a copy of which will be made available to Institution upon request), and may be provided meals at investigator meetings or other Abbott required meetings. Abbott will not reimburse out-of-pocket expenses if the required meeting takes place simultaneously with an industry conference or other meeting that the Investigator or other Study Staff are otherwise attending. Institution may also be reimbursed for reasonable, pre-approved, travel-related expenses for the benefit of Study Subjects required to make follow-up visits in the event of financial hardship.

8.3 Budget Closure. Final payment due to Institution under this Agreement shall be payable upon completion of all services, delivery to Abbott of all CRFs, and return to Abbott of all Study Product and Study Materials as set forth in the SOW. Any necessary reconciliation payments based on unpaid compensation or overpayments shall be made or refunded within 45 days of the notice and invoice of amount due. In the event of termination of this Agreement for any reason other than Institution's breach, Abbott shall pay Institution for services performed and non-cancelable expenses incurred to the date of termination, in accordance with the Budget.

## 9 Term and Termination.

9.1 Term. This Agreement will be effective on the Effective Date and shall expire 5 years thereafter (the "Term").

9.2. Termination by a Party. This Agreement or any individual SOW may be terminated by a party in the event of material breach that remains uncured after thirty (30) days written notice, or if determined necessary by the terminating party or EC to protect the health and safety of enrolled Subjects.

9.3. Termination by Abbott. Abbott may terminate the Agreement or any SOW without cause upon thirty (30) days' prior written notice.

9.3.4. Post Termination Requirements. In the event of individual SOW termination, Institution will cease enrollment and Study activities related to the terminated SOW for currently enrolled Subjects as directed by Abbott consistent with accepted medical practice.

9.5 Any SOW in effect at the time of the expiration or earlier termination of this Agreement, shall, notwithstanding such expiration or termination, remain in effect until the obligations of the parties thereunder have been completed or such SOW expires or is terminated on its own terms.

9.6 Individual SOWs may be terminated by mutual agreement of the parties upon written notification if the Investigator for the Study for which the SOW pertains, is unable or unwilling to perform his/her obligations and the parties are unable to agree on an acceptable replacement within a reasonable time.

## 10 Indemnification and Insurance.

10.1 Abbott Indemnification. Abbott will indemnify, defend and hold harmless Institution, UT System, UT System's Board of Regents, including their respective regents, officers, agents, and employees, and Investigator, Study Staff and the EC (solely with respect to its role in the approval and oversight of the Study) ("Indemnitees") from and against third party actions, suits, claims, and costs (including reasonable attorney fees incurred prior to engagement of counsel by Abbott) ("Losses") directly arising from (a) use of Study Products in accordance with the Study-specific Protocol or procedures that the Study Subject would not have undergone but for participation in the Study, (b) Abbott's breach of this Agreement or failure to comply with Applicable Law, or (c) Abbott's use or commercialization of the Data or Inventions produced by the Studies. Abbott's indemnification obligation will not apply to the extent that any Losses are attributable to the negligence, misconduct, failure to comply with Applicable Law or breach of this Agreement on the part of an indemnitee. Abbott's indemnification obligation will apply if Institution or an Indemnitee deviates from the Study-specific Protocol if such deviation was reasonably necessary to avoid imminent harm to a Study Subject and if any such deviation is fully and promptly disclosed to Abbott.

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10.2 Procedures. The obligation to indemnify is subject to the statutory duties of the Texas Attorney General and is conditioned upon the obligation of Indemnitees to, (i) advise Abbott of any claim or lawsuit in writing within 15 days after receipt of written notice, or within such other time that Abbott's ability and rights to defend such claim or lawsuit, as determined in Abbott's discretion, are not prejudiced, (ii) assist Abbott and its representatives in the investigation and defense of any claim for which indemnification is provided, and (iii) not compromise or otherwise settle any such claim without Abbott's prior written consent. Abbott will not compromise or settle any claim without notification and consent from the indemnitee, not to be unreasonably withheld.

10.3 Institution Insurance – Institution, as a member institution of the UT System, is an agency of the State of Texas provides professional liability insurance for its faculty physicians pursuant to The University of Texas System Professional Medical Liability Benefit Plan, under the authority of Section 59, Texas Education Code. Institution shall ensure the Investigator has and will maintain in force, during the Term of the relevant Study, adequate professional liability insurance to cover his/her obligations hereunder. Institution, an agency of the State of Texas, is subject to the provisions of Title 5, Chapter 101 of the Texas Civil Practice and Remedies Code, and the Institution's personnel or employees are subject to Title 5, Chapter 104 of the Texas Civil Practice and Remedies Code, also known as the Texas Tort Claims Act. Employees of the Institution are provided Worker's Compensation coverage under a self-insuring, self-managed program authorized by Section 503.022, Texas Labor Code.

