

AMENDMENT #2 TO THE MASTER CLINICAL STUDY AGREEMENT

This Amendment #2 (the “**Amendment**”) to the Master Clinical Study Agreement by and between

1. **AstraZeneca Pharmaceuticals LP**, a Delaware limited partnership with offices at 1800 Concord Pike, Wilmington, Delaware 19803 (“**AstraZeneca**” and/or “**Company**”); and
2. **The University of Texas Health Science Center at San Antonio, The University of Texas Health Science Center at Houston, the University of Texas Health Science Center at Tyler, the University of Texas Medical Branch at Galveston, The University of Texas Southwestern Medical Center, The University of Texas at Austin, and The University of Texas Rio Grande Valley**, each a member institution of the **University of Texas System** (“**System**”) which is located at 210 West 7th Street, Austin, Texas 78701 (individually and collectively referred to as the “**Institution**”),

with an effective date of March 27, 2015, as amended (the “**Agreement**”) is made effective on the Amendment Effective Date as defined below. AstraZeneca and Institution are hereinafter referred to individually as a “**Party**” and collectively as the “**Parties.**”

Background

WHEREAS, the Parties desire to amend, modify and restate certain terms and conditions of the Agreement.

Agreement

NOW, THEREFORE, in consideration of the mutual covenants contained in this Amendment, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, agree as follows:

1. DEFINITIONS

Any capitalized term not separately defined in this Amendment shall have the meaning ascribed to it in the Agreement.

2. MODIFICATIONS

(a) Section 2 of the Preamble is hereby amended to remove “Clinical Trials Xpress, a wholly-owned initiative of UT System.”

(b) Section 2.4 of the Agreement is hereby stricken and replaced with the following language:

During the Study and until forty five (45) days after last Subject, last visit at all Study sites Company agrees: (a) to promptly notify the Principal Investigator of any finding, urgent data and safety analyses, or Study results that may (i) impact the safety or welfare of participating or former Subjects, (ii) influence the conduct of the Study (iii) provide to Institution any serious adverse events that have been reported to the FDA or other governmental agency in relation to the Study at

Institution, or any other site, (iv) indicate unanticipated problems in the Study at Institution, or at any other site that could reasonably relate to risks to participating Subjects and/or could reasonably affect Subjects' willingness of participating Subjects to continue to participate in the Study or in the IRB's continuing approval of the Study. Institution/Principal Investigator will communicate findings to the IRB and Study Subjects, as appropriate, pursuant to Institution procedure. Company shall promptly notify the Principal Investigator of Serious, Unexpected, Suspected Adverse Reaction (SUSAR) and Unanticipated Problem reports that are submitted to the FDA that may impact the safety or welfare of Subjects that participated in the Study which may be discovered in the course of analyzing the study data.

(c) Section 2.7 of the Agreement (added by Amendment 1) is hereby stricken in its entirety.

(d) References to "Principle Investigator" in Section 3.1 are hereby replaced with "Principal Investigator."

(e) The following language is hereby added as Section 3.2.15:

ensure that each Subject: a) receives patient engagement communications and ongoing Study communications promptly upon receipt from the Company or its Designee prior to Site Closure; b) receives post Study communications provided by the Company or its Designee no later than two (2) months after Site Closure.

(f) The following language is hereby added as Section 3.3.4:

ensure that computerized system(s) used at Institution fulfil GCP requirements. In the event that the electronic medical records system do not fulfill GCP requirements, paper copies will be printed, dated and signed by the Principal Investigator.

(g) Section 12. Personal Data and Biological Materials is hereby stricken from the Agreement and replaced with the following language:

12.1 The Parties agree to comply with all Applicable Laws in relation to the protection of the personal data of Subjects, the Principal Investigator and Study Site Staff for each Study. The Institution shall maintain, and shall ensure that the Principal Investigator maintains, appropriate technical and organizational security measures to protect the confidentiality and security of Subjects' personal data.

