Version Effective Date March 2023

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* This agreement (“Agreement”) is by and between **CHOOSE APPROPRIATE AFFILIATE: Lilly USA, LLC** (“Lilly”), with its principal place of business at Lilly Corporate Center, Indianapolis, Indiana, 46285, and **NYC Research**(“Institution”) for the performance of the study (“Study”) entitled “A Phase 3, Multicenter, Randomized, Parallel-Design, Open-Label Trial to Evaluate the Efficacy and Safety of LY3209590 Compared with Insulin Degludec in Participants with Type 2 Diabetes Currently Treated with Basal Insulin (QWINT-3),” protocol **I8H-MC-BDCU** (“Protocol”), which Protocol is incorporated herein by reference. Institution shall provide the services of its Member **Anastasios Manessis, PI Title.**, as the principal investigator (“Investigator”) for the Study who has privileges to use Institution’s facilities and resources.

This Agreement sets forth the obligations of the Investigator and Institution and the obligations of Lilly.

I. INVESTIGATOR AND INSTITUTION OBLIGATIONS

Investigator and Institution shall assume the following obligations through the execution of this Agreement:

A. Conduct of the Study

1. Compliance with Protocol, Laws, Regulations: Investigator shall personally conduct or supervise the Study at Institution and any Lilly-approved sub-sites or satellite sites, if applicable (collectively “Study Site(s)”). Investigator and Institution shall comply with the following: all conditions, requirements and written directions specified by Lilly, the Protocol, and any amendments and/or addenda thereof; applicable requirements of the U.S. investigational new drug (“IND”) regulations (Title 21, Part 312.1 et seq.) and/or the Investigational Device Exemption Regulations (Title 21, Part 812.1 et seq); Good Clinical Practice Guidelines; the conditions specified in the Statement of Investigator Form (FD-1572); the approval of the Institutional Review Board(s) (“IRB”); the Code of Federal Regulations governing informed consent and IRBs (Title 21, Parts 50 and 56) and privacy of patient health information (Title 45, Parts 160 and 164); provisions of the Generic Drug Enforcement Act of 1992 (Public Law 102-282, 102nd Congress); and all other applicable federal, state and local laws, regulations, and standards. Investigator and Institution shall ensure that all of their sub-investigators, associates, colleagues, employees, agents, and contractors involved in the conduct of the Study at the Study Site(s), also understand and comply with these obligations.
2. Export Control Regulations: Investigator and Institution agree to comply with all applicable trade sanctions and export control laws and regulations, including, where applicable, the U.S. trade sanctions administered by the U.S. Treasury Department's Office of Foreign Assets Control (31 C.F.R. Part 501 et seq.), the U.S. Export Administration Regulations (15 C.F.R. Part 734 et seq.), and European Union trade sanctions and export laws (including without limitation Council Regulation (EC) No. 428/2009 (as amended)).
3. Sanctions: Investigator and Institution represent and warrants that neither Investigator, Institution and, to the best of their knowledge, its directors, executive officers, agents, shareholders, nor any person having a controlling interest in Institution are:
4. a person targeted by trade or financial sanctions under the laws and regulations of the United Nations, the United States, the European Union and its Member States, the United Kingdom or any other jurisdiction that is relevant to the execution of this Agreement;
5. incorporated or headquartered in, or organized under the laws of, a territory subject to comprehensive U.S. sanctions (each, a “Sanctioned Territory”); or,
6. directly or indirectly owned or controlled by such persons (together “Restricted Person”).

Investigator and Institution further represent and warrants that Investigator and Institution shall notify Lilly in writing immediately if Investigator, Institution or any of its directors, executive officers, agents, shareholders or any person having a controlling interest in Institution becomes a Restricted Person or if Institution becomes directly or indirectly owned or controlled by one or more Restricted Persons.

1. Financial Forms: Investigator and/or Institution shall ensure that each investigator and sub-investigator at the Study Site(s) provides Lilly with the appropriate financial information for compliance with 21 C.F.R. Part 54, and that they understand that regulations may require certain financial information to be submitted to the U.S. Food and Drug Administration (“FDA”).
2. Licensing and Debarment: International Council or Harmonization of Technical Requirements for Pharmaceuticals for Huma Use (“ICH”) guideline 4.3.1 requires that a licensed physician is responsible for patient care. Investigator and /or Institution shall ensure that a licensed physician is an investigator or sub-investigator at the Study Site(s) and shall be responsible for patient care. If Investigator and/or Institution or any person or organization performing Study responsibilities should become unlicensed or disqualified during the course of the Study, Investigator and/or Institution shall promptly notify Lilly in writing.

