CLINICAL TRIAL AGREEMENT

**BETWEEN**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**AND**

**EMORY UNIVERSITY**

THIS Agreement, entered into by and between **Emory University**, a Georgia non-profit corporation with offices at 1599 Clifton Road, NE, Mailstop 1599/001/1BA, Atlanta, Georgia 30322 (“University”) and \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, a corporation with its principal place of business at \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, hereinafter referred to as “Sponsor” is for the purpose as hereinafter set forth.

WHEREAS [ ]; and

WHEREAS [ ];

NOW THEREFORE, for and in consideration of the mutual benefits derived hereby, and other good and valuable consideration, the parties mutually agree as follows:

1. **STATEMENT OF WORK:**

University shall exercise reasonable and customary efforts to carry out the research (“Study”) set forth in the Protocol dated \_\_\_\_\_\_\_ and entitled \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_[name of protocol], attached hereto and is incorporated by reference as Exhibit A (“Protocol”). In the event of a conflict between the terms of this Agreement and the terms of the Protocol, the terms of this Agreement shall govern. Changes to the Protocol may be made only through prior written agreement between the Sponsor and University. Nothing in this Agreement shall be construed as limiting the freedom of University or Principal Investigator from engaging in similar sponsored research made through grants, contracts or other agreements with parties other than Sponsor. However, during the period of this agreement, University shall use reasonable efforts not to undertake obligations that would prevent it from conducting the Study.

1. **PRINCIPAL INVESTIGATOR**:

University’s Principal Investigator is \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ [name of PI], hereinafter referred to as “Principal Investigator”. Principal Investigator shall be responsible for the direction of the Study at University in accordance with good clinical practice, and applicable University policies, which University represents and certifies are not inconsistent with the terms of this Agreement or the Protocol. In the event that the Principal Investigator becomes no longer affiliated with University or is unable to continue to serve as the Principal Investigator for whatever reason, University shall provide prompt written notice to Sponsor. Sponsor shall have the right to approve any successor designated by University. The new Principal Investigator shall be required to agree to the terms and conditions of this Agreement. In the event a successor mutually acceptable to both University and Sponsor is not available, either party may terminate this Agreement as provided in Section 14.

The Study will be conducted under the supervision and with the approval of the IRB. University will conduct the Study only after the IRB has approved the Protocol, informed consent forms, and Study subject recruitment documents, as applicable, in writing and a copy of these approvals has been received by Sponsor. In the event of any amendment to the Protocol that requires IRB review, continuation of the Study at the University is subject to IRB approval of the amendment. Principal Investigator will keep the IRB fully informed of the progress of the Study. University will promptly forward to Sponsor copies of all correspondence to or from the IRB concerning the Study, including continuing approvals by IRB, and will notify Sponsor of any refusal of, withdrawal of, or suspension of IRB approval upon receiving such notification.

1. **PERIOD OF PERFORMANCE**:

Unless otherwise amended in accordance with Section 16, or terminated in accordance with Section 14, the effective date of this Agreement shall be the last date of execution of this Agreement and shall continue until the obligations of this Agreement and the Protocol are completed. In no case shall the Study begin until approval is received from the University’s Institution Review Board (“IRB”) and this Agreement is fully executed.

1. **RECORDKEEPING; REPORTING AND ACCESS**
   1. During the term of this Agreement and through the date of the close-out visit performed by Sponsor, University will maintain complete and accurate records of the status and progress of the Study and will provide records to Sponsor upon request. Research results and associated data contained in the Case Report Forms (CRF) and research reports generated pursuant to the Protocol shall be the property of the Sponsor, provided that University will be free to use the research results and associated data generated for any reasonable purpose, including non-commercial research, educational and patient care purposes. University will be free to publish, present and disclose the research results and associated data generated in the Study in accordance with Section 7. Sponsor may utilize all data and results for any reasonable purpose, including regulatory submissions.
   2. University and Principal Investigator, in cooperation with Sponsor, shall prepare and maintain records, reports and data as provided in the Protocol, and in accordance with all applicable local, state and federal laws and regulations. University shall cooperate with any regulatory authority with appropriate jurisdiction and allow said authorities reasonable access to relevant study records and data. If Sponsor requests that the University retain records for a period longer than U.S. laws or regulations require, Sponsor may be required to (i) pay for the continued storage of Study records by the University, or (ii) pay for costs associates with shipping such records to Sponsor. Sponsor shall respond promptly to the University’s requests regarding record disposition. University shall not destroy such records without giving Sponsor prior written notice.