12.2 The Institution shall, and will ensure that the Principal Investigator shall, ensure that any collection, handling, transportation and retention of Biological Materials in connection with a Study is carried out in accordance with the Protocol, the informed consents of Subjects, and all Applicable Laws and in such a way as to ensure that the security, integrity, quality and identity of the Biological Materials is maintained at all times.

12.3 Notwithstanding the foregoing, and with Company's prior written consent, Institution may contribute Biological Materials collected from Study Subjects during their participation in a Study, but not needed for use in the Study ("**Secondary Biological Samples**"), to a tissue bank for research purposes not specified in the Protocol ("**Non-Protocol Research**"), provided that (1) Institution provides each Study Subject from whom Secondary Biological Samples are

obtained with a separate Informed Consent, which has been approved by the IRB, advising the Subject that Institution shall collect, transfer and use Secondary Biological Samples for its own research purposes, which are not related to the AstraZeneca Test Drug, or its mechanism of action, target or chemical/biological class or to Company's Protocol, (2) no samples containing AstraZeneca Test Drug are obtained or used as Secondary Biological Samples, (3) Company is in no way billed for either the time, procedural costs, or Institutional administrative costs associated with such Non-Protocol Research, and (4) no (i) Company Confidential Information, AstraZeneca IP, data, or (ii) other information that could link the Secondary Biological Sample to Company Confidential Information, AstraZeneca IP, the AstraZeneca Test Drug, or its mechanism of action, target or chemical/biological class, to the Company's Study, or data, is available to any Institution investigator or personnel or third-party for Non-Protocol Research. For the avoidance of doubt, and without limitation, Institution may not annotate Secondary Biological Samples with information related to the name of the AstraZeneca Test Drug, its mechanism of action, target or chemical/ biological class, the administration of, response to, or adverse events associated with a Study Drug; while annotations not related to the AstraZeneca Test Drug, such as a subject's age, gender and clinical diagnosis, are permitted. Institution agrees that it shall not conduct Non-Protocol Research using Secondary Biological Samples that is duplicative or incorporates the objectives of the Protocol.

(h) Section 16.1 is hereby amended to state the Agreement will remain in effect until the end of ten (10) calendar years after the Effective Date of the Agreement (March 16, 2015).

(i) Appendix 2 –Clinical Study Addendum of the Agreement is hereby replaced with the attached Appendix 2A. All references to “Addendum” in the Agreement shall be replaced with “Project Agreement.”

(j) Appendix 4 – Administrative Contact Person and Address for Each Institution is hereby deleted in its entirety and hereby replaced with the attached revised and updated Appendix 4.

3. AMENDMENT EFFECTIVE DATE

This Amendment shall be effective as of March 15, 2020 (“**Amendment Effective Date**”).

4. ENTIRE AGREEMENT

This Amendment, together with the Agreement, constitutes the entire agreement between the Parties with respect to the subject matter of the Agreement. The Agreement together with this Amendment supersedes all prior agreements, whether written or oral, with respect to the subject matter of the Agreement, as amended. Each Party confirms that it is not relying on any representations, warranties or covenants of the other Party except as specifically set out in the Agreement as amended. Nothing in this Amendment is intended to limit or exclude any liability for fraud. All schedules referred to in this Amendment are intended to be and are hereby specifically incorporated into and made a part of the

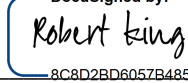
Agreement. The Parties hereby agree that subject to the modifications specifically stated in this Amendment, all terms and conditions of the Agreement shall remain in full force and effect.

[Signature Page Follows]

EXECUTION

THIS AMENDMENT TO the MASTER CLINICAL STUDY AGREEMENT IS EXECUTED by the authorized representatives of AstraZeneca and Institution as of the dates indicated below.