Investigator and Institution agree that they are not and have not been debarred or disqualified from participating in clinical research by any United States regulatory authority or by any other regulatory authority, and that no person or organization shall participate with this Study that is or has been debarred or disqualified by any regulatory authority from participating in clinical research. In the event Investigator and/or Institution or any person or organization they use or involve in connection with the Study should become debarred or disqualified during the course of the Study, Investigator and/or Institution shall promptly notify Lilly in writing.

1. Referral Fees: Investigator and Institution shall not pay fees for the referral of patients.
2. IRB Approval and Informed Consent: Prior to beginning the Study, Investigator and Institution shall obtain approval from the IRB for the Study and the informed consent document. Investigator and Institution shall only use an informed consent document which has been reviewed and approved by Lilly and the IRB.
3. Monitoring and Audit Access: Lilly, Lilly-designated representatives, and domestic or foreign regulatory agencies may inspect the procedures, facilities, and Study records (including portions of other pertinent records for all patients in the Study) of Institution and any contractor, agent, or Study Site(s) that is used in conducting the Study. Whenever possible, such inspections shall occur during normal business hours and upon reasonable advanced notice. Lilly and Lilly-designated representatives shall abide by all applicable privacy laws and Institution’s privacy regulations. When the data are reviewed by Lilly or a Lilly-designated representative, Investigator and/or Institution shall have all reasonably available data obtained through the preceding day complete and ready for evaluation.

Investigator and/or Institution shall provide Lilly with immediate notice of any governmental or regulatory review, audit, or inspection of the facility or processes related to the Study and shall provide. Lilly with the opportunity to assist Investigator and/or Institution in preparing for and responding to any such review, audit, or inspection. Information obtained from such reviews, audits, or inspections may be shared with Lilly and Lilly-designated representatives.

1. Adverse Event Reporting: Investigator and/or Institution shall report all adverse events, serious adverse drug reactions, serious unexpected adverse drug reactions, and pregnancy events that Investigator and/or Institution become aware of during the Study to Lilly in accordance with the reporting procedures specified in the Protocol. Nothing herein or in the Protocol limits Investigator and/or Institution from reporting such events to the IRB or regulatory authorities in accordance with applicable laws and regulations and/or the requirements of such entities.
2. Safety Reporting: In compliance with 21 CFR 312.55, Lilly shall include a Study data and safety monitoring plan in the Protocol or separately which will be reviewed and approved by Institution’s IRB.  As such, Lilly shall keep Investigator informed of new observations discovered by or reported to Lilly related to the Study drug(s), particularly with respect to adverse events and safe use and information that could affect the safety or medical care of current or former subjects, influence the conduct of the Study, or alter the IRB’s approval.  Such information will be promptly provided to Investigator and will be distributed to Investigator in accordance with 21 CFR 312.32. Institution and Investigator shall review safety information in whatever form Lilly provides it.
3. Confidential Information, Data Privacy and Security : Institution and Investigator represent and certify that they have documented information security policies, standards and/or procedures in place to protect the confidentiality and integrity of including, but not limited to: Confidential Information, defined below, sensitive information, or any other special classification of information given protection under local privacy laws (including its collection, use, storage, and disclosure), in addition to protected health information and individually identifiable health information, as those terms are defined under the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations set forth in 45 CFR §§ 160 and 164 (HIPAA”) (together, “Protected Data”) which include a procedure or process for identifying threats and vulnerabilities to their information system(s) and training their personnel accordingly.

Institution shall notify Lilly, via email at privacy@lilly.com, within 24 hours of suspected or known security incidents that have potential impact to individually identifiable health information Lilly Data, or any other confidential information provided or generated under this Agreement. In addition, Institution shall have a documented process to ensure compliance with this notification requirement.

1. Breach: Investigator and/or Institution shall promptly notify Lilly in the event Investigator and/or Institution breach any of the terms and/or obligations contained in this Agreement or become aware of such breach.

