MASTER SERVICES AGREEMENT FOR RESEARCH PROJECTS USING PI-2620

by and among

University of North Texas Health Sciences Center
Institute for Translational Research
3500 Camp Bowie Blvd.
Fort Worth, TX 76107
USA

and

Life Molecular Imaging SA
Route de l'Ecole 13
1753 Matran
Switzerland

Master Services Agreement for Research Projects using PI-2620

This Master Services Agreement for Research Projects using PI-2620 (the "AGREEMENT"), is entered into upon date of last signature (the "EFFECTIVE DATE") between

University of North Texas Health Sciences Center having its registered office at 3500 Camp Bowie Blvd, Fort Worth, TX 76107 ("INSTITUTION")

and

Life Molecular Imaging SA, having its registered office at Route de l'Ecole 13 in 1753 Matran, Switzerland ("LMI")

Preamble

WHEREAS, INSTITUTION desires to conduct multiple research projects using LMI's 18F-labeled Tau imaging agent PI-2620 (hereinafter referred to as the "TAU TRACER") (the "RESEARCH PROJECTS"); and

WHEREAS, LMI is interested in increasing its knowledge about TAU TRACER and has agreed to provide such support under the terms and conditions of this AGREEMENT; and

WHEREAS, the INSTITUTION is willing to provide the PRINCIPAL INVESTIGATOR with adequate resources to conduct the STUDY.

NOW, THEREFORE, in consideration of the premises and agreed upon conditions set forth below, the parties agree as follows:

DEFINITIONS:

"**Affiliate**" shall mean any company directly or indirectly controlled by LMI or to a third party in case of a change of control. For this purpose, the term "controlled" and shall mean ownership, directly or indirectly, or at least fifty percent (50%), or the maximum percentage allowed by law in the given country, of the voting stock or general partnership interest of such corporation, partnership, or other entity.

"**Applicable Law**" shall mean all statutes, codes, ordinances, decrees, rules, regulations (including regulations of regulatory authorities like FDA), municipal by-laws, judicial, administrative, ministerial, governmental or regulatory judgments, orders, decisions, rulings or awards, restraints or any provisions, of such laws, including general principles of common and civil law and equity to the extent applicable in the respective country where the STUDY is conducted, binding on the Person referred to in the context in which the word is used and the term 'Applicable Law' means any of the foregoing.

"**Confidential Information**" shall mean any information, which is disclosed by either LMI or the INSTITUTION pursuant to this AGREEMENT, including, but not limited to, all technical information, unpublished data, sales information, drawings, descriptions and know-how, whether marked as "Confidential" or not. If information is disclosed orally, it will be confirmed in writing

as confidential within 30 days of disclosure.

"**Principal Investigator**" shall mean the holder of the independent grant and lead researcher in charge of the team and responsible for the conduct of the Study at INSTITUTION.

"**Protocol**" shall mean the description of the objectives, design, methodology, statistical considerations, and organization of the Study as outlined in **Exhibit A-1**.

"**Regulatory Authority(ies)**" means any federal, national, multinational, state, provincial or local regulatory agency, department, bureau or other governmental entity with authority to approve Study for a pharmaceutical product in a country, including without limitation the EMA in the EU and the FDA in the US.

"**Study**" shall mean the investigation on human subjects as outlined in **Exhibit A-1** generally intended to investigate or verify the clinical or pharmacological effects or to study absorption, distribution, metabolization or excretion, with the aim of ascertaining the safety or efficacy of a medicinal product.

1. Scope of the Agreement

1.1. The scope of this AGREEMENT is the supply of TAU TRACER by LMI to INSTITUTION for the RESEARCH PROJECTS as defined in individual Project Orders substantially in the form as outlined in **Exhibit A** (each, a "Project Order") and as accompanied by the respective Protocol (**Exhibit A-1**) applicable for each individual Research Project. Each Project Order shall be subject to the terms and conditions set forth in this AGREEMENT. Each Project Order shall identify the number of expected doses of TAU TRACER to be ordered, prices and additional terms and conditions, if any. There will be no limit to the number of Project Orders that may be entered into pursuant to this Agreement. If any provision in a Project Order conflicts with the terms and conditions contained in the body of this Agreement, the language in the body of this Agreement shall prevail. Notwithstanding the foregoing, the parties may agree to modify the terms and conditions of this Agreement with respect to a given Project Order by setting forth such modifications in a Project Order under a section entitled "Modifications to Agreement Terms and Conditions."

1.2. RESEARCH PROJECTS are funded by various governmental agencies, philanthropic organizations, any other public or private entities or individuals or public-private partnerships.

1.3. Unless explicitly agreed otherwise for a specific RESEARCH PROJECT, LMI will generally have no role or participation in the RESEARCH PROJECTS other than the supply of TAU TRACER as set forth in the respective Project Orders.

1.4. USE, DISTRIBUTION, AND CONTROL OF TAU TRACER

1.4.1. INSTITUTION agrees that TAU TRACER supplied under this AGREEMENT:

- shall be used only for the RESEARCH PROJECTS in accordance with Applicable Laws and PROTOCOL; and
- shall not be used, directly or indirectly, for commercial purposes or any other purposes.

1.4.2. INSTITUTION agrees not to transfer TAU TRACER supplied under this AGREEMENT to any third party without the prior written permission of LMI. In addition, INSTITUTION shall ensure that all persons under its direct control and supervision who have access to TAU TRACER supplied hereunder and Confidential Information (as defined below) are subject to and comply with the obligations and terms of this AGREEMENT.

1.5. LMI will have no role or participation in the RESEARCH PROJECT other than the supply of TAU TRACER as set forth in this AGREEMENT.

2. Responsibilities and Obligations of the Institution/Principal Investigator

2.1. Compliance with Applicable Law

The INSTITUTION assumes all legal responsibility as sponsor of the STUDY, except in regard to the manufacture, shipment, or quality of the TAU TRACER as specified in this AGREEMENT or in a Project Order.

The INSTITUTION agrees to comply with all Applicable Laws in the conduct of the STUDY, including but not limited to the International Conference on Harmonization ("ICH"), Guidelines for GCP, and the Food and Drug Administration ("FDA") or any other equivalent Food and Drug Authority and applicable requirements governing individual health protected information including the Health Insurance Portability and Accountability Act ("HIPAA").

The INSTITUTION and PRINCIPAL INVESTIGATOR represent that the STUDY will be conducted in accordance with the provisions of the PROTOCOL, the terms and conditions of this AGREEMENT and all Applicable Law.

INSTITUTION and PRINCIPAL INVESTIGATOR shall be responsible to obtain and maintain all regulatory approvals including the positive statement(s) from the applicable institutional review board or ethics committees.

INSTITUTION and PRINCIPAL INVESTIGATOR shall ensure that the study subjects included in the STUDY are insured in accordance with Applicable Law.

INSTITUTION and PRINCIPAL INVESTIGATOR shall ensure that the STUDY and its results (the latter subject to Section 5) are listed according to Applicable Law. Principal Investigator agrees to register the STUDY under the respective Project Order on www.clinicaltrials.gov, if required, within 21 days after first patient's first visit, in compliance with the FDA Amendment Act of 2007.

The parties agree to abide by all applicable privacy laws pertaining to confidentiality and disclosure of protected health information with regard to all information or records obtained and reviewed in the course of conducting the STUDY and shall permit access to such information or records only as defined in the applicable data protection laws.

It is INSTITUTION's responsibility to obtain from each trial subject prior to enrollment an informed consent including the use of anonymized data by LMI for further research and registration purposes.

2.2. Representations

The INSTITUTION and PRINCIPAL INVESTIGATOR represent and certify that to the best of their knowledge, they and their employees, affiliates, agents, sub-investigators and any others who may be participating in the STUDY have never been (a) debarred or (b) to the best of their knowledge, convicted of a crime for which a person can be debarred under the Applicable Law, or any other similar law of country where STUDY will take place. The INSTITUTION and PRINCIPAL INVESTIGATOR shall use the TAU TRACER solely for academic, non-commercial diagnostic research, provided further that INSTITUTION or PRINCIPAL INVESTIGATOR shall not sell, supply, or grant any rights under or access to, whether directly or indirectly, the TAU TRACER to any third party in any manner, except as provided under the AGREEMENT.

