UNIVERSITY OF LOUISVILLE RESEARCH FOUNDATION
CLINICAL STUDY AGREEMENT
FOR INDUSTRY SPONSORED – NONFEDERAL FUNDING

THIS AGREEMENT made this_____day of_20 , by and between the University of Louisville Research Foundation, Inc. (hereinafter "ULRF") a Kentucky non-profit corporation having an office at MedCenter One, 501 E. Broadway, Suite 200,, Louisville, Kentucky 40202-1798 as the agent of the University of Louisville (hereinafter "UofL") for receiving grants and research agreements from external funding sources and which owns and controls intellectual property on behalf of UofL (collectively "Institution") and, _____ with a principal place of business at_____(hereinafter "SPONSOR").

WHEREAS, SPONSOR desires to provide funding in support of the clinical research study in return for receiving certain rights in the study results;

WHEREAS, the ULRF agrees to conduct a clinical research study entitled, _____ according to the Protocol No._____ attached as Exhibit A provided, however, ULRF's

obligation to conduct the study is expressly conditioned upon the approval of UofL's Institutional Review Board, and other UofL review committees as applicable, as set forth in Section 11. The ULRF agrees to devote reasonable efforts in order to perform efficiently the work required under this Agreement. The ULRF agrees that it will comply with all applicable laws, rules and regulations relating to the conduct of such study, particularly such laws, rules and regulations concerning or promulgated by the Food and Drug Administration; and

WHEREAS, the study contemplated by this Agreement is of mutual interest and benefit to ULRF and SPONSOR, and will further the instructional and research objectives of UofL in a manner consistent with its status as a nonprofit educational and healthcare institution;

NOW, THEREFORE, the parties hereto agree as follows:

1. DEFINITIONS

As used herein, the following terms shall have the following meanings:

1.1. "Principal Investigator" shall mean the investigator under whose supervision the study is conducted and shall mean Dr. _____, Department of _____.

1.2. Effective Date and Term" is_____, 20___to_____, 20___.

1.3. "Study" shall mean the description of the study in the Protocol entitled _____ _____, dated_____, 20___, which is attached hereto as Exhibit "A" and hereby made a part of this Agreement.

1.4. "Study Drug/Device" and/or Study Materials are_____provided by SPONSOR for use in the Study._____is_____by the U.S. Food and Drug Administration ("FDA").

1.5. "Facility" is _____ which is the site for the Study and where the subjects are registered as in-patients or out-patients.

1.6. "Protocol-Induced Injury" is an injury or illness resulting from an adverse reaction to or caused by the intervention, drugs and/or devices (e.g. Study Drug/Device) necessary solely to satisfy the requirements of the Protocol.

2. CONDUCT OF THE STUDY

2.1. ULRF shall commence the performance of the study promptly after the effective date of this agreement, provided approvals have been obtained as required pursuant to section 11, and shall use reasonable efforts to perform such study substantially in accordance with the terms and conditions of this Agreement.

3. PAYMENT SCHEDULE

3.1. Payments shall be made payable to the University of Louisville Research Foundation, Inc. and forwarded to the following address:

U.S. Mail:
Sponsored Programs Administration
Financial Division
University of Louisville
The Nucleus
300 E. Market Street
Suite 300
Louisville, KY 40292

UPS or FEDEX:
Sponsored Programs Administration
Financial Division
University of Louisville
The Nucleus
300 E. Market Street
Suite 300
Louisville, KY 40202-1959

Specify project ID # OICxyynnnn on check/accompanying materials

[or if billing and invoicing handled by the department:
Department Name
Department Building & Room
Street Address
Louisville, KY 402__
Attention: Name of Dept Contact Project ID OICxyyxxxx

3.2. It is agreed that the SPONSOR will reimburse the ULRF in a timely manner for an amount not to exceed $_____ in accordance with the approved budget and payment schedule attached as Exhibit B. Invoices not paid within thirty (30) days of the later of invoice date or receipt date of invoice are subject to 1% per month interest on the unpaid balance for any amounts not in dispute. SPONSOR acknowledges that the ULRF has included facilities and administrative costs for this clinical study. For purposes of identification, payments will include the project ID, title of the project and the name of the Principal Investigator.

