**RESEARCH AGREEMENT**

This Research Agreement entered into this \_\_\_\_\_\_\_ day of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ by and between the Board of Supervisors of Louisiana State University and Agricultural and Mechanical College, herein represented by Louisiana State University Health Sciences Center – New Orleans (hereinafter "Institution") and \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (hereinafter "Sponsor") to conduct a study entitled:  
\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

is subject to the following terms and conditions:

**Protocol**

In consideration of amount paid in paragraph (2), clinical investigation by Institution will be undertaken in accordance with the terms of Protocol No.\_\_\_\_\_\_\_\_\_\_ approved by the Sponsor and approved by the Louisiana State University Health Sciences Center Institutional Review Board on

|  |  |
| --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| (date) | IRB approval# |

by reference made a part of this Agreement.

**Funded Amount**

Sponsor will pay Institution to conduct this study, the amount of $\_\_\_\_\_\_\_\_\_. Fifty (50%) of personnel costs shall be paid by Sponsor to Institution upon execution of this Agreement plus 25% of the remaining budget. The balance of these funds will be paid in the following manner: (Complete as necessary)

|  |  |
| --- | --- |
| All payments will be made | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  | (quarterly or monthly) |
| and will be sent to: | Joshua Kelly  Collections Manager  LSU Health Sciences Center – Accounting Services  433 Bolivar Street, Room 619  New Orleans, LA 70112  (504) 680-9469 phone  (504) 247-2913 blackberry  (504) 613-4686 fax  [jkel14@lsuhsc.edu](mailto:Mhotar@lsuhsc.edu) |
| Tax I.D. Number: | 72-6087770 |

It is expected that these funds will be expended in accordance with the budget attached, however, Institution will have the discretion to rebudget between categories to reflect actual expenditures.

Sponsor agrees to pay Institution $2000.00 (unless expected revenue for the Institution is less than $25,000.00 in which case the Sponsor agrees to pay $500.00) for LSUHSC-NO Institutional Review Board (IRB) review of study protocol and related documents. This is a one time, non-refundable fee covering initial review, consideration of all amendments, consideration of all serious adverse events, and continuing review and re-approval activities. The fee is also non-refundable should the protocol be disapproved by the IRB. This fee is in addition to any other facilities and administration (indirect costs) and direct costs related to this project and paid by the Sponsor.

Invoices for IRB fees should be mailed to:

**Reporting Requirements** - (Complete as necessary)

**Term of Agreement**

This Agreement shall begin on \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ and shall not extend beyond the estimated completion date of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, unless further extended by amendment of this Agreement, which amendment shall be in writing and signed by all parties to this Agreement.

**Confidentiality**

"Confidential Information" shall mean information that is disclosed or submitted in writing from one party to the other party, and that is clearly marked "CONFIDENTIAL INFORMATION" in bold letters in conspicuous locations by the disclosing party. "Confidential Information" shall also include information that is initially disclosed orally -- provided that within seven (7) days of the initial oral disclosure, the disclosed information is reduced to writing by the disclosing party; and provided that the writing is clearly marked "CONFIDENTIAL INFORMATION" in bold letters in conspicuous locations; and provided that the writing thus marked is delivered to all personnel of the receiving party to whom the oral disclosure was made. Confidential Information shall be received and maintained by the receiving party in strict confidence, and shall not be disclosed to any third party. Neither party shall use the other party's Confidential Information for any purpose other than purposes related to the performance of the Project. The parties may disclose Confidential Information to their employees requiring access for these purposes; provided, however, that prior to making any such disclosures each such employee shall be apprised of the duty and obligation to maintain Confidential Information in confidence and not to use such information for any purpose other than in accordance with the terms and conditions of this Agreement. Neither party will be held financially liable for any inadvertent disclosure of the other party's Confidential Information, but each agrees to use reasonable efforts not to disclose any Confidential Information of the other party. Should either party realize that one party has inadvertently disclosed any of the other's Confidential Information to a third party, the parties shall promptly confer as to what course of action is appropriate under the circumstances. On written request, the party who made the inadvertent disclosure shall promptly notify the third party that an inadvertent disclosure had been made of confidential materials, and shall request the third party promptly to return all copies of the disclosed Confidential Information.