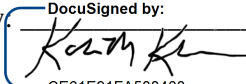
ASTRAZENECA PHARMACEUTICALS LP

By: 
Name: Robert King
Title: Manager CBCSI
Date: 20 April 2020

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT SAN ANTONIO

By: 
Name: Chris Green
Title: Senior Director, Sponsored Programs
Date: April 6, 2020

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON

By: 
Name: Kathleen Kreidler
Title: Associate Vice-President, Sponsored Research
Date: April 7, 2020

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT TYLER

By: _____
Name: _____
Title: _____
Date: _____

THE UNIVERSITY OF TEXAS MEDICAL BRANCH AT GALVESTON

By: _____
Name: _____
Title: _____
Date: _____

THE UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER

By: _____
Name: _____
Title: _____
Date: _____

THE UNIVERSITY OF TEXAS AT AUSTIN

By: _____
Name: _____
Title: _____
Date: _____

THE UNIVERSITY OF TEXAS RIO GRANDE VALLEY

By: _____
Name: _____
Title: _____
Date: _____

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JS

EXECUTION

THIS AMENDMENT TO the MASTER CLINICAL STUDY AGREEMENT IS EXECUTED by the authorized representatives of AstraZeneca and Institution as of the dates indicated below.

ASTRAZENECA PHARMACEUTICALS LP

By: _____
Name: _____
Title: _____
Date: _____

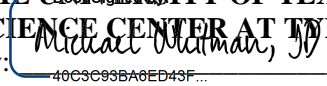
THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT SAN ANTONIO

By: _____
Name: _____
Title: _____
Date: _____

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON

By: _____
Name: _____
Title: _____
Date: _____

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT TYLER

By: 
Name: Michael whitman, JD
Title: Director, Office of Sponsored Programs
Date: 3/16/2020 | 3:28:44 PM CDT

THE UNIVERSITY OF TEXAS MEDICAL BRANCH AT GALVESTON

By: _____
Name: _____
Title: _____
Date: _____

THE UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER

By: _____
Name: _____
Title: _____
Date: _____

THE UNIVERSITY OF TEXAS AT AUSTIN

By: _____
Name: _____
Title: _____
Date: _____

THE UNIVERSITY OF TEXAS RIO GRANDE VALLEY

By: _____
Name: _____
Title: _____
Date: _____

EXECUTION

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ASTRAZENECA PHARMACEUTICALS LP

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT SAN ANTONIO

By: _____

By: _____

Name: _____

Name: _____

Title: _____

Title: _____

Date: _____

Date: _____

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT TYLER

By: _____

By: _____

Name: _____

Name: _____

Title: _____

Title: _____

Date: _____

Date: _____

THE UNIVERSITY OF TEXAS MEDICAL BRANCH AT GALVESTON

THE UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER

By:  _____

By: _____

Name: Lori Simon

Name: _____

Title: Director, Office of Clinical Research

Title: _____

Date: 06-Apr-2020

Date: _____

THE UNIVERSITY OF TEXAS AT AUSTIN

THE UNIVERSITY OF TEXAS RIO GRANDE VALLEY

By: _____

By: _____

Name: _____

Name: _____

Title: _____

Title: _____

Date: _____

Date: _____

EXECUTION

THIS AMENDMENT TO the MASTER CLINICAL STUDY AGREEMENT IS EXECUTED by the authorized representatives of AstraZeneca and Institution as of the dates indicated below.

ASTRAZENECA PHARMACEUTICALS LP

By: _____
Name: _____
Title: _____
Date: _____

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT SAN ANTONIO

By: _____
Name: _____
Title: _____
Date: _____

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON

By: _____
Name: _____
Title: _____
Date: _____


THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT TYLER

By: _____
Name: _____
Title: _____
Date: _____

THE UNIVERSITY OF TEXAS MEDICAL BRANCH AT GALVESTON

By: _____
Name: _____
Title: _____
Date: _____

THE UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER

By:  _____
Name: Megan G. Marks, Ph.D.
Title: Asst. VP, Sponsored Programs Administration
Date: 4/9/2020

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JS

THE UNIVERSITY OF TEXAS AT AUSTIN

By: _____
Name: _____
Title: _____
Date: _____

THE UNIVERSITY OF TEXAS RIO GRANDE VALLEY

By: _____
Name: _____
Title: _____
Date: _____

EXECUTION

THIS AMENDMENT TO the MASTER CLINICAL STUDY AGREEMENT IS EXECUTED by the authorized representatives of AstraZeneca and Institution as of the dates indicated below.