2.3. Further Representations

2.3.1 PRINCIPAL INVESTIGATOR and INSTITUTION represent and warrant to LMI that, to the best of their knowledge:

a. neither any employee of the PRINCIPAL INVESTIGATOR or INSTITUTION involved in the Study, nor any subcontractor or employee of a subcontractor involved in the Study, has been debarred by any health authority, including the FDA pursuant to its authority under

Sections 306(a) and (b) of the U.S. Food, Drug, and Cosmetic Act (21 U.S.C. § 335(a) and (b));

b. neither the PRINCIPAL INVESTIGATOR or INSTITUTION involved in the Study nor, to the extent applicable, any employee of the PRINCIPAL INVESTIGATOR or INSTITUTION involved in the Study, subcontractor or employee of a subcontractor involved in the Study, is the subject of any investigation or proceeding which may result in debarment by the FDA or other health authorities; and

c. the PRINCIPAL INVESTIGATOR or INSTITUTION will promptly notify LMI in writing if the INVESTIGATOR becomes aware of any such debarment, investigation or proceeding of the PRINCIPAL INVESTIGATOR or INSTITUTION or, to the extent applicable, any employee of the PRINCIPAL INVESTIGATOR or INSTITUTION, subcontractor or employee of a subcontractor.

d. they are entitled to carry out the RESEARCH PROJECT in accordance to the PROTOCOL and Applicable Laws and have all licenses and permits to do so which shall be maintained valid throughout the Term of this AGREEMENT;

e. PRINCIPAL INVESTIGATOR agrees to provide Data and Safety Reports to LMI as set forth in Sec. 4 and agrees that LMI may use personal data of PRINCIPAL INVESTIGATOR for the registration, administration, evaluation and publication of the STUDY and its results, if any.

f. PRINCIPAL INVESTIGATOR and INSTITUTION agree to inform LMI of any delays occurring during the STUDY under the respective Project Order and/or events that may lead to a loss in quality of STUDY data or delay in the STUDY timeline under a respective Project Order.

2.4. Institutional Research Resources

The INSTITUTION agrees to provide all personnel, facilities, and resources, as required, to accomplish the objectives of the STUDY. Notwithstanding the foregoing, Institution shall not be obligated to provide financial resources in order to replace a loss of third-party funding in support of the research of Principal Investigator.

3. LMI Supply

3.1. Conditions of Supply

LMI will supply PI-2620 in dose numbers and at prices as set forth in the respective Project Orders and as set forth in this AGREEMENT.

Such LMI Supply will be subject to the following conditions:

(a) The TAU TRACER shall be used by INSTITUTION and PRINCIPAL INVESTIGATOR only for the performance of the Research Projects in accordance with the PROTOCOL, instructions provided with the supply shipment of TAU TRACER, Applicable Law and this AGREEMENT;

(b) INSTITUTION and PRINCIPAL INVESTIGATOR agree not to chemically, physically or otherwise modify the TAU TRACER;

(c) INSTITUTION and PRINCIPAL INVESTIGATOR agree to assume full responsibility for appropriate handling of TAU TRACER at the clinical site and shall follow the respective order procedure as described in **Exhibit A-2**;

(d) INSTITUTION and PRINCIPAL INVESTIGATOR shall not provide the TAU TRACER to any third party without the prior written consent of LMI;

(e) INSTITUTION and PRINCIPAL INVESTIGATOR agree to assure dose accuracy by

determining the radioactivity shortly prior and after administration;

(f) INSTITUTION and PRINCIPAL INVESTIGATOR will promptly notify LMI should any Regulatory Authority conduct or give notice to conduct an inspection at any of the sites conducting a Research Project and supply all pertinent information. LMI shall have the right to be present;

(g) Subject to applicable data protection laws and other Applicable Law, LMI retains the right to audit PRINCIPAL INVESTIGATOR's records or any other documentation relating to the STUDY during or following the STUDY. INSTITUTION agrees to maintain accurate and detailed records of information pertaining to the STUDY and agrees to grant access to LMI at investigator's site for audit purposes. Such audit will require reasonable prior written notice by LMI;

(h) INSTITUTION and PRINCIPAL INVESTIGATOR agree to hold, maintain and act in accordance with all applicable GCP and GMP standards for the receipt, labeling, application, documentation and destruction of the TAU TRACER.

3.2 Supply Distribution Schedule

LMI agrees to use reasonable endeavors to provide TAU TRACER to INSTITUTION in accordance with the following schedule:

(a) From March 1, 2021 to April 16, 2021 or until such time as TAU TRACER is manufactured in Dallas, Texas, whichever is earlier: at its sole expense, LMI will arrange to have TAU TRACER flown in from Sanford, Florida and delivered to INSTITUTION on Monday of each week in sufficient time for a first injection to occur at 1:00 P.M. local time. The minimum dose order for flown-in doses shall be four (4) doses and the maximum dose order shall be eleven (11) flown-in doses. INSTITUTION will place orders or is entitled to cancel already placed Product orders without any cost latest by 12:00 pm (local time) five (5) business days prior to the business day the TAU Tracer shall be delivered to INSTITUTION.

(b) From April 16, 2021 or from such time as TAU TRACER is manufactured in Dallas, Texas, whichever is earlier, to the expiration or earlier termination of this AGREEMENT: at its sole expense, LMI will arrange to have TAU TRACER delivered from Dallas, Texas to INSTITUTION on Monday and Friday of each week in sufficient time for a first injection to occur at 9:30 A.M. local time. The minimum dose order shall be two (2) doses and the maximum dose order shall be fifteen (15) doses. INSTITUTION will place orders or is entitled to cancel already placed Product orders without any cost latest by 12:00 pm (local time) two (2) business days prior to the business day the TAU Tracer shall be delivered to INSTITUTION.

LMI shall promptly notify INSTITUTION and PRINICIPAL INVESTIGATOR of any delay or shortage in the TAU TRACER supply in accordance with the specified schedule. Such notification shall be given to the following email addresses: Kelly.Berry@unthsc.edu and ITR@unthsc.edu and are for planning purposes only and shall not relieve LMI of its obligations to supply the TAU TRACER in accordance with this AGREEMENT. The Parties shall discuss and agree how to remedy delay or shortage most expeditiously by either delivery of Product or crediting the amounts. LMI's liability for loss or damage as a result of failure to deliver or arrange delivery of Products in a reasonable time shall not in any circumstances whatever exceed a sum equal to the amount of the LMI's charges for the relevant Product delivery plus court costs and expenses. For the avoidance of doubt, LMI shall not in any circumstances whatsoever be liable for indirect or consequential loss such as (but not limited to) loss of profit, loss of market, or the consequences of delay or deviation, however caused.

3.3 Compliance with Applicable Law

(a) LMI represent that the manufacture, labeling and STUDY supply will be conducted in accordance with the applicable TAU TRACER Specifications and cGMP.

(b) Manufacture, labeling, and shipment of TAU TRACER shall adhere with the terms and

conditions of this AGREEMENT and all Applicable Law.

(c) LMI shall be responsible to obtain and maintain all regulatory approvals needed for manufacture, labeling, supply and shipment of TAU TRACER excluding any regulatory approvals needed to be applied for and maintained by INSTITUTION in its capacity as sponsor and conductor of the STUDY INSTUTUTION shall assist LMI with any reasonable request in preparing and updating any required regulatory submission and all other documentation required by any competent Regulatory Authorities in connection with the supply of TAU TRACER to INSTUTUTION by LMI.

(d) If there is a possible or confirmed interruption in the supply of TAU TRACER, LMI will promptly notify INSTITUTION and PRINCIPAL INVESTIGATOR and supply all relevant information should any Regulatory Authority conduct or give notice to conduct an inspection of the manufacturing facilities for TAU TRACER.

4. Study Information

4.1. Study Information Provided to LMI

The PRINCIPAL INVESTIGATOR shall provide LMI within two weeks of knowledge the following information:

a. Prior to the initiation of any specific RESEARCH PROJECT

- a copy of the award letter from the funding agency or other confirmation of funding source
- a copy of the IRB Study Approval letter and without explicit request of LMI any renewal or update of the same within 10 business days following receipt of such update by INSTITUTION; and
- a copy of the approval for the conduct of the RESEARCH PROJECT from the relevant regulatory authority, including the applicable identifier of the RESEARCH PROJECT (IND number), or if not applicable, evidence or written confirmation from the PRINCIPAL INVESTIGATOR that all regulatory requirements are fulfilled.

b. During the RESEARCH PROJECTS

- the date of the first patient recruitment;
- completion of a monthly report to provide updates on recruitment, safety, and other study related information. PRINCIPAL INVESTIGATOR / INSTITUTION shall inform LMI within 24 hours upon gaining knowledge of any issues, positive or negative, raised by the Regulatory Authorities or ethics committees with regard to the RESEARCH PROJECTS.

c. Upon completion of the RESEARCH PROJECTS

- the date of completion of any RESEARCH PROJECT (last patient last visit);
- the total number of patients recruited in the course of the RESEARCH PROJECT.

4.2. Pharmacovigilance

Throughout the course of the RESEARCH PROJECT, the PRINCIPAL INVESTIGATOR and study personnel agree to comply with the obligations of adverse event reporting as set forth in the (the "SAFETY REPORTING REQUIREMENTS") in **Exhibit B**.

PRINCIPAL INVESTIGATOR shall report to LMI and any time upon LMI's request, not more frequently than six months, on the state of advancement of the STUDY. PRINCIPAL INVESTIGATOR shall provide basic demographic data and anonymized DICOM files of the imaging data and send LMI final written

report summarizing results of the STUDY upon completion or termination of the STUDY.