Nothing contained herein will in any way restrict or impair either party's right to use, disclose, or otherwise deal with any Confidential Information that:

* At the time of receipt is public knowledge, or after receipt becomes public knowledge through no act or omission of the receiving party; or
* Was known to the receiving party as evidenced by written records prior to the disclosure by the providing party; or
* Is received from a third party who did not, directly or indirectly, obtain the information or material from the providing party; or
* Is required to be disclosed by a court or government agency, provided that the providing party is given reasonable notice and opportunity to contest the required disclosure; or
* Is reasonably believed by either party to have significant implications for public health or public safety, provided in either case that the providing party is given reasonable notice and opportunity to contest the disclosure; or
* Is published by Institution in accordance with the provisions of the “Publications” Article contained herein.

The confidentiality obligations of this Article shall survive termination of the Agreement or a period of three (3) years.

If any patent rights, trade secret rights, or other intellectual property rights of a party are reflected in or included in any Confidential Information that is disclosed to the other party, the receiving party shall not thereby acquire any license or other rights under those patent rights, trade secret rights, or other intellectual property rights of the disclosing party; except that Institution shall have a limited license under any such rights of Sponsor, this license being limited to Institution's activities in performing the Project.

**Publication Rights**

Sponsor recognizes that under Institution policy the results of the Study must be publishable, and agrees that researcher(s) engaged in the Study shall be permitted to present at symposia, international, national, or regional professional meetings and to publish in journals, theses, or dissertations, or otherwise publish through means of their choosing, methods and results of the Study; and that Institution shall own the copyright in such works, except to the extent that Institution has waived ownership of copyright in favor of the authors under Institution’s Bylaws and Regulations.

Institution will provide Sponsor with a copy of any proposed publication or presentation for review and comment at least sixty (60) days prior to such presentation or submission for publication. At the expiration of the sixty (60) day period, Institution may proceed with the presentation or submission for publication unless Sponsor has notified Institution in writing that such proposed publication and/or presentation discloses Confidential Information. Institution hereby agrees to make any changes or deletions prior to publication or presentation necessary to prevent disclosure of Confidential Information.

Further, upon the request of Sponsor, Institution will delay publication or presentation an additional sixty (60) days to permit Sponsor to take necessary actions to protect its intellectual property interests.

If a Study is being conducted as part of a multi-center clinical trial, the first publication of the results of the Study shall be in the form of a multi-center publication authored by investigators in that Study. However, in the event a multi-center publication is not forthcoming within twenty-four (24) months following completion of the Study at all sites, Institution may publish Institution’s Study results without obtaining Sponsor’s approval as enumerated above.

**Patent Rights**

The parties shall retain title to any patent or other intellectual property rights and inventions made by their respective employers in the course of the study. In the event the Institution is an inventor, Sponsor shall have a first right to negotiate for an exclusive world-wide royalty-bearing license to all rights in the invention. The Institution shall promptly notify Sponsor of any such invention and shall assist Sponsor in gaining patent protection for the invention. Sponsor shall reimburse the Institution for all reasonable expenses incurred thereby. If Sponsor commercializes the invention, Sponsor shall pay Institution a reasonable royalty rate based on the relative contribution to the invention and the commercial value of the invention. If Sponsor and Institution fail to finalize a license agreement in 180 days, the Institution is free to negotiate with any other entity without obligation to the Sponsor.

**Indemnification**

Sponsor shall indemnify, defend, and hold harmless Institution and Institution's board of supervisors, agents, students, officers, board members, employees, and anyone for whom Institution may be liable (collectively, "Indemnitees") against any and all claims, costs, or liabilities, including incidental and consequential damages, together with attorney's fees and court costs at both trial and appellate levels, for any loss, damage, injury, or loss of life, caused by the actions of Sponsor or of its officers, servants, agents, or by any third party acting on behalf of or under authorization from Sponsor in the performance of this Agreement, or for losses arising out of the use by Sponsor or by any third party acting on behalf of or under authorization from Sponsor, of products or processes developed or made as a result of information or materials received from Institution.