B. Clinical Trial Materials and Record Retention

1. Clinical Trial Materials: Clinical trial materials, including Study drug(s) and/or device(s), furnished for the Study shall be used solely for the Study under the Protocol and may not be used for any other purposes. Investigator and Institution shall follow Lilly’s instructions related to disposition of clinical trial materials. Investigator and Institution shall be responsible for compliance with all laws and regulations applicable to any destruction or disposition of clinical trial materials at the Study Site(s).
2. Record Retention: Lilly requires that all Study records must be retained for fifteen (15) years after completion or termination of the Study; provided, however, that in the unlikely event that ICH or FDA record retention requirements, are longer than fifteen (15) years, Lilly shall notify Investigator and/or Institution regarding any additional length of time that records must be retained to meet such requirements. The Investigator and/or Institution shall use their best efforts to prevent premature destruction of Study records.

If there is a change of responsibility/ownership of Study records (ex. Investigator retires or hospital closes), Institution and/or Investigator must promptly notify Lilly.

C. Data

1. All data generated in connection with the Study (“Lilly Data”) shall be the sole property of Lilly and shall be subject to the obligations of Confidentiality and Non-Use set forth herein. The term Lilly Data shall not include patient medical records, except to the extent they are recorded in case report forms, raw source data, “Source Documents” and “Source Data” as defined in ICH guidelines, other personal records, and the Investigators personal notes. Institution and/or Investigator shall have the right to use Lilly Data for their own internal non-commercial educational, research, quality assurance, and/or patient care purposes, provided that Institution and Investigator shall, for all such uses and for as long as they retain such Lilly Data, remain in compliance with their obligations under this Agreement.
2. Institution and/or Investigator shall use their best efforts to enter all Lilly Data within five (5) business days from the end of the patient visit/cycle or receipt of the underlying data (e.g., local lab results) and to complete all data queries within five (5) business days of the request date unless Institution has a policy or procedure that dictates a different timeframe for data entry, in which case Institution and/or Investigator shall promptly inform Lilly and request that such timeframe is documented in the Study monitoring plan. Notwithstanding the foregoing, Lilly may request shortened timelines based on Study needs, such as for interim analysis and database lock, and Institution and Investigator will use their best efforts to meet such shortened timelines.
3. To the extent the Protocol requires Institution and/or Investigator’s use of electronic tools belonging to a vendor contracted by Lilly (“third-party technology’) solely for purposes related to the Protocol, Lilly shall comply with its responsibilities under applicable data laws regarding the processing of coded and non-coded Lilly Data uploaded into the third- party technology. Any coded and/or non-coded data used or accessed by Institution and/or Investigator outside of that which is required by the Protocol shall fall under Institution and/or Investigator’s legal responsibilities under applicable data laws.

D. Publications

Notwithstanding the obligations of Confidentiality and Non-Use set forth herein, Investigator and Institution shall be free to publish and present their results of the Study subject to the following conditions: Lilly Study team shall be furnished with a copy of any proposed publication or presentation, via trackable format, for review and comment at least thirty (30) calendar days prior to such presentation or submission for publication.

At the expiration of such thirty (30) day period, Investigator and/or Institution may proceed with the presentation or submission for publication; provided, however, in the event Lilly has notified Investigator or Institution in writing that Lilly reasonably believes that it must take action to protect its intellectual property interests, such as the filing of a patent application claiming an invention or a trademark registration application, Investigator and/or Institution shall either:

1. delay such publication or presentation for an additional sixty (60) calendar days or until the foregoing action(s) has/have been taken, whichever shall first occur; or
2. if Investigator and/or Institution are unwilling to delay the publication or presentation, Investigator and/or Institution shall remove from the publication or presentation the information which Lilly has specified it reasonably believes would jeopardize its intellectual property interests.

Additionally, if the Study is part of a multi-center Study, Institution and Investigator shall delay publication of their results of the Study until the results of the multi-center Study are published or presented, provided that if the results of the multi-center Study are not published or presented within twenty four (24) months of the termination, conclusion, or abandonment of the Study by all sites, Institution and Investigator may publish their results of the Study without further delay subject to the terms above.

Notwithstanding the foregoing, scientific conclusions and professional judgments regarding the results of a Study in any publication submitted by Investigator shall be determined solely by Investigator and will adhere to the policies and principles of the International Committee of Medical Journal Editors and other major medical journals and will not be subject to censor or unreasonable control or delay by Lilly.