c) Sponsor shall promptly report to University, at the address referenced in Section 15 (Notices), any findings from monitoring or safety reporting of this Study that could (i) affect the safety of Study subjects, (ii) affect the Study subjects’ willingness to continue participation in the Study, (iii) influence the conduct of research, or (iv) alter the IRB’s approval to continue the Study. In addition, Sponsor and University shall immediately notify each other, as well as notify the responsible IRB of any aspects of the Protocol, including any unanticipated problems discovered during site monitoring that pose risks to subjects or that may adversely affect the safety, well-being or medical care of subjects. Sponsor acknowledges and agrees that University may communicate any of the above aforementioned findings to both current and former Study participants.

d) Authorized representatives of Sponsor, upon reasonable advance notice and during regular business hours, shall have the right, to the extent allowed by applicable law, and University’s policies pertaining to subject confidentiality, to inspect University’s facilities used in the conduct of the Study and to inspect and copy records relating to the Study (including, without limitation, access to records as necessary for study monitoring or to audit the conduct of the Study in accordance with Sponsor standards). Sponsor will maintain the confidentiality of any subject-identifiable medical records. Sponsor shall hold confidential all subject and University information to which Sponsor shall have access under this Agreement.

e) Notwithstanding anything to the contrary contained in this Agreement, including, but not limited to, any confidentiality and nondisclosure provisions thereof,  University will provide inspection access to its Investigational Drug Service (IDS) facilities to all monitors and auditors from any entities with whom it has clinical trial agreements in order to enable these monitors to carry out their monitoring duties under Federal Food and Drug Administration (FDA) and Good Clinical Practice (GCP) requirements.

1. **FUNDING AND PAYMENT**
   1. In consideration for the performance under the terms of this Agreement, Sponsor shall pay University a total in accordance with the attached budget, incorporated and referenced herein as Exhibit B. The Parties represent that the compensation provided for the performance under this Agreement is consistent with fair market value and the payment thereof has not been made in exchange for any explicit or implicit agreement that University purchase, recommend or otherwise arrange for the use of any Sponsor product. Invoices shall be sent to the following:

[insert Sponsor’s address for invoicing]

* 1. All payments shall refer to this Agreement, the Principal Investigator and Project #\_\_\_\_\_\_\_\_\_\_\_\_\_. Checks will be made payable to Emory University (Tax ID: 58-0566256) and forwarded to this address:

Emory University

Office of Grants & Contracts Accounting

1599 Clifton Rd NE, 4th Floor

Mailstop: 1599-001-1BH

Atlanta, GA 30322

Attn: Director

1. **CONFIDENTIALITY INFORMATION:**
   1. Any confidential information disclosed to University and/or Principal Investigator shall be in writing and clearly marked by Sponsor as “Confidential” or if disclosed orally, shall accompany written notification within thirty (30) days of disclosure. Sponsor shall not disclose confidential information to the University unless it is necessary to the Study. University shall protect Sponsor’s Confidential and Proprietary information with the same degree of case as University’s own confidential information.
   2. The University’s and Principal Investigator’s obligations of confidentiality under this Agreement will exist during performance of this Agreement and for three (3) years following termination or expiration of this Agreement, unless disclosure is required by applicable law, regulation, judicial order or subpoena. Exceptions to this requirement are:

if Confidential Information is known to University and/or Principal Investigator without restriction prior to disclosure under this Agreement;

if Confidential Information is developed independently by University and/or Principal Investigator without knowledge or use of Confidential Information disclosed by Sponsor under this Agreement;

if Confidential Information is disclosed to University and/or Principal Investigator by a third party without an obligation of confidentiality;

if Confidential Information is available to the public through no fault of the University and/or Principal Investigator;

if Confidential Information is published or disclosed in accordance with the terms of this Agreement.