**Investigator Meetings**

Where the Agreement between the Institution and Sponsor recommend or obligate the Principal Investigator, Study Nurse, or other representative to attend an Investigators’ Meeting, it is understood and agreed that Sponsor will provide and pay all reasonable and appropriate expenses, including transportation, room and board, and incidental expenses.

It is the understanding of the parties that attending of the Investigators’ Meetings is reasonable and necessary to ensure all parties engaged in the study have a clear understanding of the protocol.

It is the understanding of the parties that the compensation for attending the Investigators’ meeting is fair and reasonable, and that said payments represent fair market value and are not merely a token arrangement.

It is the understanding of the parties that attending of the Investigators’ Meetings does not constitute any form of payment for referral and that neither the person attending the Investigators’ Meeting nor the Institution is obligated to Sponsor in any way.

It is the understanding of the parties that attending the Investigators’ Meeting does not obligate either party to ensure a certain number of patients will be enrolled in a study and does not constitute a promise of payment in the future.

Both parties agree that if any physicians, healthcare professionals, study nurses, or other personnel connected with the Institution are engaged by Sponsor to act as consultants, advisors, or researchers in connection with various types of marketing and research activities, these arrangements will only be for a legitimate purpose and all payments for said activities shall be fair and reasonable. These activities may include, but are not limited to: performing research, data collection, consulting services, serving on advisory boards, and taking part in focus groups.

**Human Subjects Protection and HIPAA**

Human Subjects Protection:

The parties agree that research investigators are entrusted with an essential role in assuring the adequate protection of human subjects. In activities they conduct or which are conducted under their direction, they have a direct and continuing responsibility to safeguard the rights and the welfare of the individuals who are or may become subjects of the research. Investigators must comply with the DHHS regulations, with the applicant organization's Assurance of Compliance, and with the requirements and determinations of the IRB concerning the conduct of the research. Investigators must ensure the minimum of unnecessary risks to subjects by using procedures which are consistent with sound research design. Whenever appropriate, investigators should use procedures already being performed on the subjects for diagnostic or treatment purposes. Risks to subjects must be reasonable in relation to anticipated benefits, if any, to subjects, and to the importance of the knowledge that may reasonably be expected to result. Investigators must obtain the legally effective informed consent of each subject or of the subject's legally authorized representative before involving the subject in the research, to the extent required by and in accordance with 45 CFR 46, or as required by applicable Federal, State, or local law. The consent form must be approved by the IRB.

HIPAA:

Sponsor agrees to be bound by the requirements contained in the HIPAA Privacy Rule 42 C.F.R. 164.501 et seq. Sponsor acknowledges that disclosure of Protected Health Information in violation of the patient authorization or in breach of this Agreement will cause irreparable damage to Institution. Both parties hereto therefore agree that all Protected Health Information will be kept confidential and will not be released for any purpose other than authorized by the patient, enumerated in this Agreement or as provided by law. The Sponsor agrees that Sponsor, and any of its agents, will disclose Protected Health Information only to those individuals who agree to be bound by the terms of this Section and who reasonably require such information for the performance of this Agreement.

Sponsor further agrees to indemnify and hold harmless Institution for any and all damages arising out of Sponsor’s unauthorized release/re-disclosure of Protected Health Information, including, but not limited to damages, fines, penalties, attorney fees, and interest.

**Animal Subjects Protection**

Institution agrees to comply with all relevant statutes, legislation, regulations and guidelines for the care, welfare and ethical treatment of animals in the country where the Project is being performed. Institution further agrees to comply with the “3Rs” Principles – reducing the number of animals used, replacing animals with non-animal methods whenever possible and refining the research techniques used. All work must be conducted in adherence to the core principles for animals identified below. Local customs, norms, practices or laws may be additive to the core principles, but Institution agrees to comply as a minimum with these core principles: (a) access to species appropriate food and water; (b) access to species specific housing, including species appropriate temperature and humidity levels; (c) access to humane care and a program of veterinary care; (d) animal housing that minimizes the development of abnormal behaviors; (e) adherence to principles of replacement, reduction and refinement in the design of *in vivo* or *ex vivo* studies; (f) review of study design and purpose by institutional ethical review panel; (g) commitment to minimizing pain and distress during *in vivo* and *ex vivo* studies; (h) work is performed by staff trained to conduct the procedures for which they are responsible; (i) training is documented and verified; and (j) processes are in place to minimize animal use.