E. Inventions

In consideration of Lilly providing support for the Study, if during the course of the Study or within one (1) year after termination of this Agreement, Investigator and/or Institution or, if applicable, sub-investigators and/or their institutions, conceive or actually reduce to practice what Investigator and/or Institution believe to be a new invention occurring as a result of the performance of the Study covered by this Agreement or involving the Study drug(s), device(s), or simple derivatives of the Study drug(s) (“Lilly Invention”), Investigator and/or Institution shall promptly notify Lilly. The Lilly Invention shall be the sole property of Lilly. As such, Institution and Investigator hereby assign exclusive ownership of any such Lilly Invention to Lilly. Additionally, Investigator and/or Institution agree that they will not attempt to reverse engineer the Lilly Study drug.

F. Publicity

Consistent with the obligations of Confidentiality and Non-Use set forth herein, Investigator and Institution shall comply with the following:

(1) Solicitation of patients: Lilly and the IRB must approve, in writing, the text of any communication soliciting patients for the Study before placement. Such communications must comply with applicable laws and guidelines.

(2) Press releases: Lilly must approve, in writing, press statements by Investigator and/or Institution regarding the Study or the Study drug(s) or devices(s) before the statements are released.

(3) Inquiries from media and financial analysts: Investigator and/or Institution may receive inquiries from reporters or financial analysts regarding Lilly, the Study, and/or Study drug(s) or device(s). Investigator and/or Institution shall contact Lilly’s Corporate Communications Department at Lilly in Indianapolis, Indiana (317276-3402) to discuss such inquiries before responding to them.

(4) Use of name: Lilly, Investigator, and Institution shall not use the name or names of another party or their employees in any advertising or sales promotional material or in any publication without prior written permission; provided, however, Investigator’s and Institution’s names and business contact information may be used in Study publications and communications, including clinical trial web sites and Study newsletters, and Lilly may disclose Investigator’s and Institution’s name, the type of services performed for Lilly under this Agreement, the existence and terms of this Agreement, and the amount of compensation Lilly paid in exchange for the services or the services of any sub-investigator, in order to comply with financial transparency commitments. Investigator and Institution shall be responsible for ensuring that all sub-investigators have consented to these same terms of disclosure.

H. Controlled Drugs and Substances

If the Study involves the use of a controlled drug or substance, Investigator and Institution shall provide Lilly a photocopy of the appropriate current Drug Enforcement Agency registration certificate before Study drug(s) or device(s) is shipped to the investigational Study Site(s).

1. Contract Research Organization Involvement

Lilly may authorize a contract research organization (“CRO”) to perform certain sponsor obligations in connection with this Study and/or this Agreement.  In such event, the terms and conditions of this Agreement shall also apply to CRO with regard to the delegated sponsor obligations. If Lilly elects to utilize a CRO in connection with this Study and/or this Agreement, Investigator and Institution shall cooperate with such CRO in performing this Study.

J. Equipment

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

K. Home Health Care

If utilizing a Lilly qualified home health care company, the Investigator and Institution will reasonably cooperate with home health care companies/staff and will ensure implementation of the Study in accordance with the Protocol. As applicable, home health care company employees and functions shall be identified on the site’s delegation log. Institution agrees to comply with applicable privacy laws and regulations when transferring participant Protected Data to the home health care company, including execution of any necessary privacy agreements. Consistent with the terms of the Study Budget, any such home health care visit shall occur in place of the on-site visit. For the avoidance of doubt, Lilly will compensate Institution once under this section; for either the home health care visit or the on-site visit, whichever the case may be.

II. LILLY SUPPORT

Lilly shall provide Investigator and/or Institution with Study drug(s) and/or device(s) as applicable to the Study, at Lilly’s expense. In addition, Lilly shall provide financial support for the Study as follows:

1. Payee

Payment in connection with the Study shall be made to Institution as Institution is named in an IRS W-9 form, and to the address listed in the Lilly Supplier Information Form provided by Institution to Lilly. Institution shall provide Lilly with a completed “Registro de Comerciantes” (Registry of Merchant) form before any payments are made to Institution. All amounts due to Institution for services rendered under this Agreement shall be paid net of any Puerto Rico taxes required to be withheld from amounts paid for services rendered unless a Total or Partial Waiver is provided. That is, the payment shall be adjusted for a 10% withholding tax if applicable parties is/are a Puerto Rico resident on amounts exceeding $500.00 in any given year, 20% withholding tax if a non-resident USA citizen, and 29% withholding tax if a nonresident alien. The applicable party shall be solely responsible for payment of any additional applicable taxes.

