

**INDUSTRY-SPONSORED RESEARCH
AND CLINICAL COLLABORATION AGREEMENT**

This INDUSTRY-SPONSORED RESEARCH AND CLINICAL COLLABORATION AGREEMENT (“**Agreement**”) is executed this day of _____, 2018, to be effective October 1, 2018 (“**Effective Date**”), by and between the Board of Supervisors of Louisiana State University and Agricultural and Mechanical College (“**LSU**”), a Louisiana constitutional corporation, Ochsner LSU Health System of North Louisiana, a Louisiana nonprofit corporation (“**OLHS-NL**”), and Ochsner Clinic Foundation d/b/a Ochsner Health System (“**Ochsner**”), a Louisiana nonprofit corporation. LSU, OLHS-NL, and Ochsner may hereinafter be referred to individually as a “**Party**” and collectively as the “**Parties.**”

RECITALS

WHEREAS, LSU is a constitutional corporation and land-grant public university established in 1853 and is tax-exempt as a governmental unit under Section 115 of the Internal Revenue Code of 1986, as amended (the “**Code**”);

WHEREAS, LSU operates and administers the affairs of Louisiana State University Health Sciences Center at Shreveport (“**HSC-S**”), which is comprised of the School of Medicine (“**Medical School**”), School of Allied Health and School of Graduate Studies;

WHEREAS, HSC-S’s and the Medical School’s mission is to (a) train Louisiana’s health care workforce through effective and innovative medical education programs, (b) discover new knowledge and to refine or expand existing knowledge through scientific research, and (c) provide high quality, patient-centered, cost-effective clinical care (collectively, the “**Academic Mission**”);

WHEREAS, Ochsner is a tax-exempt organization within the meaning of Section 501(c)(3) of the Code whose mission is to serve, heal, lead, educate and innovate through operation of an integrated health care system comprised of hospitals, clinics and other health care facilities offering medical education, research, and a continuum of care to benefit the communities in which it operates throughout Louisiana (the “**Ochsner Mission**”);

WHEREAS, OLHS-NL is or will become a tax-exempt organization within the meaning of Section 501(c)(3) of the Code that will oversee and operate the Ochsner LSU Physician Group, L.L.C. (“**OLPG**”) and the hospital facilities located in Shreveport and Monroe, Louisiana previously owned and operated by HSC-S (individually a “**Hospital**” and collectively, the “**Hospitals**”) to serve patients in North Louisiana;

WHEREAS, LSU, OLHS-NL, and Ochsner are committed to implementing a new public/private partnership model to serve the citizens of North Louisiana beginning on the Effective Date through OLHS-NL’s ownership and management of the Hospitals and OLPG;

WHEREAS, the organizational structure of OLHS-NL is designed to align the financial incentives of the Hospitals and OLPG for the benefit of the Hospitals, OLPG, and HSC-S, including the Medical School (collectively, the “**Academic Medical Center**” or “**AMC**”), and to better serve the Academic Mission and the Ochsner Mission;

WHEREAS, the Parties understand and agree that the financial soundness of OLHS-NL's clinical enterprise is critical to the Academic Mission and the overall success of the AMC;

WHEREAS, to achieve their shared goals and vision of and commitment to a state-of-the-art AMC serving North Louisiana and the surrounding area and to further support the Academic Mission and the Ochsner Mission, LSU, OLHS-NL, and Ochsner desire to collaborate with respect to medical education, research and clinical care;

WHEREAS, OLHS-NL and Ochsner own and possess patient network, databases and other resources that provide data, research subjects, and other information not readily available to HSC-S and that make collaborative research studies more robust;

WHEREAS, the Parties and their respective physicians, faculty, and other practitioners possess clinical and research knowledge and capabilities that are necessary to conduct collaborative research studies and that are necessary for studies to be in compliance with federal laws, regulations, and rules pertaining to research studies;

WHEREAS, to create a stable delivery system of healthcare services for patients in North Louisiana, the Parties wish to integrate and coordinate Industry Sponsored Research (“**ISR**”) with outpatient and community-based services provided by OLPG and Ochsner and inpatient and outpatient services provided by the Hospitals; and

WHEREAS, the Parties also wish to collaborate with respect to developing and implementing clinical and medical education programs to improve the delivery of clinical care to the low-income and needy population in North Louisiana.

NOW, THEREFORE, in consideration of the premises, the mutual benefits to the Parties to be derived from this Agreement and the obligations and responsibilities set forth in this Agreement, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree, with the intent to be legally bound, as follows:

ARTICLE I. COLLABORATION GOALS AND OBJECTIVES

The Parties agree that a collaborative pursuit of strategic opportunities in medical education, research and clinical care will equip the AMC to better serve patients in North Louisiana. By taking a collaborative approach, the Parties desire to establish and maintain an integrated delivery system and environment in which HSC-S employed faculty exclusive of any Ochsner Physician (as defined below) (the “**HSC-S Faculty**”) work collaboratively with physicians employed or contracted through the North Louisiana Department, a division of Ochsner Clinic, LLC, a wholly owned subsidiary of Ochsner (with or without an Adjunct Academic Appointment (as defined in the Academic Clinical Collaboration Agreement among Ochsner, LSU, and OLHS-NL) (“**Ochsner Physicians**”) to conduct ISR.

ARTICLE II. MEDICAL RESEARCH COLLABORATION

Section 2.01. Commitment to Medical Research. The Parties are committed to performing joint ISR. The Parties are also committed to (i) expanding the AMC's medical education programs, improve access to diverse training sites and patients, and retain quality residents, fellows, and allied health professionals in North Louisiana; and (ii) developing strategies and processes for collaborative medical and scientific research projects designed to improve clinical care and health outcomes in North Louisiana

Section 2.02. Restriction to Industry-Sponsored Research. Subject to Section 2.04, the Parties agree that any joint research conducted under this Agreement shall be limited to industry-sponsored, non-federally funded, research (ISR). HSC-S's independent industry-sponsored, non-federally funded, research (ISR) and federally funded and investigator-initiated research projects (the "**LSU Independent Research**") and Ochsner's industry-sponsored, non-federally funded, research and federally funded and investigator-initiated research projects (the "**Ochsner Independent Research**") are excluded from, outside the scope of, and not subject to or governed by the provisions of this Agreement. Notwithstanding the preceding sentence, nothing in this Agreement shall prevent (i) faculty of OLHS-NL and/or Ochsner Physicians from participating in LSU Independent Research or Ochsner Independent Research as Principal, Co-Investigator, or Sub-Investigators, or (ii) faculty of HSC-S from participating in Ochsner Independent Research as Principal, Co-Investigator, or Sub-Investigators, as mutually agreed to by the Parties. HSC-S reserves all rights, title, and interest in and to any intellectual property developed as a result of any LSU Independent Research, and Ochsner reserve all rights, title, and interest in and to any intellectual property developed as a result of any Ochsner Independent Research. Any use by Ochsner of data created or transferred by HSC-S in connection with any LSU Independent Research and any use by HSC-S of data created or transferred by Ochsner in connection with any Ochsner Independent Research shall be governed by the terms of separately negotiated data use agreements. Notwithstanding any other provision in this Section 2.02 or in this Agreement, HSC-S must be engaged in any ISR conducted at the Hospital(s); provided, however, that this requirement shall not preclude Ochsner or any Ochsner Physician from independently engaging in ISR conducted at non-Hospital locations that uses Hospital resources (e.g., Hospital equipment or personnel).

