



## CLINICAL STUDY AGREEMENT

THIS AGREEMENT, by and between The Board of Supervisors of Louisiana State University and Agricultural and Mechanical College (hereinafter referred to as "LSU" ) and \_\_\_\_\_, having a principal place of business at \_\_\_\_\_ (hereinafter referred to as "Sponsor").

WHEREAS LSU desires to conduct a "Clinical Study" of Sponsor's proprietary drug or device, pursuant to a mutually agreed upon protocol, which shall be incorporated herein as Appendix A,

WHEREAS the "Clinical Study" contemplated by this Agreement is of mutual interest and benefit to LSU and Sponsor, will further the Instructional, Research and Public Service missions of LSU and may derive benefit for both Sponsor and LSU through the advancement of knowledge.

THEREFORE Sponsor and LSU have entered into this Clinical Study Agreement (the "Agreement"), effective the first day of the Project Period defined below.

### Article 1 – Project Period

1.1 "Project Period" means the period from \_\_\_\_\_ to \_\_\_\_\_.

### Article 2 – Study and Study Materials

2.1 "Clinical Study" is described in the scope of work set forth in Appendix A, LSU Proposal Number \_\_\_\_\_, under the direction of \_\_\_\_\_ as Principal Investigator ("P.I.").

2.2 LSU shall use reasonable efforts to perform the Clinical Study substantially in accordance with the terms of this Agreement.

2.3 Sponsor will provide LSU with sufficient numbers or amounts of its proprietary drug or devices (collectively, "Study Materials") to enable LSU to conduct the Study.

### Article 3 - Reports

3.1 LSU shall provide written progress reports to Sponsor as stated in Appendix A. On either party's request, the parties shall confer to discuss the status of the Project and any proposed changes to the Project.

### Article 4 – Payment

#### **COST REIMBURSEMENT**

4.1 Sponsor shall reimburse LSU's reasonable expenses in conducting the Project. Without Sponsor's prior written consent, these expenses shall not exceed \_\_\_\_\_ dollars (\$\_\_\_\_\_). LSU shall invoice Sponsor for \$\_\_\_\_\_ upon execution of this Agreement. LSU shall invoice Sponsor for additional payments of \$\_\_\_\_\_ each on \_\_\_\_\_ and \_\_\_\_\_. Sponsor will pay

invoices within 30 days. LSU shall submit financial reports of expenditures by major cost categories on a cumulative basis. The initial financial report shall be submitted within 20 days after the end of the first full calendar quarter of the Project Period. Subsequent financial reports will be submitted within 20 days after the end of each calendar quarter, and a final financial report shall be submitted within 90 days of the end of the Project Period or within 90 days of termination of the Agreement. If the payments made to LSU exceed expenditures, then the difference shall be refunded to Sponsor with the final financial report.

**FIXED PRICE (OPTION 1)**

**4.1** The total amount Sponsor shall pay LSU under this Agreement is \_\_\_\_\_ dollars (\$\_\_\_\_\_). LSU shall invoice Sponsor for \$ \_\_\_\_\_ upon execution of this Agreement. LSU shall invoice Sponsor on the first of each month thereafter during the Project Period, for \_\_\_\_\_ additional payments of \$ \_\_\_\_\_ each. Sponsor will pay invoices within 30 days. Any unexpended funds will be retained by LSU.

**OR**

**FIXED PRICE (OPTION 2)**

**4.1** The total amount Sponsor shall pay LSU under this Agreement is \_\_\_\_\_ dollars (\$\_\_\_\_\_). LSU shall invoice Sponsor for \$ \_\_\_\_\_ upon execution of this Agreement. LSU shall invoice Sponsor for additional payments of \$ \_\_\_\_\_ each on \_\_\_\_\_ and \_\_\_\_\_. Sponsor will pay invoices within 30 days. Any unexpended funds will be retained by LSU.

**4.2** Payment will be made via either electronic transfer (wire or ACH) or check and will reference the invoice number and name of the Principal Investigator for purposes of identification.

Electronic transfer to:

J.P. Morgan Chase Bank, NA  
Baton Rouge, LA  
Account # 7900000051  
ABA/Routing # 065400137  
Name on Account: Louisiana State University  
Invoice # \_\_\_\_\_

Checks shall be made payable to Louisiana State University, and shall be mailed to:

Louisiana State University  
Office of Accounting Services  
Sponsored Program Accounting  
Baton Rouge, Louisiana 70803-2901  
Invoice # \_\_\_\_\_

- 4.3 LSU is authorized to incur pre-award costs up to six months prior to the Project Period. However, LSU shall not receive more funds than the total provided in Paragraph 4.1.
- 4.4 LSU shall retain title to any equipment purchased with funds provided by Sponsor.
- 4.5 If Sponsor loans any equipment or supplies to LSU, Sponsor shall bear all risk of damage or loss to the equipment or supplies, except to the extent due to LSU's willful or intentional acts. Sponsor shall maintain all such equipment or supplies while in LSU's custody.
- 4.6 Notwithstanding anything in this Agreement to the contrary, in the event of early termination of this Agreement under Article 9, Sponsor shall pay all costs accrued by LSU as of the date of termination, including all non-cancelable obligations and all non-cancelable contracts; provided that this obligation shall not be construed to authorize payment in excess of the total amount provided in Paragraph 4.1.

