**CLINICAL TRIAL AGREEMENT 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**

**AND**

**[INSERT SPONSOR NAME]**

This Clinical Trial Research Agreement (the “**Agreement**”) is entered into as of this \_\_\_\_\_\_ day of \_\_\_\_\_\_\_\_\_\_\_\_, 20\_\_ (the “**Effective Date**”) by and between:

**[INSERT SPONSOR NAME]**, (the “**Sponsor**”)

And

**THE BOARD OF SUPERVISORS OF LOUISIANA STATE UNIVERSITY AND AGRICULTURAL AND MECHANICAL COLLEGE,** herein represented by **LOUISIANA STATE UNIVERSITY HEALTH SCIENCES CENTER – NEW ORLEANS** (the “**Institution**”)

Collectively referred to as the “**Parties**” or individually as “**Party**”.

**RECITALS**

WHEREAS, Sponsor desires Institution to conduct a clinical trial entitled, “[INSERT STUDY TITLE]” (the “**Study**”), and such Study is of mutual interest and benefit to the Parties; and,

WHEREAS, the Study will be conducted under the direction of [INSERT PI NAME] (the “**Principal Investigator**”), an employee of Institution.

**NOW, THEREFORE**, the Parties are subject to the following terms and conditions:

1. **CONDUCT OF THE STUDY**

Principal Investigator will use reasonable efforts to perform the Study in accordance with the Study protocol (the “**Protocol**”), applicable laws, and good clinical practices. Principal Investigator will not initiate any Study activities until all applicable approvals, including approvals from the Institutional Review Board (the “**IRB**”) and the FDA or HHS, are received. Any modification or addendum to the Protocol must be approved by the IRB to become effective.

Principal Investigator shall not implement any deviation from, or changes to, the Protocol without the approval of the Sponsor and prior review and approval from the IRB, except to eliminate an immediate hazard to the Study Subject.

If the Principal Investigator becomes unable or unwilling to fulfill his or her duties, Institution shall promptly nominate one or more qualified successor(s) to serve as Principal Investigator. Institution will not substitute another person to perform the duties of Principal Investigator without the prior written consent of Sponsor.

Sponsor shall perform, and ensure that any Contract Research Organization (the “**CRO**”) appointed by it performs, all obligations with respect to the Study in accordance with the Protocol, applicable law, and the terms of the applicable informed consent.

1. **HUMAN SUBJECTS PROTECTION AND HIPAA**

The parties agree that the Principal Investigator is entrusted with an essential role in assuring the adequate protection of human subjects. The parties have a direct and continuing responsibility to safeguard the rights and welfare of the individuals who are or may become subjects of the Study (the “**Study Subject**”) in activities conducted or those that are conducted under their direction.

Principal Investigator and all other Study personnel (the “**Study Team**”) must comply with applicable regulations, including but not limited to, those of the FDA or HHS, the applicant organization’s Assurance of Compliance, and with the requirements and determinations of the IRB concerning the conduct of the research. The Principal Investigator and Study Team must ensure the minimum of unnecessary risks to subjects by using procedures which are consistent with sound research design. Whenever appropriate, Study Team 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 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.

Sponsor agrees to be bound by the requirements contained in the HIPAA Privacy Rule 42 CFR 164.501 et seq. The 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 the Institution. Both parties, therefore, agree that all Protected Health Information will be kept confidential and will not be released for any purpose other than those authorized by the patient, enumerated in this Agreement, or as provided by law. The Sponsor agrees that the 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 shall provide written notice to Institution of any unauthorized access to or disclosure of individually identifiable personal information within five [5] business days of becoming aware of such occurrence. Such notice shall include the timing and nature of the breach. Sponsor shall take all responsible measures to remedy the breach. The Sponsor further agrees to indemnify and hold harmless the Institution for any and all damages arising out of the Sponsor’s unauthorized release/re-disclosure of Protected Health Information including, but not limited to, damages, fines, penalties, attorney’s fees, and interest.

1. **STUDY DRUG/DEVICE**

Sponsor shall provide to the Institution, at the Sponsor’s sole expense, quantities of the Study Drug/Device sufficient for the conduct of the Study.

Promptly following the completion of the Study or effective date of termination, if this Agreement is terminated in accordance with Section 7 herein, Institution shall return or dispose of any unused Study Drugs/Devices as directed by Sponsor in accordance with applicable law and at Sponsor’s sole expense.