Section 2.03. Research Contracts. All ISR performed under the Agreement shall be conducted in accordance with the terms of the Protocol, be consistent with applicable state and federal laws, and conform to HSC-S and LSU System and Ochsner policies and procedures. The Parties acknowledge and agree that (i) HSC-S and HSC-S Faculty must follow all HSC-S and LSU System policies and procedures to engage in any ISR and (ii) Ochsner and Ochsner Physicians must follow all Ochsner policies and procedures to engage in any ISR.

Section 2.04. Research Committee. The Parties shall establish a Research Committee, consisting of up to six (6) members, with three (3) members appointed by HSC-S and three (3) members appointed by Ochsner ("**Research Committee**"). The names of the initial Research Committee members are set forth in Exhibit A. HSC-S and Ochsner may remove or replace each of their respective members at will. The functions of the Research Committee include, but are not limited to:

- (a) Assessing institutional capacity and available data to identify new research areas of focus between the Parties;
- (b) Making recommendations regarding coordination of efforts for joint ISR and other joint research between the Parties;
- (c) Making recommendations regarding how to improve the performance of clinical trials and how to coordinate resources of the AMC;
- (d) Establishing a Master Charge List for services to be provided by physicians and/or OLHS-NL hospitals for ISR;
- (e) Making recommendations regarding the feasibility of proposed ISR;
- (f) Making recommendations regarding the need for changes to policies and procedures for the conduct of ISR;
- (g) Gathering and interpreting metrics related to the conduct of ISR; and
- (h) Exploring other avenues for research collaboration between Ochsner and HSC-S other than ISR.

Section 2.05. OLHS-NL Data. To the extent relevant to the development or performance of joint ISR, OLHS-NL agrees to provide HSC-S and Ochsner access to any de-identified data recorded and stored on the Hospitals' electronic medical records system(s), including, but not limited to, data recorded and stored on EPIC and any other data developed by OLHS-NL as part of ISR ("**OLHS-NL Data**"). OLHS-NL shall retain all rights, title and interest, including, but not limited to, intellectual property rights, in and to the OLHS-NL Data. The other Parties may use OLHS-NL Data solely for the purpose of performing the specific ISR for which the OLHS-NL Data was created or transferred under this Agreement and shall not sell or transfer any OLHS-NL Data to any other person or entity without OLHS-NL's prior written consent. Unless otherwise agreed by OLHS-NL in writing, within thirty (30) days after expiration or termination of this Agreement, the other Parties shall return any OLHS-NL Data in their possession or control to OLHS-NL.

Section 2.06. Collaboration Data. All data created by the Parties during the performance of a joint ISR that constitutes or incorporates a combination of Ochsner Data, HSC-S Data and/or OLHS-NL Data shall be deemed "**Collaboration Data**" for purposes of this Agreement. Each Party may use Collaboration Data, provided that such use is for purposes associated with the joint ISR. The Party who uses the Collaboration Data must give the other Party written notification of its intent to use the Collaboration Data at least thirty (30) days prior to its use. Collaboration Data used for publication, at a conference, or presented in some other manner or context must be for the sole purpose of discussing the joint ISR, and the user agrees to acknowledge and give credit to the other Party for its research contributions. Any use of the Collaboration Data for purposes outside the ISR must be approved in advance by the Research Committee. Ownership, rights, title and interest in and to such derivative data shall be governed by the provisions regarding Intellectual Property contained in Section 2.16 of this Agreement.

Section 2.07. Reciprocal Institutional Review Boards. The Party who will perform the ISR may elect to use the other Party's Institutional Review Board (the "**IRB**" or "**IRB of Record**") to review and oversee the ISR. In making such determination, the primary investigator may take into consideration, among other things, the knowledge, skills, expertise, or disciplines of the Parties' IRBs regarding the subject matter of the ISR. The IRB of Record will have ultimate authority over the conduct and integrity of the ISR and the other Parties involved in the ISR shall cede review of ISR to the IRB of Record. For any multi-site ISR involving industry-sponsored clinical trials, the Parties may use external IRBs. The Parties acknowledge and agree that HSC-S Faculty must notify the Assistant Vice Chancellor for Research Management in writing prior to using any IRB other than the HSC-S IRB.

Section 2.08. Institutional Review Board Requirements. The following requirements apply to each Party's IRB:

- (a) Terms. All parties agree that terms used in this section of this Agreement shall have the same meaning as those used in 45 CFR 160.103 and 164.501, Title 38 Part 16, 45 CFR 46.102 of the Code of Federal Regulations, and Title 21, part 50 and 56 of the Code of Federal Regulations.
- (b) Protection of Human Subjects.
 - (1) Each Party is responsible for implementing and maintaining its Human Research Protections Program ("**HRPP**") which establishes institutional policies and procedures for protecting human subjects with respect to research in compliance with its Federal Wide Assurance. Each IRB will provide a statement that its IRB membership complies with the federal regulations. Each Party shall have/has the right to review and retain the IRB roster upon request.
 - (2) The Parties are responsible for complying with all determinations of the IRB of Record with respect to human research for all ISR and will accept the final authority and decisions of the IRB of Record, including but not limited to, directives to terminate participation in research study activities or requirements to participate in education and training required by the IRB. Research that has been approved by the IRB of Record may be subject to further review and approval by the Parties. However, the Parties may not approve the research if it has been denied by the IRB of Record.
 - (3) The Parties are responsible for ensuring that researchers and research staff promptly report any proposed changes in the ISR and will not initiate changes without prior approval by the IRB of Record, except where necessary to eliminate an apparent immediate hazard to a subject.
 - (4) The Parties are also responsible for ensuring that researchers:
 - a. Comply with and abide by all determinations of the IRB of Record, including but not limited to, directives to terminate participation in ISR.

- b. Not enroll subjects for ISR prior to the IRB of Record's review and approval.
 - c. Accept primary responsibility for safeguarding the rights and welfare of each research subject, and that the subject's rights and welfare must take precedence over the goals and requirements of the ISR.
 - d. Adhere to the following: (1) Sponsor requirements; (2) IRB of Record's applicable policies and procedures; and (3) all applicable laws and regulations, in their current form, and as revised hereafter from time to time, including but not limited to: (i) The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research (or other internally recognized equivalent); (ii) Title 45, Part 46 of the Code of Federal Regulations (the Common Rule); (iii) the relevant statutes, rules, regulations, and policies of the U. S. Food and Drug Administration; (iv) Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d-2) ("HIPAA"), the Health Information Technology for Economical and Clinical Health Act ("HITECH Act"), and regulations promulgated thereunder (collectively, "HIPAA Regulations") and applicable state law, including those provisions that relate to Business Associates; (v) Good Clinical Practice Guidelines; (vi) International Conference on Harmonization (ICH); and (vii) all other applicable federal, international, state and local laws, regulations and policies that may provide additional protection for human subjects participating in research conducted under this Agreement.
- (5) The IRB of Record will approve alterations or waivers for use or disclosure of protected health information for any ISR. OLHS-NL, HSC-S, and/or Ochsner, as applicable, will submit the appropriate request form to the IRB of Record.
- (c) Education and Training. When an ISR is reviewed and approved by the IRB of Record, the Parties will ensure that research staff will complete all training required by the IRB of Record prior to initiating the study. Evidence of completed training must be provided to the IRB of Record at the time of any ISR submission and must be accepted and approved by OLHS-NL, HSC-S, and/or Ochsner's, as applicable, HRPP prior to the beginning ISR activities.
- (d) Reporting Obligations.
- (1) Investigator: For ISR, Investigator must report any of the following events

in accordance with the federal regulations for protection of human subjects:

- Unanticipated problems involving risks to participants or others,
- Changes to the protocol taken without prior IRB of Record approval to eliminate an apparent immediate hazard to a subject or protocol deviation/violation,
- Knowledge of new information that indicates a new or increased risk, or a safety issue,
- Premature suspension or termination of the research by the sponsor or the investigator,
- Failure to follow the protocol due to the action or inaction of the investigator or research staff,
- Written monitoring reports from the sponsor or CRO,
- Non-compliance with the federal regulations governing human research or with the requirements or determinations of the IRB of Record, or allegations of such non-compliance,
- Audit, inspection or inquiry by a federal agency or Sponsor quality audit,
- Incarceration of a subject in a study not approved by the IRB of Record to involve prisoners,
- Complaint of a subject that cannot be resolved by the research team,
- Breach of subject confidentiality,
- Unanticipated adverse device effect,
- Suspension or termination of research, and Serious or continuing non-compliance. Serious non-compliance includes deviations from the IRB of Record's guidelines, IRB of Record's approved protocol, ICH-E6 Good Clinical Practices or applicable regulations, that have or could potentially affect
 - o the safety, rights and welfare of the research subject(s); or
 - o integrity of the data or outcome of the study

Notwithstanding the preceding, the Parties acknowledge and agree that HSC-S must follow its standard operating procedures (SOPs) regarding when events must be reported.

(2) IRB of Record:

- The IRB of Record will take minutes of its meetings in which an ISR for the Parties is reviewed. A notice of the IRB's action will be provided to the Parties.
- The IRB of Record will document all findings and actions regarding the Parties' ISR taken outside of convened meetings, and will provide copies of such documentation to the Parties upon request.
- The IRB of Record will report any suspension or termination of the Parties' ISR immediately to the HSC-S, OLHS-NL, and/or Ochsner.
- The IRB of Record will report to the Parties any request for audit, investigation or external review of the Parties' ISR, including by a government regulatory agency.
- The IRB of Record will report to the Parties any noncompliance with the federal regulations, as it relates to the Parties' ISR.

Notwithstanding the preceding, the Parties acknowledge and agree that HSC-S and HSC-S Faculty must follow its standard operating procedures (SOPs).

- (e) Local Context Issues. Each Party's IRB will retain review of local context issues. Local context issues may include, but are not limited to, the following: conflict of interest policy, extent of existing populations eligible for enrollment, safeguards used to protect those populations, privacy and confidentiality protections, and any other study specific requirement.
- (f) Conflicts of Interest. The Parties will each comply with their respective Conflicts of Interest policies. The Parties acknowledge and agree that HSC-S and HSC-S Faculty must comply with Chancellor's Memorandum 23 for all research in which it participates. Each Party will provide a copy of its Conflicts of Interest Policy upon request. The Parties will promptly report Conflicts of Interest to the IRB of Record and shall establish a plan to mitigate any known conflict of interest
- (g) Compliance with FWA Requirements. The Parties acknowledge that continuation of this Agreement depends upon the maintenance of a current FWA. Each Party shall notify the other Party within thirty (30) days of the termination for any reason of the notifying Party's FWA. A party's failure to maintain a current FWA shall be considered a material breach of this Agreement and will be grounds for termination of the Agreement.
- (h) Access to ISR Records. The Parties will maintain all necessary records in support

of the ISR conducted. Each IRB will maintain all necessary records in support of the ISR reviewed for the Parties. Records will be kept by each Party in accordance with federal regulations and institutional policies.

- (1) Each Party shall make available to the IRB of Record, and shall cause its employees and agents to make available to the IRB of Record, documentation required by the IRB of Record to perform the services hereunder. Each Party shall protect the confidentiality of all such documentation in accordance with relevant federal and state laws and regulations.
- (2) Each IRB shall prepare and maintain documentation relating to the ISR as required by the federal regulations and other requirements made known in writing by the Parties involved in the ISR. Each IRB shall cooperate with the Parties' reasonable requests to inspect and copy, at the requesting Party's sole cost, such documentation related to the ISR.
- (3) In connection with the performance of the obligations set forth herein, the Parties may have access to certain oral and written information concerning each other that is non-public, confidential and/or proprietary in nature. The Parties acknowledge the confidential or proprietary nature of such information and agree to comply with the confidentiality obligations set forth in Section 2.13 of this Agreement. The Parties further agree to limit access to and use of such information to those employees to whom such information is necessary to fulfill their respective obligations under this Agreement.
- (4) The IRB of Record has the right to perform audits or request that the local research site HRPP perform audits and site visits including, externally directed (for-cause audits), periodic and random audits, or compliance reviews at any research site for any collaborative ISR. A minimum of 5 business days' notice will be given to Investigators and research staff prior to any audit and site visit, set at a mutually convenient time. Compliance with all applicable federal, state, and local laws in the jurisdiction where the research is taking place, research subject safety, and the IRB requirements will be assessed. Full cooperation of all research and administrative personnel is expected and required; a lack of cooperation may result in the suspension of IRB approval for additional ISR projects.
 - (i) Compliance with HIPAA and State Laws Regarding Privacy and Security of Health Information. Each Party agrees to maintain the confidentiality, privacy, and security of "Protected Health Information" (as defined under HIPAA) to the extent required by law and the Parties' policies. Each Party agrees to comply with HIPAA, the HITECH Act, and the implementing regulations set forth at 45 CFR Parts 160, 162 and 164. Each Party further agrees to comply with all State laws regarding the privacy and security of protected health and personal

information.

- (j) **Non-Exclusivity.** Nothing in this Agreement is intended to limit the right of any Party, through any IRB, to provide review and continuing oversight of human subjects research conducted by or on behalf of any other person or entity, LSU Independent Research, or Ochsner Independent Research.

Section 2.09. IRB Approval Required to Conduct Studies. Each IRB will follow its own standard operating procedures and processes in accordance with its accreditation standards and federal regulatory requirements.

- (a) No ISR may commence until written IRB approval from the IRB of Record is obtained. Prior to issuing such approval, the IRB of Record shall ensure that all local context issues have been addressed.
- (b) All ISR shall be conducted in accordance with all applicable federal and state laws and regulations for protecting the rights, safety and welfare of human subject and for the control of investigational drugs and devices, including Good Clinical Practice Guidelines.
- (c) Except in the case of a medical emergency, or otherwise where necessary for subject safety, no changes in or deviations from the applicable Protocol shall be made without the IRB of Record and Sponsor's written approval.
- (d) OLHS-NL, as operator of the Hospitals, is to direct all questions regarding the conduct of the ISR to the Investigator.
- (e) Any substitution or replacement of an Investigator during the course of a ISR will be communicated to the Sponsor, the IRB of Record, and the Parties involved in the ISR.