Abbott Insurance - Abbott will obtain and maintain on its behalf during the term of the Agreement, at its own cost and expense, Commercial General Liability insurance including products liability, contractual liability and clinical trial insurance, providing coverage resulting from bodily injury, property damage, personal injury, and advertising injury with a minimum limit of \$3,000,000 per occurrence and \$3,000,000 in the aggregate.

The above required insurance policies shall be insured through licensed insurers authorized to do business and on a policy form(s) approved for use in the jurisdiction of the Agreement and have a minimum A.M. Best financial rating of "A-", size "IX".

Each party shall provide the other a certificate of insurance signed by an authorized representative evidencing the required coverage upon written request. In the event of any notice or action to cancel, non-renew, or materially change any of the above required insurance, each party shall provide the other thirty (30) days notice of such change, as applicable. It is further acknowledged between the parties that the minimum limits of liability or conditions required in this insurance paragraph do not in any way limit any indemnity obligation or other liability under this Agreement.

**11 Subject Direct Injury.** Abbott will reimburse the Institution, at rates consistent with fair market value for industry-sponsored studies, the costs of providing reasonable and necessary medical diagnosis and treatment of any adverse reaction, illness or injury directly arising from the use of the Study Product in accordance with the applicable Protocol or non-standard-of-care procedure that the Subject would not have undergone but for participation in the applicable Study. Abbott's obligation to reimburse will not apply if such adverse reaction, illness or injury is attributable to (i), the negligence or misconduct of Institution, Investigator or Study Staff, (ii) the known risk of an FDA-approved treatment or device of the type being studied, (iii) failure to adhere to the applicable Protocol (with exceptions for deviations reasonably necessary to avoid imminent harm to a Study Subject), (iv) failure to comply with Applicable Law, or (v) the natural progression of a pre-existing condition (not exacerbated by the Study) or underlying illness, whether or not previously diagnosed. Abbott's agreement to reimburse these costs is provided as reasonable consideration for Subjects' willingness to participate in the Study, and does not constitute an admission of liability for any injury.

## 12 Representations and Warranties.

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- 12.1 The terms of this Agreement and performance of services are valid and binding obligations of Institution, and, to Institution's knowledge and upon reasonable inquiry, are not inconsistent with any other contractual or legal obligation (including acceptance of any meals and/or reimbursement of reasonable and necessary travel expenses) it or Investigator may have or with Institution's policies and procedures or those of any institution or organization with which either is associated.
- 12.2 Investigator is not under investigation or subject to any disciplinary action by any medical board, and Investigator has a medical license, or equivalent, that has not been restricted or suspended by any medical board in any way. If any of foregoing occurs, Institution or Investigator shall as soon as reasonably possible notify Abbott.
- 12.3 Neither Institution, Investigator, nor any Study Staff shall make or accept, directly or indirectly, any offer or promise or authorization of a bribe, kickback, payoff or other payment or gift intended to improperly influence any person including an agent, government official, political party or candidate for public office to exercise their discretionary authority or influence to benefit any party to this Agreement.
- 12.4 Neither Institution, Investigator, nor any Study Staff are currently, nor have they been within the past five (5) years from the Effective Date of the Agreement or any SOW, debarred, disqualified, or excluded under any Applicable Law from: (i) providing goods or services to a regulated health care company, (ii) participating in clinical research, (iii) participating in a government procurement or non-procurement program, or (iv) participating in a reimbursed government-funded or financed healthcare program (each, a "Restriction"). Institution agrees to promptly notify Abbott if any such Restriction is proposed, pending or occurs during the applicable Term.
- 12.5 Institution and Investigator have the experience, capabilities, adequate subject population, and resources, including but not limited to sufficient personnel and equipment, to efficiently and expeditiously perform each Study in a professional and competent manner and in accordance with all Applicable Law.
- 12.6 Except for the limited warranties expressly set forth herein, the UT System and each Institution expressly and specifically disclaims any warranties of results, title, merchantability, or fitness for a particular purpose, as well as all implied warranties, including any implied warranties arising from a course of dealing or performance or usage of trade.