1. **COMPENSATION**

As consideration for the performance under the terms of the Agreement, Sponsor shall pay Institution for the participation in the Study in accordance with the Protocol and the compensation schedule set forth in Attachment X, attached hereto and incorporated herein by reference. The Parties agree that the compensation being paid to Institution under this Agreement constitutes the fair market value of the services provided.

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

 Phone: (504) 680-9469

 Fax: (504) 613-4686

 Email: jkel14@lsuhsc.edu

 Tax ID Number: 72-6087770

No amounts paid under this Agreement are intended to be for, no shall be construed as, an offer or payment made in exchange for explicit or implicit agreement to purchase, prescribe, recommend, or provide a favorable formulary status for any Sponsor product or service.

The Sponsor agrees to pay the Institution $2,500.00 for Institution IRB review of the Protocol and related documents. This is a one time, non-refundable fee covering initial review. 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: [INSERT INVOICE CONTACT]

1. **REPORTING REQUIREMENTS**

[INSERT REPORTING REQUIREMENTS]

1. **TERM**

This Agreement shall commence on the Effective Date, and, unless earlier terminated as expressly provided herein, shall remain in full force and effect until the completion of all Study activities required under the Protocol.

1. **TERMINATION**

Either Party may terminate this Agreement immediately upon written notice to the other Party upon occurrence of any of the following events:

1. If Institution and Sponsor are unable to secure a substitute Principal Investigator in accordance with Section 1 herein;
2. If Institution or Sponsor determines that termination is necessary to protect the safety of Study Subjects;
3. If approval for the Study is not granted, or is revoked or suspended by the IRB;
4. If the Study is placed on a clinical hold by, as applicable, the FDA or HHS; or,
5. Upon the occurrence of an event qualifying as a termination event under the Protocol.

Either party may terminate this Agreement upon written notice to the other Party if the other Party materially breaches this Agreement, and the breaching Party fails to cure the breach within thirty [30] days after receipt of written notice of the breach.

If this Agreement is terminated before completion of the Study, Institution shall immediately cease enrolling Study Subjects and shall cease conducting the procedures set out in the Protocol to the extent that doing so is medically permissible and appropriate for the safety and well-being of the Study Subjects.

If this Agreement is terminated before completion of the Study, within thirty [30] days following the effective date of termination, Sponsor shall pay Institution:

1. Those fees and cost items set forth in the budget that have been earned or incurred prior to effective date of termination; and,
2. Any expenses incurred by Institution in terminating the Study, including the non-cancelable commitments made prior to Institution’s receipt of notice of termination.

No termination hereunder shall constitute a waiver of any rights or causes of action that either party may have based upon events occurring prior to the effective date of termination.

1. **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 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 Study.

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 party 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 party’s Confidential Information to a third party, the parties shall promptly confer as to what course of action is appropriate under the circumstances. Upon written request, the party who made the inadvertent disclosure shall promptly notify the third party that inadvertent disclosure had been made of confidential materials and shall request the third party promptly return all copies of the disclosed Confidential Information.

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

1. At time of receipt is public knowledge, or after receipt becomes public knowledge through no act or omission of the receiving party;
2. Was known to the receiving party as evidenced by written records prior to the disclosure by the providing party;
3. Is received from a third party who do not, directly or indirectly, obtain the information or material from the providing party;
4. 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;
5. Is reasonably believed by either party to have significant implications for public health or public safety, provided in either vase that the providing party is given reasonable notice and opportunity to contest the disclosure; or
6. Is published by Institution in accordance with Section 9 herein.

The confidentiality obligations of this article shall survive termination of the Agreement for 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 or other intellectual property rights of the disclosing party; except that the Institution shall have a limited license under such rights of the Sponsor, this license being limited to the Institution’s activities in performing the Study.

The terms of this Agreement supersede any previous non-disclosure agreements or any other preliminary representations or understandings that have been entered into by the parties of this Agreement with regard to the Study. The terms of this Agreement will be treated as confidential; however, the existence of the Agreement and Study will not be confidential and Institution may disclose any of the terms herein:

1. As required by law or regulatory authority including applicable Medicare documentation and payment requirements;
2. To Medicare and other pater representatives for purposes of establishing rights to reimbursement or responding to audits or inquiries; and,
3. For other legitimate business, payment, and operations purposes including, without limitation, disclosures for purposes of due diligence and accreditation.

Upon completion of the Study or termination of this Agreement, Institution shall, at the direction of Sponsor, return or destroy all Confidential Information, at Sponsor’s sole expense. Institution and its IRB may each retain one archival copy of all Confidential Information for the purpose of demonstrating its compliance with its obligations herein.