**Subject Injury Reimbursement**

For the purposes of this Section, “Injury” means bodily injury, sickness or disease, including mental injury or mental anguish, sustained by a person, including death resulting from any of these at any time. In the event of a Subject Injury, Sponsor agrees to reimburse the Institution, other accredited medical care providers, or Subjects (as appropriate) for any medical care required by Subjects that occurs as a direct result of participation in the Study and that is not covered by the Subjects' medical insurance. Institution will bill patient’s insurance for the items or services needed for the reasonable and necessary care arising from the provision of an investigational item or service, in particular, for the diagnosis or treatment of complications per CMS rule 310.1 (commonly referred to as the Final National Coverage Decision). If, after billing the patient’s insurance and exhausting any appropriate appeals process, unpaid expenses remain, Sponsor shall be responsible for all costs including: (a) all reasonable and associated costs incurred and associated with the diagnosis of an adverse event involving the Study Drug(s)/Device(s) or a Protocol procedure; and (b) all reasonable and associated costs incurred for treatment of an Injury to the Subject if Sponsor and Institution together determine that the adverse event was reasonably related to administration of the Study Drug(s)/Device(s) or a Protocol procedure; provided, however, that: (i) the adverse event is not attributable to the negligence or misconduct by Institution, Investigator, or any sub-investigator or agent of Institution; (ii) the adverse event is not attributable to any underlying illness, whether previously diagnosed or not; and (iii) the Study Drug(s)/Device(s) or Protocol procedure was administered in accordance with the Protocol.

**Research Site Monitoring**

**Sponsor Monitoring.**

Sponsor and its representatives will be provided access to the premises, facilities, Study Records, investigators, and research staff as required to accomplish research site monitoring activities. Monitoring by Sponsor does not relieve Institution of any of its regulatory obligations under this Agreement.

Sponsor agrees to report promptly to the Institution findings that could affect the safety of participants or influence the conduct of the study.

**Inspections and Audits**

The Study is subject to inspection and audits by regulatory agencies worldwide, including, but not limited to the FDA. Regulatory inspections may occur during and after completion of the Study and may include auditing of Study Records. Sponsor may also choose to audit Study Records as part of its monitoring of Study conduct.

* + 1. Notification. Institution will notify Sponsor as soon as reasonably possible if the site is inspected or scheduled to be inspected by a regulatory agency in relation to the Study. Likewise, Sponsor will notify Institution and IRB as soon as reasonably possible if LSUHSC-NO investigator is inspected by the FDA concerning conduct of the study.

* + 1. Cooperation. Institution and Sponsor will cooperate with regulatory agency and/or Sponsor representatives in the conduct of inspections and audits and will ensure that Study Records are maintained in a way that facilitates such activities.
    2. Resolution of Discrepancies. Institution will promptly resolve any discrepancies that are identified between the Study Data and the subject’s medical records.

**Data and Safety Monitoring**

Sponsor acknowledges that is has the responsibility to conduct data and safety monitoring. Monitoring will be performed on a regular basis, and conclusions of the Data and Safety monitoring entity reported to the Institution. Recommendations that emanate from monitoring activities will be reviewed by Sponsor and addressed. Sponsor assumes responsibility for informing Institution concerning the data and safety monitoring policy and procedures. Institution will provide feedback to Sponsor on a regular basis, including findings from adverse-event reports, and recommendations derived from data and safety monitoring.

Notification of Results

Sponsor shall promptly report to Institution any findings from monitoring or safety reporting of this Study or studies using the same or similar Study Drug / Device or treatment regimen, whether ongoing or ended, that could:

(i) affect the safety of Study subjects,

(ii) affect Study subjects’ willingness to continue participation in the Study,

(iii) influence the conduct of the research, or

(iv) alter the IRB’s approval to continue the Study.

Sponsor acknowledges and agrees that Institution may communicate any of the afore-mentioned findings to both current and former Study subjects, as well as any participants in studies using the same or similar Study Drug / Device or treatment regimen.