**13 Contacts and Notices.** Any questions regarding a Study should be directed to the Clinical Project Manager assigned to Institution for that Study, as identified in other correspondence. Any notice required pursuant to this Agreement shall be in writing, personally delivered or sent by certified mail, return receipt requested, or recognized courier service to the other party at the address set forth below. Notices shall be deemed effective on the date received if personally delivered or sent by certified mail or recognized courier.

**If to Institution:**

See Exhibit B

**with a copy to:**

The University of Texas System  
Attn: Office of General Counsel – Intellectual Property  
201 West 7<sup>th</sup> Street  
Austin, TX 78701

**If to Abbott:**

If to Abbott:  
Clinical Contracts Senior Manager  
6901 Preston Road  
Plano, Texas 75024

**with a copy to:**

Divisional Vice President & Associate General Counsel  
Corporate Legal  
Dept. 32CO, Bldg. AP6A-1  
Abbott Laboratories  
100 Abbott Park Road  
Abbott Park, IL 60064-6011 U.S.A.  
Fax : 847-938-1200

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## 14 Miscellaneous.

- 14.1 Publicity. Except when required by Applicable Law, the parties shall not disclose the existence or terms of this Agreement or any SOWs, or use the name, trademark, service mark, or logo of the other party in any publicity, advertising or information that is disseminated to any third person or to the general public without the other party's prior written approval. The parties shall have the right to post publicly registered information (clinicaltrials.gov or equivalent) about the Study on their publicly accessible web sites. Institution shall comply with applicable laws regarding disclosure of industry support (financial or otherwise), including, without limitation, in connection with publications and presentations subject to the applicable provisions of this Agreement.
- 14.2 Independent Contractor. Institution and Investigator's relationship to Abbott under this Agreement is that of an independent contractor. Neither party has authority to bind or act on behalf of the other party.
- 14.3 Assignment and Subcontracting. Institution may not assign this Agreement or any SOW to any other party without Abbott's prior written consent. Assignment shall not relieve Institution of responsibility for the performance of any accrued obligation. Any permitted assignee shall assume all obligations of Institution under this Agreement. If Institution is permitted to subcontract any duty hereunder to any third party, such subcontractor shall execute an agreement obligating such subcontractor to comply with the terms and conditions hereof, and Institution shall remain responsible and liable for the acts or omissions of such subcontractor activities as if such activities had been performed by Institution.
- 14.4 Governing Law and Arbitration. [Intentionally Omitted]
- 14.5 Survival. Notwithstanding expiration or termination of this Agreement for any reason, rights and obligations which by the terms of this Agreement survive termination of the Agreement will remain in full force and effect.
- 14.6 Severability. If any provision, right or remedy provided for herein is held to be unenforceable or inoperative by a court of competent jurisdiction, the validity and enforceability of the remaining provisions will not be affected thereby.
- 14.7 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.
- 14.8 Entire Agreement. This Agreement, including 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 conflict between provisions of an individual SOW, the Protocol and this Agreement, 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, unless superseding text appears in the SOW. None of this Agreement or any of its terms, including any SOW, attachment or exhibit hereto, may be amended, restated or otherwise altered except by written agreement signed by the parties.
- 14.9 Texas State Law. The Parties are aware of the possibility that there are or could be constitutional and statutory limitations on the ability of an Institution, each a state agency, to enter into certain terms and conditions of this Agreement, including, but not limited to, those relating to warranties, limitations on damages, limitations of periods to bring legal action, waivers of remedies, dispute resolution, indemnities, and confidentiality. In any event, the provisions of this Agreement shall be enforceable to the full extent authorized by law, including the Constitution and laws of the State of Texas. Neither the execution of this Agreement by an Institution nor any conduct, action, or inaction of any representative of the UT System or an Institution constitutes or is intended to constitute a waiver of the UT System's, any Institution's, or the state's sovereign immunity.

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

Abbott Laboratories  
By: Gary Thompson  
Name: Gary Thompson

Title: Divisional Vice President, Global Clinical Operations

Date: June 30, 2020 | 3:57:45 PM CDT

The University of Texas Health Science Center at San Antonio  
By: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_

The University of Texas Health Science Center at Houston

By: \_\_\_\_\_

Name: Kathleen Kreidler

Title: \_\_\_\_\_

Date: \_\_\_\_\_

Digitally signed by Kathleen Kreidler  
DN: postalCode=77030, ou=UTHEALTH NON-ESCROW, o=The University of Texas Health Science Center at Houston, street=7000 Fannin, Suite 1200, st=TX, l=Houston, c=US, cn=Kathleen Kreidler, email=kathleen.kreidler@uth.tmc.edu  
Date: 2020.06.25 09:32:08 -05'00'

The University of Texas Health Science Center at Tyler

By: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_

The University of Texas Southwestern Medical Center

By: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_

The University of Texas Medical Branch at Galveston

By: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_

The University of Texas at Austin

By: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_

The University of Texas Rio Grande Valley

By: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_

CONFIDENTIAL

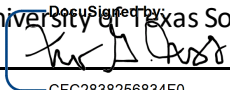
**IN WITNESS WHEREOF**, the parties have caused this Agreement to be executed by their duly authorized representatives.