5. Publication

5.1. If legally required, INSTITUTION shall publish or post the results of the STUDY under a respective Research Project within 12 months of the end of the STUDY. Prior to publication or presentation of STUDY results, either Party agrees to provide the other Party with such presentation, abstract, or manuscript at least 30 days prior to its presentation or submission for the sole purpose of allowing the other Party to review for Confidential Information and to protect any existing or future patents. Such Publication shall be delayed for a 60-day period or until the patent application is filed by the other Party, whichever is less. Such review by the other Party does not include editorial privileges. The publishing Party shall remove such Confidential Information identified by the other Party, excluding results of the STUDY. The PRINCIPAL INVESTIGATOR shall acknowledge LMI contributions in all publications, where appropriate. LMI shall acknowledge PRINCIPAL INVESTIGATOR and INSTITUTION contributions in all publications, where appropriate, unless otherwise requested by PRINCIPAL INVESTIGATOR and INSTITUTION.

5.2. In case of a premature termination of the STUDY, results should be posted within 12 months after the date of the last observation of the last patient who remains enrolled in the STUDY or after the date the decision that has been made to terminate the STUDY, whichever happens first. For prematurely terminated STUDIES which have been terminated due to safety reasons information describing reasons for terminating the STUDY, especially noting any discernable threat (not previously disclosed on the label) to patient health should be posted within 30 days after termination of the STUDY.

The summary should conform to ICH E3 principles and to the template published in the Federal Register, Vol. 61, July 17, 1996, Page 37320 et seq: The summary should also reflect not only the generic and brand names of the LMI product(s) involved, but also a listing of all aliases under which the LMI product(s) may be known at the time of posting, including serial numbers, code names and chemical descriptions.

6. Invoicing and Payment

6.1. LMI will invoice INSTITUTION in accordance with the terms and conditions (i) set forth in Exhibit C (if applicable) or (ii) as otherwise described in the relevant Project Order. All prices specified in Exhibit C or a relevant Project Order are inclusive of all taxes except value added tax (“VAT”), goods and service/harmonized sales tax (“GST/HST”), or the local equivalent.

6.2. The parties agree to fully cooperate with each other to enable each party to more accurately determine its own tax liability. Each party shall provide and make available to the other party, upon written request, any exemption certificates, resale certificates, information regarding out of state or out of country sales or use of equipment, materials or services, and any other information reasonably requested by the other party.

6.3. Upon request and with reasonable notice, INSTITUTION reserves the right to audit LMI’s records to confirm that INSTITUTION is being invoiced in accordance with pricing as specified in this AGREEMENT and the relevant Project Order. In the event of a neutral third-party verifiable over-charge, LMI agrees to refund INSTITUTION for the over-charge amount within 30 days of receipt of written notice.

7. Confidentiality and Non-Disclosure

The parties to this AGREEMENT agree not to disclose confidential information obtained during the course of this AGREEMENT. "CONFIDENTIAL INFORMATION" shall mean any information, which is

disclosed by either LMI or the INSTITUTION pursuant to this AGREEMENT, including, but not limited to, all technical information, unpublished data, sales information, drawings, descriptions and know-how, whether marked as "Confidential" or not. If information is disclosed orally, it will be confirmed in writing as confidential within 30 days of disclosure. In the event that the INSTITUTION shares LMI's CONFIDENTIAL INFORMATION with other employees, officers, directors, agents, affiliates, or other investigators engaged by the INSTITUTION to assist with the conduct of the STUDY, the INSTITUTION shall be responsible for the compliance of such persons with the provisions contained in this Section with respect to the non-disclosure and non-use of LMI's CONFIDENTIAL INFORMATION. Each, the INSTITUTION and LMI further agree to use such CONFIDENTIAL INFORMATION only for the purpose of fulfilling their obligations under this AGREEMENT and, to return all CONFIDENTIAL INFORMATION to the disclosing party at the end of the STUDY.

The obligation of non-disclosure does not apply to information which either LMI, PRINCIPAL INVESTIGATOR, INSTITUTION (as applicable) can establish with evidence was:

(a) in the public domain at the time of disclosure through no fault of receiving party;

(b) was known to the receiving party prior to its receipt hereunder, as evidenced by written documentation;

(c) was disclosed by a third party not under an obligation of non-disclosure;

(d) was required by law to be disclosed, provided that prior notice of any such disclosure was provided to the non-disclosing party to allow the non-disclosing party the opportunity to legally contest such requirement;

(e) was independently developed without reference to or knowledge of CONFIDENTIAL INFORMATION of the other party, as evidenced by written records.

The obligations of confidentiality will exist during the performance of this Agreement and for five (5) years following termination or expiration of this Agreement, unless disclosure is required by law or regulation.

8. Ownership of Inventions

The Parties do not expect any patentable inventions will be conceived in the course of the STUDY. Should however any inventions be made by the Parties in the course of carrying out the STUDY such inventions shall be handled according to the following provision:

A. TAU TRACER Inventions

The manufacturing, quality control, formulation and use of the TAU TRACER is based on the CONFIDENTIAL INFORMATION and instructions provided by LMI. INSTITUTION and PRINCIPAL INVESTIGATOR shall not modify manufacturing, quality control or formulation within the scope of this Study.

The parties agree that any inventions or discoveries made in the course of carrying out the STUDY which are improvements of the TAU TRACER (e.g. manufacturing, quality control, formulation, indications) or any invention that incorporates the composition of matter of TAU TRACER or any invention which in any way incorporate the CONFIDENTIAL INFORMATION of LMI related to the TAU TRACER will be the property of LMI ("TAU Inventions").

B. INSTITUTION Inventions

All other inventions made in the course of carrying out the STUDY not related to the TAU TRACER will be owned by INSTITUION ("Institution Inventions"). INSTITUTION inventions could include general improvements, e.g. directed to patient management, image acquisition, image reconstruction or interpretation.

In the event of a new patentable Invention that is a TAU TRACER Invention, PRINCIPAL INVESTIGATOR and INSTITUTION agree to assist LMI, to their reasonable ability during normal business hours, in its patent application process by delivering and executing any and all instruments necessary to make, file and prosecute all such applications. LMI shall compensate INSTITUTION for any such assistance.

9. Insurance

The INSTITUTION warrants that it maintains, at its sole cost and expense, a self-insurance program providing general liability coverage in amounts sufficient to discharge INSTITUTION's and PRINCIPAL INVESTIGATOR obligations under this AGREEMENT. Further, if and to the extent required by Applicable Law, INSTITUTION represents and certifies that it will hold adequate insurance for Study subjects under the RESEARCH PROJECT. The INSTITUTION shall maintain such insurance as required by Applicable Law.

LMI warrants that it maintains, at its sole cost and expense, policies of general liability insurance and product liability insurance in amounts sufficient to discharge LMI's obligations under this AGREEMENT but in any event not less than $2 million per occurrence and $4 million in the annual aggregate. LMI shall maintain such insurance for a term of three (3) years after the expiration or sooner termination of this Agreement or as required by Applicable Law, whichever is longer. Upon request, LMI shall provide INSTITUTION with written evidence of such insurance.

10. Term and Termination

10.1. This AGREEMENT shall be effective as of the EFFECTIVE DATE and continue for five (5) years following the EFFECTIVE DATE of this AGREEMENT. Project Orders associated with this AGREEMENT shall terminate as of the termination date of this AGREEMENT unless otherwise agreed to in writing by the Parties in an amendment to this AGREEMENT or the Project Orders.

10.2. In the event that any Party shall be in material breach or material default of any of its obligations under this AGREEMENT or a Project Order associated with this AGREEMENT and shall fail to remedy such default within 30 days after receipt of written notice of such default, the non-defaulting party shall have the option of terminating this AGREEMENT and Project Orders associated with this AGREEMENT by giving written notice of termination to the defaulting party which shall be effective immediately after expiration of the 30 day cure period for default. Material breach or material default by any party means (a) a failure of the party to perform a material obligation under this Agreement or a Project Order associated with this AGREEMENT for reasons not excused under Section 13 (Force Majeure); or (b) any representation or warranty made by a party to this Agreement proves to be knowingly false or erroneous in any way when made or at any time shall fail to be true and correct in all material respects. A failure to perform a minor part of this AGREEMENT does not constitute a material breach. Regarding Product delivery, failure to perform a material obligation means non-delivery of Product on 3 successive agreed upon TAU delivery days.

10.3. Either party shall have the right to terminate this AGREEMENT and Project Orders associated with this AGREEMENT upon immediate written notice, if the emergence of any adverse reaction or side effect with the TAU TRACER is of such magnitude or incidence, to support termination.

10.4. INSTITUTION shall have the right to terminate this AGREEMENT and Project Orders associated with this AGREEMENT immediately with written notice to LMI in the event of a failure on LMI's part to ensure ongoing delivery of LMI's Neuraceq® (florbetaben F 18 injection) (hereinafter referred to as "AMYLOID TRACER") under a Master Services Agreement entered into between the Parties or the agreement serving the Health & Aging Brain among Latino Elders (HABLE) ATN study, as may exist now or in the future or any Project Order associated with those agreements. INSTITUTION shall have the right to terminate under this Section 10.4 in the event of LMI's failure to deliver the

AMYLOID TRACER (excluding a Force Majeure Event) for a period lasting longer than 30 days and manufacture cannot be resumed or be covered from other LMI manufacturing sites.