ASTRAZENECA PHARMACEUTICALS LP

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT SAN ANTONIO

By: _____
Name: _____
Title: _____
Date: _____

By: _____
Name: _____
Title: _____
Date: _____

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT TYLER

By: _____
Name: _____
Title: _____
Date: _____

By: _____
Name: _____
Title: _____
Date: _____

THE UNIVERSITY OF TEXAS MEDICAL BRANCH AT GALVESTON

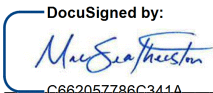
THE UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER

By: _____
Name: _____
Title: _____
Date: _____

By: _____
Name: _____
Title: _____
Date: _____

THE UNIVERSITY OF TEXAS AT AUSTIN

THE UNIVERSITY OF TEXAS RIO GRANDE VALLEY

By:  _____
Name: Mark Featherston
Title: Assistant Director, Office of Sponsored Projects
Date: 2020-04-17 | 09:53:55 PDT

By: _____
Name: _____
Title: _____
Date: _____

EXECUTION

THIS AMENDMENT TO the MASTER CLINICAL STUDY AGREEMENT IS EXECUTED by the authorized representatives of AstraZeneca and Institution as of the dates indicated below.

ASTRAZENECA PHARMACEUTICALS LP

By: _____

Name: _____

Title: _____

Date: _____

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT SAN ANTONIO

By: _____

Name: _____

Title: _____

Date: _____

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON

By: _____

Name: _____

Title: _____

Date: _____

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT TYLER

By: _____

Name: _____

Title: _____

Date: _____

THE UNIVERSITY OF TEXAS MEDICAL BRANCH AT GALVESTON

By: _____

Name: _____

Title: _____

Date: _____

THE UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER

By: _____

Name: _____

Title: _____

Date: _____

THE UNIVERSITY OF TEXAS AT AUSTIN

By: _____

Name: _____

Title: _____

Date: _____

THE UNIVERSITY OF TEXAS RIO GRANDE VALLEY

By: *Karen Martirosyan*
Karen Martirosyan (Apr 9, 2020)

Name: Dr. Karen Martirosyan

Title: AVP for Research Enhancement

Date: Apr 9, 2020

Appendix 4

AUTHORIZED REPRESENTATIVES OR HIS/HER DESIGNEE

The University of Texas Health Science Center at San Antonio	The University of Texas Health Science Center at Houston
<p>Attention: Chris Green Senior Director, Office of Sponsored Programs</p> <p>7703 Floyd Curl Drive, Mail Code 7828 San Antonio, Texas 78229-3900 USA Phone: 210-567-2340; Fax: 210-567-8107 Email: grants@uthscsa.edu Tax ID: 74-1586031</p>	<p>Attention: Kristin L. Parks Director, Clinical Research Finance and Administration Office of Sponsored Projects Administration Fannin Street, UCT1002 Houston, Texas 77030 USA Phone: 713-500-3063 Fax: 713-383-3746 Email: Kristin.Parks@uth.tmc.edu Tax ID: 74-1761309</p> <p>Overnight address: 7000 Fannin Street, Suite UCT 1007-2 Houston, Texas 77030 USA</p>
The University of Texas Health Science Center at Tyler	The University of Texas Medical Branch at Galveston
<p>Attention: Michael S. Whitman Director, Office of Sponsored Programs 11937 U.S. Hwy. 271 Tyler, Texas 75708-3154 USA Phone: 903-877-7392; Fax: 903-877-7689 Email: Grants@uthct.edu</p>	<p>Attention: Lori Simon Director, Office of Clinical Research 6.170 Research Bldg. #6 Galveston, Texas 77555 USA Phone: 409-772-1978; Fax: 409-772-1968 Email: lasimon@utmb.edu Email: clinical.research@utmb.edu</p>
The University of Texas Southwestern Medical Center	The University of Texas at Austin
<p>Attention: Julia Spesivtseva Director, Clinical Research Services Sponsored Programs Administration 5323 Harry Hines Boulevard Dallas, Texas 75390-9020 USA Phone: 214-648-9877; Fax: 214-648-4671 Email: julia.spesivtseva@utsouthwestern.edu Tax ID: 75-6002868</p>	<p>Attention: Mark Featherston Assistant Director Office of Sponsored Projects 3925 W. Braker Lane WPRC, Suite 3.340 Austin, Texas 78759 USA Phone: 512-471-6424; Fax: 512-471-6564 Tax ID: 74-6000203 Email: mark.featherston@austin.utexas.edu</p>
The University of Texas Rio Grande Valley	
<p>Attention: Glorimar Colon Executive Director for Research Compliance & Export Controls 1201 West University Drive Edinburg, Texas 78539 USA Phone: 956-665-3008 Email: Glorimar.colon@utrgv.edu Dept: sponpro@utrgv.edu Tax ID: 46-5292740</p>	