Section 2.10. Consistency in HIPAA Authorizations and Informed Consents. The Parties will implement a consistent process for patient disclosures pursuant to HIPAA regulations set forth in 45 C.F.R. Part 164, and patient informed consent pursuant to 45 C.F.R. Part 46 (or any other international, federal, or local law, regulation, rule, or procedural standards selected on the FWA for the IRB) and approved for use by the IRB. The Parties will obtain, document, and maintain records of HIPAA authorizations and informed consents as required by law. Such authorizations and consents shall be universal, permitting any disclosures of patient data, including medical records and other confidential medical data, to HSC-S, Ochsner and/or OLHS-NL to effectuate any ISR. Further, the HIPAA authorization and informed consent forms shall permit patients to opt out of disclosures of such patient's confidential data for research, bio-banking or other uses.

Section 2.11. Continuation of Existing Research. This Agreement shall not limit the Parties' ability to continue their respective ISR or activities existing prior to the Effective Date.

Section 2.12. Confidentiality. Each Party acknowledges that the methods, operations and other information regarding the Parties and the business of the Parties under this Agreement

are confidential and proprietary. Each Party shall cause all information disclosed to it by any other Party (the “**Disclosing Party**”) in connection with this Agreement or any ISR to be treated as “**Confidential Information**” according to the same internal security procedures and with the same degree of care regarding its secrecy and confidentiality as the Party receiving the Confidential Information (the “**Receiving Party**”) treats similar information of its own within its organization. Confidential Information does not include that part of the Confidential Information of a Disclosing Party that a Receiving Party demonstrates (a) was, is, or becomes generally available to the public other than as a result of a breach of this Section 2.12 by the Receiving Party or its representatives; (b) was or is developed by the Receiving Party independently of and without reference to any Confidential Information of the Disclosing Party; or (c) was, is, or becomes available to the Receiving Party on a non-confidential basis from a third party not bound by a confidentiality agreement or any legal, fiduciary or other obligation restricting disclosure.

- (a) Disclosure and Use of Confidential Information. Subject to Section 2.12(e) below, each Party agrees that Confidential Information to the extent allowed by law (a) shall be kept confidential by the Receiving Party; (b) shall not be used for any reason or purpose other than to evaluate and perform under this Agreement; and (c) without limiting the foregoing, shall not be disclosed by the Receiving Party to any other person, except in each case as otherwise expressly permitted by the terms of this Agreement or with the prior written consent of an authorized representative of the Disclosing Party. A Party shall disclose the Confidential Information of the other Party only to its representatives who require such material and are informed of the obligations of this Section. Each Party shall (x) enforce the terms of this Section as to its respective representatives; (y) take such action to the extent necessary to cause its representatives to comply with the terms and conditions of this Section; and (z) be responsible and liable for any breach of the provisions of this Section by it or its representatives.

- (b) Legal Proceedings. Subject to Section 2.12(e) below, if a Receiving Party becomes compelled by law or is requested by a governmental body having regulatory jurisdiction over the this Agreement or the ISR to make any disclosure that is prohibited or otherwise constrained by this Section, that Receiving Party shall provide the Disclosing Party with prompt notice of such compulsion or request so that it may seek an appropriate protective order or other appropriate remedy or waive compliance with the provisions of this Section. In the absence of a protective order or other remedy, the Receiving Party may disclose that portion (and only that portion) of the Confidential Information of the Disclosing Party that, based upon advice of the Receiving Party’s counsel, the Receiving Party is legally compelled to disclose or that has been requested by such governmental body, provided, however, that the Receiving Party shall use reasonable efforts to obtain reliable assurance that confidential treatment will be accorded by any person to whom any Confidential Information is so disclosed. The provisions of this Section do not apply to any proceedings between the Parties to this Agreement.

- (c) Return or Destruction of Confidential Information. Except as required by law, if this Agreement is terminated, each Receiving Party shall, to the extent allowed by law, (a) destroy all Confidential Information of the Disclosing Party prepared or generated by the Receiving Party without retaining a copy of any such material; (b) promptly deliver to the Disclosing Party all other Confidential Information of the Disclosing Party, together with all copies thereof, in the possession, custody or control of the Receiving Party or, alternatively, with the written consent of the Disclosing Party, destroy all such Confidential Information; and (c) certify all such destruction in writing to the Disclosing Party, provided, however, that the Receiving Party may retain a list that contains general descriptions of the information it has returned or destroyed to facilitate the resolution of any controversies after the Disclosing Party's Confidential Information is returned.
- (d) Attorney-Client Privilege. The Disclosing Party is not waiving, and will not be deemed to have waived or diminished, any of its attorney work-product protections, attorney-client privileges, or similar protections and privileges as a result of disclosing its Confidential Information (including Confidential Information related to pending or threatened litigation) to the Receiving Party, regardless of whether the Disclosing Party has asserted, or is or may be entitled to assert, such privileges and protections. The Parties (a) share a common legal and commercial interest in all of the Disclosing Party's Confidential Information that is subject to such privileges and protections; (b) are or may become joint defendants in legal proceedings to which the Disclosing Party's Confidential Information covered by such protections and privileges relates; (c) intend that such privileges and protections remain intact should any party become subject to any actual or threatened legal proceeding to which the Disclosing Party's Confidential Information covered by such protections and privileges relates; and (d) intend that after the consummation of the Collaborative Agreements (as that term is defined in the Academic and Clinical Collaborative Agreement) the Receiving Party shall have the right to assert such protections and privileges. No Receiving Party shall admit, claim, or contend, in proceedings involving any Party or otherwise, that any Disclosing Party waived any of its attorney work-product protections, attorney-client privileges, or similar protections and privileges with respect to any information, documents or other material not disclosed to a Receiving Party due to the Disclosing Party disclosing its Confidential Information (including Confidential Information related to pending or threatened litigation) to the Receiving Party.
- (e) HIPAA Override. Notwithstanding anything to the contrary in this Agreement, any Confidential Information which constitutes Protected Health Information as defined by HIPAA shall be maintained by the Parties in accordance with the provisions of HIPAA and the HITECH Act and the rules and regulations promulgated thereunder, and such provisions, rules, and regulations shall take precedence over any other provisions of this Agreement governing Confidential Information to the extent there is a conflict between the terms of this Agreement and such provisions, rules, and regulations of HIPAA and the HITECH Act and each Party will act in accordance therewith.

Section 2.13. Employee Matters.