#### **Article 5 – Confidential Information**

- 5.1 "**Confidential Information**" shall mean information that one party discloses to the other, and that is conspicuously marked "**CONFIDENTIAL INFORMATION.**" "**Confidential Information**" shall also include information that is initially disclosed orally -- provided that within seven days the information is reduced to writing, is conspicuously marked "**CONFIDENTIAL INFORMATION,**" and a copy of the information thus marked is delivered to the receiving party. Each party shall hold the other party's Confidential Information in strict confidence, and shall not disclose it to any third party. Neither party shall use the other party's Confidential Information for any purpose other than to perform its obligations under the Agreement, or to evaluate a potential license under Article 8. A receiving party shall use reasonable efforts not to disclose the other's Confidential Information, but neither party will be financially liable for an inadvertent disclosure. Should either party realize that an inadvertent disclosure to a third party has occurred, then the parties shall promptly confer to determine an appropriate course of action. On request by the other party, the party who has made an inadvertent disclosure shall promptly notify the third party that the disclosure was inadvertent, and shall request that the third party promptly return all copies of the disclosed Confidential Information.
- 5.2 This Agreement shall not be construed to prevent a party from disclosing information that: (a) at the time of receipt is public knowledge, or later becomes public knowledge through no fault of the receiving party; or (b) is shown by written records to have been in the possession of the receiving party prior to its disclosure; or (c) is received from a third party who neither directly nor indirectly obtained it from the providing party; or (d) is required to be disclosed by a court or government agency, or is reasonably believed by either party to have significant implications for public health or public safety -- provided in such a case that the providing party is given reasonable notice and opportunity to contest the disclosure.
- 5.3 Study Materials supplied to LSU by Sponsor under this agreement will be considered Confidential Information of Sponsor and will not be distributed by LSU to any third party.

**5.4** These confidentiality obligations shall continue until three years after the termination of the Agreement.

#### **Article 6 - Publications**

**6.1** Whereas LSU is an institution of higher education, and whereas the freedom to publish is of cardinal importance to universities and to their personnel, it is understood that LSU, the P.I., and other LSU personnel shall be free to make such publications as they see fit concerning the Project, except as provided in Article 5 respecting Sponsor's Confidential Information. LSU shall own the copyright in such works, except to the extent that LSU's Bylaws waive ownership of copyright in favor of the authors.

#### **Article 7 - Publicity**

**7.1** Sponsor may not make any use of LSU's name, marks, insignia, logos, campus, department, center, institute, or of the name of any LSU employee; in news releases, advertisements, promotional materials, or otherwise. Notwithstanding the foregoing, LSU's name may be used without prior approval when and as necessary for 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 Sponsor state or imply that LSU in any way endorses or supports a particular investment, stock purchase, product, or treatment.

#### **Article 8 - Intellectual Property Rights**

**8.1** All inventions arising out of the Clinical Study will be promptly disclosed to Sponsor. University shall not obtain or attempt to obtain patent coverage on Sponsor provided materials or information, without the express written consent of Sponsor. All inventions, patent applications, or patents made during the Clinical Study which name at least one employee of LSU as an inventor shall be owned as follows:

**8.1.1** Inventions which involve the use of, composition of, or improvement to Sponsor provided materials or information, or a derivative, analogue thereof shall belong to Sponsor; and

**8.1.2** Inventions which cover a scientific process, technique, procedure, medium, device or other process which is not unique to Sponsor provided materials or information shall be owned by LSU. Sponsor shall be given an option to negotiate a license thereto.

#### **Article 9 - Term and Termination**

**9.1** This Agreement is effective during the Project Period, unless terminated earlier in accordance with its terms. Either party may terminate this Agreement on thirty days written notice.

**9.2** If the P.I. becomes unable or unwilling to continue the Project, and a mutually acceptable substitute is not available, LSU and Sponsor each shall have the option to terminate the Project.

**9.3** If either party commits a material breach of this Agreement, and fails to remedy that breach within thirty days of written notice, the other party may, at its option, in addition to any other legal remedies, terminate this Agreement immediately upon written notice.

- 9.4** In the Court's discretion, the prevailing party in any dispute arising out of this Agreement may be awarded reasonable attorneys' fees, court costs and expenses, including those associated with appellate or enforcement proceedings.
- 9.5** Termination of this Agreement for any reason shall not affect rights and obligations accrued prior to termination, nor release the parties from their respective rights and obligations under Articles 4, 5, 6, 7, 8, 10, 11, 12, 13 and 14.