Abbott Laboratories  
By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_  
Date: \_\_\_\_\_

The University of Texas Health Science Center at San Antonio  
By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_  
Date: \_\_\_\_\_

The University of Texas Health Science Center at Houston  
By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_  
Date: \_\_\_\_\_

The University of Texas Health Science Center at Tyler  
By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_  
Date: \_\_\_\_\_

The University of Texas Southwestern Medical Center  
By:  \_\_\_\_\_  
Name: Megan G. Marks, Ph.D.  
Title: Asst. VP, Sponsored Programs Administration  
Date: 6/25/2020

The University of Texas Medical Branch at Galveston  
By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_  
Date: \_\_\_\_\_

The University of Texas at Austin  
By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_  
Date: \_\_\_\_\_

The University of Texas Rio Grande Valley  
By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_  
Date: \_\_\_\_\_

**CONFIDENTIAL**

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Abbott Laboratories

By: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_

The University of Texas Health Science Center at San Antonio

By: \_\_\_\_\_

Name: Chris G. Green, CPA

Title: Sr. Director, Office of Sponsored Programs

Date: 30 June 2020

Digitally signed by Chris G. Green, CPA  
DN: cn=Chris G. Green, CPA, o=UT  
Health San Antonio, ou,  
email=greenc@uthscsa.edu, c=US  
Date: 2020.06.30 14:25:03 -0500



The University of Texas Health Science Center at Houston

By: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_

The University of Texas Health Science Center at Tyler

By: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_

The University of Texas Southwestern Medical Center

By: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_

The University of Texas Medical Branch at Galveston

By: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_

The University of Texas at Austin

By: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_

The University of Texas Rio Grande Valley

By: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

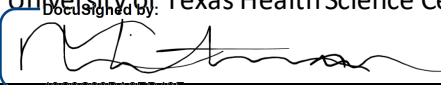
Date: \_\_\_\_\_

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

Abbott Laboratories  
By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_  
Date: \_\_\_\_\_

The University of Texas Health Science Center at San Antonio  
By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_  
Date: \_\_\_\_\_

The University of Texas Health Science Center at Houston  
By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_  
Date: \_\_\_\_\_

The University of Texas Health Science Center at Tyler  
By:   
Name: Michael Whitman, JD  
Title: Director, Office of Sponsored Programs  
Date: 6/23/2020 | 10:58:58 AM CDT

The University of Texas Southwestern Medical Center  
By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_  
Date: \_\_\_\_\_

The University of Texas Medical Branch at Galveston  
By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_  
Date: \_\_\_\_\_

The University of Texas at Austin  
By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_  
Date: \_\_\_\_\_

The University of Texas Rio Grande Valley  
By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_  
Date: \_\_\_\_\_

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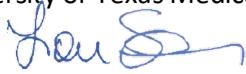
Abbott Laboratories  
By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_  
Date: \_\_\_\_\_

The University of Texas Health Science Center at San Antonio  
By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_  
Date: \_\_\_\_\_

The University of Texas Health Science Center at Houston  
By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_  
Date: \_\_\_\_\_

The University of Texas Health Science Center at Tyler  
By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_  
Date: \_\_\_\_\_

The University of Texas Southwestern Medical Center  
By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_  
Date: \_\_\_\_\_

The University of Texas Medical Branch at Galveston  
By:  \_\_\_\_\_  
Name: Lori Simon  
Title: Director, Office of Clinical Research  
Date: 23-Jun-2020

The University of Texas at Austin  
By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_  
Date: \_\_\_\_\_

The University of Texas Rio Grande Valley  
By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_  
Date: \_\_\_\_\_

**CONFIDENTIAL**

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Abbott Laboratories  
By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_  
Date: \_\_\_\_\_

The University of Texas Health Science Center at San Antonio  
By: \_\_\_\_\_  
Name: \_\_\_\_\_  
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Date: \_\_\_\_\_

The University of Texas Health Science Center at Houston  
By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_  
Date: \_\_\_\_\_

The University of Texas Health Science Center at Tyler  
By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_  
Date: \_\_\_\_\_