- (a) Employee Supervision. Each Party shall be responsible for the conduct and direct supervision of its employees, agents and contractors participating in research, including assurance of said employee's compliance with the terms and conditions of the Agreement.
- (b) Employee Compensation and Benefits. Each party shall be solely responsible for all compensation, benefits and other consideration to be paid to or received by that Party's respective employees.
- (c) Employee Assignment. Either or both Parties may assign employees to assist in tasks related to ISR.
- (d) Employee Qualification. When engaged in research, the parties represent, certify and covenant that the Investigator is, and at all times during the course of the study shall, remain qualified by training and experience with appropriate expertise to conduct the study.
- (e) Employee Licenses. When engaged in research, the Parties represent, certify, and covenant that they and their employees have, and at all times during the course of the ISR shall have, the appropriate licenses, approvals and certifications necessary to safely, adequately and lawfully perform the research activities.
- (f) No Conflicts. When engaged in research, the Parties represent, certify and covenant that no Party's employees, Investigator(s), or any other person who is engaged in activities in the ISR (or any member of their immediate families) (i) is subject to any conflicting obligations, (ii) has any financial, proprietary, equity or other interest in the Sponsor of the study, (iii) has any financial or outcome interest of the ISR, (iv) has entered into any agreement with respect to the ISR that might interfere with the performance of the ISR or that might impair the acceptance of the resulting data by the United States Food and Drug Administration ("FDA") or other regulatory authorities that might create a conflict of interest. The Parties and Investigators will comply with all disclosure requirements of the FDA and other regulatory authorities with respect to conflicts of interest. The Parties have appropriate methods in place to manage, eliminate or otherwise resolve conflicts of interests.

Section 2.14. Facility Use.

- (a) Use of Hospital and Hospital Facilities. The Parties acknowledge and agree that HSC-S investigators may use OLHS-NL hospitals and hospital facilities (the "**Hospitals**" or singularly, the "**Hospital**") to conduct certain ISR contemplated by this Agreement. For the avoidance of doubt, the Parties shall not use and this Agreement shall not apply to any other research performed at Ochsner's hospitals or hospital facilities, nor shall it apply to any research performed by HSC-S at hospitals that are not owned and/or operated by OLHS-NL and/or Ochsner.

- (b) Conduct of Study. ISR procedures performed at Hospitals will be performed under the supervision and direction of the Principal Investigator of the ISR. The Hospitals will comply with the directives of the IRB of Record and the Principal Investigator respecting conduct of the ISR. The Hospitals and their staff shall strictly adhere to the terms of the study protocol applicable to the Hospitals.
- (c) Compliance with Law. OLHS-NL represents, warrants and covenants that the Hospitals will participate in the ISR and perform their obligations under this Agreement in compliance with all applicable federal, state, and local laws, regulations and guidelines, including but not limited to, the Medicare/Medicaid Anti-kickback statute, the Social Security Act of 1935, as amended, the Controlled Substances Act, as amended, and the regulations promulgated thereunder, including the U.S. Drug Enforcement Agency regulations at 21 C.F.R. §1300 et seq., HIPAA, the HITECH Act, and the regulations promulgated thereunder, and the Federal Food, Drug and Cosmetic Act of 1938, as amended, and all applicable regulations promulgated thereunder including regulations of the FDA.
- (d) Monitoring of Study. OLHS-NL will permit Sponsor or Sponsor's designee to access Hospital facilities in accordance with the agreement between OLHS-NL, HSC-S and/or Ochsner and the Sponsor; provided, however, that such access shall be subject to Sponsor's agreement to comply with the Hospital facilities' confidentiality and other policies and procedures governing protection of patient confidentiality and the Hospitals' proprietary systems.
- (e) Licenses. OLHS-NL shall ensure that Hospitals shall obtain and keep in full force and effect any licenses, certifications, accreditations, permits or registrations necessary for Hospitals to provide its facilities and services under this Agreement.
- (f) Insurance. OLHS-NL shall ensure that Hospitals shall maintain, in full force and effect during the term of this Agreement, reasonable, customary, and legally required insurance consistent with the scope of services being provided under this Agreement, including professional liability insurance, workers' compensation insurance, automobile liability insurance (if legally required), and general liability coverage with coverage for Security Incidents and Breaches of Unsecured Protected Health Information (as those terms are defined by HIPAA). Professional liability insurance shall include coverage for data breach and network security. All insurance shall be provided by financially stable insurance carriers properly licensed to write and issue require coverage.

Section 2.15. Intellectual Property, Publication and Related Matters.

- (a) Background IP. Each Party and/or its affiliates shall be and shall remain the owner of any data, including but not limited to documents, know-how, information, material, substances, and any other intellectual property, which were

or are developed independent of the activities contemplated by this Agreement, (the “**Background Intellectual Property**”), and this Agreement shall not affect the ownership of any Background Intellectual Property regardless of whether such materials or intellectual property are provided to the other Party for use in the ISR.

- (b) Patents and Inventions. All rights, title and interest to any discovery, concept, or idea, whether or not patentable, made during the conduct of the ISR and arising directly from the performance of the ISR or the Protocol shall be governed by the terms and conditions of the agreement between OLHS-NL, HSC-S, and/or Ochsner and the Sponsor, as well as LSU’s policy on patents and inventions.

All other inventions or discoveries arising out of the work to be performed under this Agreement, whether patentable or not, conceived by any Principal Investigator or other individual who is an employee of HSC-S (“**University Inventions**”) shall be the property of HSC-S. All other inventions or discoveries arising out of the work to be performed under this Agreement, whether patentable or not, conceived by any Principal Investigator or other individual who is an employee of Ochsner (“**Ochsner Inventions**”) shall be the property of Ochsner. All inventions or discoveries arising out of the work to be performed under this Agreement, whether patentable or not, jointly conceived by employees or agents of Ochsner, HSC-S, and/or OLHS-NL (and which shall have Principal Investigators from both HSC-S and Ochsner) (“**Joint Inventions**”) shall be the joint property of Ochsner, OLHS-NL and/or HSC-S. All inventions and any information with respect thereto shall be subject to the confidentiality obligations as set forth in this Agreement.

HSC-S and Ochsner shall be permitted to use any Joint Inventions made or developed by HSC-S or Ochsner, subject to the obligations set forth in Section 2.12 (Confidentiality), for internal, non-commercial research and for educational purposes and for the preparation of publications in accordance with Section 2.15(c) below.

- (c) Publications. The Parties’ right to publish and present the results and data generated in the ISR shall be governed by the agreement between OLHS-NL, HSC-S, and/or Ochsner and the Sponsor.

ARTICLE III. COLLABORATION ON OTHER RESEARCH

The Parties agree that the OLHS-NL Hospitals and associated clinics will remain available for research programs of HSC-S and Ochsner. The Parties shall use their best efforts to expand HSC-S and Ochsner’s research programs at the Hospitals and associated clinics and to evaluate other geographic areas for such expansion based on the recommendations of the Research Committee.

ARTICLE IV. CLINICAL COLLABORATION

Section 4.01. Clinical Initiatives. The Parties shall work together to establish and implement clinical initiatives to improve the quality, scope and efficiency of health care services available in North Louisiana. In particular, the Parties will focus efforts on expanding access to primary care, improving outcomes for diabetic patients, improving outcomes for patients with hypertension, avoiding excessive use of emergency departments, and other quality improvements in clinical outcomes. To that end, the Parties are working to effectuate the integration of the OLPG into the OLHS-NL clinical enterprise. Notwithstanding anything herein to the contrary, the Parties recognize and agree that their efforts to improve the quality of care and reduce the cost of clinical care to patients are subject to and conditioned on the availability of funding for clinical services at the AMC and adequate funding to OLHS-NL under the Cooperative Endeavor Agreement with the State of Louisiana, through the Division of Administration.