3.3. In the event of termination, the sum for professional services and expenses payable under this Agreement shall be limited to the pro-rated fees based on actual work performed and actual expenses committed pursuant to the protocol. Any unexpended funds not due under this calculation but already paid shall be returned to the SPONSOR.

4. CONFIDENTIALITY

4.1. In performance of the clinical study, either party may disclose information to the other party which it considers to be proprietary and confidential (hereinafter Confidential Information). All such information shall be designated confidential at the time of disclosure by the disclosing party either orally or in writing. If designated confidential orally, the disclosing party shall within 30 days of the date of disclosure confirm in writing the confidential nature of such information. Both parties shall use reasonable efforts to ensure said Confidential Information is kept confidential. Except as otherwise provided herein, for a period of three (3) years following the date of such disclosure, the recipient will not disclose the Confidential Information without the consent of the disclosing party and shall use the Confidential Information only for the purposes of this Agreement. Notwithstanding the foregoing, recipient may transfer Confidential Information to those of its employees, officers, directors and agents and that of the Facility (which agrees by separate agreement to keep the Confidential Information confidential as outlined in the Agreement) as may be reasonably necessary to carry out the performance of this Agreement. Information shall not be subject to the aforementioned restrictions where the:

a) information was possessed by receiving party prior to receipt from disclosing party other than through prior disclosure by the disclosing party as evidenced by receiving party's business records;

b) information published or available to the general public otherwise than through a breach of this Agreement;

c) information obtained by receiving party from a third party with a valid right to disclose it;

d) information was independently developed by employees, agents or consultants of receiving party who had no knowledge of or access to the information as evidenced by receiving party's business records;

e) information for which the receiving party obtains the disclosing party's prior written permission to publish or which is disclosed in the necessary course of the prosecution of patent applications upon intellectual property developed pursuant to this Agreement; or

f) information required to be disclosed by operation of law, regulation, Attorney General decisions that carry the force of law, or court order.

4.2. SPONSOR shall be provided patient information as allowed by law and will maintain the confidentiality of all such patient information, unless specifically required to disclose such information by law.

5. PUBLICITY

5.1. SPONSOR will not use the name of the ULRF, UofL, nor of any employee, student, trustee or officer thereof, in advertising or publicity, including news releases, without the prior written consent of the ULRF. ULRF will not use the name of the SPONSOR, nor any employee of SPONSOR, in any advertising or publicity, including news releases, without the prior written approval of SPONSOR.

5.2. Notwithstanding anything to the contrary, Institution is not prohibited from disclosing the name of the Sponsor, the name of the investigator(s), a non-confidential

title/description of the study, the total estimated budget [or total projected amount to be paid by Sponsor for the study, and the study period in its Institutional reports.

6. PUBLICATIONS

6.1. SPONSOR recognizes that under UofL policies, the results of the clinical study must be publishable and agrees that UofL and UofL investigators have the right to publish and otherwise publicly disclose any information gained in the course of the study. In order to permit SPONSOR an opportunity to determine if patentable inventions are disclosed, the Principal Investigator will provide SPONSOR with copies of any proposed publication or presentation by project investigators prior to submission for publication. Whenever possible, efforts will be made by the Principal Investigator to provide copies of drafts of intended articles or abstracts as soon as they reach a stage suitable for distribution. SPONSOR shall have thirty (30) days, after receipt of said copies, to object to such proposed presentation or proposed publication because there is patentable subject matter which needs protection. In the event that SPONSOR makes such an objection, said Principal Investigator and other project investigators shall refrain from making such publication or presentation for a reasonable time, not to exceed 3 months, from the date of receipt of such objection, in order for the ULRF or SPONSOR to file a patent application(s) directed to the patentable subject matter contained in the proposed publication or presentation.