The University of Texas Southwestern Medical Center  
By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_  
Date: \_\_\_\_\_

The University of Texas Medical Branch at Galveston  
By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_  
Date: \_\_\_\_\_

The University of Texas at Austin  
By:  Digitally signed by Mark Featherston  
Date: 2020.06.23 12:00:23 -05'00'  
Name: Mark Featherston  
Title: Assistant Director, Office of Sponsored Projects  
Date: 23 June 2020

The University of Texas Rio Grande Valley  
By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_  
Date: \_\_\_\_\_

**CONFIDENTIAL**

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Abbott Laboratories  
By: \_\_\_\_\_  
Name: \_\_\_\_\_  
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The University of Texas Health Science Center at San Antonio  
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Date: \_\_\_\_\_

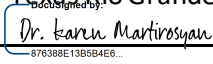
The University of Texas Health Science Center at Houston  
By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_  
Date: \_\_\_\_\_

The University of Texas Health Science Center at Tyler  
By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_  
Date: \_\_\_\_\_

The University of Texas Southwestern Medical Center  
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Name: \_\_\_\_\_  
Title: \_\_\_\_\_  
Date: \_\_\_\_\_

The University of Texas Medical Branch at Galveston  
By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_  
Date: \_\_\_\_\_

The University of Texas at Austin  
By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_  
Date: \_\_\_\_\_

The University of Texas Rio Grande Valley  
By:  \_\_\_\_\_  
Name: Dr. Karen Martirosyan  
Title: Associate Vice President for Research Enhancement  
Date: 6/22/2020



Attachments:

Exhibit A Form of Statement of Work

Exhibit B Administrative Contacts for Each Institution

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**EXHIBIT A**  
**Form of Statement of Work**

This Statement of Work is issued under the Master Agreement effective Insert Date MCSA was fully executed (the “Master Agreement”) by and between Insert International Abbott Affiliate (“Abbott”) and Insert Institution Name (“Institution”). This Statement of Work includes the terms and conditions of the Master Agreement, which are hereby incorporated herein by this reference.

1. Protocol; Conduct of Study.

- (a) Institution and Investigator (defined below) will conduct the Study in relation to the Abbott product(s) Insert Product(s) Name (the “Study Product(s)”) pursuant to the terms of this Statement of Work and the Master Agreement and in strict adherence to Protocol No. Insert # entitled “Insert Protocol Title” (the “Protocol”), as the same may be amended from time to time in writing by Abbott, and any other written instruction that may be provided from time to time to Institution by Abbott. Investigator hereby acknowledges reviewing and understanding the Protocol, as evidenced by the Investigator’s signature on the Investigator Agreement(s) contained within the Protocol, as may be amended from time to time (as described in this section), all of which are incorporated herein by reference.
- (b) The Study will be conducted under the direction and supervision of [Insert Investigator] with a principal place of business located at [Insert Address (“Investigator”).
- (c) Institution will ensure that subject data, as required in the Protocol, is entered into the CRFs (whether electronic or paper) within ten (10) business days of subject visit.

2. Compensation.

- (a) In consideration for Institution’s services hereunder, Abbott shall pay Institution as per the Budget attached hereto as Appendix 1 and in accordance with the terms of the Master Agreement.
- (b) The Budget is based on the full performance of services contemplated by this Statement of Work and full compliance with the terms of the Budget and Master Agreement (including the Protocol). Abbott will not be responsible for paying for subject visits or treatments for a subject that is enrolled or treated in violation of the Protocol (except as allowed under Section 11 of the Agreement) or for the data contained in a CRF which is not complete and accurate. If Abbott has previously paid for such services, the overpayment shall be deducted from the next payment (or the final payment, as described in Section 8 (Compensation) of the Master Agreement).

3. Study Term. This Statement of Work shall be effective upon full execution by the parties (the “Effective Date”), and shall terminate on the later of: (i) one (1) year from the Effective Date; (ii) the date of Study database lock if there is subject enrollment under this Statement of Work in the Study; or (iii) the date of completion of all the obligations of the parties hereunder (the “Term”), unless terminated earlier pursuant to the terms of the Master Agreement or this Statement of Work.

4. Notices. Any notice required or otherwise made pursuant to this Statement of Work shall be in writing, personally delivered or sent by certified mail, return receipt requested, or recognized courier service, properly addressed, or by facsimile with confirmed answer-back, to the other party at the address set forth below. Notices shall be deemed effective (a) on the date received if personally delivered or sent by certified mail or recognized courier, or (b) upon the date of confirmed answer-back if sent by facsimile.