Section 4.02. Financing Clinical Initiatives. Through the integration of the clinical faculty and Ochsner Physician services with the AMC, the Parties intend to improve the overall financial and clinical operations of OLHS-NL and its subsidiaries. Nonetheless, the Parties recognize and agree that the financial health of OLHS-NL and the AMC is paramount for the ability to effectuate high quality medical education and research.

Section 4.03. Recruitment and Retention of Physicians. The Parties acknowledge that there is a lack of access to adequate physician care services in North Louisiana. To address this shortage and improve access to primary, secondary and preventative health services in North Louisiana, the Parties shall work together to retain and recruit physicians to expand access to care.

ARTICLE V. MEDICAL EDUCATION COLLABORATION

The Parties agree that the Hospitals and associated clinics will serve as the Medical School's principal teaching site, and will remain available for teaching, research and clinical care programs of the Medical School. The Parties shall use their best efforts to expand the Medical School's and Ochsner's teaching, research and clinical care programs at the Hospitals and associated clinics and to evaluate other geographic areas for such expansion.

ARTICLE VI. TERM AND TERMINATION

Section 6.01. Term. Unless earlier terminated as provided herein, the initial term of this Agreement (the "**Initial Term**") shall be ten (10) years, beginning on the Effective Date, and shall automatically renew for two (2) successive five (5) year terms (each a "**Renewal Term**"), for a total term ("Term") of twenty (20) years, unless a Party gives written notice of its intent not to renew the Agreement for a Renewal Term (a "**Non-Renewal Notice**") not less than six (6) months prior to the expiration of the Initial Term or the Renewal Term then in effect, as applicable.

Section 6.02. Events of Default. It shall be an event of default ("Event of Default") hereunder:

- (a) If a Party: (a) fails to cure a Financial Default (as defined in the ACCA) in full within the Financial Default Cure Period (as defined in the ACCA), or (b) incurs three (3) or more Financial Defaults in any given fiscal year during the Term regardless of whether cured.
- (b) If a Party fails to perform any other material obligation under the terms of this Agreement, such failure shall be subject to the Dispute Resolution provisions set forth in ARTICLE 9 of the ACCA. This Section 6.02. (b) is not applicable to a Financial Default addressed in Section 6.02. (a) above.

Section 6.03. Termination Events. Any Party may give a termination notice prior to the expiration of the Initial Term or Renewal Term upon the occurrence of any of the following events:

- (a) Termination by Mutual Consent. This Agreement may be terminated by the mutual, written consent of the Parties.
- (b) Federal Healthcare Program Exclusion. If a Party is excluded from participation in a federal healthcare program including, without limitation, the Medicare or Medicaid program, either Party may immediately terminate this Agreement.
- (c) Loss of Tax Exempt Status. In the event a Party determines that this Agreement would result in the loss of such Party's tax exempt status.

Section 6.04. Termination for Bankruptcy; Receivership. This Agreement shall terminate if a Party applies for or consents to the appointment of a receiver, trustee or liquidator of such party or of all or a substantial part of its assets, files a voluntary petition in bankruptcy, makes a general assignment for the benefit of creditors, files a petition or an answer seeking reorganization or arrangements with creditors or to take advantage of any insolvency law, or if an order, judgment or decree shall be entered by any court of competent jurisdiction, on the application of a creditor, adjudicating such party bankrupt or insolvent, and such order, judgment or decree shall be entered by any court of competent jurisdiction, on the application of a creditor, adjudicating such Party bankrupt or insolvent, and such order, judgment or decree shall continue unstayed and in effect for any period of ninety (90) consecutive days.

Section 6.05. Termination for Financial Default. In accordance with Section 6.02. Section 6.02. (a) above, the non-defaulting party may terminate this Agreement if the defaulting party (a) fails to cure a Financial Default in full within the Financial Default Cure Period, or (b) incurs three (3) or more Financial Defaults in any given fiscal year within the Term regardless of whether cured.

Section 6.06. Termination for Failure to Resolve Disputes. This Agreement may terminate if there is a failure to resolve to the Disputing Party's (as defined in the ACCA)

satisfaction two (2) material Disputes (as defined in the ACCA) initiated in the same fiscal year or three (3) material Disputes initiated in any two consecutive fiscal years upon conclusion of the Dispute Process set forth in ARTICLE 9 of the ACCA, including through the issuance of a final decision in any arbitration proceeding initiated in accordance with Section 9.1.3(5) of the ACCA.

Section 6.07. Termination of Collaborative. Upon termination of the ACCA, CEA or, unless otherwise agreed by the parties, any other Collaborative Agreement (as defined in the ACCA), this Agreement shall automatically terminate.

Section 6.08. Wind Down Activities. Upon termination of this Agreement for any reason, the Parties' obligations hereunder shall completely cease; provided, however, that the Parties shall perform and make payments for such matters as are necessary to wind up their activities pursuant to this Agreement in an orderly manner and to comply with the six (6)-month Wind Down Period and Wind Down Process described in the ACCA.

Section 6.09. Effect of Termination. Any ISR shall terminate upon the expiration or termination of this Agreement. Notwithstanding the preceding sentence, the Parties shall take all reasonable and necessary steps for the protection of human subjects research participants in any ISR.

ARTICLE VII. INDEMNIFICATION

Each Party (an "**Indemnitor**") shall indemnify and hold harmless, to the extent permitted by law, the other Party, its officers, directors, board members, agents, and employees (collectively, the "**Indemnitees**") for all costs, expenses, losses, damages, fines, penalties, forfeitures or liabilities (including, without limitation, interest which may be imposed by a court in connection therewith), court costs, litigation expenses, expert witness fees, reasonable attorneys' fees, and any other cost of defense, (collectively, the "**Damages**") arising from (a) Indemnitor's breach of this Agreement; or (b) the negligent actions or inactions of the Indemnitor, its officers, directors, Board members, agents, or employees.

ARTICLE VIII. REPRESENTATIONS AND WARRANTIES

Section 8.01. LSU Representations and Warranties. LSU represents and warrants that the statements contained in this Section 8.01. are correct and complete as of the Effective Date:

- (a) LSU is a public constitutional corporation organized under the laws of Louisiana. LSU is validly existing and in good standing under the laws of Louisiana.
- (b) This Agreement constitutes the legal, valid and binding obligation of LSU, enforceable against it in accordance with its terms, and any other agreement executed and delivered by LSU in connection with this Agreement will constitute the legal, valid and binding obligation of LSU, enforceable against it in accordance with its terms. LSU's Board of Supervisors has authorized the execution and delivery of this Agreement and such other documents to which it is a party and the performance of all of LSU's obligations hereunder and thereunder.

- (c) To LSU's knowledge, neither the execution and delivery of this Agreement nor the consummation or performance of any obligation under any of the Collaborative Agreements will, directly or indirectly (with or without notice or lapse of time):
 - (i) Conflict with any resolution adopted by LSU's Board of Supervisors;
 - (ii) Give any governmental body or other person the right to any successful remedy or relief under any legal requirement to which LSU may be subject, to the extent such remedy or relief would have a material impact on the AMC;
 - (iii) Contravene, conflict with, or result in a violation or breach of any of the terms or requirements of, or give any governmental body the right to revoke, withdraw, suspend, cancel, terminate or modify any governmental authorization held by LSU;
 - (iv) Cause Ochsner or OLHS-NL to become subject to, or to become liable for any material payment of, any material liability of LSU; or
 - (v) Result in any material change in the funding available to HSC-S under State appropriations and/or the State budget.