Sponsor agrees that it will register the Study in accordance with Section 801 of the FDA Amendments Act of 2007 and in accordance with the guidelines/recommendations of the International Committee of Medical Journal Editors ("ICMJE") such that the Study will be eligible for publication in publications observing such guidelines/recommendations.

This paragraph is optional and may be used if appropriate for multi-center studies:
[Notwithstanding the foregoing, UofL agrees that if the Research is part of a multi-center study, the first publication of the results of the Research shall be made in conjunction with the results from the Investigators at the other study centers. However, if a multi-center publication is not forthcoming within one year following completion of this Agreement study, UofL will be free to publish.]

7. INTELLECTUAL PROPERTY

7.1. It is recognized and understood that certain existing inventions and technologies are the separate property of the ULRF and SPONSOR and are not affected by this Agreement, and neither party shall have any claims to or rights in such separate inventions and technologies. All inventions, improvements, modifications and/or discoveries which are conceived, invented, authored and/or reduced to practice by one or more employees of UofL in performance of the Research are "ULRF Inventions". All inventions, improvements, modifications and/or discoveries which are conceived, invented, authored and/or reduced to practice jointly by one or more employees of UofL and by one or more employees of SPONSOR in performance of the Research are "Joint Inventions". For the purposes of this Section 7, inventorship and authorship shall be determined in accordance with the provisions for determining inventorship and authorship under Titles 17 and 35 of the United States Code.

7.2. ULRF Inventions and Joint Inventions submitted to SPONSOR pursuant to this Section are Confidential Information until such time as SPONSOR is notified in writing that the Inventions have been appropriately protected.

Note: Sections 7.1 and 7.2 may be replaced with alternate language granting SPONSOR rights in the Intellectual Property which is developed in accordance with the Protocol for solely sponsor developed Protocols for multi-center studies:

8. GRANT OF RIGHTS

8.1. ULRF grants, to the extent it is able to do so under its policies, the SPONSOR the first option, at the SPONSOR's sole election, for an exclusive, worldwide license to ULRF's rights in any ULRF Invention or Joint Invention. Such license shall be for fair and valuable consideration and shall include a commercially reasonable royalty rate and, subject to UofL's policies, shall include other such terms as are typical in licenses of similar technology from not-for-profit organizations to for-profit organizations. The option shall extend for an option time period of 6 months from the date of disclosure of the ULRF Invention or Joint Invention to SPONSOR.

8.2. If SPONSOR elects not to exercise it's option pursuant to this Section or fails to negotiate a license agreement to the disclosed ULRF Invention or Joint Invention during said 6 month option period, then:

a) ULRF shall have no further obligation and SPONSOR shall have no further right to the ULRF Invention and ULRF may license its interest in the ULRF Invention to any party upon terms ULRF deems appropriate;

b) Either party shall pay a royalty on any product from a Joint Invention, such rate to be one-half the rate of the relevant industry standard;

c) Either party is free to license any third party under Joint Inventions. Each party shall fully account to the other for compensation derived from such license, with two-thirds of the compensation to the licensing party and one-third to the non-licensing party.

8.3. Any license granted to SPONSOR by ULRF shall include a royalty-free, non-exclusive license in favor of the ULRF and the Principal Investigator(s) to use the inventions and/or discoveries for noncommercial, educational and research purposes.

9. CLINICAL DATA AND REPORTING

9.1. Any medical records and any source documents generated pursuant to this Agreement shall be the property of ULRF [if hospital involved, please add: and/or Facility.]. SPONSOR shall retain ownership of all completed case medical record forms supplied by SPONSOR and ULRF shall be entitled to retain one copy of said case medical record forms.