The following information shall be provided to Institution regarding each payment designated for patient services: Protocol alias, Investigator name, patient number, patient visit number, and visit payment amount. For each payment made in reimbursement of invoiceable expenses, Lilly shall provide a remittance advice containing either a description of the reimbursement and/or Institution’s invoice number. Inquiries regarding payment status or clarification should be addressed to Lilly at: [TCC\_Finance@lilly.com](mailto:TCC_Finance@lilly.com).

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

B. Payment Schedule

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

1. Invoiceable Expenses: Upon receipt of the fully executed Agreement, Lilly shall provide Institution and/or Investigator with the purchase order number and information on how to invoice through the Lilly web invoicing system. Within forty-five (45) calendar days of proper submission of an invoice(s) detailing the work performed or actual costs incurred consistent with the Budget, Lilly shall reimburse Institution for such invoiceable expenses. Invoiceable amounts in the Budget represent the maximum amount payable. Increases to such invoiceable expenses shall only be paid upon advance, written approval from Lilly. Requests for payment for services provided by a third party shall require submission, by Institution, of that third party’s invoice which shall serve as the basis for payment to Institution. Lilly shall reimburse Institution for all reasonable and customary local IRB fees actually incurred during the course of the Study as supported by Institution providing Lilly with the IRB fee schedule, official costing documentation from the IRB department or the IRB third party invoice in accordance with the invoiceable process set forth above.Additionally, reasonable and customary costs incurred for required unscheduled visits or additional Protocol-required procedures that are not related to adverse events shall be paid by Lilly in accordance with the invoiceable process set forth above, provided that Lilly agrees to the visit or procedure in advance.Costs for adverse events shall be evaluated in accordance with section II.C. Subject Injury Reimbursement.

1. If applicable to this Study, for any amounts designated on the Budget specified as either patient advertising or recruitment activities, Lilly shall pay Institution for such activities up to the maximum amounts set forth for each such activity on the Budget. In addition, only those advertising or recruitment activities that are of the type and nature of those set forth on Exhibit B shall be compensated by Lilly. In order to receive payment for advertising or recruitment activities, the submission requirements that are set forth in Exhibit B must be met, as well as an invoice detailing the services performed or costs incurred must be submitted to Lilly in accordance with the terms above.
2. Payment Eligibility: To be eligible for payment, the procedures must be performed in full compliance with the Protocol and this Agreement, and the data submitted must be complete and correct. For data to be complete and correct, each patient must have signed an IRB-approved consent document, and all procedures designated in the Protocol must be carried out on a “best efforts” basis; omissions must be satisfactorily explained. It is expected that for all items required under the Protocol for which Lilly has agreed to provide compensation, Lilly shall be the sole source of compensation. Investigator and Institution shall not seek payment from any third-party payor, whether public or private, for any costs covered by payments made by Lilly under this Agreement. Lilly must have a completed IRS W-9 and Lilly Supplier Information Form before any payments may be made. If any payments exceed the amount owed for work performed under the Protocol, Institution shall return the excess balance to Lilly. To the extent Investigator and/or Institution shall provide reimbursement to Study patients (e.g., in the informed consent document) in excess of or in addition to what is set forth in the Budget, Investigator and/or Institution are responsible for making such payments and Lilly is not liable for such payments. Matters in dispute shall be payable upon mutual resolution of such dispute.

Institution and Investigator shall use their best efforts to submit all Study related payment requests to Lilly within one (1) year of database lock. Institution and Investigator understand that any payment requests submitted more than one (1) year after database lock may be denied by Lilly.

1. Meetings and Training: In addition, if Lilly requests the attendance of Investigator and/or Institution’s personnel to attend a Study startup meeting or other meeting necessary to provide information regarding the Study, or Study drug(s) or device(s), Lilly shall provide reimbursement for reasonable and necessary travel and lodging expenses (including meals and snacks) that are incurred to attend such meeting(s), provided that attendance at such meeting(s) has been approved in advance by Lilly. Lilly shall make such reimbursements within thirty (30) calendar days of receiving acceptable detailed documentation of such expenses, provided that Lilly receives such documentation within sixty (60) calendar days of the date that the expenses were incurred.
2. Subject Injury Reimbursement

Lilly shall reimburse Institution or the service provider for the following additional costs:

(1) All reasonable and customary costs incurred that are associated with the diagnosis of an adverse event involving the Study drug(s), device(s), or a Protocol procedure; and

(2) All reasonable and customary costs incurred for treatment of physical injury to the subject if Lilly determines after consulting with Investigator that the adverse event was reasonably related to administration of the Study drug(s), device(s), or Protocol procedure, provided that:

(a) the adverse event is not attributable to the negligence or misconduct of Investigator and/or Institution or any of their agents, contractors, or employees;

(b) the adverse event is not attributable to any underlying illness, whether previously diagnosed or not; and

(c) Investigator and Institution have adhered to and complied with the specifications of the Protocol and all recommendations furnished by Lilly for the use and administration of any drug or device used in the Study, provided that deviations from the Protocol and recommendations resulting from an imminent threat to the health or safety of a Subject that do not cause the injury to the Subject will not disqualify Institution and/or Investigator from reimbursement under this provision.