Section 8.02. Ochsner represents and warrants that the statements contained in this Section 8.02. are correct and complete as of the Effective Date:

- (a) Ochsner is a nonprofit corporation organized under the laws of Louisiana. Ochsner is validly existing and in good standing under the laws of Louisiana.
- (b) This Agreement constitutes the legal, valid and binding obligation of Ochsner, enforceable against it in accordance with its terms, and any other agreement executed and delivered by Ochsner in connection with this Agreement will constitute the legal, valid and binding obligation of Ochsner, enforceable against it in accordance with its terms. Ochsner's Board of Directors has authorized the execution and delivery of this Agreement and such other documents to which it is a party and the performance of all of Ochsner's obligations hereunder and thereunder.
- (c) To Ochsner's knowledge, neither the execution and delivery of this Agreement nor the consummation or performance of any obligation under any of the Collaborative Agreements will, directly or indirectly (with or without notice or lapse of time):
 - (i) Breach any resolution adopted by Ochsner's Board of Directors;
 - (ii) Give any governmental body or other person the right to any successful remedy or relief under any legal requirement to which Ochsner may be subject, to the extent such remedy or relief would have a material impact on the AMC;
 - (iii) Contravene, conflict with, or result in a material violation or material breach of any of the terms or requirements of, or give any governmental

body the right to revoke, withdraw, suspend, cancel, terminate or modify any governmental authorization held by Ochsner; or

- (iv) Cause LSU to become subject to, or to become liable for any material payment of, any material liability of Ochsner.

ARTICLE IX. MISCELLANEOUS

Section 9.01. Trade Secret Protection. Any trade secrets of a Party shall be entitled to all of the protections and benefits under applicable trade secret law and any other applicable law. If any information that a Party deems to be a trade secret is found by a court of competent jurisdiction not to be a trade secret for purposes of this Section 9.01. such information shall still be considered Confidential Information of that Party for purposes of this Section 9.01 to the extent included within the definition. In the case of trade secrets, each Party hereby waives any requirement that the other Party submit proof of the economic value of any trade secret or post a bond or other security.

Section 9.02. Public Records Request. The financial and other records created by, for or otherwise belonging to Ochsner and OLSH-NL shall remain in the possession, custody, and control of Ochsner and OLSH-NL, respectively, regardless of whether, or the method by which, LSU reviews and/or audits such records in connection with the rights and obligations of this Agreement. The Parties consider records of Ochsner and OLHS-NL to be proprietary to Ochsner and OLHS-NL, and to the extent that Ochsner or OLHS-NL makes any such records or documents available to LSU, such records shall be clearly marked as confidential and/or proprietary to indicate its or their position that such records or documents are not public records. To the extent LSU receives or learns of a public records request for documents pursuant to La. R.S. 44:1, et seq. (the “**Public Records Act**”) which may include this Agreement or any documents marked as confidential and/or proprietary to Ochsner or OLHS-NL, LSU will give notice to Ochsner and OLHS-NL that LSU has received or learned of such a public records request prior to producing any documents considered to be proprietary to Ochsner or OLHS-NL. In the event that Ochsner or OLHS-NL objects to the production and believes that the records are not subject to production pursuant to the Public Records Act, Ochsner or OLHS-NL will immediately so notify LSU and take such action as Ochsner or OLHS-NL deems necessary to protect the disclosure of such records. Ochsner and OLHS-NL will defend, indemnify, and hold harmless LSU and its employees, officers, attorneys, and agents from and against any costs, expenses, liabilities, attorneys’ fees, losses, damages, fines, and/or penalties resulting from or relating to LSU’s failure to produce such documents in response to a public records request.

Section 9.03. Parties Bound. This Agreement shall bind and shall inure to the benefit of the Parties and their respective successors and permitted assigns.

Section 9.04. Governing Law. This Agreement will be governed by and construed under the laws of the State of Louisiana without regard to conflicts-of-laws principles that would require the application of any other law.

Section 9.05. Jurisdiction, Venue and Service of Process. The exclusive venue for any lawsuit filed by any Party to this Agreement or any party to any other Collaborative Agreement (as defined in the ACCA) and arising out of or related to any Collaborative Agreement is the

Nineteenth Judicial District Court for the Parish of East Baton Rouge, State of Louisiana. The Parties agree that any of them may file a copy of this Section with any court as written evidence of the knowing, voluntary, and bargained agreement between the Parties irrevocably to waive any objections to venue or to convenience of forum as set forth hereinabove. Process in any lawsuit referred to in the first sentence of this Section may be served on any party anywhere in the world.

Section 9.06. Rule of Construction. The Parties acknowledge and agree that this is a negotiated agreement, in which all Parties have received the assistance and advice of competent legal counsel; and accordingly that the rule of construction that any ambiguities are to be construed against the drafting Party shall not apply.

Section 9.07. Severability. If any term, provision, covenant or condition of this Agreement is held unenforceable or invalid for any reason and not susceptible to reformation due to a change in applicable legal requirements, the remaining portions or provisions shall continue in full force and effect, unless the effect of such severance would be to substantially alter this Agreement or obligations of the Parties, in which case this Agreement may be immediately terminated.

Section 9.08. Integration. This Agreement constitutes the entire agreement of the Parties with respect to the subject matter hereof. This Agreement cancels and supersedes all prior research agreements and understandings, oral or written, among the Parties.

Section 9.09. Non-Waiver. No waiver of any breach or default hereunder shall be considered valid, unless in writing and signed by the Party giving such waiver. No such waiver shall be deemed a waiver of any subsequent breach or default of a similar nature.

Section 9.10. Notices. All notices, demands and other communications to be given or delivered pursuant to or by reason of the provisions of this Agreement shall be in writing and shall be deemed to have been given and received (i) if by hand or electronic delivery, when delivered; (ii) if given by nationally recognized and reputable overnight delivery service, the business day on which the notice is actually received by the Party; (iii) if given by certified mail, return receipt requested, postage prepaid, three (3) business days after posted with the United States Postal Service. Notices, demands and communications to the Parties shall, unless another address is specified in writing, be sent to the addresses indicated below:

If to LSU:

Board of Supervisors of Louisiana State
University and Agricultural and
Mechanical College
3810 West Lakeshore Drive
Baton Rouge, LA 70808
Attention: F. King Alexander, President

With a copy to:

Taylor, Porter, Brooks & Phillips LLP
8th Floor Chase Tower South
451 Florida Street
Baton Rouge, LA 70801
Attention: Patrick D. Seiter, Esq.

And

Louisiana State University Health Science
Center at Shreveport

1501 Kings Hwy.
Shreveport, LA 71103
Attention: Chris Kevil, Ph.D.
Vice Chancellor for Research

If to OLSH-NL:

Ochsner LSU Health System
of North Louisiana
1541 Kings Highway
Shreveport, Louisiana 71103
Attention: President

If to Ochsner:

Ochsner Clinic Foundation
1514 Jefferson Highway
New Orleans, LA 70121
Attention: Chief Administrative Officer

With a copy to:

Office of Legal Affairs
Ochsner Clinic Foundation
1450 Poydras Street, Suite 2250
New Orleans, LA 70112
Attention: General Counsel

Section 9.11. Form of the Agreement. All pronouns and any variations thereof shall be deemed to refer to the masculine, feminine or neuter, single or plural, as the identity of the person(s) or thing(s) may require. Article and Section headings are included for convenience of reference only and shall not define, limit, extend or otherwise affect the interpretation of this Agreement or any of its provisions.