9.2. ULRF shall be entitled to retain ownership of the data arising out of this clinical study. Subject to Sections 6 and 7, SPONSOR shall have access to the data and may freely use the data in connection with regulatory submissions to governmental regulatory bodies.

10. TERMINATION

10.1. The study may be terminated prior to completion by written notice from the SPONSOR to the ULRF or by the ULRF to the SPONSOR for any of the following reasons:

a) Notification to the SPONSOR from Federal or State Regulatory Authorities to terminate said study;

b) Determination by the SPONSOR or the ULRF that the ULRF, after reasonable opportunity, is unable for any reason to perform the study satisfactorily as required in the protocol;

c) Inability of the Principal Investigator to continue the study at the ULRF and a successor acceptable to both ULRF and SPONSOR is not available.

Written notice of its decision to exercise such termination right shall be given to the ULRF by the SPONSOR or to the SPONSOR by the ULRF by Certified Mail, delivered fifteen (15) days before said termination of the study. Immediately upon receipt of a notice of termination by either the SPONSOR or the ULRF, the ULRF shall stop entering patients into the study and shall cease conducting procedures, to the extent medically permissible, on patients already entered into the investigational protocol. In the event of termination, expenses payable to the ULRF shall be as stated in Section 3.

10.2. Termination or completion of this Agreement shall not relieve the obligations undertaken by the parties in sections 4, 5, 6, 7, 10, 11 and 13.

11. HUMAN SUBJECTS RELATED PROVISIONS

11.1. SPONSOR shall cooperate with Principal Investigator in preparing and filing the Study protocol, informed consent form, and other information with UofL's or with an Institution designated Institutional Review Board ("IRB") (e.g. when an institutional conflict of interest needs to be managed.) Principal Investigator shall apply for approval to conduct the Study with the IRB and other appropriate review committees/Facility approvals as applicable. The Study shall not begin until said approvals are obtained. ULRF reserves the right to terminate the Study if the IRB, or other UofL review committees/Facility authorizations as applicable, subsequently suspends or withdraws its approval/authorization of the Study.

11.2. SPONSOR agrees to promptly notify Institution of any findings or information (including Study results, information discovered during site monitoring visits or by data safety monitoring committees, or other problems of which SPONSOR becomes aware) that: involve risks to subjects or others, could influence the conduct of the Study, may adversely affect the safety, well-being or medical care of subjects or others, affect the subjects' willingness to continue their participation in the Study, alter the risk/benefit ratio of the Study, alter the conduct of the Study, or alter the designated IRB's approval to continue the Study.

11.3. SPONSOR agrees to promptly notify the designated IRB of any such findings or information as outlined in 11.2. The designated IRB, via the Principal Investigator, will communicate such findings or information, by an appropriate communications plan recommended by the designated IRB, to the respective individual subjects when those findings or results could directly affect the subjects' safety, well-being or medical care.

11.4. SPONSOR and Institution agree that the rights and welfare of human subjects will be protected in accordance with the principles of the Belmont Report and applicable policies set forth in 45 CFR 46 and 21 CFR 50 and 56. SPONSOR and Institution acknowledge their respective responsibility for the proper and safe performance of their respective efforts/services involving human subjects.

11.5. SPONSOR and Institution agree (1) to comply with all applicable laws, rules and regulations relating to the conduct of such Study, including any applicable laws, rules and regulations concerning or promulgated by the Food and Drug Administration (FDA) and (2) to perform its activities in accordance with good clinical practices.