Project Agreement to Master Clinical Study Agreement

Clinical Study Project Agreement

Study Code: **INSERT**

**PROJECT AGREEMENT
TO
MASTER CLINICAL STUDIES AGREEMENT**

by and between

AstraZeneca Pharmaceuticals LP

and

The University of Texas Health Science Center at San Antonio, The University of Texas Health Science Center at Houston, the University of Texas Health Science Center at Tyler, the University of Texas Medical Branch at Galveston, The University of Texas Southwestern Medical Center, The University of Texas at Austin, and The University of Texas Rio Grande Valley, each a member institution of the University of Texas System

AstraZeneca Test Drug **INSERT**

Study Name **INSERT**

Principal Investigator **INSERT**

Sponsor of this Study **INSERT**

Site Number **INSERT**

Project Agreement to Master Clinical Study Agreement

PROJECT AGREEMENT

STUDY CONTRACT

STUDY CODE: **INSERT**

This Project Agreement (“**Project Agreement**”), made effective as of the last date of the signatures below (the “**Effective Date**”), is by and between:

- (1) **INSERT** (“**Company**”); and
- (2) **INSERT** (the “**Institution**”)

BACKGROUND

AstraZeneca Pharmaceuticals LP and The University of Texas Health Science Center at San Antonio, The University of Texas Health Science Center at Houston, the University of Texas Health Science Center at Tyler, The University of Texas Medical Branch at Galveston, The University of Texas Southwestern Medical Center, The University of Texas at Austin, and The University of Texas Rio Grande Valley, each a member institution of the University of Texas System entered in to a Master Clinical Study Agreement dated March 16, 2015, as amended (the “**Agreement**”).

- (a) The Company intends to conduct the Study identified on the cover page of this Project Agreement.
- (b) In accordance with the terms of the Agreement, the Company wishes to engage the Institution to conduct the Study on its behalf.
- (c) References in the Agreement to:
 - the “Company” shall be deemed to be references to the Company entering into this Project Agreement as identified above; and
 - “The Parties” and to all other terms shall be construed accordingly.

AGREED TERMS

1. STUDY

- 1.1 Institution shall conduct the Study pursuant to the terms and conditions of the Agreement, the Protocol and this Project Agreement.
- 1.2 The Institution has designated the Principal Investigator identified on the cover page of this Project Agreement to be responsible for the day-to-day conduct of the Study, including training, leading and supervising Study Site Staff.

2. RESPONSIBILITIES OF THE PARTIES

- 2.1 The Sponsor of the Study shall be as identified on the cover page of this Agreement and will be responsible for conducting the Study in accordance with this Agreement, the Protocol and Applicable Laws. **OR INSERT** has assumed the role of Sponsor of the Study, and has engaged the Company to conduct and manage the Study in accordance with this Agreement, the Protocol and Applicable Laws, and has authorized it to enter into this Agreement.
- 2.2 The Institution shall have the responsibilities set out in the Agreement and the Annexes to this Project Agreement.