If to Institution:

If to Investigator:

**CONFIDENTIAL**

Insert Name  
Insert Address  
Phone : Insert #  
Fax : Insert #

Insert Name  
Insert Address  
Phone : Insert #  
Fax : Insert #

If to Abbott:  
Insert Name  
Insert Title  
Insert Abbott Entity Name  
Insert Address  
Phone : Insert #  
Fax : Insert #

with a copy to:  
Divisional Vice President and  
Associate General Counsel  
Corporate Legal  
Dept. 32RO, Bldg. AP6A-1  
Abbott Laboratories  
100 Abbott Park Road  
Abbott Park, IL 60064-6011

- 5. Counterparts. 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.
- 6. Entire Agreement. This Statement of Work and the Master 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 or appendices 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 Master Agreement, the terms and provisions of the Master 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 ABBOTT ENTITY NAME IN ALL CAPS

INSERT NAME OF INSTITUTION IN ALL CAPS

By:

By: DRAFT – NOT FOR SIGNATURE

Name:

Name:

Title:

Title:

Date:

Date:

I acknowledge ant I have read this Statement of Work and the Master Agreement and agree to be

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bound by the provisions of this Statement of Work  
and Master Agreement.

By: DRAFT – NOT FOR SIGNATURE

Name: Insert Name of Investigator \_\_\_\_\_

Title: Investigator

Date:

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**APPENDIX 1**  
Budget  
For the  
[Insert Name of Study]

The items listed on this Budget with assigned dollar amounts (inclusive of overhead) represent the only items for which Sponsor will make payment (exclusive of travel reimbursement or "Other Expenses" described above). Sponsor will not make payment for any items on this Budget that do not contain an assigned dollar amount.

**[BUDGET WORKSHEET TO BE INSERTED AS EXHIBIT D-1]**

**Payment Disbursement**

**Study related disbursement will be made to Institution in the following manner (Please check one):**

**Direct Deposit - If you would like to receive ECH direct deposit option, please contact Sponsor for Direct Deposit Services Authorization form.**

Payable to: \_\_\_\_\_

Tax ID #: \_\_\_\_\_

NPI #: \_\_\_\_\_

**Standard Disbursement**

Payable to: \_\_\_\_\_

Address: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Attn: \_\_\_\_\_

Email address: \_\_\_\_\_

Phone: \_\_\_\_\_

Tax ID #: \_\_\_\_\_

NPI #: \_\_\_\_\_

**Please submit all invoices to Sponsor at the following email address (please include protocol title and PI name on invoice):**


[Clinical\\_Invoices@abbott.com](mailto:Clinical_Invoices@abbott.com)

*Or*

**Clinical Administrative Services  
Abbott  
15900 Valley View Court  
Sylmar, CA 91342**

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**EXHIBIT B**  
**ADMINISTRATIVE CONTACT PERSON AND ADDRESS FOR EACH INSTITUTION**