In order for Lilly to comply with reporting requirements under the Centers for Medicare and Medicaid Services (CMS) Section 111 of the Medicare, Medicaid and SCHIP Extension Act of 2007 (MMSEA 111), Institution shall be required to submit, upon request, documentation required by Lilly regarding any request for payment of subject injury costs. Such documentation must be provided to Lilly prior to Lilly making any such payment.

1. Limit of Patient Entry or Enrollment and Study Termination

Lilly reserves the right to limit entry or enrollment of additional patients at any time. Lilly also reserves the right to terminate Investigator’s, Institution’s, or any patient’s participation in the Study or the Study itself at any time for any reason.

Investigator and/or Institution may terminate their participation in the Study upon thirty (30) calendar days written notice in the event (1) there is a breach of a material provision of this Agreement by Lilly, which breach is not cured by Lilly within ninety (90) calendar days following receipt from Investigator and/or Institution of written notice thereof; (2) if the Investigator becomes unavailable due to death, disability, or is no longer affiliated with Institution, and Lilly and Institution are unable to agree upon an acceptable replacement; or (3) if the authorization and approval to perform the Study is withdrawn by the FDA or by the IRB.

Payments shall be made for all work that has been performed up to the date of termination and shall be limited to reasonable non-cancelable costs which were incurred by Investigator and/or Institution in connection with the Study as required under the Protocol and contemplated in the Budget.

1. Study Term

The term of this Agreement shall be from the date the Agreement is fully executed on the date of last signature until the completion of the Study, which is expected to occur approximately three (3) months after database lock for the Study, but in no event prior to completion of the Protocol and any amendments thereto and completion of all data queries, unless terminated earlier pursuant to the termination clause of this Agreement.

III. CONFIDENTIALITY AND NON-USE

(1) Confidential Information in connection with the Study: All information provided to Investigator and/or Institution by Lilly or Lilly-designated representatives, or generated by Investigator and/or Institution in connection with the Study (“Confidential Information”), shall be kept in confidence and not used for any purpose not expressly provided for in this Agreement for five (5) years after the termination or conclusion of the Study except in accordance with the Publications section of this Agreement, or to the extent that Lilly gives Investigator and/or Institution written permission or particular Confidential Information is required by laws or regulations to be disclosed to the IRB, the patient, local regulatory agencies, or the FDA. To the extent disclosure is requested by any other person or entity, Investigator and/or Institution shall promptly notify Lilly and shall not disclose any Confidential Information without Lilly’s prior written consent. If such disclosure is sought by a third party under a claim of legal right, Investigator and Institution shall reasonably cooperate with Lilly in the event Lilly wishes to take legal action to challenge such claim or the disclosure; provided, however, in no event shall Investigator and/or Institution be obligated to defy any law, regulation, or judicial or governmental order. Investigator and Institution shall be responsible for ensuring that their employees, sub-investigators, contractors, and agents are obligated to these same, or substantially similar, terms of confidentiality and non-use. The terms of confidentiality and non-use set forth herein shall supersede any prior terms of confidentiality and non-use agreed to by the parties in connection with this Study. The terms of this Agreement shall also be considered Confidential Information and may be disclosed only to the extent required by law, necessary for approval of this Study, or as permitted by Lilly in writing.

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

1. is or later becomes part of the public domain other than through breach of this Agreement by Investigator and/or Institution.;
2. was known by Investigator and/or Institution prior to disclosure by Lilly or becomes known from an independent source who is in rightful possession and not under an obligation of confidentiality with respect to such Confidential Information, as can be shown by prior written documentation; or
3. is independently developed, as shown by written documentation, by Investigator and/or Institution personnel without use or reliance on Confidential Information.