* 1. Nothing herein shall restrict the ability of or prohibit disclosures of Confidential Information by University to the extent necessary to provide patient care for any Study subject participating in the Study under this Agreement.
  2. Research Results and associated data generated under this Agreement will be considered confidential until the first publication or presentation thereof of data according to the terms of this Agreement or one (1) year after conclusion or termination of the Study at all sites.
  3. In the event Sponsor comes into contact or otherwise has access to Study participant’s medical records, the Sponsor shall hold in confidence the identity of the participant and shall comply with all applicable laws regarding the confidentiality of such records. Sponsor will review and approve the informed consent document and any Health Insurance Portability and Accountability Act (“HIPAA”) authorization document. Sponsor agrees that should it gains access to any protected health information of Study participants, Sponsor will treat such protected health information in accordance with informed consent document, any HIPAA authorization document, and all applicable laws and regulations. If Sponsor gains access to any protected health information that is not covered by an informed consent or HIPAA authorization, Sponsor shall hold such information in the strictest confidence, and shall not remove records containing such information from the University and, if inadvertently removed, shall immediately return any records containing such information to the University.

1. **PUBLICATIONS:**

University and the Principal Investigator shall be free to publish or present the data, methods and results of the Study in accordance with the following provisions:

* 1. Manuscripts and abstracts proposed to be published or presented shall be submitted to the Sponsor for review and comment at least thirty (30) days prior to submission for publication or presentation to allow Sponsor to review the proposed publication or presentation to determine whether any rights to patentable inventions and/or Confidential Information is disclosed. Expedited reviews for abstracts or poster presentations may be arranged if mutually agreeable to the Sponsor and University or Principal Investigator. Upon review, Sponsor shall have the right to request removal of any rights to patentable inventions and/or Confidential Information proposed in the publication or presentation. University and/or Principal Investigator will consider in good faith such requests and will delete, at Sponsor’s request, any Confidential Information. If Sponsor determines that the proposed publication or presentation contains patentable subject matter which requires protection, University agrees to delay the publication or presentation for a period of time not to exceed sixty (60) days for the purpose of filing patent applications.
  2. University and Principal Investigator agree that if the Study is part of a multi-center study, the first publication of the results of the Study shall be made in conjunction with the results at the other Study sites. However, in the event no publication of the multi-center study has been made within twelve (12) months of the completion or termination of the Study at all study sites, the University and/or Principal Investigator may be free to publish or present the results and data from the University’s individual site.
  3. Sponsor, at its election, shall be entitled to receive in any such publication an acknowledgement of its sponsorship of the Study.

1. **INVENTIONS AND PATENTS**
   1. Pre-existing Intellectual Property. It is recognized and understood that ownership of inventions, discoveries, and other technological developments (“intellectual property”) existing prior to the Effective Date of this Agreement, are the separate property of Sponsor or University and are not affected by this Agreement, and neither party shall have any claims to or rights in such intellectual property. .
   2. Ownership and Title. Ownership and title to any invention or discovery that is confirmed through performance of the Study that relates to an indication, use, formulation or dosage of the Study Drug/Device shall be the property of Sponsor (“Sponsor Inventions”).
   3. Title to any inventions or discoveries arising from this Study and conceived and reduced to practice solely by Sponsor shall be owned by Sponsor. Title to any invention or discoveries arising from this Study and conceived and reduced to practice solely by University, that are not Sponsor Inventions, shall be owned by University. Title to any invention or discoveries arising from this Study and conceived and reduces to practice jointly by University and Sponsor, that are not Sponsor Inventions, shall be jointly owned.
   4. License. Sponsor hereby grants to University a perpetual, non-exclusive, non-transferable, paid-up license, without right to sublicense, to use Sponsor Inventions, subject to the obligations set forth in Section 6 (Confidentiality), for internal, non-commercial research and educational purposes.
2. **INDEPENDENT CONTRACTORS:**

With respect to its relation to Sponsor under this Agreement, University is an independent contractor and shall be free to exercise its discretion and independent judgment as to the method and means of performing the Study. University and its employees and students shall not, by virtue of this Agreement, be employees of Sponsor and, accordingly, shall not be entitled to any benefits or privileges provided by Sponsor to its employees.