10.5. Either party shall have the right to terminate this AGREEMENT and Project Orders associated with this AGREEMENT without cause upon 90 days written notice.

10.6. Except as expressly required by Applicable Law, if either party terminates this AGREEMENT in accordance with any of the provisions of this AGREEMENT, neither party will be liable to the other because of such termination for compensation, reimbursement, or damages on account of the loss of prospective profits or anticipated income or on account of expenditures, inventory, or commitments given or received in connection with the Research Projects. For the sake of clarity, termination will not, however, relieve either party of obligations or rights incurred prior to the Effective Date of the termination.

11. Use of Institution Name/Public Statements

LMI, INSTITUTION, and PRINCIPAL INVESTIGATOR agree that they will not at any time during the term of this AGREEMENT use the name or logo of the other Party without prior written consent. LMI may, however, disclose to any governmental agency the fact that the STUDY utilizing the TAU TRACER, is being or has been conducted at the INSTITUTION under the direction of the PRINCIPAL INVESTIGATOR.

12. Warranty, Indemnification and Limitation of Liability

12.1 Each Party represents and warrants that (i) it is duly incorporated or organized, validly existing and in good standing under the laws of the state of its incorporation or organization; (ii) it has the power, authority and legal right to enter into this Agreement and to perform the obligations hereunder; (iii) all necessary consents, approvals and authorizations of governmental authorities and other persons required to be obtained related to the performance of this Agreement have been obtained; (iv) the execution and delivery of this Agreement will not conflict with or violate any requirement of any Applicable Law.

12.2 Except for warranties expressly given in this Agreement, LMI makes no representation or warranty of any kind as to the satisfactory quality, merchantability, activity, and fitness for a particular purpose or suitability of TAU TRACER for the Research Project or that TAU TRACER has the effect expected of it.

12.3 Except for warranties expressly given in this Agreement, INSTITUTION makes no representation or warranty of any kind as to the satisfactory quality, merchantability, activity, and fitness for a particular purpose or suitability of the Research Project or the results thereof.

12.4 Subject to Sec. 12.6 LMI will indemnify, defend and hold harmless the INSTITUTION, their respective employees, including the PRINCIPAL INVESTIGATOR and any sub-investigator, (individually an "INDEMNITEE" and collectively, the "INDEMNITEEs") from and against any and all actions, suits, claims, proceedings, investigations, demands, costs and expenses (including reasonable attorney fees), judgments, liabilities, losses, personal injuries (including death), or other damages (collectively "LOSSES"), that are asserted to have arisen from the manufacture, labeling, supply and shipment of TAU TRACER in non-compliance with the specifications stated in the respective cross-referenced Investigational New Drug (IND), except and to the extent such LOSSES arise from the breach by such INDEMNITEE of (a) Applicable Law; (b) the STUDY PROTOCOL; or (c) INDEMNITEE's obligations under this AGREEMENT.

12.5 Subject to Sec. 12.6 and to the extent allowed by the laws and Constitution of the State of Texas, INSTITUTION and Principal Investigator will indemnify, defend and hold harmless LMI and its respective employees, Affiliates, directors, (individually an "LMI INDEMNITEE" and collectively, the "LMI INDEMNITEES") from and against any and all actions, suits, claims, proceedings, investigations,

demands, costs and expenses, (including reasonable attorney fees), judgments, liabilities, losses, personal injuries (including death) or other damages (collectively "LOSSES"), that have asserted to have arisen from the STUDY/ PROTOCOL or Outline, a breach by INSTITUTION or Principal Investigator of a contractual obligation under this AGREEMENT or a Project Order, or liability or infringement of any third party intellectual property rights which may arise from the use, storage or handling of the TAU TRACER by INSTITUTION or PRINCIPAL INVESTIGATOR not in accordance with the Applicable Laws, PROTOCOL, or instructions of LMI (if any), except and to the extent such LOSSES arise from the breach by LMI of (a) Applicable Law or (b) LMI's obligations under this AGREEMENT.

12.6 NOTWITHSTANDING THE FOREGOING, IN NO EVENT SHALL EITHER PARTY, TOGETHER WITH ITS AFFILIATES AND ANY OF ITS RESPECTIVE DIRECTORS, OFFICERS, EMPLOYEES, SUBCONTRACTORS, CONSULTANTS AND AGENTS, BE LIABLE FOR PUNITIVE, CONSEQUENTIAL, INCIDENTAL, SPECIAL, EXEMPLARY, OR INDIRECT DAMAGES (INCLUDING WITHOUT LIMITATION LOST REVENUES, LOST PROFITS, OR LOST SAVINGS), REGARDLESS OF WHETHER THAT PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

13. Force Majeure

No liability shall result from, nor shall either Party be in breach or default for, delay in performance or non-performance, in whole or in part, by such Party to the extent that such delay or non-performance is caused by an event of Force Majeure. Force Majeure means an event that is beyond a non-performing party's and/or its Affiliates and/or its subcontractors reasonable control, including but not limited to, acts of government, fires, floods, epidemics, pandemics, quarantine, interruptions or stops of supplies of materials, electricity failures, cyclotron or reactor failures, accidents, acts of God, wars, natural disasters, riots, strikes, lockouts or other concerted acts of workmen.

14. Miscellaneous.

14.1. Independent Contractors

LMI and INSTITUTION shall at all times act as independent parties and nothing contained in this AGREEMENT shall be construed or implied to create an agency or partnership relationship.

14.2. Assignment

INSTITUTION is not entitled to assign or transfer any rights and obligation arising from this AGREEMENT in whole or in part without the prior written agreement of LMI.

LMI shall have the right, at the sole discretion of LMI, to assign, sell, or otherwise transfer this AGREEMENT to an Affiliate contingent on Affiliate assuming all rights and obligations of LMI under this AGREEMENT without the prior written agreement of INSTITUTION. LMI shall have the right, at the sole discretion of LMI, to assign, sell, or otherwise transfer this AGREEMENT to an Affiliate contingent on Affiliate assuming all rights and obligations of LMI under this AGREEMENT. LMI shall have the right to assign, sell, or otherwise transfer to an Affiliate under this section 14.2 without the prior written agreement of INSTITUTION but shall provide INSTITUTION with written notice of such assignment and a copy of the agreement with Affiliate.

14.3. Authority of Signatories

The Parties represent and certify that the individuals executing this AGREEMENT on their behalf have the required authority to bind the Parties to the terms of this AGREEMENT.

14.4. Notices

Any notice or communication required or permitted to be given or made under this AGREEMENT by one of the parties hereto to the other shall be in writing and shall be deemed to have been

sufficiently given or made for all purposes on the date of mailing by certified mail, postage prepaid, addressed to such other party at the respective address referenced below:

LMI:

Life Molecular Imaging SA
Route de l'Ecole 13
1753 Matran
Switzerland

[redacted]

[redacted]

INSTITUTION:

University of North Texas Health Science Center
ATTN: Institute for Translational Research

[redacted]

PRINCIPAL INVESTIGATORS:

All physicians as stipulated for in the separate Project Order.

14.5. Severability

If any one or more of the provisions of this AGREEMENT shall be held to be invalid, or unenforceable, the validity and enforceability of the remaining provisions of this AGREEMENT shall not in any way be affected or impaired.

14.6. Choice of Law

Intentionally left blank.

14.7. Entirety

This AGREEMENT represents the entire AGREEMENT of the parties with respect to the subject matter hereof and it expressly supersedes all previous written and oral communications between the parties. No amendment, alteration, or modification of this AGREEMENT shall be valid unless executed in writing by authorized signatories of all parties.

14.8. Waiver

The failure of any party hereto to insist upon strict performance of any provision of this AGREEMENT will not constitute a waiver of that provision or right.

***See UNTHSC Standard Addendum attached for additional Terms and Conditions.**

IN WITNESS WHEREOF, the parties hereto have caused this AGREEMENT to be executed in one or more counterpart(s) by their duly authorized representatives to be effective as of the EFFECTIVE DATE.

[redacted]

Date: 4/14/2021

Date: 4/7/2021

HSC Contract # 2021-0041

[redacted]

PRINCIPAL INVESTIGATOR

[redacted]

Date: 4/5/2021

STANDARD ADDENDUM TO AGREEMENT

Contracts with the **University of North Texas Health Science Center at Fort Worth** ("University" or "Institution") are subject to the following terms and conditions, which are incorporated for all purposes into the Agreement to which they are attached. In the event of a conflict between the Agreement and this Addendum to Agreement, this Addendum shall govern unless **Exhibit A** of the Project Orders individually entered into for individual studies provide explicitly otherwise under Section Modifications to Agreement Terms and Conditions. Any term or condition of the Agreement that is not superseded by a term or condition of this Addendum shall remain in full force and effect.

Payment. Payment will be made in accordance with the terms of University's purchase order following the payment arrangements and order process provided for in the relevant Project Orders. LMI must be in good standing, not indebted to the State of Texas, and current on all taxes owed to the State of Texas for payment to occur.

