MEMORANDUM OF UNDERSTANDING (MOU) 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 (LSUHSC-NO) AND

 [SITE]

FOR DESIGNATION OF INSTITUTIONAL REVIEW BOARD (IRB) OF RECORD

1. PURPOSE AND SCOPE

This MOU between the LSUHSC-NO, a State institution of higher learning in the State of Louisiana and [SITE] establishes an agreement for the designation of IRB responsibilities.

WHEREAS, Federal regulations found at 45 CFR 46.114 allow for reliance agreements between institutions when the institutions are engaged in cooperative research projects, in order to avoid duplication of effort; and

WHEREAS, the LSUHSC-NO faculty are conducting human subjects research (hereinafter “cooperative research”); and

WHEREAS, [SITE] and its employees or agents will collaborate as a study site and/or study personnel; and

WHEREAS, the LSUHSC-NO IRB, as a qualified IRB, will review the cooperative research, [SITE] wishes to rely on the review of the LSUHSC-NO IRB for the cooperative research, and the LSUHSC-NO IRB is receptive to [SITE] relying on its review, the LSUHSC-NO IRB and [SITE], as parties, create this agreement in accordance with the terms and conditions herein.

The parties hereby agree as follows:

1. [SITE] may rely on the review by the LSUHSC-NO IRB in accordance with the terms of this MOU for the review and continuing oversight of the cooperative research for the entire duration of the research, until it has been closed by the LSUHSC-NO IRB.
2. The parties acknowledge each party is responsible for the development and operation of its own human subjects protections programs. Each party reserves the right and retains the ultimate responsibility to determine what research is appropriate to be conducted at its own facilities. Neither party will assume responsibility for any other aspects of the other party’s human subjects protection programs or human subjects research operations. Each party will remain responsible for ensuring its own compliance with applicable Federal, State, and local laws regarding human subjects research.
3. During the term of this MOU, each party will maintain an approved Federalwide Assurance (FWA) of compliance with the Office for Human Research Protections (OHRP), and upon request, provide a copy of its FWA to the other party, and abide by the terms and conditions of their respective FWA and this MOU. In the

Event a party’s FWA is amended in a manner that impacts this reliance agreement, such party will notify the other party and promptly supply a copy of the amended FWA to the other party.

1. For the research covered by this agreement, [SITE] agrees to comply with requests for information in its possession that is necessary for oversight by the LSUHSC-NO IRB.
2. [SITE] agrees that its employees or agents engaged in the research shall be required to sign the Collaborator Attestation attached to this Agreement.
3. LSUHSC-NO shall perform all of the functions required under applicable federal, state, and local laws and regulations, whether foreign or domestic, for reviewing and approving human subjects research in connection with the cooperative research, including, without limitation, 45 CFR 46 and 21 CFR 50 and 56. LSUHSC-NO’s review and approval shall also be conducted in accordance with all relevant institutional policies regarding human subjects research. The investigators of [SITE] will abide by all conditions and determinations made by LSUHSC-NO in connection with its review and approval of the cooperative research.
	1. [SITE] will not conduct the cooperative research if it has not been reviewed and approved by LSUHSC-NO.
	2. [SITE] will obtain review and approval from LSUHSC-NO prior to the implementation of any amendments to the cooperative research.
	3. [SITE] will not conduct the cooperative research if it is suspended or terminated by LSUHSC-NO.
4. Both parties shall ensure adherence to this agreement and shall ensure that its employees, investigators, and agents adhere to the applicable federal, state, and local laws, regulations and policies regarding the conduct of human subjects research, including but not limited to, 45 CFR part 46 and 21 CFR parts 50 & 56 and other applicable governmental regulations and guidance.
5. This Agreement shall not cover any negligence, malpractice or other wrongful acts on the part of either party. Each party shall be responsible for its own losses, damages, costs, claims, suits, and expenses, including the costs of handling and defending such claims.
6. REPORTING
7. Each party shall immediately notify the other party, in writing, of any serious or continuing non-compliance issues involving the cooperative research.
8. Each party shall immediately notify the other, in writing (within at least five

(5) working days), if and when an oversight agency or organization initiates any action regarding such noncompliance.

1. LSUHSC-NO shall immediately report, in writing, to [SITE] any determinations made by the IRB of suspension or termination of IRB approval involving the cooperative research.
2. Each party shall immediately notify the other, in writing, if any investigator or other employee or research personnel involved in the cooperative research is suspended, debarred, or receives any other restriction of any duties whether clinical or research related.
3. Each party shall immediately notify the other of any information which it may acquire about the cooperative research that may be relevant to a determination of non-compliance, unanticipated problems involving risks to subjects or others (including adverse events), or suspension or termination of the research.
4. ADDITIONAL TERMS AND CONDITIONS
5. Termination

Without cause, either party to this MOU shall have the right to terminate the MOU by giving written notice to the other party of such termination at least thirty (30) calendar days before the effective date of such termination.