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

(2) Confidential Information for Lilly Publication and Authorship: In the event Investigator is invited to be an author of a Lilly publication or presentation during the course of or after the conclusion of the Study covered by this Agreement, Investigator and Institution shall hold all new Confidential Information (including data from other investigator sites for multi-site studies) provided to Investigator or Institution by Lilly or Lilly-designated representatives, or generated by Investigator or Institution in connection with such authorship, in confidence for five (5) years from the date of such disclosure or the generation of Confidential Information, as applicable. This obligation survives the expiration, cancellation or termination of this Agreement.

IV. SITE PERSONNEL DATA NOTICE

Lilly may, to the extent allowed by applicable laws, collect information from Investigator and Institution personnel, including names, titles, and business contact information (“Site Personnel Data”) and may provide that information to Lilly’s business partners and vendors working with Lilly on matters related to the Study solely to fulfill Lilly’s business functions including:

1. Compliance with U.S. regulations regarding possible financial conflicts of interest;
2. Assessment of personnel qualifications to conduct the Study;
3. Quality control and Study management; and
4. Disclosures to IRBs or federal or foreign regulatory authorities in connection with their performance of review or oversight responsibilities for the Study.

Site Personnel Data may also be aggregated with data from other Lilly sources and evaluated for business decisions, including those involving future research. Lilly may store or process such Site Personnel Data in the U.S. or other countries at Lilly or Lilly-associated facilities as long as a business need or legal obligation exists.

Some of this Site Personnel Data may be considered sensitive under applicable laws, such as information about your health or medical diagnosis and demographic information collected in some circumstances, such as race, ethnic origin, and sexual orientation. We may process your sensitive Site Personal Data with your consent, or as otherwise permitted by law.

Lilly does not use or disclose your sensitive Site Personnel Data except for limited purposes that are authorized by law. For example, Lilly may collect information about your health or medical diagnosis to provide you specific functionality or products or services that you have requested. California law does not afford you rights to limit the use or disclosure of sensitive Site Personnel Data for these purposes, although we may nonetheless ask for your consent or provide you choices about how we use this information depending on the relevant context.

Investigator and/or Institution personnel may have access to Site Personnel Data about themselves that Lilly has collected and may have corrections made to Site Personnel Data about themselves that is inaccurate. Investigator and/or Institution may contact Lilly with inquiries regarding Lilly’s collection or use of Site Personnel Data. Lilly agrees to - not sell or use the collected Site Personnel Data for any purpose outside the scope of uses described herein. Lilly will comply with all applicable laws, standards, and regulations regarding Lilly’s use and disclosure of Site Personnel Data.

V. INDEMNIFICATION AND INSURANCE

1. Indemnification

In consideration of the performance by Investigator, Institution, and their staff, officers, agents, and employees (“Indemnitees”) of the Study, Lilly shall indemnify, defend, and hold harmless the Indemnitees from and against loss, damage, cost, and expense of claims and suits (including reasonable legal fees and the cost and expense of handling such claims and defending such suits) resulting from an injury to a patient seeking damages alleged to have been directly caused or contributed to by any substance or procedure administered in accordance with the Protocol;

In order for Indemnification obligations to become applicable, Indemnitees must have adhered to and complied with all applicable federal, state, and local regulations (including, without limitation, obtaining informed consents, and IRB approvals), the specifications of the Protocol, and all recommendations furnished by Lilly for the use and administration of any drug or device described in the Protocol and Lilly is promptly notified of any such claim or suit.

Upon notice that claims have been made or suits have been filed and indemnification has been requested by Indemnitees, Lilly requires that:

(1) the Indemnitees cooperate fully in the investigation and defense of any such claim or suit;

(2) Lilly retains the right to defend the lawsuit in any manner it deems appropriate, including the right to retain counsel of its choice; and,

1. Lilly shall have the sole right to settle the claim or suit; provided, however, that Lilly shall not admit fault on Indemnitees’ behalf without Indemnitees’ advance written permission.

In addition, Lilly’s obligation of indemnification shall not extend to any loss, damage, or expense arising from the negligence, willful malfeasance, or unlawful act or malpractice by the Indemnitees, it being understood that the administration of any substance in accordance with the Protocol shall not constitute negligence, willful malfeasance, or unlawful act or malpractice for purposes of this Agreement. Lilly hereby agrees that any deviations from, or failures to adhere to, the terms of the Protocol that are mutually agreed upon in writing by all parties to the Study (including the IRB) or any deviations from the Protocol that are necessary to eliminate an immediate safety hazard to the Study participants are not considered violations of the Protocol or failures to adhere to the terms of the Protocol pursuant to this provision.