Eligibility to Receive Payment. By entering into and performing under this Agreement, LMI certifies that under Section 231.006 of the Texas Family Code and under Section 2155.004 of the Texas Government Code, it is not ineligible to receive the specified payment and acknowledges that this Agreement may be terminated and payment may be withheld if this certification is inaccurate.

Tax Exempt. University is exempt from the payment of taxes and will provide necessary documentation confirming its tax-exempt status.

Breach of Contract Claims against University. Chapter 2260 of the Texas Government Code establishes a dispute resolution process for contracts involving goods, services, and certain types of projects. To the extent that Chapter 2260, Texas Government Code, is applicable to this Agreement and is not preempted by other applicable law, the dispute resolution process provided for in Chapter 2260 and the related rules adopted by the Texas Attorney General pursuant to Chapter 2260, shall be used by LMI to attempt to resolve any claim for breach of contract against University that cannot be resolved in the ordinary course of business.

Governing Law and Venue. This Agreement shall be construed and enforced under and in accordance with the laws of the State of Texas. The Agreement is made and entered into, and is performable in whole or in part, in the State of Texas, and venue for any suit filed against University shall be subject to the mandatory venue statute set forth in § 105.151 of the Texas Education Code.

No Excess Obligations. In the event this Agreement spans multiple fiscal years, University's continuing performance under this Agreement is contingent upon the appropriation of funds to fulfill the requirements of the contract by the Texas State Legislature. If the Legislature fails to appropriate or allot the necessary funds, or if such appropriation is reduced by the veto of the Governor or by any means provided in the appropriations act, University shall issue written notice to LMI that University may terminate the Agreement without further duty or obligation to the extent such appropriation of funds is withdrawn or reduced by law or governmental authority decision.

Travel Expenses. In the event the Agreement required University to reimburse LMI for travel expenses, then reasonable travel, meals, and lodging expenses shall be charged in accordance with and shall not exceed State of Texas travel, meal, and lodging reimbursement guidelines applicable to employees of the State of Texas.

Delivery. Delivery shall be FOB Destination unless mutually agreed otherwise between the Parties under the relevant Project Order.

Public Information. University shall release information to the extent required by the Texas Public Information Act and other applicable law. If requested, LMI shall make public information available to University in an electronic format. The requirements of Subject J, Chapter 552, Texas Government Code, may apply to this contract and LMI agrees that the contract can be terminated if LMI knowingly or intentionally fails to comply with a requirement of that subchapter. Further, LMI agrees (1) to preserve contracting information for the duration of the contract and according to University records retention requirements; (2) to promptly provide contracting information to University when requested; and (3) upon completion of the contract to provide, at no cost, all contracting information to University or to preserve all contracting information according to University's records retention requirements.

Required Posting of Contracts on Website. LMI acknowledges and agrees that University is required by Section 2261.253 of the Texas Government Code to post each contract it enters into for the purchase of goods or services from a private contract partner on its Internet website, including any terms and conditions otherwise marked confidential and/or proprietary. University and LMI agree to post only such contract information that is lawfully required.

Insurance. University, as an agency of the State of Texas, is insured for general liability insurance under a self-insurance program covering its limits of liability. The parties agree that such self-insurance by University shall, without further requirement, satisfy all general liability insurance obligations of University under the Agreement. Further, the University assures that the self-insurance program provides what has been determined to be adequate professional liability coverage for its physicians and staff participating in any research and study performance activities.

HIPAA. The parties understand and agree that this Agreement may be subject to the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the administrative regulations and/or guidance which have issued or may in the future be issued pursuant to HIPAA, including, but not limited to, the Department of Health and Human Services regulations on privacy and security, and Texas state laws pertaining to medical privacy (collectively, "Privacy Laws"). LMI agrees to comply with all Privacy Laws that are applicable to this Agreement and to negotiate in good faith to execute any amendment to this Agreement that is required for the terms of this Agreement to comply with applicable Privacy Laws. In the event the parties are unable to agree on the terms of an amendment pursuant to this paragraph within thirty (30) days of the date the amendment request is delivered by a party to the other, this Agreement may be terminated by either party upon written notice to the other party.

Debarment. LMI certifies that neither it nor any of its Principals (officers, directors, owners, partners, key employees, principal investigators, researchers or management or supervisory personnel) is presently debarred, suspended, proposed for debarment, declared ineligible or excluded from participation in this transaction or in any federal grant, benefit, contract or program (including but not limited to Medicare and Medicaid and Federal Health Care Programs) by any Federal department or agency. (See Executive Orders 12549 and 12689, 45 CFR part 76, 48 CFR part 9; 42 USC sect. 1320a-7). LMI shall notify University within three (3) days of its receipt of an initial sanction notice, notice of proposed sanction or of the commencement of a formal investigation, or the filing of any charges by any governmental regulatory or law enforcement agency that effects this certification.

Israel Non-Boycott Verification. If the Agreement is subject to Texas Gov't Code Section 2270.002, LMI hereby represents, verifies, and warrants that it does not boycott Israel and will not boycott Israel during the term of the Agreement.

Limitations. University is subject to constitutional and statutory limitations on its ability to enter into certain terms and conditions of the Agreement, which may include those terms and conditions relating to: liens on University property; disclaimers and limitations of warranties; disclaimers and limitations of liability for damages; waivers, disclaimers, and limitations on legal rights, remedies, requirements, and processes; limitations of time in which to bring legal action; granting control of litigation or settlement to another party; liability for acts or omissions of third parties; payment of attorney's fees; dispute resolution; and indemnities. Terms and conditions relating to these limitations will only be binding on University to the extent permitted by the Constitution and the laws of the State of Texas.

Life Molecular Imaging Ltd (LMI)	**INSTITUTION: UNIVERSITY OF NORTH TEXAS**
[redacted]	
Date: 4/14/2021	Date: 4/7/2021

Exhibit A

to the Master Services Agreement for Research Projects using PI-2620:

SAMPLE

PROJECT ORDER TEMPLATE

Title [You may add the Project number or other unique identifier: XXX]

This Project Order effective [Month, Day, Year] entered into under the [TITLE OF AGREEMENT] by and between Life Molecular Imaging SA ("LMI") and [COMPANY] ("Company") effective [Month, Day, Year] (the "Agreement"), is hereby agreed to by the parties.

Capitalized terms not defined in this Project Order shall have the meanings ascribed thereto in the Agreement. Any appendices and exhibits attached to this Project Order shall be deemed to be incorporated herein by this reference.

The parties agree that this format of Project Order may vary from the format attached to the Agreement as a "sample" but it is substantially similar.

Notwithstanding the Agreement, the parties agree that any modification to the Agreement shall be set forth below under the section entitled "Modifications to Agreement Terms and Conditions" and shall not apply to any other Project Order unless expressly stated otherwise in such other Project Order. For purposes of this Project Order, all terms and conditions of this Agreement not expressly modified in this Project Order shall remain in full force and effect.

1. **Modifications to Agreement Terms and Conditions:**

None/or make respective additions.

2. **LMI Supply**

LMI will supply XX TAU TRACER doses at a price of XXX USD (in words: _____ USD) per dose exclusive of delivery cost.

3. **Study Information**

The PRINCIPAL INVESTIGATOR shall provide LMI within two weeks of knowledge the following information:

a. Prior to the initiation of any specific RESEARCH PROJECT

- a copy of the award letter from the funding agency or other confirmation of funding source
- a copy of the IRB Study Approval letter
- a copy of the approval for the conduct of the RESEARCH PROJECT from the relevant regulatory authority, including the applicable identifier of the RESEARCH PROJECT (IND number), or if not applicable, evidence or written confirmation from the Principal Investigators that all regulatory requirements are fulfilled.

Protocol of the respective RESEARCH PROJECT to be attached as **Exhibit A-1**.

IN WITNESS WHEREOF, the Parties have caused this Project Order to be duly executed by their respective duly authorized representatives.

Life Molecular Imaging SA

Dr. Ludger Dinkelborg
Director of the Board
Date:

INSTITUTION
DO NOT SIGN

Name:
Title:
Date:

Read and understood:

PRINCIPAL INVESTIGATOR

DO NOT SIGN

Name:
Title:
Date

Exhibit A-1

to the Master Services Agreement for Research Projects using PI-2620:

Protocol for Research Project xxxx

[Add Protocol/Study Outline for each new Research Project here]

Exhibit A-2

to the Master Services Agreement for Research Projects using PI-2620

TAU TRACER (PI-2620) Supply

LMI will supply TAU TRACER doses in volumes agreed upon in the respective Project Order each as a prefilled syringe of PI-2620, containing at least a radioactivity of 185 MBq (5 mCi) at time point of administration.

Manufacturer

LMI has contracted the manufacturing of the PI-2620 to the contract manufacturing organization Sofie Inc., 21000 Atlantic Blvd., Suite 730, Dulles, VA 20166, USA. The designated manufacturing site(s) and details of the delivery schedule are listed below.

Changes to the delivery schedule shall be discussed in good faith and mutually agreed between LMI, PRINCIPAL INVESTIGATOR and the manufacturer.