1. **USE OF SPONSOR’S OR UNIVERSITY’S NAME:**

Sponsor and University agree that it shall not use the name, symbol, and/or marks of the other in any advertising or publicity material or make any form of representation or statement in relation to the Study which would constitute an express or implied endorsement by University of any commercial product or service, and that it shall not authorize others to do so, without first having obtained written permission from the other Party. This shall not include legally required disclosure by University or Sponsor that indentifies the existence of this Agreement. Notwithstanding any provision of this Agreement to the contrary, University reserves the right to register the Study consistent with the requirements of the International Committee of Medical Journal Editors (*see, inter alia,* “ClinicalTrials.gov Scope Expanded,” NLM Technical Bulletin, No. 345-, July-August 2005; Clinical Trial Registration: A Statement from the International Committee of Medical Journal Editors,” Annals of Internal Medicine, Vol. 141, No. 6, September 21, 2004).

1. **INDEMNIFICATION AND INSURANCE**
   1. Sponsor agrees to indemnify, defend and hold harmless the University, its trustees, officers, agents and representatives and employees, including the Principal Investigator from any and all losses, injuries, harm, liabilities, claims, actions, suits, costs and expenses, including, reasonable attorney’s fees, for personal injury (including death) or economic loss arising out of or connected with the performance of the Study, including the use by Sponsor of Study results.
   2. The obligation of indemnification under this Section shall not apply to the extent that liabilities are caused by (i) failure of the University and/or Principal Investigator to use the Study Drug/Device in accordance with the Protocol or other written instructions of Sponsor or (ii) the negligence and willful misconduct of Principal Investigator or any other employee of University. Deviations from the Protocol for reasons of patient safety that may arise out of medical necessity shall not nullify Sponsor's indemnification obligations hereunder; provided that University’s actions related to such deviations do not constitute negligence.
   3. University shall promptly notify Sponsor of any claim or suit against any party to be indemnified hereunder, and shall allow Sponsor to have full control of any disposition or settlement of such claim or suit, and shall fully cooperate with Sponsor regarding such disposition or settlement.

* 1. During the performance of this Agreement, Sponsor warrants that it has and shall maintain sufficient general and product liability insurance to meet its indemnification obligation in this Agreement. Sponsor agrees that such coverage shall be in an amount not less than $1,000,000 per occurrence, $3,000,000 in the aggregate and shall provide evidence of such coverage upon University’s request. Sponsor shall further provide written notice to University at least thirty (30) days prior to the cancellation, non-renewal or material change in such insurance. The amount of Sponsor’s insurance coverage shall not be construed as creating a limit on Sponsor’s indemnification obligations assumed herein.

1. **Subject Injury:**

University policy requires Sponsor to select one of the foregoing OPTIONS with respect to the manner in which payment for Subject Injury Costs will be handled under this Agreement.

**OPTION 1:** The sponsor may choose not to pay for Subject Injury Costs for any subject, no matter if the subject is insured, or how he/she is insured.

**OPTION 2:** The sponsor may choose to pay for Subject Injury Costs for all subjects, no matter if the subject is insured, or how he/she is insured.

**OPTION 3**: The sponsor may choose to pay for Subject Injury Costs for uninsured subjects or subjects with Medicare/Medicaid and to pay any part of Subject Injury Costs for privately insured subjects that are not covered and/or paid by their private insurance.

Sponsor agrees to OPTION \_\_\_\_\_\_\_ under this Agreement and further agreed that this OPTION shall be consistent with the subject injury language in the informed consent document pursuant to subjects’ participation under this Agreement.

1. **WARRANTIES:**

This Study is experimental in nature. Except as expressly set forth in this Agreement, UNIVERSITY makes no representations and extends no warranties of any kind, either express or implied with regard to THE Study. There are no express or implied warranties of merchantability or fitness for a particular purpose, or that SPONSOR use of the Study DELIVERABLES OR INTELLECTUAL PROPERTY will not infringe any third party patent, copyright, trademark, or other third party rights. UNIVERSITY makes no representation as to the usefulness of Study DELIVERABLES OR INTELLECTUAL PROPERTY. If SPONSOR chooses to exploit Study DELIVERABLES OR INTELLECTUAL PROPERTY in any manner whatsoever, SPONSOR does so At its own risk.