Project Agreement to Master Clinical Study Agreement

3. PAYMENT

3.1 In consideration of the services rendered under this Project Agreement, the Company shall pay the Institution in accordance with Annex A to this Project Agreement.

4. THIS PROJECT AGREEMENT

4.1 This Project Agreement and its Annexes attached form an integral part of the Agreement, and for the avoidance of doubt, apply to the conduct of the Study only, and do not apply to any other study that Institution and Company may conduct.

5. TERMINATION

5.1 In addition to the termination provisions set out in the Agreement:

5.1.1 either Party may terminate the Study with immediate effect at any time upon written notice to the other Party if on reasonable grounds it believes the Study should cease in the interest of the health, safety or well-being of Subjects; and

5.1.2 the Company may terminate or suspend the Study immediately for any reason whatsoever upon written notice to Institution.

6. ENTIRE AGREEMENT

6.1 With respect to this Study, this Project Agreement and its Annexes, together with the Agreement, constitute the entire Agreement between the Parties.

7. EXECUTION

7.1 This Project Agreement may be executed in two or more counterparts, each of which shall be deemed an original and all of which shall together be deemed to constitute one and the same agreement.

7.2 Each signatory to this Project Agreement personally represents that, to the best of his/her knowledge, he/she has authority to legally bind his/her respective Party to this Project Agreement. The signatories are not otherwise Parties to this Project Agreement, except as elsewhere set forth in this Project Agreement.

7.3 The Parties agree that execution of this Project Agreement by industry standard electronic signature software and/or by exchanging PDF signatures shall have the same legal force and effect as the exchange of original signatures, and that in any proceeding arising under or relating to this Project Agreement, each Party hereby waives any right to raise any defense or waiver based upon execution of this Project Agreement by means of such electronic signatures or maintenance of the executed Project Agreement electronically.

Project Agreement to Master Clinical Study Agreement

AGREED by the Parties on the dates indicated below

SIGNED for and on behalf of **SIGNED** for and on behalf of
INSERT **INSERT**

Signature:

Signature:

Name:

Name:

Title:

Title:

Date:

Date:

Although not a Party to this Project Agreement, Principal Investigator acknowledges that he/she is an employee of Institution or Study Site (as applicable), and has read the Master Agreement and this Project Agreement, and understands his/her obligations as Principal Investigator thereunder.

READ and ACKNOWLEDGED by:

Principal Investigator

Signature:

Name:

Title:

Date:

Project Agreement to Master Clinical Study Agreement

ANNEX A - PAYMENT

I. ENROLLMENT

Institution acknowledges that the Study is part of a multi-center clinical study, and agrees that when the enrollment goal for the Study as a whole is reached enrollment will be closed at all sites, including Institution, regardless of whether Institution or any other site has reached its individual enrollment goal.

II. IRB FEES

If using a central IRB, the Company will reimburse reasonable IRB fees for the initial IRB review directly to the central IRB. If Institution incurs any required fees from a local IRB as a condition of using a central IRB, Company will reimburse Institution for those fees as reflected in Annex C.

If a local IRB is used, the Company will reimburse Institution for reasonable IRB fees for the initial IRB review, in accordance with Annex C, attached hereto, upon receipt of documentation of IRB review and receipt of an invoice. The Company will reimburse Institution or Central IRB for annual IRB review and/or Protocol amendments, as necessary. (See Invoices Section below).

III. ADMINISTRATIVE START-UP FEE

Upon receipt and submission of all required Institution regulatory documents and this signed Project Agreement, Institution shall forward to the Company an itemized invoice documenting work completed and costs incurred.