Clinical Trial Site (exact delivery address)	**Manufacturing Site**	**Phone/ Email**	**PI-2620 Supply Day**	**PI-2620 Supply Time**

Ordering Procedure

Beside the PRINCIPAL INVESTIGATOR, the following designees are entitled to place orders:

Name/Function	**Site for delivery (exact address)**	**Phone**	**Email**

Dose orders can be placed by:

- Faxing or emailing a completed dose order form
- Online ordering using Pinestar NMIS software
- Online ordering using eDose connect

LMI will conduct a training on “placing orders for PI-2620”. A study-specific dose order form will be completed and include the following information if applicable:

- FOR ALL TYPES OF DOSES
    - Delivery location: Facility Name, Phone No. and Customer Number (Acct#)
    - Staff person placing order (Full Name)
    - Ordering Physician (Full Name)
    - Nuclear Medicine Physician’s signature (If Available)

- Patient reference
- Injection Date & Time
- When ordering PI-2620 for the Study, please include Study name/ID
- Principle Investigator

Fax is the preferred method for placing orders. LMI will provide an order form *to be provided by LMI*. Order confirmation must be requested/ obtained by the person placing the order.

The order and/or cancellation has to take place up to 12:00 pm (local time) two (2) business day prior to the business day TAU TRACER shall be delivered to the clinical study site. Delivery of the injection will be done at least 30 minutes prior to the injection time as mentioned in this order form.

In case of cancellation, PRINCIPAL INVESTIGATOR or his/her designee has to inform the manufacturing site without undue delay by phone with follow-up in writing but in no case later than 12:00 pm (local time) two (2) business day prior to the business day TAU TRACER shall be delivered to the clinical study site.

Exhibit B

to the Master Services Agreement for Research Projects using PI-2620

Safety Reporting Requirements

As LMI is not the sponsor of this trial, the PRINCIPAL INVESTIGATOR is responsible for all pharmacovigilance obligations and safety reporting pursuant to the Applicable Laws and regulations in the country/countries where the study is performed.

The PRINCIPAL INVESTIGATOR shall report to LMI safety relevant information:

For Life Molecular Imaging	
For case reports	**Life Molecular Imaging Drug Safety Unit** **Email:** [redacted] **Address:** SCRATCH Pharmacovigilance GmbH Schlossstr. 25 35510 Butzbach Germany
For technical complaints	**Quality Assurance Unit, Life Molecular Imaging GmbH** **Email:** [redacted] **Address** Life Molecular Imaging GmbH Tegeler Straße 6-7 13353 Berlin Germany

Safety Event	Time of Occurrence post injection	Reporting
Any SAE **(regardless of causal relationship to LMI product)**	Up to 2 days	Immediately, but no later than 2 business days after awareness of event
Serious Adverse Reactions **(related to LMI product)**	Occurring at any time after exposure	Immediately, but no later than 2 business days after awareness of event
Exposure during pregnancy	Any time	Within 2 business days after awareness of pregnancy and again within 20 calendar days once the outcome of the pregnancy is known
Adverse Drug Reactions (ADRs) i.e. Spontaneous reports of suspected related AEs	Any time	Within 2 business days after awareness of event
Extraordinary Situations such as: • Exposure during breastfeeding • Data on use in Children • Reports on compassionate use/named patient use • Lack of efficacy or effect • Report of suspected transmission of infectious agents • Reports of Overdose (accidental or intentional), • Abuse of Product • Misuse of product • Reports of Medication Error (e.g. inadvertent administration via incorrect route) • Drug exposure via mother or father or other • Occupational exposure	Any time	Within 2 business days after awareness of event

In addition,

- any communication concerning safety related information to regulatory authorities or ethics committees including but not limited to:
    - Annual Safety Reports/relevant parts of IND reports for the STUDY;
    - Any other safety related reports, issues and queries that are either raised by or communicated to the regulatory authorities or ethics committees.
    - Within 48 hours any quality issue (technical complaint) regarding the product.

PRINCIPAL INVESTIGATOR and INSTITUTION and their supporting CROs commit to promptly respond to any query from LMI regarding adverse event documentation.

The PRINCIPAL INVESTIGATOR / INSTITUTION may report safety relevant information using either their own forms or the reporting form (1st Contact Sheet) provided by LMI.

A. All communication with LMI will be in English.

B. Safety Event information will be provided to LMI using the attached 1st Contact Sheet, or alternatively the Council for International Organizations of Medical Sciences (CIOMS) form or other Institutional reporting form may be used as long as all required information is included.

C. All Safety Events will be transferred via fax or secure email.

D. All Safety Event for Exchange will be sent to phv@life-mi.com by Sponsor. All reports must contain, but not limited to, the following:

1. name and contact information of the reporter
2. description of the reported safety relevant information
3. patient identified by one or more of the following:
    i. patient initials
    ii. patient number
    iii. age
    iv. sex

E. Additional information requested if available:

1. name and batch number of the study drug(s) (including administration time point and date) if available
2. Investigator assessment of study drug causality.

Requirements for Reporting of Safety Relevant Information

The PRINCIPAL INVESTIGATOR / INSTITUTION may report safety relevant information using either their own forms or the reporting form (1st Contact Sheet) provided by LMI.

All reports must contain, but not limited to, the following:

1. name and contact information of the reporter
2. name and batch number of the TAU TRACER(s) (including administration time point and date)
3. description of the reported safety relevant information
4. patient identified by one or more of the following:
    a. patient initials
    b. patient number
    c. age
    d. sex
5. investigator assessment of TAU TRACER causality.

Definitions

The following definitions, which are consistent with ICH regulations/guidance, will be used:

Adverse Event (AE)	Any untoward medical occurrence in a patient or a clinical investigation subject administered a pharmaceutical product and which does not necessarily have to have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding, for example), symptom or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. *[Source ICH E2A]*
Serious Adverse Event (SAE)	A SAE or reaction is any untoward medical occurrence that at any dose: - results in death, - is life-threatening, - requires inpatient hospitalization or prolongation of existing hospitalization, - results in persistent or significant disability/incapacity, or - is a congenital anomaly/birth defect. NOTE: The term "life-threatening" in the definition of "serious" refers to an event in which the patient was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe. *[Source: ICH E2A]*
Adverse Drug Reaction (ADR)	An ADR is an AE suspected to be causally related to a medicinal product. An ADR is a response to a medicinal product which is noxious and unintended. Response in this context means that a causal relationship between a medicinal product and an adverse event is at least a reasonable possibility (i.e. the relationship cannot be ruled out). Adverse reactions may arise from use of the product within or outside the terms of the marketing authorization or from occupational exposure. Conditions of use outside the marketing authorization include overdose, misuse, abuse and medication errors. *[Sources EMA GVP Annex I, and ICH E2A]*
Unexpected Adverse Reaction	An adverse reaction, the nature or severity of which is not consistent with the applicable product information (e.g. investigator's brochure for an unauthorized investigational product or summary of product characteristics for an authorized product).
Suspected Unexpected Serious Adverse Reaction	A serious adverse reaction in subjects given a drug that may or may not be dose related, but are unexpected, as they are not consistent with current information. A SUSAR may occur during clinical trials or clinical care.

Life Molecular Imaging	**1st Contact Sheet**
Life Molecular Imaging GmbH Tegeler Straße 6-7 13353 Berlin Germany	Receipt: Date: (Will be filled out by LMI)

Please forward report to LMI: **Fax No.: +49 (0) 30 46 11 24 629** or
Email: GRA@life-mi.com

Original Reporter / Source	
☐ Physician ☐ Pharmacist ☐ Patient / Consumer ☐ Health Authority	☐ Registry ☐ Other: ……..
Country of Occurrence	

Original Reporter Information	
Name	
Address	
Tel. / Mobile	
Email	
Profession	

Suspect Drug(s)

Suspect Drug(s) (Please specify brand name if known)	**Activity at time of injection**	**Batch number**	**Route**	**Last time applied prior to event**	**Indication**	**Action Taken Towards Drug(s)** (e.g. discontinuation etc.)

Patient Information		
Patient Initials	**Birth Date or Age**	**Gender** ☐ Male ☐ Female

Adverse events or other safety relevant information

Event(s)	**Start date / time**	**End date / time**

Immediately life-threatening	☐ Yes ☐ No	Hospitalised (or hospitalisation prolonged)	☐ Yes ☐ No
Death	☐ Yes ☐ No	Permanent damage or disability	☐ Yes ☐ No
Congenital / birth defect	☐ Yes ☐ No		

Person filling in this report	
Name (print) **/ Company**	
Tel. / Mobile	
Email	
Report received at (date and time)	

Life Molecular Imaging GmbH Tegeler Straße 6-7 13353 Berlin Germany	**1st Contact Sheet**
	Receipt: Date: (Will be filled out by LMI)
Please forward report to LMI:	**Fax No.: +49 (0) 30 46 11 24 629** or **Email: GRA@life-mi.com**

Date _____ **Signature** _____

Exhibit C

to the Master Services Agreement for Research Projects using PI-2620

Invoicing and Payment

LMI will invoice INSTITUTION on the first business day of each month for payment due NET thirty (30) days from receipt of invoice. All prices are inclusive of all taxes except value added tax ("VAT"), goods and service/harmonized sales tax ("GST/HST"), or the local equivalent.