11.6. UofL as a hybrid covered entity will comply with all applicable federal, state, and local laws and regulations relating to the privacy of patient health information, including, but not limited to, the Health Insurance Portability and Accountability Act of 1996 and regulations, laws and guidelines related thereto (collectively, the "HIPAA Privacy Regulation"). Prior to participation of each subject in the Study, Institution will ensure that a properly executed written consent and authorization approved by SPONSOR, Institution and UofL IRB or the Institution designated IRB/Privacy Board (the "Authorization") is obtained from each human subject or the subject's authorized representative to document the subject's express written authorization for the use by Institution, and disclosure to SPONSOR of protected health information pursuant to the HIPAA Regulations. Principal Investigator, Institution and SPONSOR will cooperate in the amendment of the Authorization or other documents as may be necessary, from time to time, to comply with the HIPAA Privacy Regulation to the extent the HIPAA Privacy Regulation applies to Principal Investigator, Institution or SPONSOR, to ensure that the Study data may be used by SPONSOR or Institution for the purposes specifically identified in this Agreement and the HIPAA Authorization. In accordance with the HIPAA Authorization, SPONSOR may add data collected under the Study to its research databases in order to study the safety and effectiveness of the Study Device or Study Drug, to evaluate a new use of the Study Device or Study Drug, and to conduct performance reviews of the Study Device or Study Drug or retrospective reviews of the Study or the study data. SPONSOR will be entitled to review and revise as appropriate such Authorization or other document or any modification thereof prior to use by Institution, subject to subsequent approval by the designated Institutional Review Board/Privacy Board. Institution will provide access to each executed Authorization to SPONSOR before such subject participates in the Study. SPONSOR agrees that its actions will abide by all written representations made by SPONSOR to subjects in both the final informed consent form and the HIPAA Authorization.

11.7. Should any human subject participating in the Study suffer a Protocol-Induced Injury, SPONSOR will pay for reasonable and necessary costs of diagnostic, therapeutic and medical treatment including hospitalization costs ("Treatment Costs") for such Protocol-Induced Injuries. SPONSOR will reimburse ULRF, Facility, and/or subjects for such Treatment Costs dependent upon by whom the Treatment Costs were incurred. SPONSOR will not be responsible for paying for Treatment Costs associated with the treatment of normal progression of the subject's disease nor for injuries resulting from interventions that the subjects would have incurred had they not participated in the Study. Additionally SPONSOR will not be responsible for Treatment Costs to the extent such Protocol-Induced Injury is caused by the malpractice, negligence, error or omission ("Negligence") by the Investigator, Institution, Facility or any of their respective employees, agents or affiliates, except to the extent such Negligence is caused by SPONSOR or SPONSOR's employees, agents or affiliates. The obligation of SPONSOR under this section shall survive termination of this Agreement.

12. INDEPENDENT PARTIES

12.1. For the purposes of this Agreement, the parties shall be independent contractors. Nothing contained herein shall be deemed or construed to create between the parties hereto a partnership or joint venture or the relationship of agent and principal.

13. INDEMNIFICATION

13.1. SPONSOR shall defend, indemnify and hold harmless ULRF, UofL, the Principal Investigator and any of ULRF or UofL's faculty, students, employees, trustees, officers, affiliates and agents and their respective successors, heirs and assigns (hereinafter referred to collectively as the "Indemnified Persons") from and against any and all liability, claims, lawsuits, losses, damages, costs, expenses (including attorney's fees) (collectively "Losses") and other liabilities asserted by third parties, both government and non-government, resulting from or arising out of the clinical study carried out pursuant to this agreement. Notwithstanding the foregoing, SPONSOR's indemnification obligations under this subsection shall not apply to any Losses to the extent such Losses are attributable to the gross negligence or willful misconduct of any of the Indemnified Persons. ULRF shall notify SPONSOR upon learning of the institution or threatened institution of any such liability, claims, lawsuits, losses, damages, costs and expenses. SPONSOR represents that it carries insurance coverage to protect against liability under this provision in amounts equal to at least three million dollars ($3,000,000) per occurrence combined single limit and ten million dollars ($10,000,000) annual aggregate, and SPONSOR agrees to furnish ULRF a certificate of insurance acceptable to ULRF indicating the required coverage.