Section 9.12. Amendment. This Agreement may be amended or modified only in writing signed by the Parties.

Section 9.13. Further Cooperation. In order to confirm this Agreement or carry out its provisions or purposes, each Party shall cooperate with the other and shall take such further action and execute and deliver such further documents as the other may reasonably request.

Section 9.14. Assignability. No Party may assign its rights or delegate its duties (by subcontract or otherwise) under this Agreement without the prior written consent of the other Parties.

Section 9.15. No Third Party Beneficiaries. Nothing in this Agreement shall be construed as conferring any benefit, either directly or indirectly, on any person or entity not a Party to this Agreement.

Section 9.16. Referrals. The Parties acknowledge that none of the benefits granted hereunder are conditioned on any requirement that any physician make referrals to, be in a position to make, or influence referrals to, or otherwise generate business for, the entities within or outside of the Academic Medical Center.

Section 9.17. Force Majeure. No Party shall be liable nor deemed to be in default for any delay or failure in performance under this Agreement or other interruption in rights or duties that results directly or indirectly from Acts of God, civil or military authority, acts of terror, war, accidents, fires, explosions, earthquakes, floods, failure of transportation, strikes or other work interruptions by a Party's employees, or any similar or dissimilar cause beyond the reasonable control of a Party.

Section 9.18. Additional Instruments. Each of the Parties shall, from time to time, at the request of any other Party, execute, acknowledge and deliver to the other Parties any and all further instruments that may be reasonably required to give full force and effect to the provisions of this Agreement.

Section 9.19. Multiple Counterparts. Provided all Parties execute an identical copy of this Agreement, the Parties acknowledge and agree that these multiple counterparts will be considered fully executed originals.

Section 9.20. Time Periods. Time periods expressed by a specified number of days shall be based on calendar days.

Section 9.21. Execution Warranty. Each person signing this Agreement on behalf of a Party represents that the execution of this Agreement has been duly authorized by the Party for which representative is signing, and that no restrictions or restrictive agreements exist that prevent either the execution or the carrying out of this Agreement by such Party.

Section 9.22. ACCA Dispute Process. The Parties expressly acknowledge and agree that the Dispute Process set forth in Article 9 of the ACCA is the exclusive means by which the Parties will resolve Disputes (as defined in the ACCA), and in the event of any Dispute that the Parties are unable to resolve to their mutual satisfaction pursuant to the Dispute Process, including, without limitation, any claim that a Party has failed to participate in the Dispute Process in good faith, such Dispute may be addressed and the Parties may be adequately compensated through a claim for monetary damages. Accordingly, no Party shall be entitled, at law or in equity, to enforce any provision of this Agreement by a decree of specific performance, temporary, preliminary, or permanent injunctive, or other equitable relief to resolve any Dispute arising under this Agreement, and the Parties expressly waive any rights they may otherwise have to pursue such equitable relief. In the event that any Party elects to incur legal expenses to pursue a claim for monetary damages under this Agreement, the prevailing Party will be entitled to recover such legal expenses, including, without limitation, reasonable attorneys' fees, costs and necessary disbursements, in addition to such other money damages to which such Party shall be entitled.

Section 9.23. Records Retention. The Parties agree to retain this Agreement (including all amendments and supplements hereto) and any of their books, documents, and records which may serve to verify the costs of this Agreement for a period of ten (10) years after the provision of any services related to an ISR, or as otherwise required by law. All Parties agree to allow the Secretary of the Department of Health and Human Services and the Comptroller General to access this Agreement, as well as the books, documents and records kept in connection with the services and ISR in the event that such access is requested in writing and is made in accordance

with applicable federal regulations. The auditors of the OLHS-NL, the Louisiana Legislative Auditor's Office, Office of the Governor, and the –State of Louisiana, through the Division of Administration shall have the right upon reasonable written notice to inspect and audit, during regular business hours and at no expense to such Party, the books and records pertaining to this Agreement. This section shall survive the termination of the Agreement.

Section 9.24. Name and Trademark. Except as provided in this Agreement or in any ISR, no Party shall use another Party's name, symbol, or trademark in any marketing, advertising, or any other public communications without the prior written consent of the other Party regarding the use of its name, symbol, or trademark.

Section 9.25. Nondiscrimination and Affirmative Action. The Parties agree to abide by the requirements of the following as applicable: Title VI of the Civil Rights Act of 1964 and Title VII of the Civil Rights Act of 1964, as amended by the Equal Employment Opportunity Act of 1972, Federal Executive Order 11246 as amended, the Rehabilitation Act of 1973, as amended, the Vietnam Era Veteran's Readjustment Assistant Act of 1974, Title IX of the Education Amendments of 1972, the Age Discrimination Act of 1975, the Fair Housing Act of 1968 as amended, and Parties agree to abide by the requirements of the Americans with Disabilities Act of 1990. Parties agree not to discriminate in employment practices, and will render services under this Agreement without regard to race, color, religion, sex, national origin, veteran status, political affiliation, or disabilities.

Section 9.26. No Debarment. The Parties represent, certify, and covenant that neither they, nor any Investigator, nor any other person who assists in performing the ISR or provides services under this Agreement have ever been or are currently debarred or otherwise disqualified by the FDA or any other governmental or regulatory authority or professional body. The Parties are not aware of any circumstance under which an Investigator or any other person who assists in performing the ISR or who provides services under this Agreement has engaged in any conduct or activity that could lead to any of the aforementioned disqualification or debarment actions and has no notice that the FDA or other regulatory authority intends to seek disqualification or debarment. The Parties will not use the services of any person who is debarred or proposed for debarment, or otherwise disqualified or suspended from performing an ISR, providing services under this Agreement, or otherwise subject to any restrictions or sanctions. If any of the Parties or an Investigator, or any other person who provides services under this Agreement or is engaged in research activities (i) comes under investigation by the FDA or another governmental or regulatory authority for debarment action or disqualification, (ii) is debarred or disqualified, or (iii) engages in any conduct or activity that could lead to any of the aforementioned disqualification or debarment actions, the Party learning of the same shall promptly notify the others in writing thereof.

[Signatures on following pages.]

IN WITNESS WHEREOF, the parties have executed this Agreement by and through their duly authorized representatives effective as of the date and year first above written.

Board of Supervisors of Louisiana State University and Agricultural and Mechanical College

By: _____

Name: _____

Title: _____

Ochsner LSU Health System of North Louisiana

By: _____

Name: _____

Title: _____

Ochsner Clinic Foundation

By: _____

Name: _____

Title: _____

Exhibit A

The initial members of the Research Committee will be as follows:

LSU Designated Directors

Chris Kevil, Ph.D
Pat F. Bass III, M.D.
John Maloy J.D.

Ochsner Designated Directors

Edmond Kabagambe, Ph.D
Leonardo Seoane, M.D.
Eboni Price-Haywood, M.D.