1. Confidentiality/HIPAA
	1. Individual information: The parties agree to maintain strict confidentiality of all information received or obtained in connection with the performance of this MOU (whether or not such information involves the cooperative research) which relates to or identifies a particular research subject or any other specific individual, including but not limited to, the name, address, medical treatment, or condition, financial status, or any other personal information which is deemed to be confidential or private in accordance with applicable local, State, or Federal law whether foreign or domestic (including, without limitation, the Health Insurance Portability and Accountability Act of 1996 and any regulations and official guidance thereunder (as amended)) and standards of professional ethics. The parties will notify their respective employees, contractors, agents, and representatives of this confidentiality requirement and require them to maintain the confidentiality of such information.
	2. [SITE] shall promptly notify LSUHSC-NO of any unauthorized use, loss or disclosure of individually identifiable patient or human subject information or violations of information security laws, regulations, or policies.
2. Documentation

LSUHSC-NO shall maintain all documents reviewed by LSUHSC-NO in connection with the cooperative research, including any communication with investigators, and make those documents available to [SITE] upon request. As applicable, [SITE] personnel will maintain copies of signed consent forms associated with the cooperative research in accordance with the LSUHSC-NO Records Retention Policy. Upon request, LSUHSC-NO shall make available to [SITE] all IRB minutes concerning the cooperative research. If any governmental or regulatory authority notifies LSUHSC-NO that it will inspect [SITE]’s records, facilities, or procedures, or otherwise take action related to the cooperative research, LSUHSC-NO shall promptly notify [SITE] and provide [SITE] with copies of any reports issued by the investigating authority, including any response by LSUHSC-NO.

1. Assignment and Binding Effect

Neither party shall assign, subcontract, or transfer any of its rights or obligations under this MOU to a third party without prior written consent of the other party. If any assignment, subcontract, or transfer of rights does occur in accordance with this MOU, this MOU shall be binding upon and inure to the benefit of the parties hereto and their respective successors or assigns.

1. Independent Contractor

Each party shall be considered to be an independent party and shall not be construed to be an agent or representative of the other party, and therefore, shall have no ability to bind the other party or have any liability for the acts or omissions of the other party. In addition, neither party, nor any of its employees, agents, or subcontractors, shall be deemed to be employees or agents of the other party. Therefore, neither party nor any of its employees, agents or subcontractors, shall be entitled to compensation, workers’ compensation, or employee benefits of the other party by virtue of this MOU.

1. Amendment, Modification and Waiver

This MOU shall not be altered or otherwise amended except pursuant to an agreement, in writing, signed by each of the parties. A waiver, by either party, of a breach of any provision of this MOU must be in writing and shall not

operate or be construed as a waiver of any subsequent breach. The failure of a party, in any instance, to insist upon the strict performance of the terms of this MOU shall not be construed to be a waiver or relinquishment of any of the terms of this MOU, whether at the time of the party’s failure to insist upon strict performance or at any time in the future, and such term or terms shall continue in full force and effect unless amended or waived in writing in accordance with this MOU.

1. Survival

The provisions of this MOU relating to confidentiality and documentation of records shall survive the termination of this MOU.

1. Contact Information for the Cooperative Research in this MOU

All notices hereunder by any party to the other shall be in writing and delivered to the contact listed below, All notices will be delivered personally, by certified or registered mail, return receipt requested, or by overnight courier.

LSUHSC-NO:

Michael E. Hagensee, MD, PhD

Executive Director, Office of Research Services Louisiana State University Health Sciences Center - New Orleans

433 Bolivar Street, Suite 206

New Orleans, LA 70112

T: 504.568.4985

F: 504.568.8808

E: mhagen@lsuhsc.edu

1. [SITE] (this is for the administrative person with daily knowledge about the cooperative research, typically the individual named as the “Human Protections Administrator” on the FWA)

Name:

Title:

Phone:

Email:

Approved by:

[SITE]’s CEO, COO Date

OR OTHER SIGNING OFFICIAL

LSU Health Sciences Center – New Orleans Date Janet H. Southerland, DDS, MPH, PhD

Vice Chancellor for Academic Affairs Institutional Official

# Collaborator Attestation

For Research Conducted by Louisiana State University Health Sciences Center – New Orleans

As a collaborator on cooperative research with the LSUHSC-NO, I confirm that I have adequate time, assistance, equipment, and support to safely conduct this study.

I acknowledge that I am participating in research that is approved and overseen by the LSUHSC-NO’s institutional review board (IRB).

I accept responsibility to follow the IRB-approved protocol. I agree not to initiate any changes in the approved research prior to IRB approval, except where necessary to eliminate apparent immediate hazards to study subjects.

I agree to provide any information needed by the LSUHSC-NO Investigator to manage the overall conduct of the study.

Except where informed consent and HIPAA authorization have been formally waived by the IRB, I will seek, document and maintain records of informed consent and HIPAA authorization from each prospective subject or his/her legally authorized representative, as applicable to my collaboration with the research.

I agree to report any protocol violations, complaints, subject injuries and unanticipated problems involving risks to subjects or others to the LSUHSC-NO Investigator or LSUHSC-NO study team within five business days of my awareness.

I agree to report all Serious Adverse Events (SAEs) within two business days of my awareness. SAEs include any medical events that result in hospitalization, are life-threatening, or results in a significant disability.

I will maintain current training in human subjects protection and current disclosure of conflicts of interest as required by LSUHSC-NO. I agree to inform the LSUHSC-NO Investigator or LSUHSC-NO study team of any new information on conflicts of interest related to my collaboration with the study.

I agree to maintain all required research records, including consent forms, during the study. I recognize the authority of LSUHSC-NO to inspect those records.

# Collaborator Attestation

For Research Conducted by Louisiana State University Health Sciences Center – New Orleans

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