1. Insurance

Lilly warrants that it maintains a policy or program of insurance or self-insurance at levels sufficient to support the obligations of indemnification provided above. Upon written request, Lilly will provide evidence of its insurance or, if self-insured, its most recent audited financial statement to Institution.

VI. SURVIVORSHIP CLAUSE

The obligations under the sections INVESTIGATOR AND INSTITUTION OBLIGATIONS, PAYMENT SCHEDULE, SUBJECT INJURY REIMBURSEMENT, SITE PERSONNEL DATA, INDEMNIFICATION, SURVIVORSHIP, WAIVER, and SEVERABILITY shall survive the expiration, termination, or cancellation of this Agreement.

VII. INDEPENDENT CONTRACTOR

Investigator, Institution, and Lilly shall be acting as independent contractors and not as agents, partners, or employees of any other party. No party has the authority to make agreements with third parties that are binding on any other party.

IX. ASSIGNMENT

Institution shall not assign, transfer, or otherwise delegate any of its obligations under this Agreement without Lilly’s prior written consent in each instance. Institution and Investigator acknowledge that Lilly will have the right to assign this Agreement to any of its affiliates, to a contract research organization in connection with the transfer of sponsor obligations, in connection with a merger or other corporate reorganization, or otherwise in connection with the transfer of all or substantially all of Lilly’s assets that bear on the Study drug(s) or device(s)

X. AMENDMENTS

The terms of this Agreement may be amended by an instrument in writing signed by the parties to this Agreement. Changes or modifications to the Protocol, the Study Budget and/or Institution or Investigator information may be communicated without an amendment to the Agreement via email correspondence or letter.

Institution and Investigator shall use their best efforts to review any amendments to this Agreement in good faith and in a timely manner and, if applicable, to facilitate the timely execution of said amendments (whenever reasonably practicable within thirty (30) business days from receipt of the amendment from Lilly), including providing or obtaining any requisite documentation or approvals (i.e., IRB approval).

XI. WAIVER

The waiver by any party of a breach or violation of any provision of this Agreement shall neither operate as, nor be construed as, a waiver of any subsequent breach of this Agreement.

XII. [SEVERABILITY](file:///C:/Users/V3x5537/Desktop/LOA%20NGD.docx#TABLE_OF_CONTENTS)

In the event that any provision of this Agreement is found invalid or unenforceable pursuant to judicial decree or decision, that provision(s) is deemed severed from this Agreement and the remainder of this Agreement shall remain valid and enforceable according to its terms.

XIII. BINDING EFFECT, COUNTERPARTS AND ELECTRONIC TRANSMISSIONS

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

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

*Signature Page Follows*

|  |  |  |
| --- | --- | --- |
| Agreed and Accepted: |  | Agreed and Accepted: |
| **Lilly USA, LLC / Eli Lilly Export SA, Puerto Rico Branch** |  | NYC Research |
|  |  |  |
|  |  |  |
| [Authorized Signatory and Title] |  | (Signature of Authorized Official) |
| Trial Capabilities Center |  |  |
|  |  |  |
|  |  | (Typed or Printed Name) |
| This Agreement was prepared by: |  |  |
| [Name] |  |  |
|  |  | (Title of Authorized Official-required) |
|  |  |  |
|  |  |  |
|  |  | (Date) |
|  |  |  |
|  |  | Agreed and Accepted: |
|  |  | **Investigator** |
|  |  |  |
|  |  | Anastasios Manessis, PI Title. |
|  |  |  |
|  |  |  |
|  |  | (Date) |

If this Agreement is acceptable, please sign and return all pages (including attachments) to Lilly USA, LLC in one of the three methods outlined below.  If you have questions, please call your Trial Capabilities Associate.

(1)    Forward the scanned (.pdf) or electronically signed document to your Trial Capabilities Associate

(2)    Send by facsimile transmission to (317) 453-8500 or toll free at (866) 922-2854

(3)    Mail to:  Trial Capabilities Center, Lilly Corporate Center, Drop Code 1703, Indianapolis, Indiana, 46285

**EXHIBIT A**

**STUDY BUDGET**

**Exhibit B**

[Primary TCA to copy correct version of Exhibit B and place into study-specific CTA template for country if Exhibit B is applicable. Delete page if Exhibit B does not apply]