<p><b>The University of Texas at Austin</b> Mark Featherston Assistant Director Office of Sponsored Projects 3925 W. Braker Lane WPRC, Suite 3.340 Austin, Texas 78759 Phone: 512-471-6424 Fax: 512-471-6564 Tax ID: 74-600023 Email: <a href="mailto:mark.featherston@austin.utexas.edu">mark.featherston@austin.utexas.edu</a></p>	<p><b>The University of Texas Southwestern Medical Center</b> Julia Spesivtseva Director, Clinical Research Services Sponsored Programs Administration 5323 Harry Hines Blvd. Dallas, TX 75390-9020 Phone: 214-648-9877 Fax: 214-648-4671 Email: <a href="mailto:Julia.spesivtseva@utsouthwestern.edu">Julia.spesivtseva@utsouthwestern.edu</a> Tax ID: 75-6002868</p>
<p><b>The University of Texas Health Science Center at San Antonio</b> Chris G. Green Director, Office of Sponsored Programs 7703 Floyd Curl Dr, Mail Code 7828 San Antonio, TX 78229-3900 Phone: 210-567-2340 Fax: 210-567-8107 Email: <a href="mailto:contracts@uthscsa.edu">contracts@uthscsa.edu</a></p>	<p><b>The University of Texas Health Science Center at Houston</b> Kristin L. Parks Director, Clinical Research Finance and Administration Office of Sponsored Projects Administration Fannin Street, UCT1002 Houston, TX 77030 Phone: 713-500-3063 Fax: 713-383-3746 Email: <a href="mailto:Kristin.Parks@uth.tmc.edu">Kristin.Parks@uth.tmc.edu</a> Tax ID: 74-1761309</p> <p><b>Overnight address is:</b> 7000 Fannin Street, Suite UCT 1007-2 Houston, TX 77030</p>
<p><b>The University of Texas Health Science Center at Tyler</b> Michael S. Whitman Director, Office of Sponsored Programs 11937 U.S. Hwy. 271 Tyler, TX 75708-3154 Phone: 903-877-7392 Fax: 903-877-7689 Email: <a href="mailto:Grants@uthct.edu">Grants@uthct.edu</a> Email: <a href="mailto:Michael.Whitman@uthct.edu">Michael.Whitman@uthct.edu</a></p> 	<p><b>The University of Texas Medical Branch at Galveston</b> Lori Simon Director, Office of Clinical Research 301 University Boulevard Research Bldg. #6, 6.170 Galveston, TX 77555-0342 Phone: 409-772-1978 Fax: 409-772-1968 Email: <a href="mailto:lasimon@utmb.edu">lasimon@utmb.edu</a> Email: <a href="mailto:clinical.research@utmb.edu">clinical.research@utmb.edu</a></p>
	<p><b>The University of Texas Rio Grande Valley</b> Glorimar Colón Executive Director for Research Compliance and Export Controls 1201 West University Drive Edinburg, TX 78539 Phone: 956-665-3008 Fax: 956-665-2940 Email: <a href="mailto:glorimar.colon@utrgv.edu">glorimar.colon@utrgv.edu</a> Dept: sponpro@utrgv.edu</p>

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## Certificate Of Completion

Envelope Id: BD0F6CD0A08F434FA848BCDC70542CC3	Status: Completed
Subject: Please DocuSign: Harmonized Master-UTH-PE-30June2020.pdf	
Source Envelope:	
Document Pages: 22	Signatures: 1
Certificate Pages: 4	Initials: 0
AutoNav: Enabled	Envelope Originator:
Envelopeld Stamping: Enabled	Ralph Ablorh-Quarcoo
Time Zone: (UTC-06:00) Central Time (US & Canada)	One Lillehei Plaza
	St. Paul, MN 55117
	ralph.ablorhquarcoo@abbott.com
	IP Address: 165.225.217.61

## Record Tracking

Status: Original 6/30/2020 3:32:41 PM	Holder: Ralph Ablorh-Quarcoo ralph.ablorhquarcoo@abbott.com	Location: DocuSign
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## Signer Events

Gary Thompson  
gary.thompson@abbott.com  
Divisional Vice President, Global Clinical Operations  
St. Jude Medical is now Abbott  
Security Level: Email, Account Authentication (Optional)

## Signature

DocuSigned by:  
**Gary Thompson**  
3D0F128E96C7447...

Signature Adoption: Pre-selected Style  
Using IP Address: 104.129.202.83

## Timestamp

Sent: 6/30/2020 3:34:29 PM  
Viewed: 6/30/2020 3:57:40 PM  
Signed: 6/30/2020 3:57:45 PM

**Electronic Record and Signature Disclosure:**  
Accepted: 4/13/2020 5:02:59 PM  
ID: 51f853be-57c2-4015-91c3-d6aa719706f2

In Person Signer Events	Signature	Timestamp
Editor Delivery Events	Status	Timestamp
Agent Delivery Events	Status	Timestamp
Intermediary Delivery Events	Status	Timestamp
Certified Delivery Events	Status	Timestamp
Carbon Copy Events	Status	Timestamp
Witness Events	Signature	Timestamp
Notary Events	Signature	Timestamp
Envelope Summary Events	Status	Timestamps
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Certified Delivered	Security Checked	6/30/2020 3:57:40 PM
Signing Complete	Security Checked	6/30/2020 3:57:45 PM
Completed	Security Checked	6/30/2020 3:57:45 PM
Payment Events	Status	Timestamps
Electronic Record and Signature Disclosure		

## **ELECTRONIC RECORD AND SIGNATURE DISCLOSURE**

From time to time, St. Jude Medical, Inc. (we, us or Company) may be required by law to provide to you certain written notices or disclosures. Described below are the terms and conditions for providing to you such notices and disclosures electronically through the DocuSign system. Please read the information below carefully and thoroughly, and if you can access this information electronically to your satisfaction and agree to this Electronic Record and Signature Disclosure (ERSD), please confirm your agreement by selecting the check-box next to 'I agree to use electronic records and signatures' before clicking 'CONTINUE' within the DocuSign system.