#### **Article 10 - Independent Contractors**

- 10.1** In the performance of all obligations under this Agreement: **(a)** Each party shall be an independent contractor. Neither party shall be entitled to any benefits applicable to employees of the other party. **(b)** Neither party is authorized to act as agent for the other for any purpose. Neither party shall enter into any contract, warranty, or representation as to any matter on behalf of the other party. Neither party shall be bound by the acts of the other party.
- 10.2** Each party represents that it is acting on its own account and not on behalf of another private or governmental party. Sponsor represents that none of the funding to be provided under this Agreement is derived from a contract or grant from the United States government. Neither this Agreement nor any rights under this Agreement may be assigned by either party without the prior written consent of the other party.

#### **Article 11 – Insurance and Indemnity**

- 11.1** LSU represents that LSU has adequate liability insurance, such protection being applicable to LSU's officers, employees, and agents while acting within the scope of their employment by LSU. LSU has no liability insurance as such that extends protection to any other person.
- 11.2** Each party shall indemnify, defend, and hold harmless the other party, and its officers, directors, agents and employees, from and against any and all losses, liabilities, demands, suits, judgments and claims, including reasonable attorneys' fees, to the extent that such losses, liabilities, demands, suits, judgments, claims, or fees are attributable to the willful act, fault, omission, or negligence of the indemnifying party, or of its employees, servants, or agents, in performing its obligations under this Agreement; provided, however, that neither party shall hereby be liable for consequential damages.
- 11.3** Sponsor shall indemnify, defend, and hold harmless LSU and LSU's officers, directors, agents and employees, from and against any and all losses, liabilities, demands, suits, judgments and claims, including reasonable attorneys' fees, for losses arising out of the use, by Sponsor or by a third party acting with Sponsor's authorization, of products or processes developed or made as a result of information or materials received from LSU.

#### **Article 12 –Shipment of Study Materials**

- 12.1** If Study Materials are supplied by Sponsor to LSU, then on LSU's request Sponsor shall accept, at Sponsor's expense, any unused portions of the Study Materials supplied by Sponsor (and, in the case of biological materials, any progeny of such materials), including the containers in which the

Study Materials are shipped, provided that the Study Materials and containers are properly labeled by LSU upon their return to Sponsor. Further, for each Study Material supplied, Sponsor shall furnish LSU with sufficient information to identify precautions needed to help protect the health and safety of personnel using the Materials and of the public; the information thus to be supplied by Sponsor shall include all pertinent material safety data sheets.

### **Article 13 – Export Controls**

**13.1** As an institution of higher education with many foreign employees, students and visitors, LSU intends to conduct the Project as fundamental research under U.S. export regulations. Accordingly, Sponsor warrants that it will not transfer its export-controlled materials or information to LSU.

### **Article 14 - Miscellaneous**

**14.1** This Agreement shall be construed in accordance with the laws of the State of Louisiana.

**14.2** Any controversy arising out of or related to this Agreement that cannot be resolved by the parties shall be adjudicated only in a court of competent jurisdiction in East Baton Rouge Parish, State of Louisiana. Both parties consent to such venue and jurisdiction.

**14.3** This Agreement constitutes the entire understanding between Sponsor and LSU, and supersedes any prior agreement or understanding on the same subject matter. Any modification, extension, or amendment to this Agreement shall not be effective unless reduced to writing and signed by both parties.

**14.4** LSU makes no representation or warranty regarding what the results of the Project will be.

**14.5** Nothing in this Agreement shall be construed to limit the freedom of the P.I. or any other LSU personnel from engaging in research in the same field that is covered by this Agreement. Sponsor acknowledges that the rights specified in this Agreement are subject to the rights of other sponsors in other research agreements to which LSU is a party.

**14.6** Any otherwise irresolvable inconsistency shall be resolved by giving precedence in the following order: (a) first, to the main body of this Clinical Study Agreement, and (b) second, to the attached Statement of Work (Appendix A). This Agreement shall not be altered by the acknowledgement or acceptance by LSU of any purchase order form or similar document containing terms or conditions at variance with, or in addition to those set forth herein.

**14.7** If any part of this Agreement is deemed void or unenforceable by a court of competent jurisdiction, the remaining provisions shall remain in full force and effect. Furthermore, in lieu of that invalid part, there shall be automatically added to this Agreement a provision as similar in terms to that invalid part as may be possible, legal, valid, and enforceable.

**14.8** Notices, invoices, and other communications shall be deemed made if sent postage prepaid, addressed as shown below, or to such other address as a party may hereafter designate by written notice:

If to Sponsor (Business Matter):	If to LSU (Business Matter):  Darya Courville, Executive Director Office of Sponsored Programs 202 Himes Hall Louisiana State University Baton Rouge, Louisiana 70803 Phone: 225-578-2760 Fax: 225-578-2751 Email: osp@lsu.edu
If to Sponsor (Technical Matter):	If to LSU (Technical Matter):

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed.

**Sponsor**

**Board of Supervisors of Louisiana State LSU  
and Agricultural and Mechanical College**

\_\_\_\_\_  
BY: \_\_\_\_\_

\_\_\_\_\_  
BY: Darya Courville  
Executive Director  
Office of Sponsored Programs

Date: \_\_\_\_\_

Date: \_\_\_\_\_