The Administrative Start-up Fee shall be paid in accordance with Annex C, attached hereto, may include, but is not limited to, the following types of activities:

- Protocol Review
- Determine potential number of eligible subjects
- Regulatory documentation
- IRB submission, copies, amendments
- Informed consent document

IV. PER SUBJECT PAYMENT

Per Subject payment shall be made for **evaluable, eligible** Subjects only. An eligible Subject is one from whom informed consent has been obtained, who meets the inclusion/exclusion requirements of the Protocol, and who was enrolled by Institution. An evaluable Subject is one for whom all CRFs have been completed in accordance with the Protocol, who has completed the appropriate Study procedures as set forth in the Protocol, and undergone the evaluations required by the Protocol for assessment of efficacy and safety. Per Subject visit payments shall become payable for each evaluable, eligible Subject upon Company's receipt of all Study Documentation, including completed CRFs (Data will be entered into the WBDC system within two (2) business days, within one (1) business day for SAE data and three (3) business days for data queries). Per-Subject payment includes all subject-related costs such as compensation for Protocol procedures as described in Annex C attached hereto, (excluding procedures identified by Institution as standard of care) and Subject reimbursement (if applicable) as well as non-subject costs such as overhead expenses and administration costs.

The Company shall pay the per Subject payment to Institution, on a **INSERT** basis throughout the term of the Study according to Annex C, attached hereto. The Company shall pay any invoices within sixty (60) days of the date of receipt by the Company.

Project Agreement to Master Clinical Study Agreement

Payments will be made in the amount of 90% of the actual visit totals and the Final Payment will include the cumulative 10% of the actual visit totals that occurred.

Final payment for the Study will be made after all evaluable, eligible, enrolled Subjects have completed all procedures for the Study as set forth in the Protocol, all CRFs have been completed (which includes signing (electronic or wet ink) by Principal Investigator) when required and verified against original supporting source documentation in accordance with the procedures as stated in the Protocol, all outstanding data queries have been resolved and returned, close-out audits (visits) have been completed, Principal Investigator's final report has been received by the Company, and all Materials have been returned to the Company, or the Company's Designee.

V. SCREEN FAILURES

INSERTED ON STUDY BASIS

VI. DISCONTINUED SUBJECTS

If a Subject discontinues participation in the Study, or this Project Agreement is terminated, only those costs incurred up until the date of discontinuation or termination will be paid, according to the above-referenced per Subject payment schedule, provided that all CRFs have been completed by Institution and subsequently reviewed by the Company. If a Subject discontinues between visits and does not complete each of the Study visits, Institution will be paid only for visits that the Subject completes. If a Subject fails to complete all required procedures in a visit, Institution may invoice for procedures actually completed.

VII. INVOICES

Invoices must be submitted for all necessary costs, excluding per Subject visit totals, in accordance with the Protocol and as reflected in Annex C attached hereto.

Invoices should be submitted to:

INSERTED ON STUDY BASIS

Invoices shall include the Study Code Number: **INSERT**, name of AstraZeneca Test Drug: **INSERT**, and Principal Investigator name.

VIII. PAYEE

All payments required hereunder, with exception of reimbursement of Accommodation expenses incurred by Permitted Attendees at Study Meetings under Section XI below, if applicable, shall be made payable to **INSERT PAYEE NAME AND ADDRESS**

All payments shall be accompanied with detailed remittance advice. Payment will be made to the Payee in the form as designated in a separate payment information form. The Payee's 9 Digit Tax Identification Number and SSN/EIN designation will be required on W-9 before any payments can be made under this Agreement.

Project Agreement to Master Clinical Study Agreement

In case of changes in the Payee's address, Institution is obliged to inform the Company in writing. The parties agree that in case of changes in address which do not involve a change of Payee, tax numbers, or tax exempt status, no further amendments are required.

IX. CONDITIONS OF PAYMENT

The Company shall have no obligation to reimburse Institution for authorized expenses that are not invoiced pursuant to Invoice Section above within -one-hundred and twenty (120) after the date that Institution incurred such expenses. In addition, Institution will have sixty (60) days from the receipt of the final Study payment to dispute any claimed payment discrepancies occurring during the course of the Study.

X. REIMBURSEMENT FOR ACCOMMODATION EXPENSES AT STUDY MEETINGS

Reimbursement of expenses incurred while attending Study meetings can only be paid after this Project Agreement is fully executed. There are two (2) options for reimbursement:

Option 1: Reimbursement to the payee named in Invoice Section above.