1. **PUBLICATION**

The Sponsor recognizes that, under Institution policy, the results of the Study must be publishable, and agrees that researchers 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 the Institution shall own the copyright in such works, except to the extent that the Institution has waived ownership of the copyright in favor of the author’s under the Institution’s bylaws and regulations.

The Institution will provide the 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, the Institution may proceed with the presentation or submission for publication, unless the Sponsor has notified the Institution in writing that such proposed publication and/or presentation discloses Confidential Information. The Institution hereby agrees to make any changes or deletions prior to publication or presentation necessary to prevent the disclosure of Confidential Information.

Further, upon the request of the Sponsor, the Institution will delay publication or presentation an additional sixty (60) days to permit the 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 the investigators in that Study. However, in the event that a multi-center publication is not forthcoming within twenty-four (24) months following completion of the Study at all sites, the Institution may publish the Institution’s Study results without obtaining the Sponsor’s approval as enumerated above.

1. **DATA OWNERSHIP**

**“Study Data”** shall mean any data generated by the Institution and its Principal Investigator in the course of performing the Study including, without limitation, case report forms, clinical findings and results, Investigator interim and final reports, and adverse event reports. Study Data shall be the exclusive property of Sponsor provided, however, that Institution and its Principal Investigator shall have the right to use the Study Data for their own patient care and internal teaching and research purposes; and to evidence compliance with regulatory requirements related to the Study and this Agreement.

**“Source Documents”** shall mean Study Subject’s original medical records and other original Institutional records kept in the ordinary course of its operations, including pharmacy, imaging, and laboratory records documenting Study Subject’s care and treatment at Institution or its affiliated hospital(s) and medical practice(s). Source Documents shall remain the property of Institution.

1. **INTELLECTUAL PROPERTY**

 All Intellectual Property belonging to either Party prior to the execution of this Agreement shall remain the separate property of that Party. In addition, all Intellectual Property developed by a Party during the Study term independent of the Study and the other Party’s Confidential Information shall be the separate property of the Party that developed it. Nothing in this Agreement shall give either Party claim or right to the separate Intellectual Property belonging to the other Party.

Institution shall promptly and fully disclose to Sponsor all patentable inventions and discoveries conceived and reduced to practice in the direct performance of the Study and which necessarily use or necessarily incorporate the Study Drug/Device (the “**Study Inventions**”). Institution shall assign all right, title, and interest in and to any Study Inventions to the Sponsor. Institution will reasonably cooperate to effect the foregoing, including providing reasonable assistance in connection with prosecuting relevant patents, at the sole expense of Sponsor.

Title to other inventions other than Study Inventions (the “**Other Inventions**”) shall reside with Sponsor if Sponsor personnel are sole inventors, with Institution if Institution personnel are sole inventors, and shall be held jointly if both Institution and Sponsor personnel are inventors, with each Party having the full right to practice and license such Other Inventions subject only to similar rights of the other Party.

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 at Sponsor’s sole expense. 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.

Institution shall retain a royalty-free, irrevocable license to use all Study Inventions or Other Inventions licensed or assigned to Sponsor herein for its own internal noncommercial research, educational, and patient care purposes.

1. **INDEMNIFICATION**

Sponsor shall indemnify, defend, and hold harmless the Institution and the Institution’s Board of Supervisors, agents, students, officers, board members, employees, and anyone for whom the Institution may be liable (collectively, the “**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 the Sponsor or of its officers, servants, agents, or by any third party acting on behalf of or under authorization from the Sponsor in the performance of this Agreement, or for losses arising out of the use by the Sponsor or by any third party acting on behalf of or under authorization from the Sponsor, of products or processes developed or made as a result of information or materials received from the Institution.

1. **INVESTIGATOR MEETINGS**

Where the Agreement between the Institution and the Sponsor recommends or obligates the Principal Investigator, Study Nurse, or other representative to attend an Investigators’ Meeting, it is understood and agreed that the 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 attendance 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 attendance 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 the Sponsor in any way.

It is the understanding of the parties that attendance of 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 physician, healthcare professional, Study nurse, or other personnel connected with the Institution are engaged by the 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.