13.2. SPONSOR agrees to provide a letter of indemnification for Facility upon request, which shall provide an equivalent indemnification for Facility as provided in 13.1.

14. ASSIGNMENT

14.1. This Agreement shall not be assigned by SPONSOR without the prior written consent of the ULRF.

15. GOVERNING LAW

15.1. This Agreement shall be governed and construed in accordance with the laws of the Commonwealth of Kentucky without giving effect to the conflict of laws provisions.

16. NOTICES

16.1. All notices, invoices, payments and other communications that any of the parties hereto are required or may desire to deliver to the other party hereto shall be in writing and shall be deemed given as of the date it is received by the other party. Notices shall be given to the parties at the addresses listed below:

If to SPONSOR:

If to ULRF:
For administrative notice:

Director, Clinical Contracts Division
University of Louisville Research Foundation, Inc.
MedCenter One
501 East Broadway, Suite 200
Louisville, KY 40202-1798

For technical notice:

[Investigator/Research Coordinator's Name]
[Dept and Building Address] University of Louisville
Louisville, KY 40292

17. **ADDITIONAL PROVISIONS**

17.1 In the event any part, article, section, subsection, clause, paragraph or subparagraph of this Agreement shall be held to be indefinite, invalid, illegal or otherwise voidable or unenforceable, the entire Agreement shall not fail on account thereof, and the balance of the Agreement shall continue in full force and effect.

17.2 A waiver by either party of a breach or violation of any provision of this Agreement will not constitute or be construed as a waiver of any subsequent breach or violation of that provision or as a waiver of any breach or violation of any other provision of this Agreement.

17.3 No exercise of a specific right or remedy by any party precludes it from or prejudices it in exercising another remedy or maintaining an action to which it may otherwise be entitled either at law or in equity.

17.4 During the performance of this Agreement, SPONSOR and ULRF shall not discriminate against any employee or applicant for employment because of race, color, sex, sexual preference, age, religion, national or ethnic origin, handicap, or because he or she is a disabled veteran or veteran of the Vietnam era.

17.5 Each party shall comply with all laws, regulations and other legal requirements applicable to them in connection with this Agreement.

18. **AGREEMENT MODIFICATION**

18.1 This Agreement is the final and complete understanding of the parties with respect to the subject matter hereof superseding all prior agreements, understandings and discussions relating thereto. No amendments or changes to this Agreement shall be valid unless the change is made in writing and signed by authorized representatives of the parties hereto. The appendices will be binding upon the parties hereto except to the extent they may conflict with the terms and conditions contained within this Agreement, in which case the terms and conditions of the Agreement will govern.

[The remainder of this page is blank. Signature page follows.]

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed by their duly authorized representatives,

THE UNIVERSITY OF LOUISVILLE RESEARCH FOUNDATION, INC.	{SPONSOR NAME}
Signature: _____	Signature: _____
Printed Name: _____	Printed Name: _____
Title: _____	Title: _____
Date: _____	Date: _____

Principal Investigator, while not a party to this Agreement, by his/her signature acknowledges that he/she: (1) has read and agrees to abide by the terms and conditions that apply to the Principal Investigator, (2) agrees to communicate the terms and conditions of this Agreement to and use reasonable efforts to ensure compliance with its applicable obligations by all personnel who are providing services under or assisting with the Study under his/her supervision or direction; (3) agrees to conduct/perform the research as outlined in the Research Statement of Work, (4) has no consulting agreements with SPONSOR/CRO, and (5) if applicable, will see that the work within the scope of this agreement is performed in accordance with an approved University/Institution management plan.[1]

Principal Investigator: _____

Signature: _____

Printed Name: _____

Title: _____

Date: _____

[1] "Management Plan" means a written plan for the management, reduction or elimination of a potential financial conflict of interest relating to research. It relies upon, and is therefore limited by, good faith disclosures about significant financial interests made, and other information provided by, a covered individual to the University.

EXHIBIT A

EXHIBIT B