Invoices will be sent to the following:

Name of Contact:	[redacted]
Department:	Institute for Translational Research
Street Address:	3500 Camp Bowie Blvd HP 5th Floor
City, Zip Code:	Fort Worth, TX 76107-2699
Telephone number:	[redacted]
Fax number:	
Email of contact:	[redacted]

Preferred method of contact for invoicing: **email to invoices@untsystem.edu and cc** [redacted]

Please provide the contact detail (Phone/Email) if different from above, for follow-up on Payment/Invoices.

Payment shall be made in US Dollars in accordance with the payment terms set forth on the Invoice. All payments shall be submitted to:

Life Molecular Imaging SA
Route de l'Ecole 13
1753 Matran
Switzerland

Exhibit A

PROJECT ORDER No. 01

This Project Order effective upon date of last signature entered into under the **Master Services Agreement for Research Projects using PI-2620** by and between Life Molecular Imaging SA ("LMI") and **University of North Texas Health Sciences Center** having its registered office at 3500 Camp Bowie Blvd, Fort Worth, TX 76107 ("INSTITUTION") effective 4/14/2021 (the "Agreement"), is hereby agreed to by the parties.

Capitalized terms not defined in this Project Order shall have the meanings ascribed thereto in the Agreement. Any appendices and exhibits attached to this Project Order shall be deemed to be incorporated herein by this reference.

Whereas, pursuant to Section 3 of the AGREEMENT, LMI and INSTITUTION wish to enter into this Project Order for the purpose of setting forth the RESEARCH STUDY TITLE, PRINCIPAL INVESTIGATOR of the RESEARCH STUDY, and specific terms and conditions for the conduct of this RESEARCH STUDY.

Now, therefore, pursuant to and subject to the terms and conditions of the AGREEMENT and in consideration of the promises and mutual covenants contained herein, the Parties agree to the following:

1. RESEARCH STUDY Information:

   RESEARCH STUDY TITLE: Health & Aging Brain among Latino Elders (HABLE) ATN Study
   PRINCIPAL INVESTIGATOR: [redacted]
   Total Number of Expected Scans: 4000

2. LMI Supply

   Starting upon date of last signature, LMI will supply 4000 doses of TAU TRACER through contracted manufacturer(s) at a price of $2,000 USD (two thousand US Dollars) per dose inclusive of delivery cost, for the first two doses from each manufacturing batch with a minimum of 2 (two) doses ordered per production day and batch. For each additional TAU Tracer dose ordered for the same day from the same manufacturing batch, a price of $1,200 USD (one thousand two hundred US Dollars) applies.

   TAU TRACER for this Project Order shall be supplied in accordance with the supply distribution schedule and the amounts specified in the AGREEMENT.

3. Incorporation of and Modifications to Agreement Terms and Conditions:

   Unless expressly modified herein, all terms and conditions of the AGREEMENT are incorporated by reference and shall apply to this Project Order. There are no modifications of the AGREEMENT terms and conditions under this Project Order.

Protocol of the respective RESEARCH PROJECT attached as **Exhibit A-1**.

IN WITNESS WHEREOF, the Parties have caused this Project Order to be duly executed by their respective duly authorized representatives.

Life Molecular Imaging SA

[redacted]

Date: 4/14/2021

INSTITUTION

[redacted]

Date: 4/7/2021

HSC Contract # 2021-0041

Read and understood:

PRINCIPAL INVESTIGATOR

[redacted]

Date: 4/5/2021

Exhibit A-1

to the Master Research Collaboration Agreement:

Protocol for Research Project HABLE-ATN

The 2018 NIA - Alzheimer's Association Research Framework [AT(N)] for Alzheimer's Disease (AD) provides a biological context for studying AD by incorporating state-of-the art biomarkers of amyloid (A), tau (T) and neurodegeneration (N). Despite the fact that these biomarkers vary by race/ethnicity, no prior work has systematically examined them among Mexican Americans. Given that (1) Hispanic/Latinos are projected to experience the largest growth in AD and Alzheimer's Disease Related Dementias (ADRDs) by 2060 and (2) Mexican Americans are the largest segment of the U.S. Hispanic/Latino population, there is a pressing need to study prevalence, progression and clinical impact of these biomarkers among this underrepresented group. This work addresses goals of the National Alzheimer's Project Act (NAPA), NIA Milestones for AD and ADRD research, and needs highlighted by the AT(N) framework publication. The current research team consists of leading experts in Mexican American cognitive aging, neuroimaging (PET and MRI), blood-based biomarkers as well as advanced statistical modeling. By leveraging the ongoing HABLE cohort, infrastructure and data, we will test the following Specific Aims:

Aim 1 : Examine the prevalence, progression and clinical impact of cerebral markers of the 2018 AT(N) framework among community-dwelling Mexican Americans.

Aim 2. Examine the prevalence, progression and clinical impact of blood markers of the 2018 AT(N) framework among community-dwelling Mexican Americans.

Aim 3 : To determine if blood-based biomarkers of Aβ40, Aβ42, tau and NfL can be used to screen for AT(N)-defined preclinical AD, prodromal AD and AD dementia for enrollment of Mexican Americans into novel clinical trials. The current study is highly significant for several reasons: (1) This is the first-ever large-scale multi-ethnic study of the AT(N) biomarkers, which is of tremendous importance given the racial/ethnic make-up of the U.S. population; (2) this work directly addresses goals set forth by NAPA as well NIA-Milestones for AD/ADRD science; (3) it will determine if ethnic-specific biomarker trajectories are appropriate and finally, (4) it will generate data and methods for increasing enrollment of Hispanics into clinical trials across the AT(N)-defined spectrum of AD (primary, secondary and tertiary prevention) beginning in primary care settings.

Public Health Relevance

The 2018 AT(N) Framework provides a biologically-based context for studying AD with recent work demonstrating that these core biomarkers vary by race/ethnicity. This study will examine both PET-based and blood-based biomarkers of amyloid (A), tau (T) and neurodegeneration (N) at baseline and follow-up examinations. The information gained will (1) provide data to determine if the 2018 AT(N) Framework requires ethnic adjustments, (2) create a multi-tiered system that can be deployed in primary care settings to screen Mexican Americans with blood-based tools into novel trials and (3) provide methods and data to support ethnically-appropriate tailored novel clinical trials aimed at treating and preventing AD among this underserved population.

Exhibit A-2

to the Master Research Agreement

PI-2620 Supply

LMI will supply TAU TRACER doses in volumes agreed upon in the respective Project Order each as a prefilled syringe of PI-2620, containing at least a radioactivity of 185 MBq (5 mCi) at time point of administration.

Manufacturer

LMI has contracted the manufacturing of PI-2620 to the contract manufacturing organization Sofie Inc., 21000 Atlantic Blvd., Suite 730, Dulles, VA 20166, USA. The designated manufacturing site(s) and details of the delivery schedule are listed below.

Changes to the delivery schedule shall be discussed in good faith and mutually agreed between LMI, PRINCIPAL INVESTIGATOR and the manufacturer.

Clinical Trial Site Address	**Sofie Manufacturing Site***	**Phone/ Email**	**PI-2620 Supply Day**	**PI-2620 Supply Time***
Institute for Translational Research-Imaging Center 3400 Camp Bowie Blvd., Suite 100 Fort Worth, TX 76107	4447 Brass Way Dallas, TX 75236	Phone: 877-331-2268 Fax: 214-331-2450 Orders.dallas@life-mi.com	Monday /Friday	Approx. 9:30 am Central time

*From April 16, 2021 or from such time as TAU TRACER is manufactured in Dallas, Texas, whichever is earlier, to the expiration or earlier termination of this AGREEMENT. Prior that Sec. 3.2 of the Agreement applies which means until then Product will be supplied via flights from the Sofie Florida site on Mondays only.

Ordering Procedure

Beside the PRINCIPAL INVESTIGATOR, the following designees are entitled to place orders:

Name/Function	**Site for delivery (exact address)**	**Phone**	**Email**
[redacted]	Institute for Translational Research-Imaging Center 3400 Camp Bowie Blvd., Suite 100 Fort Worth, TX 76107	[redacted]	[redacted]

[redacted]	Institute for Translational Research-Imaging Center 3400 Camp Bowie Blvd., Suite 100 Fort Worth, TX 76107	[redacted]	[redacted]

Dose orders can be placed by:

- Telephoning the pharmacist
- Faxing a completed dose order form
- Online ordering using Pinestar NMIS software
- Online ordering using eDose connect

LMI will conduct a training on "placing orders for PI-2620". The dose order form must be completed and include the following information if applicable:

- FOR ALL TYPES OF DOSES
  - Facility Name, Phone No. and Customer Number (Acct#)
  - Staff person placing order (Full Name)
  - Ordering Physician (Full Name)
  - Order reference
  - NucMed Physician's signature (If Available)
  - Patient reference
  - Injection Date & Time
  - Study Indication

  - When ordering PI-2620 for the Study, please include Study name/ID
  - Principle Investigator

If choosing to fax in the order LMI will provide an order form. Order confirmation must be requested/ obtained by orderer.