**Force Majeure**

No party shall be liable for any failure to perform its obligations, either temporarily or permanently, in connection with any action described in this Agreement, if such failure results from any act of God, riot, war, civil unrest, flood, earthquake, or other cause beyond such party’s reasonable control (including any mechanical, electronic, or communications failure, but excluding failure caused by a party’s financial condition or negligence).

**Insurance**

Sponsor agrees to carry and keep in force, at its expense, product liability insurance at an amount acceptable to Institution and shall provide evidence thereof within 10 days of execution of agreement.

**Entire Agreement**

This document contains the entire agreement and understanding between the parties, and supersedes any prior agreement or understanding associated with this same Sponsor, Protocol, and Principal Investigator. This Agreement can only be modified by written agreement duly signed by persons authorized to sign agreements on behalf of Sponsor and the Institution.

**Publicity**

Neither party may make any use of the other’s name, marks, insignia, or logos; or the name of any campus, department, center, or institute of the other party; or of the name of any employee of the other party; in news releases, advertisements, promotional materials, or otherwise, without the other party’s prior written consent for each such use, except that Institution may acknowledge Sponsor as the source of support for the Project without Sponsor’s prior consent.

Notwithstanding the foregoing, Institution’s name may be used without prior approval when and as necessary for Sponsor to supply the information that Sponsor may be required to disclose in order to comply with applicable law However, in no circumstances may Sponsor state or imply that Institution in any way endorses or supports a particular investment, stock purchase, product, or treatment.

**Termination**

This agreement may be terminated by either party providing the other party receives written notice thirty (30) days prior to the effective date of termination.

**Governing Law**

This Agreement shall be governed by the laws of the State of Louisiana.

Any controversy of fact or law arising out of or related to this Agreement that cannot be satisfactorily resolved by the parties shall be adjudicated only in a court of competent jurisdiction in East Baton Rouge Parish, State of Louisiana.

**Assignment or Subcontract**

This Agreement, and the rights and obligations hereunder, may not be assigned or transferred by either party without the prior written consent of the other party, with the following exceptions:

Institution may subcontract the performance of certain of its research activities under this Agreement to qualified third parties, provided however, (a) that such third parties perform such activities in a manner consistent with the terms and conditions contained in this Agreement; and (b) that Principal Investigator or Other Clinical Investigators have no direct or indirect financial interest in the third party

Institution shall comply with the requirements for consulting or social services contracts, as provided for under Louisiana Revised Statutes Title 39:1503 in the purchase of goods and/or certain services as provided therein.,

**Notices**

The parties will deliver notices and other communications relating to this Agreement by hand, by courier, or by a postage-paid traceable method of mail delivery, or by facsimile (so long as the equipment used can document successful transmission to the intended telephone number) to the address (or facsimile number) below, or such other address (or facsimile number) that a party may later designate:

Sponsor:

For Contract Issues:

|  |
| --- |
|  |

With a copy to:

|  |
| --- |
|  |

Institution:

For Contract Issues:

Louisiana State University Health Sciences Center

Attention: Joseph M. Moerschbaecher, III, Ph.D.,

Vice Chancellor of Academic Affairs

Resource Center: B8-9 433 Bolivar Street

New Orleans, Louisiana 70112-2223

Telephone: 504-568-4804

Fax: 504-568-5588

With a copy to:

|  |
| --- |
| Office of Research Services  Att: Grants and Contracts Section  Resource Center; Suite 206  433 Bolivar Street  Louisiana State University Health Sciences Center  New Orleans, Louisiana 70112  (504) 568-4970 tel  (504) 568-8808 fax |

IN WITNESS THEREOF, the parties have executed this agreement by their duly authorized officers on the date first herein set out:

|  |  |  |  |
| --- | --- | --- | --- |
| The Board of Supervisors of Louisiana State University and Agricultural and Mechanical College, herein represented by Louisiana State University Health Sciences Center | | Sponsor | |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |
| (Signature) | (Date) | (Signature) | (Date) |
| Typed Name: | | Typed Name: | |
| Title: | | Title: | |
|  | | | |
| I have read this agreement and understand and accept my obligations hereunder. | | | |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | |
| (Signature) | (Date) | | |
| Typed Name: | | | |
| Principal Investigator | | | |