### **Getting paper copies**

At any time, you may request from us a paper copy of any record provided or made available electronically to you by us. You will have the ability to download and print documents we send to you through the DocuSign system during and immediately after the signing session and, if you elect to create a DocuSign account, you may access the documents for a limited period of time (usually 30 days) after such documents are first sent to you. After such time, if you wish for us to send you paper copies of any such documents from our office to you, you will be charged a \$10.00 per-page fee. You may request delivery of such paper copies from us by following the procedure described below.

### **Withdrawing your consent**

If you decide to receive notices and disclosures from us electronically, you may at any time change your mind and tell us that thereafter you want to receive required notices and disclosures only in paper format. How you must inform us of your decision to receive future notices and disclosure in paper format and withdraw your consent to receive notices and disclosures electronically is described below.

### **Consequences of changing your mind**

If you elect to receive required notices and disclosures only in paper format, it will slow the speed at which we can complete certain steps in transactions with you and delivering services to you because we will need first to send the required notices or disclosures to you in paper format, and then wait until we receive back from you your acknowledgment of your receipt of such paper notices or disclosures. Further, you will no longer be able to use the DocuSign system to receive required notices and consents electronically from us or to sign electronically documents from us.

### **All notices and disclosures will be sent to you electronically**



Unless you tell us otherwise in accordance with the procedures described herein, we will provide electronically to you through the DocuSign system all required notices, disclosures, authorizations, acknowledgements, and other documents that are required to be provided or made available to you during the course of our relationship with you. To reduce the chance of you inadvertently not receiving any notice or disclosure, we prefer to provide all of the required notices and disclosures to you by the same method and to the same address that you have given us. Thus, you can receive all the disclosures and notices electronically or in paper format through the paper mail delivery system. If you do not agree with this process, please let us know as described below. Please also see the paragraph immediately above that describes the consequences of your electing not to receive delivery of the notices and disclosures electronically from us.

### **How to contact St. Jude Medical, Inc.:**

You may contact us to let us know of your changes as to how we may contact you electronically, to request paper copies of certain information from us, and to withdraw your prior consent to receive notices and disclosures electronically as follows:

To contact us by email send messages to: [mwestin@sjm.com](mailto:mwestin@sjm.com)

### **To advise St. Jude Medical, Inc. of your new email address**

To let us know of a change in your email address where we should send notices and disclosures electronically to you, you must send an email message to us at [mwestin@sjm.com](mailto:mwestin@sjm.com) and in the body of such request you must state: your previous email address, your new email address. Previous email address prior to name change.

If you created a DocuSign account, you may update it with your new email address through your account preferences.

### **To request paper copies from St. Jude Medical, Inc.**

To request delivery from us of paper copies of the notices and disclosures previously provided by us to you electronically, you must send us an email to [mwestin@sjm.com](mailto:mwestin@sjm.com) and in the body of such request you must state your email address, full name, mailing address, and telephone number. We will bill you for any fees at that time, if any.

### **To withdraw your consent with St. Jude Medical, Inc.**

To inform us that you no longer wish to receive future notices and disclosures in electronic format you may:

- i. decline to sign a document from within your signing session, and on the subsequent page, select the check-box indicating you wish to withdraw your consent, or you may;
- ii. send us an email to [mwestin@sjm.com](mailto:mwestin@sjm.com) and in the body of such request you must state your email, full name, mailing address, and telephone number. We do not need any other information from you to withdraw consent.. The consequences of your withdrawing consent for online documents will be that transactions may take a longer time to process..

### **Required hardware and software**

The minimum system requirements for using the DocuSign system may change over time. The current system requirements are found here: <https://support.docusign.com/guides/signer-guide-signing-system-requirements>.

### **Acknowledging your access and consent to receive and sign documents electronically**

To confirm to us that you can access this information electronically, which will be similar to other electronic notices and disclosures that we will provide to you, please confirm that you have read this ERSD, and (i) that you are able to print on paper or electronically save this ERSD for your future reference and access; or (ii) that you are able to email this ERSD to an email address where you will be able to print on paper or save it for your future reference and access. Further, if you consent to receiving notices and disclosures exclusively in electronic format as described herein, then select the check-box next to ‘I agree to use electronic records and signatures’ before clicking ‘CONTINUE’ within the DocuSign system.

By selecting the check-box next to ‘I agree to use electronic records and signatures’, you confirm that:

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- You can print on paper this Electronic Record and Signature Disclosure, or save or send this Electronic Record and Disclosure to a location where you can print it, for future reference and access; and
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