The order or any respective cancellation by INSTITUTION has to take place up to 12:00 pm (local time) two (2) business days prior to the business day the TAU Tracer shall be delivered to the clinical study site. Delivery of the injection will be done at least 30 minutes prior to the injection time as mentioned in this order form.

In case of cancellation, PRINCIPAL INVESTIGATOR or his designee has to inform the manufacturing site without undue delay by phone with follow-up in writing but in no case later than the 2 business days prior delivery.

Exhibit A

PROJECT ORDER No. 02

This Project Order effective upon date of last signature entered into under the **Master Services Agreement for Research Projects using PI-2620** by and between Life Molecular Imaging SA ("LMI") and **University of North Texas Health Sciences Center** having its registered office at 3500 Camp Bowie Blvd, Fort Worth, TX 76107 ("INSTITUTION") effective 4/14/2021 (the "Agreement"), is hereby agreed to by the parties.

Capitalized terms not defined in this Project Order shall have the meanings ascribed thereto in the Agreement. Any appendices and exhibits attached to this Project Order shall be deemed to be incorporated herein by this reference.

Whereas, pursuant to Section 3 of the AGREEMENT, LMI and INSTITUTION wish to enter into this Project Order for the purpose of setting forth the RESEARCH STUDY TITLE, PRINCIPAL INVESTIGATOR of the RESEARCH STUDY, and specific terms and conditions for the conduct of this RESEARCH STUDY.

Now, therefore, pursuant to and subject to the terms and conditions of the AGREEMENT and in consideration of the promises and mutual covenants contained herein, the Parties agree to the following:

1. RESEARCH STUDY Information:

   RESEARCH STUDY TITLE: **Health & Aging Brain among Latino Elders (HABLE) ATN Study in African American Population**
   PRINCIPAL INVESTIGATOR: [redacted]
   Source of Funding: NIH Grant [redacted]
   Total Number of Expected Scans: 1000

2. LMI Supply

   Starting upon date of last signature, LMI will supply 1000 doses of TAU TRACER through contracted manufacturer(s) at a price of $2,000 USD (two thousand US Dollars) per dose inclusive of delivery cost, for the first two doses from each manufacturing batch with a minimum of 2 (two) doses ordered per production day and batch. For each additional TAU Tracer dose ordered for the same day from the same manufacturing batch, a price of $1,200 USD (one thousand two hundred US Dollars) applies.

   TAU TRACER for this Project Order shall be supplied in accordance with the supply distribution schedule and the amounts specified in the AGREEMENT.

3. Incorporation of and Modifications to Agreement Terms and Conditions:

3.1 Unless expressly modified herein, all terms and conditions of the AGREEMENT are incorporated by reference and shall apply to this Project Order.

3.2 Section 10.1 of the Agreement is modified as follows:

a. The Term of this Research Study shall be two (2) years following the Effective Date of the Project Order.
b. INSTITUTION will pay LMI upon signature of this Project Order No. 2 an upfront payment of USD 1,500,000.00 (*in words* one million five hundred thousand US dollars), equalling an average net

selling price (ASP) of 1,500 USD (*in words* one thousand five hundred US dollars) per TAU TRACER dose.

c. USD 500,000.00 (*in words* five hundred thousand US dollars) of the upfront payment under Sec. 3.2 a. shall be non-refundable ("Project Initiation Milestone").
d. The upfront payment (including the Project Initiation Milestone) will be set off against and reduced in accordance with the payment amount for TAU Tracer doses ordered by INSTITUTION and delivered by LMI under this Project Order No.2 within the Term of the Research Study.
e. In the event of a residual payment amount (exceeding however in any case the Project Initiation Milestone) after termination of this Project Order, the residual amount shall be reimbursed by LMI within thirty days of receipt of invoice from INSTITUTION.

Each month, LMI shall provide INSTITUTION with written notice of the amount of set-off for the preceding month.

Upon request and with reasonable notice, INSTITUTION reserves the right to audit LMI's records to confirm the set-off is being applied in accordance with pricing as specified in this Project Order. In the event of a third-party verifiable over-charge, LMI agrees to refund INSTITUTION for the over-charge amount within 30 days of receipt of written notice.

Provided the upfront payment is paid in full within 30 days following the Effective Date of this Project Order, INSTITUTION may set off all TAU TRACER dose orders placed with and delivered by LMI for the Research Project covered by this Project Order No.2 for the period in which this Project Order is in effect.

Due to the price scheme (discounted price depending on number of doses ordered per manufacturing batch), the Parties agree on a price reconciliation to be done within 30 days following the end of each 12 months period starting with the Effective Date of this specific Research Project. If the Research Project ends earlier than on its 1st anniversary of the Effective Date, then the reconciliation shall be done within 30 days following the end of the Research Project. If the Research Project ends earlier than on the 2nd anniversary or later, then the reconciliation shall be done in addition to the annual reconciliation within 30 days following the end of the Research Project.

If following the reconciliation, the amounts due for the delivery of TAU TRACER exceed the upfront payment of USD 1,500,000.00, INSTITUTION shall remit the difference to LMI within 30 days following such reconciliation.

If following the reconciliation, the amounts due for the delivery of TAU TRACER is less than USD 1,000,000.00 (equalling the difference between upfront payment of USD 1,500,000.00 and the Initiation Milestone payment, LMI shall reimburse the difference to INSTITUTION within 30 days following such reconciliation or apply the residual amount to INSTITUTION's future orders of TAU TRACER, as specified by INSTITUTION.

Protocol of the respective RESEARCH PROJECT attached as **Exhibit A-1**.

IN WITNESS WHEREOF, the Parties have caused this Project Order to be duly executed by their respective duly authorized representatives.

Life Molecular Imaging SA

[redacted]

Date: 4/14/2021

INSTITUTION

[redacted]

Date: 4/7/2021

HSC Contract # 2021-0041

Read and understood:

PRINCIPAL INVESTIGATOR

[redacted]

Date: 4/5/2021

Exhibit A-1

to the Master Research Collaboration Agreement:

Protocol for Research Project HABLE-ATN in AA Populations

The 2018 NIA - Alzheimer's Association Research Framework [AT(N)] for Alzheimer's Disease (AD) provides a biological context for studying AD by incorporating state-of-the art biomarkers of amyloid (A), tau (T) and neurodegeneration (N). Despite the fact that these biomarkers vary by race/ethnicity, no prior work has systematically examined them among Mexican Americans. Given that (1) Hispanic/Latinos are projected to experience the largest growth in AD and Alzheimer's Disease Related Dementias (ADRDs) by 2060 and (2) Mexican Americans are the largest segment of the U.S. Hispanic/Latino population, there is a pressing need to study prevalence, progression and clinical impact of these biomarkers among this underrepresented group. This work addresses goals of the National Alzheimer's Project Act (NAPA), NIA Milestones for AD and ADRD research, and needs highlighted by the AT(N) framework publication. The current research team consists of leading experts in Mexican American cognitive aging, neuroimaging (PET and MRI), blood-based biomarkers as well as advanced statistical modeling. By leveraging the ongoing HABLE cohort, infrastructure and data, we will test the following Specific Aims:

Aim 1 : Examine the prevalence, progression and clinical impact of cerebral markers of the 2018 AT(N) framework among community-dwelling Mexican Americans.

Aim 2. Examine the prevalence, progression and clinical impact of blood markers of the 2018 AT(N) framework among community-dwelling Mexican Americans.

Aim 3 : To determine if blood-based biomarkers of Aβ40, Aβ42, tau and NfL can be used to screen for AT(N)-defined preclinical AD, prodromal AD and AD dementia for enrollment of Mexican Americans into novel clinical trials. The current study is highly significant for several reasons: (1) This is the first-ever large-scale multi-ethnic study of the AT(N) biomarkers, which is of tremendous importance given the racial/ethnic make-up of the U.S. population; (2) this work directly addresses goals set forth by NAPA as well NIA-Milestones for AD/ADRD science; (3) it will determine if ethnic-specific biomarker trajectories are appropriate and finally, (4) it will generate data and methods for increasing enrollment of Hispanics into clinical trials across the AT(N)-defined spectrum of AD (primary, secondary and tertiary prevention) beginning in primary care settings.

Public Health Relevance

The 2018 AT(N) Framework provides a biologically-based context for studying AD with recent work demonstrating that these core biomarkers vary by race/ethnicity. This study will examine both PET-based and blood-based biomarkers of amyloid (A), tau (T) and neurodegeneration (N) at baseline and follow-up examinations. The information gained will (1) provide data to determine if the 2018 AT(N) Framework requires ethnic adjustments, (2) create a multi-tiered system that can be deployed in primary care settings to screen Mexican Americans with blood-based tools into novel trials and (3) provide methods and data to support ethnically-appropriate tailored novel clinical trials aimed at treating and preventing AD among this underserved population.

Exhibit A-2

to the Master Research Agreement

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Declaration of Procurement Method

The attached contract document has been issued as a result of either a sole source or proprietary justification approved by the University of North Texas System Procurement Department.

The approved justification form is on file with the UNT System Procurement Department records.