1. **SUBJECT INJURY REIMBURSEMENT**

For purposes of this section, “**Injury**” shall mean 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, the Sponsor agrees to reimburse the Institution, other accredited medical care providers, or Subjects (as appropriate) for any medical care required by the Subjects that occur as a direct result of participation in the Study and that is not covered by the Subject’s medical insurance. The Institution will bill the 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, the Sponsor shall be responsible for all costs, including:

1. 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
2. All reasonable and associated costs incurred for treatment of an injury to the Subject if the Sponsor and the Institution together determine that the adverse event was reasonably related to the administration of the Study Drug(s)/Devices(s) or a Protocol procedure; provided however that:
	1. The adverse event is not attributable to the negligence or misconduct by the Institution, the Investigator, or any sub-investigator/agent of the Institution;
	2. The adverse event is not attributable to any underlying illness, whether previously diagnosed or not, and;
	3. The Study Drug(s)/Devices(s) or Protocol procedure was administered in accordance with the Protocol.
3. **SPONSOR MONITORING**

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

1. **REGULATORY AGENCY MONITORING**

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 an auditing of Study records. The Sponsor may also choose to audit Study records as part of its monitoring of Study conduct.

1. Notification: The Institution will notify the 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, the Sponsor will notify the Institution and the IRB as soon as reasonably possible if the LSUHSC-NO investigator is inspected by the FDA concerning the conduct of the Study.
2. Cooperation: The Institution and the Sponsor shall cooperate with the Regulatory Agency and/or the Sponsor’s representatives in the conduct of inspections and audits and will ensure that Study records are maintained in a way that facilitates such activities.
3. Resolution of Discrepancies: The Institution shall promptly resolve any discrepancies that are identified between the Study Data and the subject’s medical records.
4. **DATA AND SAFETY MONITORING**

The Sponsor acknowledges that it has the responsibility to conduct data and safety monitoring that will be performed on a regular basis with its conclusions reported to the Institution. Recommendations emanating from these monitoring activities will be reviewed by the Sponsor and addressed. The Sponsor assumes responsibility for informing the Institution concerning the data and safety monitoring policy and procedures. The Institution will provide feedback to the Sponsor on a regular basis, including findings from adverse-event reports and recommendations derived from data and safety monitoring.

During a for a period of three [3] years after the Study, 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:

1. Affect the safety of Study Subjects;
2. affect Study Subjects' willingness to continue participation in the Study;
3. influence the conduct of the research; or
4. alter the IRB's approval to continue the Study

The Sponsor acknowledges and agrees that the Institution may communicate any of the aforementioned 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.

1. **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).

1. **INSURANCE**

The Sponsor agrees to carry and keep in force, at its expense, product liability insurance at an amount acceptable to the Institution and shall provide evidence thereof within ten [10] days of request from Institution.

Institution shall maintain professional liability insurance with limits as mandated by applicable state law.

1. **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 the Institution may acknowledge the Sponsor as the source of support for the Project without the Sponsor’s prior consent.

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

1. **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.

1. **ASSIGNMENT**

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

1. The 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
2. The 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.
3. **SEVERABILITY**

In the event that any term of this Agreement becomes or is declared to be void or unenforceable, the remainder of this Agreement will continue in full force and effect.

1. **CONFLICT BETWEEN AGREEMENT AND PROTOCOL**

To the extent that terms of this Agreement conflict with the terms of the Protocol, the terms and of this Agreement will control as to legal and business matters, and the terms of the Protocol will control as to technical research and scientific matters.

1. **NOTICE**

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:

 [INSERT CONTACT INFORMATION]

 With a Copy to:

 [INSERT CONTACT INFORMATION]

Institution:

 Louisiana State University Health Sciences Center

 *Attn*: Demetrius Porche, DNS, PhD

 433 Bolivar Street, 8th Floor

 New Orleans, LA 70112-2223

 Phone: (504) 568-4804

 Fax: (504) 568-5588

 Email: dporch@lsuhsc.edu

With a Copy to:

 Louisiana State University Health Sciences Center

 *Attn*: Clinical Trials Office

 433 Bolivar Street, Suite 206

 New Orleans, LA 70112

 Phone: (504) 568-4970

 Fax: (504) 568-8808

 Email: CTO@lsuhsc.edu

1. **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 the Sponsor and the Institution.

**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 [INSERT SPONSOR NAME]**

**COLLEGE,** *herein represented by*

**LOUISIANA HEALTH SCIENCES**

**CENTER – NEW ORLEANS:**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Demetrius Porche, DNS, PhD [Authorized Official Name]

Interim Vice Chancellor for Academic Affairs [Authorized Official Title]

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date Date

**PRINCIPLE INVESTIGATOR:**

I attest that I have read this agreement and understand and accept my obligations herein:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[PI Name]

Principal Investigator

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date