1. **TERM AND TERMINATION:**
   1. Either party may terminate this Agreement upon immediate notice in order to protect the health, safety or welfare of a Study participant or if the authorization and approval to perform the study is withdrawn by the U.S. Food and Drug Administration or the IRB.
   2. Either party may terminate this Agreement for any reason upon thirty (30) days prior written notice.
   3. Either party may terminate this Agreement if the Principal Investigator is unable to continue and a successor acceptable to both the University and Sponsor is not available.
   4. Immediately upon receipt of a notice of termination, the University shall stop enrolling Study Subjects and shall cease conducting procedures on Study Subjects already enrolled in the Protocol as directed by the Sponsor, to the extent medically permissible.
   5. Within thirty (30) days after receipt of notice of termination Sponsor will make payment to the University for all services properly rendered and monies properly expended by the University up to the effective date of termination, including non-cancelable obligations properly incurred for the Study by the University prior to the effective date of termination.
   6. The completion or termination of this Agreement shall not affect the rights and obligations of the parties that accrued prior to the effective date of termination. Specifically, the rights, duties and obligations in Sections 4, 6, 7, 8, 9, 10, 11, 12, 13, 15, 16 and 17 survive the termination or expiration of this Agreement until such time as any such rights, duties or obligations are fulfilled, realized or met.
2. **NOTICES:**

Any notice required to be given under this Agreement associated with the performance of this Agreement shall be deemed made, if delivered either to the address given below or to such other address as may hereafter be specified in writing by the Parties:

|  |  |  |
| --- | --- | --- |
| If to Sponsor:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  | If to University:  Director, Contracts Administration  Office of Sponsored Programs  Emory University  1599 Clifton Road, NE  Mailstop 1599/001/1BA  Atlanta, GA 30322 |
|  |  |  |
|  |  |  |

1. **MODIFICATIONS AND AMENDMENTS**:

Alteration or modification of the provisions in this Agreement shall not be binding unless in writing and mutually agreed by the Parties hereto. This Agreement, including the Exhibits, represents the entire understanding of the Parties with respect to the subject matter hereof. In the event of inconsistency between this Agreement, and the Protocol, the terms of this Agreement shall govern. The invalidity or unenforceability of any term or provision of this Agreement shall not affect the validity or enforceability of any other term or provision hereof. Neither this Agreement nor the rights or obligations hereunder shall be assignable or otherwise transferred or subcontracted without the other party’s prior written consent.

1. **APPLICABLE LAWS**:

This Agreement shall be governed by the laws of the State of Georgia, without regard to conflicts to its principals of conflict of law. Any legal action involving this Agreement or the Study will be adjudicated in the State of Georgia and the parties agree to submit to the personal jurisdiction therein.

1. **FORCE MAJEURE**:

Neither party will be liable for any failure to perform as required by this Agreement if the failure to perform is caused by circumstances reasonably beyond its control, such as labor disturbances or labor disputes of any kind, accidents, failure of any governmental approval required for full performance, civil disorders or commotions, acts of aggression, acts of God, energy or other conservation measures, explosions, failure of utilities, mechanical breakdowns, material shortages, disease, thefts, or other such occurrences.

1. **DEBARMENT:**

University will not use in any capacity, in connection with Study, the services of any individual, corporation, partnership or association which:

* + - 1. is debarred under 21 U.S.C. 335a
      2. is disqualified as a clinical investigator under the provisions of 21 C.F.R. 312.70.

In the event that University becomes aware of the debarment or disqualification of any such individual, corporation, partnership or association providing services under this Agreement, University shall notify Sponsor.

IN WITNESS THEREOF, the parties have executed this Agreement by their duly authorized officers:

|  |  |  |
| --- | --- | --- |
| EMORY UNIVERSITY  By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_    Director  Office of Sponsored Programs  Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  | [Sponsor]  By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  |  |  |
| READ AND AGREED  By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Principal Investigator  University  Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |

EXHIBIT “A”

Protocol