Option 2: Direct reimbursement to the attendee who has incurred the expense. The attendee will receive instructions for reimbursement in the Study Meeting packet.

The Pass-Through and Expense Reimbursement Guidelines in Annex B must be followed under both options.

Project Agreement to Master Clinical Study Agreement

ANNEX B - PASS-THROUGH AND EXPENSE REIMBURSEMENT GUIDELINES

This attachment provides guidance on Pass-Through Expenses that can be charged back to the Company. Note that any Pass-Through Expenses for Covered Recipients (US physicians and teaching hospitals) will require detailed allocation as set forth in Company's Data Requirements for Payments and Transfers of Value to Covered Recipients, available at <http://www.astrazeneca-us.com/astrazeneca-purchasing-general-terms-and-conditions>.

Pass-Through Expenses must be budgeted and approved prior to initiating work with the Company and any unanticipated Pass-Through expense must also be preapproved by the Company. Service providers are expected to detail all estimated reimbursable expenses to provide clarity and detail around these costs. The Company does not permit any mark-up on Pass-Through Expenses.

Travel Expenses

All travel expenditures must be modest. Service providers are expected to use the Company's designated travel management company unless a more favorable rate can be obtained from another corporate travel agency. If a more favorable rate can be obtained, the Company will reimburse service providers for travel-related expenses as outlined below.

Air/Rail Travel

Travelers must use Economy/Coach Class for all flights and rail tickets. Business Class airfare is not reimbursable unless the trip involves an overseas flight of greater than six hours in duration. Service providers are expected to use cost savings measures whenever possible including the use of non-refundable fares and advance travel arrangements.

Ground Transportation

Travelers should use the most economical means of ground transportation. Luxury limousines, black car services, and watercraft vehicles are not reimbursable. Car rentals should only be used when other means of transportation are unavailable, more costly, or impractical. Compact or mid-sized cars should be selected whenever possible.

For travel by personal car, mileage will be reimbursed at the prevailing rate as noted by applicable government (e.g., IRS) guidelines.

Short-Term Lodging (Less than 30 days)

Travelers must select standard accommodations at reasonably priced mid-market hotels or motels. Unless prior approval is obtained, The Company will not reimburse for lodging expenses at up-market or luxury hotels (Ritz, Four Seasons, etc.).

Long-Term Lodging (30 days or More)

Service Providers on assignment for four nights a week for a period of 30 days or more are required to use long-term lodging arrangements approved by the Company project manager.

Travel Duration

If a Project Agreement trip needs to be extended, the traveler should notify the project manager for approval. If a Project Agreement trip is completed early, the traveler should return no later than the next business day. Travelers will not be reimbursed for incurred expenses thereafter.

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Non-Travel /Category Specific Expense Reimbursement

For category-specific Pass-Through Expenses, the service provider must work with the Company project manager to complete a category-specific budget worksheet. Examples of category-specific expenses are:

- Consulting and Professional Services
- Advertising Agencies
- Professional Education
- Business Insight
- Public Relations
- Clinical

Non-Reimbursable Expenses

The following expenses will not be reimbursed:

- | | | |
|--|----------------------|----------------------------|
| Overhead allocations | Administration fees | Traffic/parking violations |
| Child care fees | Personal phone calls | Life insurance |
| Health club fees | Pay TV entertainment | Loss of personal property |
| Late fees on credit cards | Air phone usage | Dry cleaning/laundry |
| Personal property insurance | Indirect expenses | Unsubstantiated expenses |
| On-site administration/ secretarial fees | Mark-ups | |

Expense Audits

Upon request, a service provider will be subject to an expense audit conducted by Company or a third party qualified to conduct a line item audit of Pass-Through Expenses.

Receipts are required for all Pass-Through Expenses. Service providers must make receipts available upon demand for up to five years in arrears.

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ANNEX C - PROTOCOL PROCEDURES AND INVOICE ITEMS COVERED IN ANNEX A

INSERTED ON STUDY BASIS